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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 412, 413, 416, 419, 424, 485, and 489

[CMS-1772-FC; CMS-1744-F; CMS-3419-F; CMS-5531-F; CMS-9912-F]

RIN 0938-AU82

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period; Final rules.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2023 based on our continuing experience with these systems. We describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system.

Please be aware that this file is not fully 508 compliant. We are working to post the fully compliant version and will make that available as soon as possible.

Also, this final rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program; the ASC Quality Reporting (ASCQR) Program; and the Rural Emergency Hospital Quality Reporting (REH) Program. We also make updates to the requirements for Organ Acquisition, REHs, Prior Authorization, and Overall Hospital Quality Star Rating. We are establishing a new provider type for REHs, and we are finalizing proposals regarding payment policy, quality measures, and enrollment policy for REHs. In addition, we are finalizing the Conditions of Participation that REHs must meet in order to participate in the Medicare and Medicaid programs. This rule also finalizes changes to the Critical Access Hospitals (CAH) CoPs for the location and distance requirements, patient's rights requirements, and flexibilities for CAHs that are part of a larger health system. Finally, we are finalizing as implemented a number of provisions included in the COVID-19 interim final rules with comment period (IFCs).

DATES: Effective Date: The provisions of this rule are effective January 1, 2023. Comment period: To be assured consideration, comments must be received at one of the addresses provided below, by [Insert date 60 days after date of filing for public inspecting at the **Federal Register**].

Incorporation by reference: The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of January 1, 2023.

ADDRESSES: In commenting, please refer to file code CMS-1772-FC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1772-FC; CMS-1744-F; CMS-3419-F; CMS-5531-FC; CMS-9912-F,

P.O. Box 8010,

Baltimore, MD 21244-1810.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1772-FC; CMS-1744-F; CMS-3419-F; CMS-5531-F; CMS-9912-F,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Elise Barringer,

Elise.Barringer@cms.hhs.gov or 410-786-9222.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at APCPanel@cms.hhs.gov.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov or Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email at Cyra.Duncan@cms.hhs.gov.

Blood and Blood Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

Cancer Hospital Payments, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at Chuck.Braver@cms.hhs.gov.

Composite APCs (Multiple Imaging and Mental Health), via email at Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

Comprehensive APCs (C-APCs), contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

COVID-19 Final Rules, contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

Hospital Inpatient Quality Reporting Program—Administration Issues, contact Julia Venanzi at Julia.Venanzi@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Shaili Patel via email Shaili.Patel@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Janis Grady via email Janis.Grady@cms.hhs.gov.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at Abigail.Cesnik@cms.hhs.gov.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes, contact Emily Yoder via email at Emily.Yoder@cms.hhs.gov.

Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs), contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

OPPS Brachytherapy, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at Erick.Chuang@cms.hhs.gov, or Scott Talaga via email at Scott.Talaga@cms.hhs.gov, or Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov, or Gil Ngan via email at

Gil.Ngan@cms.hhs.gov, or Cory Duke via email at Cory.Duke@cms.hhs.gov, or Au'Sha Washington via email at Ausha.Washington@cms.hhs.gov.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at NewTechAPCapplications@cms.hhs.gov.

OPPS Packaged Items/Services, contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov or Cory Duke via email at Cory.Duke@cms.hhs.gov.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at DevicePTapplications@cms.hhs.gov.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at Marina.Kushnirova@cms.hhs.gov.

Organ Acquisition Payment Policies, contact Katie Lucas via email at Katherine.Lucas@cms.hhs.gov, or Mandy Michael via email at Amanda.Michael@cms.hhs.gov, or Kellie Shannon via email at Kellie.Shannon@cms.hhs.gov.

Outpatient Department Prior Authorization Process, contact Yuliya Cook via email at Yuliya.Cook@cms.hhs.gov.

Overall Hospital Quality Star Rating, contact Tyson Nakashima via email at Tyson.Nakashima@cms.hhs.gov.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at PHPPaymentPolicy@cms.hhs.gov.

Request for Information on Use of CMS Data to Drive Competition in Healthcare Marketplaces, contact Terri Postma via email at Terri.Postma@cms.hhs.gov.

Rural Emergency Hospital and Critical Access Hospital Conditions of Participation (CoP) Issues, contact Kianna Banks at Kianna.Banks@cms.hhs.gov.

Rural Emergency Hospital Provider Enrollment, contact Frank Whelan via email at Frank.Whelan@cms.hhs.gov.

Rural Emergency Hospital Quality Reporting (REHQR) Program Issues, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Rural Emergency Hospital (REH) Physician Self-Referral Law Update Issues, contact Lisa O. Wilson via email at Lisa.Wilson2@cms.hhs.gov or Meredith Larson via email at Meredith.Larson@cms.hhs.gov.

Skin Substitutes, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

Use of the Medicare Outpatient Observation Notice by REHs, contact Nishamarie Sherry via email at Nishamarie.Sherry@cms.hhs.gov or Janet Miller via email at Janet.Miller@cms.hhs.gov.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at OutpatientPPS@cms.hhs.gov.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at ASCPPS@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual.

CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.
The Addenda relating to the ASC payment system are available at:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2021 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

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I. Summary and Background

A. Executive Summary of this Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2023. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other

adjustments that take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. We also make updates to the requirements for Organ Acquisition, Prior Authorization, and Overall Hospital Quality Star Rating. We are also proposing new regulatory requirements to codify payment policy, quality measures, and enrollment policy for REHs. In addition, we are finalizing the Conditions of Participation that REHs must meet in order to participate in the Medicare and Medicaid programs. This rule also finalizes changes to the Critical Access Hospitals (CAH) CoPs for the location and distance requirements, patient's rights requirements, and flexibilities for CAHs that are part of a larger health system. We thank commenters for submitting comment on the use of CMS data to drive competition in healthcare marketplaces, and the request for information on an alternative methodology for counting organs. Finally, we are finalizing as implemented, a number of provisions included in the COVID-19 interim final rules with comment period (IFCs).

2. Summary of the Major Provisions

- *OPPS Update*: For 2023, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 3.8 percent. This increase factor is based on the final hospital inpatient market basket percentage increase of 4.1 percent for

inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a final productivity adjustment of 0.3 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2023 would be approximately $86.5 billion, an increase of approximately $6.5 billion compared to estimated CY 2022 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9807 to the OPPS payments and copayments for all applicable services.

- *Data used in CY 2023 OPPS/ASC Ratesetting*: To set CY 2023 OPPS and ASC payment rates, we would normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. However, cost report data usually lags the claims data by a year and we believe that the CY 2020 cost report data are not the best overall approximation of expected outpatient hospital service costs as the majority of the cost reports we would typically use for CY 2023 rate setting have cost reporting periods that overlap with parts of the CY 2020 Public Health Emergency (PHE). In order to mitigate the impact of some of the temporary changes in hospitals cost report data from CY 2020, we are utilizing cost report data from the June 2020 extract from Healthcare Cost Report Information System (HCRIS), which includes cost report data from prior to the PHE. This is the same cost report extract we used to set OPPS rates for CY 2022. We believe using the CY 2021 claims data with cost reports data through CY 2019 (prior to the PHE) for CY 2023 OPPS ratesetting is the best approximation of expected costs for CY 2023 hospital outpatient service ratesetting purposes. As a result, we are

utilizing the CY 2021 claims data with cost reporting periods prior to the PHE to set CY 2023 OPPS and ASC payment system rates.

- *Partial Hospitalization Update:* For CY 2023, we are using the hospital-based PHP (HB PHP) geometric mean per diem costs consistent with our existing methodology. In addition, we are finalizing our proposal to use the latest available CY 2021 claims data and to continue to use the cost data that was available for the CY 2021 rulemaking. Based on public comments, and in order to pay appropriately and protect access to PHP services in CMHCs, for CY 2023 but not for subsequent years, we are applying an equitable adjustment, under the authority set forth in section 1833(t)(2)(E) of the Act, to the CY 2023 CMHC APC payment rate. For CY 2023, we are maintaining the CY 2022 CMHC APC payment rate of $142.70 as the CY 2023 CMHC APC final payment rate.

- *Changes to the Inpatient Only (IPO) List*: For 2023, we are finalizing our proposal, with modification, to remove eleven services from the Inpatient Only list.

- 340B-*Acquired Drugs*: For CY 2023, in light of the Supreme Court decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022), we are applying the default rate, generally ASP plus 6 percent, to 340B acquired drugs and biologicals in this final rule with comment period for CY 2023 and removing the increase to the conversion factor that was made in CY 2018 to implement the 340B policy in a budget neutral manner.

We are still evaluating how to apply the Supreme Court's decision to prior calendar years. In the CY 2023 OPPS/ASC proposed rule, we solicited public comments on the best way to craft any potential remedies affecting cost years 2018-2022, and we will take these comments into consideration for separate rulemaking that will be published in advance of the CY 2024 OPPS/ASC proposed rule.

- *Device Pass-Through Payment Applications*: For CY 2023, we received 8 applications for device pass-through payments. We solicited public comment on these applications and are making final determinations on these applications in this final rule with comment period. Beginning for OPPS device pass-through applications received on or after March 1, 2023, we are publicly posting online the completed application forms and related materials that we receive from applicants, excluding certain copyrighted or other materials that applicants indicate cannot otherwise be released to the public.

- *Cancer Hospital Payment Adjustment*: For CY 2023, we are continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we are using a target PCR of 0.89 to determine the CY 2023 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

- *ASC Payment Update*: For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2023, we are increasing payment rates under the ASC payment system by 3.8 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 4.1 percent reduced by a productivity adjustment of 0.3 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment,

utilization, and case-mix) for CY 2023 will be approximately $5.3 billion, an increase of approximately $230 million compared to estimated CY 2022 Medicare payments.

- *Changes to the List of ASC Covered Surgical Procedures*: For CY 2023, we are finalizing our proposal, with modification, to add four procedures, to the ASC CPL based upon existing criteria at § 416.166.

- *Hospital Outpatient Quality Reporting (OQR) Program*: For the Hospital OQR Program measure set, we are finalizing our proposals to: (1) add a data validation targeting criterion to our existing four targeting criteria that reads: "Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters," beginning with the CY 2023 reporting period/ CY 2025 payment determination; (2) align patient encounter quarters with the calendar year, beginning with the CY 2024 reporting period/ CY 2026 payment determination; and (3) change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination. We also requested comment on the future readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) measure or another volume indicator in the Hospital OQR Program.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program*: For the ASCQR Program measure set, we are finalizing our proposal to change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination. We also requested comment on: (1) the potential future implementation of a measures value pathways approach in the ASCQR Program; (2) the status and feasibility of interoperability initiatives in

the ASCQR Program; and (3) the potential readoption of the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7) measure or another volume indicator in the ASCQR Program.

- *Organ acquisition payment policy:* We issued a Request for Information on counting Medicare organs for use in calculating Medicare's share of organ acquisition costs, rather than making a proposal, and will use the information to inform potential future rulemaking. Also, we are finalizing our proposal to exclude research organs from the ratio used to calculate Medicare's share of organ acquisition costs and are modifying our requirement to offset costs by allowing providers to follow their accounting practices of adjusting costs, offsetting revenue or establishing a non-reimbursable cost center, which will maintain or lower the cost of procuring and providing research organs to the research community. Finally, we are finalizing our proposal to cover as organ acquisition costs certain hospital services provided to donors whose death is imminent, to promote organ procurement and enhance equity.

- *Rural Emergency Hospitals (REH) and Critical Access Hospital Conditions of Participation (CoP):* We are finalizing the Conditions of Participation that REHs must meet in order to participate in the Medicare and Medicaid programs. This rule also finalizes changes to the Critical Access Hospitals (CAH) CoPs for the location and distance requirements, patient's rights requirements, and flexibilities for CAHs that are part of a larger health system.

- *Rural Emergency Hospitals (REH): Provider Enrollment*: We are outlining provider enrollment requirements for REHs. The most important of these are that REHs: (1) must comply with all applicable provider enrollment provisions in 42 CFR Part 424, subpart P in order to enroll in Medicare; and (2) may submit a Form CMS-855A change of information application (rather than an initial enrollment application) to convert to an REH.

● *Rural Emergency Hospitals (REH) Physician Self-Referral Law Update*: We are finalizing revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party. We are not finalizing the proposed exception for ownership or investment interests in an REH.

● *Rural Emergency Hospital Quality Reporting (REHQR) Program*: For the REHQR Program, we are finalizing our proposal to require a QualityNet account and Security Official (SO) requirement in line with other quality programs for purposes of data submission and access of facility level reports. Also, we requested information on: (1) measures recommended by the National Advisory Committee on Rural Health and Human Services and additional suggested measures for the REHQR Program, and (2) requested comments on rural telehealth, behavioral and mental health, maternal health services, emergency services, and health equity.● *Overall Hospital Quality Star Ratings*: For the Overall Hospital Quality Star Ratings, we are finalizing amending § 412.190(c) to state the use of publicly available measure results on Hospital Compare or its successor websites from a quarter within the previous 12 months (instead of the "previous year").

• *REH Payment Policy*: Section 125 of the Consolidated Appropriations Act of 2021 (CAA) established a new provider type called REHs, effective January 1, 2023. REHs are facilities that convert from either a critical access hospital (CAH) or a rural hospital (or one treated as such under section 1886(d)(8)(E) of the Social Security Act) with less than 50 beds, and that do not provide acute care inpatient services with the exception of post-hospital extended care services furnished in a unit of the facility that is a distinct part licensed as a skilled nursing facility. By statute, REH services include emergency department services and observation care

and, at the election of the REH, other outpatient medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking.

By statute, covered outpatient department services provided by REHs will receive an additional 5 percent payment for each service. Beneficiaries will not be charged a copayment on the additional 5 percent payment.

We are finalizing all covered outpatient department services, other than inpatient hospital services as described in section 1833(t)(1)(B)(ii) of the Act, that would otherwise be paid under the OPPS as REH services. REHs would be paid for furnishing REH services at a rate that is equal to the OPPS payment rate for the equivalent covered outpatient department service increased by 5 percent. Also, we are finalizing our proposal that REHs may provide outpatient services that are not otherwise paid under the OPPS (such as services paid under the Clinical Lab Fee Schedule) as well as post-hospital extended care services furnished in a unit of the facility that is a distinct part of the facility licensed as a skilled nursing facility; however, these services would not be considered REH services and therefore would be paid under the applicable fee schedule and will not receive the additional 5 percent payment increase that CMS will apply to REH services.

Finally, we are finalizing that REHs would receive a monthly facility payment of $272,866. After the initial payment is established in CY 2023, the monthly facility payment amount will increase in subsequent years by the hospital market basket percentage increase.

- *Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process:* We are adding Facet joint interventions as a category of services to the prior authorization process for hospital outpatient departments beginning for dates of service on or after July 1, 2023.

- *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes*: For CY 2023, we are considering mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes as covered outpatient department services payable under the OPPS and have created OPPS-specific coding for these services. We are finalizing our proposal to require an in-person service within 6 months prior to the initiation of the remote service and then every 12 months thereafter, that exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis. We are clarifying that the requirement that an in-person visit occur within 6 months prior to the initial mental health telehealth service does not apply to beneficiaries who began receiving mental health telehealth services in their homes during the PHE or during the 151-day period after the end of the PHE. We are also finalizing our proposal that audio-only interactive telecommunications systems may be used to furnish these services in instances where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology.

- *Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients*: For CY 2023, to improve clarity, we are finalizing our proposal to replace cross-references at § 410.27(a)(1)(iv)(A) and (B) and § 410.28(e) to the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii) with the text of those definitions. We also are finalizing our proposal to revise § 410.28(e) for clarity so that certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law.

- *Exemption of Rural Sole Community Hospitals (SCH) from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)*: We are finalizing our proposal to exempt rural Sole Community Hospitals (rural SCHs) from the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines).

- *Final Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators:* As discussed in section X.H of this final rule with comment period, the Biden-Harris Administration has made it a priority to ensure America is prepared to continue to respond to COVID-19, and to combat future pandemics. To improve hospital preparedness and readiness for future threats, we are finalizing our proposal to provide payment adjustments to hospitals under the IPPS and OPPS for the additional resource costs they incur to acquire domestic NIOSH-approved surgical N95 respirators. These surgical respirators, which faced severe shortage at the onset of the COVID-19 pandemic, are essential for the protection of beneficiaries and hospital personnel that interface with patients. The Department of Health and Human Services (HHS) recognizes that procurement of domestic NIOSH-approved surgical N95 respirators, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals. The payment adjustments will account for these additional resource costs.

We believe the payment adjustments will help achieve a strategic policy goal, namely, sustaining a level of supply resilience for surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We are

finalizing our proposal that the payment adjustments will commence for cost reporting periods beginning on or after January 1, 2023.

- *Finalization of Certain COVID-19 Interim Final Rules With Comment Period Provisions:* In this final rule with comment period, we are responding to public comments and stating our final policies for certain provisions in the IFCs titled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-5531-IFC), "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (CMS-5531-IFC), and "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-9912-IFC).

3. Summary of Costs and Benefits

In section XXV of this final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of all OPPS Changes

Table 110 in section XXV.C of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2023 compared to all estimated OPPS payments in CY 2022. We estimate that the policies in this final rule with comment period will result in a 4.5 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2023, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by

approximately $3.0 billion compared to CY 2022 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate no change in CY 2023 payments to CMHCs relative to their CY 2022 payments, based on our final policy of maintaining the CY 2022 OPPS payment rates in CY 2023.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2023 IPPS final rule wage indexes will result in a 0.2 percent increase for urban hospitals under the OPPS and no change for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C of this final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2023 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the reduction to the cancer hospital payment adjustment for CY 2023 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2023 is 0.89, equivalent to the 0.89 target PCR for CY 2022, and therefore has no budget neutrality adjustment.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2023 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 3.8 percent and applying that increase factor to the conversion factor for CY 2023. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 5.3 percent and that rural hospitals would experience an increase in payments of 2.7 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase in payments of 3.4 percent, minor teaching hospitals would experience an increase in payments of 4.6 percent, and major teaching hospitals would experience an increase in payments of 7.2 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 5.2 percent in payments, while hospitals with government ownership would experience an increase of 6.3 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 1.6 percent in payments.

We estimate that the effect of paying for drugs acquired under the 340B program at ASP plus 6 percent and removing the increase to the conversion factor that was added in CY 2018 to implement the 340B payment policy in a budget neutral manner will have varying effects across different provider categories. We note that while urban hospitals are estimated to have a 1.2 percent increase in payments, rural hospitals overall are estimated to have a 1.0 percent decrease in payments as a result of these changes.

e. Impacts of the Final ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2023 payment rates, compared to estimated CY 2022 payment rates, generally ranges between an increase of

1 and 6 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates will increase payments by $230 million under the ASC payment system in CY 2023.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148),

enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112-78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112-240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113-93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114-255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115-271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; and the Inflation Reduction Act, 2022 (Pub. L. 117-169), enacted on August 16, 2022.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural

Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C of this final rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the "2 times rule"). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as "transitional pass-through payments," for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not

eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable

items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106-113, and redesignated by section 202(a)(2) of Pub. L. 106-113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the

APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel--

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 20, 2020, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 22, 2022. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). CMS is currently accepting nominations at: https://mearis.cms.gov . In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 22, 2022, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at http://facadatabase.gov.

Comment: One commenter requested that CMS include at least one representative from the ASC community in the membership of the advisory Panel. The commenter explained that decisions regarding the clinical integrity of payment groups and relative payment weights impact ASC payments and, therefore, are of critical importance to ASCs.

Response: We thank the commenter for their suggestion. This expert panel is composed of appropriate representatives of providers (currently employed full-time by hospitals or hospital systems, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Beginning in 2019, the Panel may also include a representative of a provider with ASC expertise, who advises CMS only on OPPS APC rates, as appropriate, impacting ASC covered procedures within the context and purview of the Panel's scope. Interested individuals, including those with relevant ASC expertise, are encouraged to apply to serve on the Panel. Nominations for the Panel are currently being accepted in the new electronic application system, Medicare Electronic Application Request Information System™ (MEARIS). Interested individuals may submit nominations for themselves or others on https://mearis.cms.gov.

F. Public Comments Received on the CY 2023 OPPS/ASC Proposed Rule

We received approximately 1,599 timely pieces of correspondence on the CY 2023 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 27, 2022 (87 FR 44502) from individuals, elected officials, providers and suppliers, practitioners, and advocacy groups.

We provide summaries of the public comments and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

G. Public Comments Received on the CY 2022 OPPS/ASC Final Rule with Comment Period

We received approximately 13 timely pieces of correspondence on the CY 2022 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 16, 2021 (86 FR 63458).

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Use of CY 2021 Data in the CY 2023 OPPS Ratesetting

We primarily use two data sources in OPPS ratesetting: claims data and cost report data. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available full year of claims data would be the data from the year 2 years prior to the calendar year that is the subject of the rulemaking. As discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), unlike CY 2020 claims data, we do not believe there are overwhelming concerns with CY 2021 claims data as a result of the COVID-19 PHE. Therefore, as discussed in further detail in section X.B. of this final rule with comment period, we are finalizing our proposal to use CY 2021 claims data and the data components related to it in establishing the CY 2023 OPPS.

b. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained

in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2023 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2023, and before January 1, 2024 (CY 2023), using the same basic methodology that we described in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63466), using CY 2021 claims data. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2023, we began with approximately 180 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2021, and before January 1, 2022, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2023 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2023 OPPS/ASC proposed rule on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Addendum N to the CY 2023 OPPS/ASC proposed rule (which is available via the Internet on the CMS website at: http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html) includes

the proposed list of bypass codes for CY 2023. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2021 and, therefore, includes codes that were in effect in CY 2021 and used for billing. We proposed to retain deleted bypass codes on the proposed CY 2023 bypass list because these codes existed in CY 2021 and were covered OPD services in that period, and CY 2021 claims data were used to calculate proposed CY 2023 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more "pseudo" single procedure claims for ratesetting purposes. "Overlap bypass codes" that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to the CY 2023 OPPS/ASC proposed rule. HCPCS codes that we proposed to add for CY 2023 are identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our proposed bypass code process. We are adopting as final the proposed "pseudo" single claims process and the final CY 2023 list of bypass codes, as displayed in Addendum N to this final rule with comment period (which is available via the internet on the CMS website). For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2023, we used approximately 93 million final actions claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2021, and before January 1, 2022. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on

the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2023, we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. However, roughly half of the cost reports we would typically use for CY 2023 ratesetting purposes are from cost reporting periods that overlap with parts of CY 2020. When utilizing this cost report data, more than half of the APC geometric mean costs increased by more than 10 percent relative to estimates based on prior ratesetting cycles. While some of this increase may be attributable to changes that will continue into CY 2023, other aspects of those changes may be more specific to the COVID-19 PHE. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we described how CY 2020 claims data were too influenced by the COVID-19 PHE to be utilized for setting CY 2022 OPPS payment rates. After reviewing the cost report data from the December 2021 HCRIS data set, we believed cost report data that overlap with CY 2020 are also too influenced by the COVID-19 PHE for purposes of calculating the CY 2023 OPPS payment rates. Therefore, in order to mitigate the impact on our ratesetting process from the COVID-19 PHE effects in the CY 2020 cost report data we would typically use for this CY 2023 OPPS/ASC proposed rule, we proposed to use cost report data from the June 2020 HCRIS data set, which only includes cost report data through CY 2019, for CY 2023 OPPS/ASC ratesetting purposes.

We discuss this proposal, the public comments we received, as well as our final policy in Section X.B. of this final rule with comment period.

To calculate the APC costs on which the CY 2023 APC payment rates are based, we proposed to calculate hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2021 claims data by comparing these claims data to hospital cost reports available for the CY 2022 OPPS/ASC final rule with comment period ratesetting, which, in most cases, are from CY 2019. For the proposed CY 2023 OPPS payment rates, we proposed to use CY 2021 claims processed through December 31, 2021. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2021 (the year of claims data we used to calculate the proposed CY 2023 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2020 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Comment: One commenter requested that we revise our revenue code-to-cost center crosswalk to provide consistency with the National Uniform Billing Committee (NUBC) definitions and to improve the accuracy of cost data for OPPS ratesetting with respect to chimeric antigen receptor therapy (CAR-T) administration services. The commenter suggested the following changes:

- Revising revenue code 0871 from Reserved to describe "cell collection" and that revenue code 0871 be mapped to a primary cost center 6000 for clinic;
- Revising revenue codes 0872 and 0873 from Reserved to describe "cell processing" and remapping revenue codes 0872 and 0873 to a primary cost center 3350 for laboratory/hematology;
- Map revenue codes 0874 or 0875 to cost center 4800 for intravenous therapy in the revenue code-to-cost center crosswalk;
- Map revenue code 089x series to cost center 5600 (drugs charged to patients), or, at the very least, only map revenue codes 0891 and 0892 to cost center 5600.

Response: We appreciate the commenter's recommendation for changes to our revenue code-to-cost center crosswalk. While we believe the current APC assignment and payment rate for CPT code 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous) is appropriate, we intend to explore the implications of the commenter's recommendation further and may revisit these changes in future rulemaking.

In accordance with our longstanding policy, we proposed to calculate CCRs for the standard cost centers – cost centers with a predefined label – and nonstandard cost centers – cost centers defined by a hospital – accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. Additionally, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We have determined that hospitals are routinely reporting a number of nonstandard cost centers in this way and that including this additional data could significantly reduce certain APC

geometric mean costs. In particular, we estimate that the additional cost data from nonstandard cost centers would decrease the geometric mean cost of APC 8004 (Ultrasound Composite) by 20 percent, APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent and APC 5573 (Level 3 Imaging with Contrast) by 11 percent. In other instances, we note that there are also potential increases in the geometric mean costs of certain APCs, such as APC 5741 (Level 1 Electronic Analysis of Devices), which would increase by 4 percent, APC 5723 (Level 3 Diagnostic Tests and Related Services), which would increase by 2.6 percent, and APC 5694 (Level 4 Drug Administration), which would increase by 2.3 percent.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. Additionally, we are concerned about the significant changes in APC geometric mean costs that our analysis indicates would occur if we were to include such lines. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. For CY 2023, we proposed not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction. We solicited comment on whether there exist any specific concerns with regards to the accuracy of the data from these nonstandard cost center lines that we would need to consider before including them in future OPPS ratesetting.

For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through

67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this final rule with comment period.

Comment: One commenter supported our proposal and recommended that we not use current nonstandard lines in determining OPPS payment rates for CY 2023 without further understanding of the revenues and expenses going into those nonstandard lines.

Response: We thank the commenter for their support. While we did not receive any specific concerns from commenters with regards to the data from these nonstandard cost center lines, we agree that additional context for and analyses into these nonstandard lines would be beneficial before including them in OPPS ratesetting.

After consideration of the public comment we received, we are finalizing our proposal, without modification, not to include nonstandard cost centers on cost report lines that do not correspond to the cost center number.

2. Final Data Development and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2023. The Hospital OPPS page on the CMS website on which this final rule with comment period is posted, (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of

an administrative fee under a CMS data use agreement. The CMS website, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html, includes information about obtaining the "OPPS Limited Data Set," which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD-10-CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2021 claims that are used to calculate the proposed payment rates for the final rule with comment period.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a through II.A.2.c of this final rule with comment period to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2023 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS website at: http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html). We refer

readers to section II.A.4 of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier "PN", which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier "PN" from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2023 OPPS, we will continue to remove claim lines with modifier "PN" from the ratesetting process.

For details of the claims accounting process used in this final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We proposed in the CY 2023 OPPS/ASC proposed rule to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes

actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the proposed CY 2023 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that using this methodology in

CY 2023 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C-APCs. We proposed to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C-APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C-APCs (and, as a result, in the proposed payment rates of the C-APCs), we proposed not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C-APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 through 66796) for more information about our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C-APC).

We refer readers to Addendum B to the CY 2023 OPPS/ASC proposed rule (which is available via the Internet on the CMS website) for the proposed CY 2023 payment rates for blood and blood products (which are generally identified with status indicator "R"). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2023, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology. We did not receive any comments on our proposal to establish payment rates for blood and blood products using our blood-specific CCR methodology and we are finalizing this policy as proposed. Please refer to Addendum B to this final rule with comment period (which is available via the internet on the CMS website) for the final CY 2023 payment rates for blood and blood products.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy – cancer treatment through solid source radioactive implants – consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology

for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2023, except where otherwise indicated, we proposed to use the costs derived from CY 2021 claims data to set the proposed CY 2023 payment rates for brachytherapy sources because CY 2021 is the year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2023 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44568 through 44569), we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of the CY 2023 OPPS/ASC proposed rule (87 FR 44512 through 44513). We also proposed to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment

period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110-275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2023 payment rates for brachytherapy sources are included on Addendum B to the CY 2023 OPPS/ASC proposed rule (which is available via the Internet on the CMS website) and identified with status indicator "U".

For CY 2018, we assigned status indicator "U" (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2

for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021 and CY 2022 OPPS/ASC final rules (85 FR 85879 through 85880 and 86 FR 63469) with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2021 and for CY 2022.

We did not receive any CY 2021 claims data for HCPCS code C2645. Therefore, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2023.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. For these Low Volume APCs, which had fewer than 100 CY 2021 single claims used for ratesetting purposes in the CY 2023 OPPS/ASC proposed rule, we used up to four years of claims data to establish a payment rate for each item or service as we historically have done for low volume services assigned to New Technology APCs. Further, we calculated the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost using all claims for the APC for up to four years. For CY 2023, we proposed to designate 4 brachytherapy APCs as Low Volume APCs as these APCs meet our criteria to be designated as a Low Volume APC. For more information on the brachytherapy APCs we proposed to designate as Low Volume APCs, see section III.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44568 through 44569). In

section III.D. of this final rule with comment period, we are finalizing our proposal to designate four brachytherapy APCs as Low Volume APCs for CY 2023.

Comment: One commenter supported our proposal to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2023.

Response: We thank the commenter for their support of our proposal.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2023. Additionally, we are finalizing our proposal to continue to set the payment rates for other brachytherapy sources that are not otherwise assigned to designated Low Volume APCs for CY 2023 using our established prospective payment methodology.

The final CY 2023 payment rates for brachytherapy sources are included in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) and are identified with status indicator "U".

We continue to invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to outpatientpps@cms.hhs.gov or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C-APCs) for CY 2023

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014 but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C-APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C-APC policy (79 FR 66798 through 66810).

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 66810). We have gradually added new C-APCs since the policy was implemented beginning in CY 2015, with the number of C-APCs now totaling 69 (80 FR 70332; 81 FR 79584 through 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; and 86 FR 63474).

Under our C-APC policy, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator "J1". When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and

79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C-APC policy is included in Addendum J to this final rule with comment period (which is available via the Internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

In the interim final rule with request for comments (IFC) titled, ‘‘Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency”, published on

November 6, 2020, we stated that, effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID-19, there is an exception to the OPPS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID-19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID-19, always be separately paid and will not be packaged into a C-APC when it is provided on the same claim as the primary C-APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in section "I. Criteria for Issuance of Authorization" of the FDA letter of authorization for the emergency use of the drug or biological product, or the drug or biological product must be approved by FDA for treating COVID-19. Second, the emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by FDA to treat COVID-19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C-APC policy for COVID-19 treatments, please refer to the November 6, 2020 IFC (85 FR 71158 through 71160). Please see section XXIII.C. for additional details regarding our finalized policy, which will end when the PHE ends.

The C-APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital

outpatient claim reporting a primary service that is assigned to status indicator "J1"[1], excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator "J1" are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the "Comprehensive Observation Services" C–APC (C–APC 8011). Services within this APC are assigned status indicator "J2"[2]. . Specifically, we make a payment through C–APC 8011 for a claim that:

● Does not contain a procedure described by a HCPCS code to which we have assigned status indicator "T";

● Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);

● Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department

[1] Status indicator "J1" denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2023 Addendum D1.
[2] Status indicator "J2" denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2023 Addendum D1.

visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

● Does not contain services described by a HCPCS code to which we have assigned status indicator "J1".

The assignment of status indicator "J2" to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the

service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C-APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those

drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies[3]..

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator "J1" as a single "J1" unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C-APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator "J1" and later used to develop the geometric mean costs for the C-APC relative payment weights. (We note that we use the term "comprehensive" to describe the geometric mean cost of a claim reporting "J1" service(s) or the geometric mean cost of a C-APC, inclusive of all of the items and services included in the C-APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C-APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator "J1" according to its comprehensive geometric mean costs. For the minority of claims reporting

[3] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

more than one primary service assigned to status indicator "J1" or units thereof, we identify one "J1" service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple "J1" procedure claims to the C-APC to which the service designated as the primary service is assigned. If the reported "J1" services on a claim map to different C-APCs, we designate the "J1" service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple "J1" services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator "J1" to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired "J1" service code combinations or paired code combinations of "J1" services and certain add-on codes (as described further below) from the originating C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

● Frequency of 25 or more claims reporting the code combination (frequency threshold); and

● Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2 of this final rule with comment period, in the originating C-APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator "J1" (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of "J1" services (or combinations of "J1" services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment

for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary "J1" service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2023, we proposed to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator "J1" and any number of units of a single add-on code for the primary "J1" service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C-APC within the same clinical family of C-APCs. As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the "J1" primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C-APC. We list the complexity adjustments for "J1" and add-on code combinations for CY 2023, along with all of the other final complexity adjustments, in Addendum J to this final rule comment period (which is available via the Internet on the CMS website at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices).

Addendum J to this final rule with comment period includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this final rule with comment period also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and will be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all final reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the final geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to the CY 2023 OPPS/ASC final rule allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations. The specific C-APC complexity adjustment code combinations requested by the commenters for CY 2023 are listed in Table 1 below.

TABLE 1: C-APC Complexity Adjustments Requested by Commenters for CY 2023

Primary "J1" HCPCS/CPT Code	Secondary "J1" HCPCS/CPT code	Primary C-APC Assignment	Requested complexity adjusted C-APC assignment
20902 (Bone graft, any donor area; major or large)	**28740** (Arthrodesis, midtarsal or tarsometatarsal, single joint)	5114	5115
20982 (Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency)	**22510** (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic)	5114	5115
	22511 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral)	5114	5115
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method)	**27687** (Gastrocnemius recession (eg, strayer procedure))	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	**28270** (Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure))	5114	5115
	27687 (Gastrocnemius recession (eg, strayer procedure))	5114	5115
	27691 (Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot))	5114	5115
	28299 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with double osteotomy, any method)	5114	5115
	28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	5114	5115
37243 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance	**C1982** (Catheter, pressure-generating, one-way valve, intermittently occlusive)	5193	5194

Primary "J1" HCPCS/CPT Code	Secondary "J1" HCPCS/CPT code	Primary C-APC Assignment	Requested complexity adjusted C-APC assignment
necessary to complete the intervention; for tumors, organ ischemia, or infarction)			
37187 (Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance)	**37248** (Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein)	5193	5194
52000 (Cystourethroscopy (separate procedure))	**C9738** (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5372	5373
52214 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands)		5374	5375
52224 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy)		5374	5375
52234 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; small bladder tumor(s) (0.5 up to 2.0 cm))		5374	5375
52235 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; medium bladder tumor(s) (2.0 to 5.0 cm))		5374	5375
52240 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s))		5375	5376

Response: We reviewed the requested code combinations suggested by commenters, listed in Table 1, against our complexity adjustment criteria. The code combination for primary HCPCS code 52000 with secondary HCPCS code C9738 met our cost and frequency criteria,

qualifying for a complexity adjustment for CY 2023. The remaining code combinations failed to meet our cost or frequency criteria and do not qualify for complexity adjustments for CY 2023. Addendum J to the CY 2023 OPPS/ASC final rule with comment period includes the cost statistics for each code combination that was evaluated for a complexity adjustment.

We note that one code combination, HCPCS 20902 and HCPCS 28740, requested by comments was already proposed in the CY 2023 OPPS/ASC proposed rule and is being finalized in this final rule with comment period as a qualifying complexity adjustment. Additionally, one code combination commenters requested, HCPCS 37243 and HCPCS C1983, does not qualify for a complexity adjustment because the secondary code, C1983, is not an add-on code and does not have a J1 status indicator. Accordingly, this code combination was not evaluated for a CY 2023 complexity adjustment.

Comment: We also received support from commenters for a variety of existing and proposed complexity adjustments, including neurostimulator procedures as well as fusion and bunion surgery procedures.

Response: We thank the commenters for their support.

Comment: Several commenters requested that CMS modify or eliminate the established C-APC complexity adjustment eligibility criteria of 25 or more claims reporting the code combination (frequency) and a violation of the 2 times rule in the originating C-APC (cost) to allow additional code combinations to qualify for complexity adjustments. Some commenters expressed concern that CMS' methodology for determining complexity adjustments is unnecessarily restrictive, particularly the 25-claim threshold, and suggested that CMS implement a complexity adjustment whenever a code pair exceeds the cost threshold.

Several commenters reiterated their request to allow clusters of procedures, consisting of a "J1" code pair and multiple other associated add-on codes used in combination with that "J1" code pair to qualify for complexity adjustments, stating that this may allow for more accurate reflection of medical practice when multiple procedures are performed together or there are certain complex procedures that include numerous add-on codes. Commenters also requested that CMS continue to monitor and report on the impact of complexity adjustments.

Response: We appreciate these comments. At this time, we do not believe changes to the C-APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As we stated in the CY 2017 OPPS/ASC final rule (81 FR 79582), we believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C-APC, are appropriate to determine if a combination of procedures represents a complex, costly subset of the primary service that should qualify for the adjustment and be paid at the next higher paying C-APC in the clinical family. As we previously stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61161), a minimum of 25 claims is already a very low threshold for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58843), we do not believe that it is necessary to adjust the complexity adjustment criteria to allow claims that include more than two "J1" procedures or procedures that are not assigned to C-APCs to qualify for a complexity adjustment. As previously mentioned, we believe the current criteria are adequate to determine if a combination of procedures represents a complex, costly

subset of the primary service. We will continue to monitor the application of the complexity adjustment criteria.

After consideration of the public comments we received on the proposed complexity adjustment policy, we are finalizing the C-APC complexity adjustment policy for CY 2023 as proposed. We are also finalizing the proposed complexity adjustments with the addition of the one new code combination, primary HCPCS code 52000 with secondary HCPCS code C9738, that meet our complexity adjustment criteria.

(2) Exclusion of Procedures Assigned to New Technology APCs from the C-APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C-APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator “J1”, payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was

reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a "J1" service assigned to a C-APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator "J2" when they are included on a claim with a "J2" service (84 FR 61167). We proposed to continue to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a "J1" or "J2" service assigned to a C-APC. We did not receive any public comments on this policy and are finalizing it as proposed.

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified drugs or biologicals) from the C-APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a

HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the FDA and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 has been included in the C-APC payment when these products appear on a claim with a primary C-APC service. Packaging

payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C-APC service is consistent with our C-APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It has been our position that the total payment for the C-APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we have determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C-APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we proposed to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a "J1" service, which is the status indicator assigned to a C-APC, and a claim with a "J2" service, which is the status indicator assigned to comprehensive observation services. Please see OPPS Addendum J for the final CY 2023 comprehensive APC payment policy exclusions.

We also included a corresponding proposal in section XI "Proposed CY 2023 OPPS Payment Status and Comment Indicators" of the CY 2023 OPPS/ASC proposed rule (87 FR 44698), to add a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with HCPCS code C9399. The definition, found in Addendum D1 to the CY 2023 OPPS/ASC proposed rule, would ensure the MAC prices claims for drugs,

biologicals or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C-APC service.

Comment: Interested parties expressed support of the proposal to exclude C9399 from "J1" and "J2" claims and to add a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with C9399.

Response: We thank commenters for their support.

After consideration of the public comments we received, to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years we are finalizing, without modification, our proposal to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a "J1" service, which is the status indicator assigned to a C-APC, and a claim with a "J2" service, which is the status indicator assigned to comprehensive observation services. Please see the section titled "CY 2023 OPPS Payment Status and Comment Indicators" of this CY 2023 OPPS/ASC final rule with comment period for details regarding the new definition of status indicator "A".

(4) Additional C-APCs for CY 2023

For CY 2023, we proposed to continue to apply the C-APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C-APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our

annual review of the services and the APC assignments under the OPPS, we proposed to add one C-APC under the existing C-APC payment policy in CY 2023: C-APC 5372 (Level 2 Urology and Related Services). This APC was proposed because, similar to other C-APCs, this APC included primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other clinical APCs that have been converted to C-APCs, there are higher APC levels (Levels 3-8 Urology and Related Services) within the clinical family or related clinical family of this APC that were previously converted to C-APCs.

Comment: Commenters supported the creation of the new proposed C-APC, based on resource cost and clinical characteristics.

Response: We appreciate the commenters' support.

Comment: Several commenters were concerned that the C-APC methodology lacks the charge capture mechanisms to accurately reflect the cost of radiation oncology services, particularly the delivery of brachytherapy for the treatment of cervical cancer. They stated that this type of cancer disproportionately impacts minorities, women, and rural populations and that undervaluing brachytherapy procedures risks exacerbating existing disparities in treatment. These commenters suggested that CMS discontinue the C-APC payment policy for all brachytherapy insertion codes and allow these procedures to be reported through traditional APCs, move brachytherapy procedures (CPT codes 57155 and 58346) to higher paying C-APCs, or pay separately for preparation and planning services to more fully account for the costs associated with these procedures.

Response: We appreciate the comments. The calculations provided by commenters as to the cost of these services do not match how we calculate C-APC costs. We believe that the

current C-APC methodology is appropriately applied to these surgical procedures and is accurately capturing costs, particularly as the brachytherapy sources used for these procedures are excluded from C-APC packaging and are separately payable. This methodology also enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves.

We also reviewed the request by commenters to move brachytherapy procedures, CPT code 57155 and CPT code 58346, to a higher paying C-APC. For CPT code 57155, the claims data in the two times rule evaluation show that this code is being paid at the appropriate level in C-APC 5415 (Level 5 Gynecologic Procedures). For CPT code 53846, given that this code has less than 100 claims, it does not meet the significance threshold of the two times rule evaluation and we do not believe the few claims available provide an accurate reflection of the service's cost sufficient to move this procedure to a higher C-APC. We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

After consideration of the public comments we received, we are finalizing as proposed C-APC 5372 (Level 2 Urology and Related Services) for CY 2023. Table 2 lists the final C-APCs for CY 2023. All C-APCs are displayed in Addendum J to this CY 2023 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all of the data related to the C-APC payment policy methodology, including the list of complexity adjustments and other information for CY 2023.

TABLE 2: FINAL CY 2023 C-APCs

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	*
5373	Level 3 Urology and Related Services	UROXX	

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology/
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant

UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the

payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2023. In addition, we proposed to set the payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

Comment: Several commenters recommended that CMS change the status indicator for two neuropsychological testing codes (HCPCS 96133 and 96137) from SI = N to SI = Q3 to allow separate payment for additional hours of testing on the same date or increase the payment rate for the primary testing procedure code. The commenters noted that the payment rate for Composite APC 8010, which is capped at the maximum per diem partial hospitalization rate, is lower than the individual HCPCS code APC payment rates and does not provide sufficient payment for these procedures.

Response: After reviewing this issue, we believe the Composite APC methodology is being appropriately applied in this case, as packaging multiple testing services performed on a single date of service creates incentives for hospitals to provide these services in the most cost-efficient manner. We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal, without modification, that when the aggregate payment for specified mental health services

provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2023. In addition, we are finalizing our proposal to set the payment rate for composite APC 8010 for CY 2023 at the same payment rate that we set for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3 below.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the "with contrast" composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the "with contrast" composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2023, we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2023, except where otherwise indicated, we proposed to use the costs derived from CY 2021 claims data to set the proposed CY 2023 payment rates. Therefore, for CY 2023, the payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from CY 2021 claims available for the CY 2023 OPPS/ASC proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we have used the same methodology that we use to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as "overlap bypass codes" that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this final rule (which is available via the Internet on the CMS website[4]) and are discussed in more detail in section II.A.1.b of this final rule with comment period.

In the CY 2023 OPPS/ASC proposed rule, for CY 2023, we were able to identify approximately 0.95 million "single session" claims out of an estimated 2.0 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47.5 percent of all eligible claims, to calculate the proposed CY 2023 geometric mean costs for the multiple imaging composite APCs. Table 3 of the CY 2023 OPPS/ASC final

[4] CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1772-P); Notice of Final Rulemaking. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices

rule with comment period lists the final HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2023.

We did not receive any public comments on this policy. We are finalizing continuing the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. Table 3 below lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2023.

TABLE 3: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2023 APC 8004 (Ultrasound Composite)	**CY 2023 Approximate APC Geometric Mean Cost = $302.65**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2023 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2023 Approximate APC Geometric Mean Cost = $227.67**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye

72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2023 APC 8006 (CT and CTA with Contrast Composite)	**CY 2023 Approximate APC Geometric Mean Cost = $434.16**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye

73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2023 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2023 Approximate APC Geometric Mean Cost = $527.17**
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest

C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2023 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2023 Approximate APC Geometric Mean Cost = $845.72**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd

C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than

to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to

determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Policy and Comment Solicitation on Packaged Items and Services

For CY 2023, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2023, we did not propose any changes to the overall packaging policy previously discussed. We proposed to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

While we did not propose any changes to the overall packaging policy above, we solicited comments on potential modifications to our packaging policy, as described in section XIII.E.5 of the CY 2023 OPPS/ASC proposed rule (87 FR 44717). Specifically, we solicited comments and data regarding whether to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the HOPD setting. Details on the current ASC policy can be found in section XIII.E of this final rule with comment period.

We did not receive any public comments on our overall OPPS packaging policy and therefore, we are continuing the OPPS packaging policy for CY 2023 without modification. Specific packaging concerns are discussed in detail in their respective sections throughout this final rule with comment period.

As discussed above and in the proposed rule, we solicited comments and data regarding whether to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the HOPD setting. Details on the current ASC policy can be found in section XIII.E of this final rule with comment period. Below is a summary of the comments received in response to the comment solicitation.

Comment: Many commenters suggested CMS extend the policy described at § 416.174 to also encompass the HOPD setting. Generally, commenters believed these products serve a valuable clinical purpose and their use should be encouraged in all settings of care. Several commenters provided data regarding how packaging negatively impacted the utilization of their products in the HOPD. Some commenters conceded that it is reasonable to think that the average hospital outpatient department would be able to absorb the extra costs; however, they believe that does not mean that every hospital outpatient department would be able to do so.

Commenters also presented data showing potential access barriers affecting underserved communities. Commenters believed that the HOPD setting is more accessible to vulnerable and underserved populations relative to the ASC setting. Commenters stated that these are the populations that are also most negatively impacted by opioids.

Response: We thank commenters for their comments on the comment solicitation to expand the non-opioid drug or biological payment policy to the HOPD setting. We will take

these comments into consideration for future rulemaking. We remind interested parties that we are not modifying our policy at § 416.174 or creating new policies in response to these comment solicitations. Any change to or expansion of the policy described at § 416.174 would be done through notice and comment rulemaking.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2022 OPPS/ASC final rule with comment period (85 FR 63497 through 63498), we applied this policy and calculated the relative payment weights for each APC for CY 2022 that were shown in Addenda A and B of the CY 2022 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63466 through 63483). For CY 2023, as we did for CY 2022, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2023 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic

visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2023, as we did for CY 2022, we proposed to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2023, as we did for CY 2022, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discussed our policy, implemented beginning on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based departments (PBDs) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further,

under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2023 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2022 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2023 unscaled relative payment weights.

For CY 2022, we multiplied the CY 2022 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2021 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2023, we proposed to apply the same process using the estimated CY 2023 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2022 estimated aggregate weight by the unscaled CY 2023 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/HospitalOutpatientPPS/index.html. Click on the link labeled "CY 2023 OPPS/ASC Notice of Proposed Rulemaking", which can be found under the heading "Hospital Outpatient Prospective Payment System Rulemaking" and open the claims accounting document link at the bottom of the page, which is labeled "2023 NFRM OPPS Claims Accounting (PDF)".

We proposed to compare the estimated unscaled relative payment weights in CY 2023 to the estimated total relative payment weights in CY 2022 using CY 2021 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2023 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2023 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4152 to ensure that the proposed CY 2023 relative payment weights are scaled to be budget neutral. The proposed CY 2023 relative payment weights listed in Addenda A and B to the CY 2023 OPPS/ASC proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this CY 2023 OPPS/ASC proposed rule (87 FR 44510 through 44525).

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44644 through 44646)) is included in the budget neutrality calculations for the CY 2023 OPPS.

We did not receive any public comments on the proposed weight scalar calculation. Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2023. For CY 2023, as we did for CY 2022, we will continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2023 using geometric mean-based APC costs. For CY 2023, as we did for CY 2022, we will assign APC 5012 a relative payment weight of 1.00 and we will divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. To comply with this requirement concerning the APC changes, we will compare the estimated aggregate weight using the CY 2022 scaled relative payment weights to the estimated aggregate weight using the CY 2023 unscaled relative payment weights.

Using updated final rule claims data, we are updating the estimated CY 2023 unscaled relative payment weights by multiplying them by a weight scalar of 1.4122 to ensure that the final CY 2023 relative payment weights are scaled to be budget neutral. The final CY 2023 relative payments weights listed in Addenda A and B of this final rule with comment period (which are available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this final rule with comment period.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD rate increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD rate increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under

section 1886(b)(3)(B)(iii) of the Act. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28402), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2021 forecast of the FY 2023 market basket increase, the proposed FY 2023 IPPS market basket update was 3.1 percent. We noted in the proposed rule that under our regular process for the CY 2023 OPPS/ASC final rule, we would use the market basket update for the FY 2023 IPPS/LTCH PPS final rule, which would be based on IHS Global, Inc.'s second quarter 2022 forecast of the FY 2023 market basket increase. If that forecast is different than the market basket used for the proposed rule, the CY 2023 OPPS/ASC final rule OPD rate increase factor would reflect that different market basket estimate.

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28402), the proposed MFP adjustment for FY 2023 was 0.4 percentage point.

Therefore, we proposed that the MFP adjustment for the CY 2023 OPPS would be 0.4 percentage point. We also proposed that if more recent data become subsequently available after the publication of the CY 2023 OPPS/ASC proposed rule (for example, a more recent

estimate of the market basket increase and/or the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2023 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we proposed for CY 2023 an OPD fee schedule increase factor of 2.7 percent for the CY 2023 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.1 percent, less the proposed 0.4 percentage point MFP adjustment).

We proposed that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV of the CY 2023 OPPS/ASC proposed rule.

To set the OPPS conversion factor for 2023, we proposed to increase the CY 2022 conversion factor of $84.177 by 2.7 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2023 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0010 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2023 IPPS

wage indexes to those payments using the FY 2022 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further proposed to calculate an additional budget neutrality factor of 0.9995 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

We note that we did not include a budget neutrality factor for the proposed rule to account for the adjustment for drugs purchased under the 340B Program because we formally proposed to continue paying such drugs at ASP minus 22.5 percent, which was the same payment rate as in CY 2022. Given the timing of the Supreme Court's decision in *American Hospital Association v. Becerra,* 142 S. Ct. 1896 (2022), , we lacked the necessary time to fully incorporate the adjustments to our budget neutrality calculations to account for that decision before issuing the CY 2023 OPPS/ASC proposed rule. Instead, we included alternative files with the proposed rule that detailed the impact of removing the 340B policy for CY 2023. The final budget neutrality factor for the 340B policy is discussed later in this section and section V.B.6. of this final rule with comment period.

For the CY 2023 OPPS, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of the CY 2023 OPPS/ASC proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

We proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F of the CY 2023 OPPS/ASC proposed rule. We proposed to calculate a CY 2023 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2023 payments under section 1833(t) of the Act, including the proposed CY 2023 cancer hospital payment adjustment, to estimated CY 2023 total payments using the CY 2022

final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2023 estimated payments applying the proposed CY 2023 cancer hospital payment adjustment were the same as estimated payments applying the CY 2022 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255), we applied a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F of the CY 2023 OPPS/ASC proposed rule.

We estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2023 would equal approximately $772.0 million, which represents 0.90 percent of total projected CY 2023 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 1.24 percent estimate of pass-through spending for CY 2022 and the 0.90 percent estimate of proposed pass-through spending for CY 2023, resulting in a proposed increase to the conversion factor for CY 2023 of 0.34 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2023. We estimated for the CY 2023 OPPS/ASC proposed rule that outlier payments would be approximately 1.29 percent of total OPPS payments in CY 2022; the 1.00 percent for proposed outlier payments in CY 2023 would constitute a 0.29 percent decrease in payment in CY 2023 relative to CY 2022.

We also proposed to make an OPPS budget neutrality adjustment of 0.01 percent of the OPPS for the estimated spending of $8.3 million associated with the proposed payment

adjustment under the CY 2023 OPPS for domestic NIOSH-approved surgical N95 respirators, as discussed in section X.H of the CY 2023 OPPS/ASC proposed rule.

For CY 2023, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.7 percent (that is, the proposed OPD fee schedule increase factor of 2.7 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2023 of $85.093 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.692 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2023, we proposed to use a reduced conversion factor of $85.093 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.692 in the conversion factor relative to hospitals that met the requirements).

For 2023, we proposed to use a conversion factor of $86.785 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.7 percent for CY 2023, the required proposed wage index budget neutrality adjustment of approximately 1.0010, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9995, the proposed cancer hospital payment adjustment of 1.0000, the proposed adjustment to account for the 0.01 percentage point of OPPS spending associated with the payment adjustment for domestic NIOSH-approved surgical N95 respirators, and the proposed adjustment of an increase of 0.34 percentage point of projected

OPPS spending for the difference in pass-through spending, which resulted in a proposed conversion factor for CY 2023 of $86.785.

Comment: Many commenters believed that the proposed OPD rate increase of 2.7 percent substantially underestimated the increases in costs for labor, equipment, and supplies that hospitals are facing. Commenters also asserted that the adjusted inpatient hospital rate increase of 3.8 percent that was implemented for the IPPS and calculated using more current economic data is also inadequate to address the large cost increases faced by hospitals. Many commenters raised concerns about sharply rising labor costs, especially the cost of nursing care. Commenters stated that during the COVID-19 pandemic, hospitals greatly increased their use of contract nurses whose wages and support costs were substantially higher than nurses regularly employed by hospitals. Commenters had serious concerns about whether the market basket data that measures labor costs were measuring the increased hospital labor costs. Commenters also were in favor of eliminating or substantially reducing the productivity adjustment from the OPD rate update. They believe that disruptions caused by the pandemic, inflation, and supply-chain issues have inhibited productivity growth, and that the proposed adjustment overestimates productivity efficiencies in the hospital sector of the economy.

Commenters had several suggested actions or sources of information that could be used to measure and compensate for the increased costs hospitals face. Some commenters suggested using different measures of changes in costs and of inflation, including Medicare cost reports and the Consumer Price Index (CPI). Many commenters support a one-time Medicare payment rate increase in addition to the proposed OPD rate increase to meet current sharply rising costs and remedy what commenters said were inadequate increases to OPD rates in prior years.

One commenter contended that we do not have to accept the adjusted inpatient hospital rate increase for the final OPD rate increase, pointing out that section 1833(t)(3)(C)(iv) of the Act states that "…the 'OPD fee schedule increase factor' for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii)…" The commenter explained that section 1886(b)(3)(B)(iii) of the Act defines the IPPS market basket percentage increase that section 1833(t)(3)(C)(iv) requires to be adopted by the OPPS. The commenter believes that section 1886(d)(5)(I)(i) of the Act, which states that "(t)he Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate…," gives CMS flexibility to identify adjustments that could update the IPPS market basket to better reflect rapidly increasing input costs for hospitals.

Response: Section 1833(t)(3)(C)(iv) of the Act requires that the OPD fee schedule increase factor equal the IPPS market basket percentage increase. The IPPS authority in section 1886(d)(5)(I)(i) of the Act gives the Secretary authority to make exceptions and adjustments to IPPS payment amounts under subsection (d) of section 1886; it does not give the Secretary authority to adjust OPPS payment amounts. Section 1833(t)(3)(C)(iv) does give the Secretary discretion to substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year, but we did not propose to substitute a covered OPD services-specific increase for the market percentage increase factor for CY 2023. Where CMS does not substitute this alternative, the OPD fee schedule increase factor must equal the market basket percentage increase. And as we noted in the FY 2023 IPPS/LTCH PPS final rule,

the final IPPS market basket growth rate of 4.1 percent would be the highest market basket update implemented in an IPPS final rule since FY 1998 (87 FR 49052).

Comment: Several commenters supported our proposed OPD rate increase of 2.7 percent updated based on more current market basket information for this final rule. Some of the commenters noted that our proposed increase was the minimum amount needed to reflect hospitals' higher costs and they encouraged us to implement an OPD rate increase larger than the proposed 2.7 percent OPD rate increase.

Response: We appreciate the commenter's support for our proposed OPD rate increases. After reviewing the public comments that we received, we are finalizing these proposals with modification.

For CY 2023, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act (discussed in section II.F of this final rule with comment period). Based on the final rule updated data used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target payment-to-cost ratio for the cancer hospital payment adjustment, which was 0.90 for CY 2022, is 0.90 for CY 2023. As a result, we are applying a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For this CY 2023 OPPS/ASC final rule with comment period, based on more recent data available for the FY 2023 IPPS/LTCH PPS final rule (87 FR 49056) (that is, IGI's second quarter 2022 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2022), the hospital market basket update for CY 2023 is 4.1 percent and the productivity adjustment for FY 2023 is 0.3 percent.

We note that as a result of the modifications in final policy for the CY 2023 wage index we are also including a change to the wage index budget neutrality adjustment so that the final overall budget neutrality factor of 0.9998 would apply for wage index changes. This adjustment is comprised of a 1.0002 budget neutrality adjustment, using our standard calculation of comparing proposed total estimated payments from our simulation model using the final FY 2023 IPPS wage indexes to those payments using the FY 2022 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9996 budget neutrality adjustment for the final CY 2023 5-percent cap on wage index decreases (as discussed in section II.C of this final rule with comment period), requiring application of the 5-percent cap on CY 2022 wage indexes, to ensure that this wage index is implemented in a budget neutral manner.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2023 OPPS is 3.8 percent (which reflects the 4.1 percent final estimate of the hospital inpatient market basket percentage increase with a -0.3 percentage point productivity adjustment). For CY 2023, we are using a conversion factor of $84.177 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 3.8 percent for CY 2023, the required wage index budget neutrality adjustment of 0.9998, the adjustment to account for the change in policy for drugs purchased under the 340B Program of 0.9691, and the adjustment of 0.16 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2023 of $85.585. This information is listed in Table 4.

TABLE 4: CY 2023 CONVERSION FACTOR UPDATE

Unadjusted Conversion Factor	$84.177
OPD Fee Schedule Increase	3.8 percent

Wage Index Budget Neutrality Adjustment	0.9998
340B Budget Neutrality Adjustment	0.9691
Pass-Through Spending Adjustment	0.16 percent point
Final CY 2023 Conversion Factor	**$85.585**

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B of the CY 2023 OPPS/ASC proposed rule (87 FR 44528).

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). In the CY 2023 OPPS/ASC proposed rule (, we proposed to continue this policy for the CY 2023 OPPS. We referred readers to section II.H of the CY 2023 OPPS/ASC proposed rule (87 FR 44535 through 44536) for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule (which is available via the Internet on the CMS website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices), for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2023 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add

paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. In the CY 2023 OPPS/ASC proposed rule, we proposed to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We referred readers to the FY 2011 through FY 2022 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of "frontier States" as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; and for FY 2022, 86 FR 45178.

We did not receive any public comments on our proposal, and we are finalizing our proposal without modification.

In addition to the changes required by the Affordable Care Act, we noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44529) that the proposed FY 2023 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed

floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. We referred readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) for a detailed discussion of all proposed changes to the FY 2023 IPPS wage indexes. We noted in particular that in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28377 through 28380), we proposed a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We stated that we believe this policy would increase the predictability of IPPS payments for hospitals and mitigate instability and significant negative impacts to hospitals resulting from changes to the wage index. It would also eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties

to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: https://www.census.gov/geo/reference/county-changes.html (which, as of May 6, 2019, migrated to: https://www.census.gov/programs-surveys/geography.html). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2023, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

In the CY 2023 OPPS/ASC proposed rule, we proposed to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2023. We stated that, therefore, any policies and adjustments for the FY 2023 IPPS post-reclassified wage index, including, but not limited to, the 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY described above, would be reflected in the final CY 2023 OPPS wage index beginning on January 1, 2023. We referred readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) and the proposed FY 2023

hospital wage index files posted on the CMS website at https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-proposed-rule-home-page. With regard to budget neutrality for the CY 2023 OPPS wage index, we referred readers to section II.B of the CY 2023 OPPS/ASC proposed rule (78 FR 44528). We stated that we continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. In the CY 2023 OPPS/ASC proposed rule, we proposed to continue this policy for CY 2023 and included a brief summary of the major proposed FY 2023 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPPS for CY 2023. We referred readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) for a detailed discussion of the proposed changes to the FY 2023 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We noted that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would

apply if the hospital were paid under the IPPS. For CY 2023, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we proposed that the wage index that would apply for CY 2023 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. We stated that in addition, the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5 percent cap on wage index decreases that we may finalize for the FY 2023 IPPS wage index as discussed previously.

Comment: Multiple commenters supported our proposal for FY 2023 and subsequent years to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. Commenters stated that the proposal would provide payment stability for hospitals. Commenters also requested that the proposed 5-percent cap policy be excluded from budget neutrality, which would allow the cap to be applied while avoiding decreases to the wage index in areas with high wage indexes.

Response: We appreciate the commenters' support of our proposal in the FY 2023 IPPS/LTCH PPS proposed rule to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. We finalized this proposal and the associated proposed budget neutrality adjustment in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) and agree that the policy will promote payment stability for hospitals.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) for a detailed discussion of the wage index cap policy finalized for the FY 2023 IPPS wage index and for responses to these and other comments relating to the wage index cap policy.

As we noted, in the FY 2023 IPPS/ LTCH PPS final rule (87 FR 49018 through 49021), for FY 2023 and subsequent years, we finalized an IPPS wage index policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior fiscal year, regardless of the circumstances causing the decline. A hospital's wage index for FY 2023 will not be less than 95 percent of its final wage index for FY 2022, and for subsequent years, a hospital's wage index will not be less than 95 percent of its final wage index for the prior fiscal year. Except for newly opened hospitals, we will apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year because it would not have been assigned a wage index in the prior year. We stated in the FY 2023 IPPS/ LTCH PPS final rule (87 FR 49021) that we will apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. Specifically, we will apply a budget neutrality adjustment to ensure that estimated aggregate payments under our wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the wage index cap policy. We will apply a similar budget neutrality adjustment in the OPPS for each calendar year. For the OPPS, section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner.

Comment: One commenter was opposed to our proposal to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. The commenter stated

that our proposal goes against the purpose of having a wage index, which the commenter believes is to adjust payment rates to reflect the substantial geographic differences in hospital labor costs.

Response: We appreciate the commenter's concerns. However, we believe applying a 5-percent cap on all wage index decreases supports increased predictability about OPPS payments for hospitals in the upcoming calendar year, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a hospital would be able to more effectively budget and plan when there is predictability about its expected minimum level of OPPS payments in the upcoming calendar year. We believe that any potential difference in the wage index value hospitals in the same labor market area receive would likely be minimal and temporary.

Comment: One commenter supported the application of the imputed floor wage index policy, including the policy's definition of all-urban states as well as its non-budget neutral application as required by section 9831 of the American Rescue Plan Act of 2021. Another commenter opposed the imputed floor policy, stating that it unfairly manipulates the wage index to benefit a handful of only-urban states and territories.

Response: We appreciate the commenter's support of our application of the imputed floor wage index policy. In response to the commenter that opposed this policy, we underscore that the imputed floor was established for the IPPS wage index by section 9831 of the American Rescue Plan Act of 2021. As we stated in the CY 2022 OPPS/ASC final rule (86 FR 63502), we continue to believe that it is appropriate to apply the imputed floor policy in the OPPS in the same manner as under the IPPS, given the inseparable, subordinate status of the HOPD within the hospital overall.

Comment: Multiple commenters requested that rural emergency hospitals (REHs) be eligible to be reclassified under Medicare Geographic Classification Review Board (MGCRB) reclassification process.

Response: Pursuant to section 1861(kkk)(2)(B) of the Act, REHs may not provide acute care inpatient hospital services other than post-hospital extended care services furnished by a distinct part unit licensed as a skilled nursing facility. Therefore, REHs are considered to be non-IPPS hospitals. Non-IPPS hospitals are not eligible for Medicare Geographic Classification Review Board (MGCRB) reclassification.

After consideration of the public comments we received, we are finalizing our proposal without modification to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2023. Any policies and adjustments for the FY 2023 IPPS post-reclassified wage index will be reflected in the final CY 2023 OPPS wage index beginning on January 1, 2023, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals, and a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48990 through 49021) and the FY 2023 hospital wage index files posted on the CMS website at [https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-

page]. With regard to budget neutrality for the CY 2023 OPPS wage index, we refer readers to section II.B. of this CY 2023 OPPS/ASC final rule.

We also are finalizing our proposal without modification to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we also are finalizing our proposal without modification that the wage index that would apply for CY 2023 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities.

For CMHCs, for CY 2023, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we proposed that the wage index that would apply to a CMHC for CY 2023 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, we stated that the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases that we may finalize for the FY 2023 IPPS wage index as discussed above. Also, we proposed that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

We did not receive any public comments on these proposals, and we are finalizing these proposals without modification.

Table 4A associated with the FY 2023 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index) identifies counties eligible for the out-migration adjustment.

Table 2 associated with the FY 2023 IPPS/ LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that receive the out-migration adjustment for FY 2023. We are including the outmigration adjustment information from Table 2 associated with the FY 2023 IPPS/LTCH PPS final rule as Addendum L to this final rule, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this final rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index. At this link, readers will find a link to the final FY 2023 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB NO: 0938-0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100-04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2022 OPPS final rule Claims Accounting Narrative that is posted on our website. Due to concerns with cost report data as a result of the COVID–19 PHE, we proposed to calculate the default ratios for CY 2023 using the June 2020 HCRIS cost reports, consistent with the broader proposal regarding CY 2023 OPPS ratesetting discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682).

We did not receive any public comments on our proposal and are finalizing our proposal, without modification, to calculate the default ratios for CY 2023 using the June 2020 HCRIS cost reports, consistent with the broader proposal regarding CY 2023 OPPS ratesetting.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html; click on the link on the left of the page titled "Hospital Outpatient Regulations and Notices" and then select the relevant regulation to download the statewide CCRs and upper limit in the downloads section of the webpage.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) under Section 1833(t)(13)(B) of the Act for CY 2023

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Pub. L. 105-33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we

may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2022.

For CY 2023, we proposed to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

Comment: Two commenters requested that the 7.1 percent payment adjustment be allowed for providers other than rural SCHs and EACHs. The commenters suggested the following providers should receive the adjustment: Medicare dependent hospitals, rural referral centers, urban sole community hospitals, and rural hospitals with fewer than 100 beds that cannot be classified as SCHs or CAHs because they do not meet the mileage requirements for SCHs and CAHs.

Response: Our study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas only showed a significant difference in costs for rural SCHs. We did not identify significant cost differences between hospitals in urban areas and hospitals in rural areas for the types of hospitals described by the commenters. Therefore, we are not expanding the types of hospitals eligible for the 7.1 percent payment adjustment.

Comment: Multiple commenters are in favor of our policy to apply a 7.1 percent payment adjustment for rural SCHs, including EACHs.

Response: We appreciate the commenters' support of our policy.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue our current policy of utilizing a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the passthrough payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2023

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106-113), the Congress added section 1833(t)(7), "Transitional Adjustment to Limit Decline in Payment," to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as "held harmless" and their payments are often referred to as "hold harmless" payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a "pre-BBA amount." That is, cancer hospitals are permanently held harmless to their "pre-BBA amount," and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in

section 1833(t)(7)(F) of the Act. The "pre-BBA amount" is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The "pre-BBA amount" and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB NO: 0938-0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the "target PCR") for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 5 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2022.

TABLE 5: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2022

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89

2. Policy for CY 2023

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals, generally using the most recent submitted or settled cost report data

that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. We did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2023.

Under our established policy, to calculate the proposed CY 2023 target PCR, we used the same extract of cost report data from HCRIS used to estimate costs for the CY 2023 OPPS which, in most cases, would be the most recently available hospital cost reports. However, as discussed in section II.A.1.c and X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44510 through 44511 and 87 FR 44680 through 44682), we proposed to use cost report data from the June 2020 HCRIS data set, which does not contain cost reports from CY 2020, given our concerns with CY 2020 cost report data as a result of the COVID-19 PHE. We believe a target PCR based on the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2022 rulemaking cycle, which pre-dated the COVID-19 PHE. Therefore, for CY 2023, we proposed to continue to use the same target PCR we used for CY 2021 and CY 2022 of 0.89. This proposed CY 2023 target PCR of 0.89 includes the 1.0-percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2023. For a description of the CY 2021 target PCR calculation, on which the proposed CY 2023 target PCR is based, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (84 FR 85912 through 85914).

Comment: One commenter supported our proposed target PCR of 0.89.

Response: We thank the commenter for their support.

After consideration of the public comment we received, we are finalizing our proposal to continue to use the CY 2021 and CY 2022 target PCR of 0.89 for the 11 specified cancer hospitals for CY 2023 without modification.

Table 6 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2023, due to the cancer hospital payment adjustment policy. The cost reporting periods for all cancer hospitals in Table 6 overlaps with CY 2020 and the costs and payments associated with each cancer hospital may be impacted by the effects of the COVID-19 PHE. Therefore, the estimates in Table 6 are likely to be less accurate than in other years and may overstate the percentage increase in cancer hospital payments for CY 2023. The actual, final amount of the CY 2023 cancer hospital payment adjustment for each cancer hospital would be determined at cost report settlement and would depend on each hospital's CY 2023 payments and costs from the settled CY 2023 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 6: Estimated CY 2023 Hospital-Specific Payment Adjustment For Cancer Hospitals To Be Provided At Cost Report Settlement

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2023 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	45.5%
050660	USC Norris Cancer Hospital	31.7%
100079	Sylvester Comprehensive Cancer Center	24.1%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1%
220162	Dana-Farber Cancer Institute	42.7%
330154	Memorial Sloan-Kettering Cancer Center	69.2%
330354	Roswell Park Cancer Institute	15.2%
360242	James Cancer Hospital & Solove Research Institute	12.9%
390196	Fox Chase Cancer Center	23.5%
450076	M.D. Anderson Cancer Center	49.4%

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2023 due to Payment Adjustment
500138	Seattle Cancer Care Alliance	46.1%

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2022, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $6,175 (the fixed-dollar amount threshold) (86 FR 63508 through 63510). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process

for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2021 OPPS payments, using CY 2021 claims available for this final rule with comment period, is approximately 1.16 percent. Therefore, for CY 2021, we estimate that we exceeded the outlier target by 0.16 percent of total aggregated OPPS payments.

For this final rule with comment period, using CY 2021 claims data and CY 2022 payment rates, we estimate that the aggregate outlier payments for CY 2022 would be approximately 1.26 percent of the total CY 2022 OPPS payments. We provide estimated CY 2023 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts - Provider-Specific Data file on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

2. Outlier Calculation for CY 2023

For CY 2023, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate

for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this final rule with comment period.

To ensure that the estimated CY 2023 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $8,350.

We calculated the proposed fixed-dollar threshold of $8,350 using the standard methodology most recently used for CY 2022 (86 FR 63508 through 63510). For purposes of estimating outlier payments for CY 2023, we use the hospital-specific overall ancillary CCRs available in the April 2022 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate the CY 2023 hospital outlier payments, we inflate the charges on the CY 2021 claims using the same proposed charge inflation factor of 1.13218 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28667). We used an inflation factor of 1.06404 to estimate CY 2022 charges from the CY 2021 charges reported on CY 2021 claims before applying CY 2022 CCRs to estimate the percent of outliers paid in CY 2022. The proposed methodology for determining these charge inflation factors, as well as the solicitation of comments on an alternative approach, is discussed

in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28667 through 28678). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR adjustment factor that we proposed to apply for the FY 2023 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2023 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2023, we proposed to apply an adjustment factor of 0.974495 to the CCRs that were in the April 2022 OPSF to trend them forward from CY 2022 to CY 2023. The methodology for calculating the proposed CCR adjustment factor, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28668). We note that we proposed to use the April 2022 OPSF for purposes of estimating costs for the OPPS outlier threshold calculation whereas in Section X.D. of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682) we discussed using June 2020 HCRIS data extract for modeling hospital outpatient costs in construction of our CY 2023 OPPS relative weights. For modeling estimated outlier payments, since the April 2022 OPSF contains cost data primarily from CY 2021 and CY 2022 and is the basis for current CY 2022 OPPS outlier payments, we stated that we believe the April 2022 OPSF provides a more updated and accurate data source for determining the CCRs that will be applied to CY 2023 hospital outpatient claims. Therefore, we explained that we believe the April 2022 OPSF is a

more accurate data source for determining the fixed-dollar threshold to ensure that the estimated CY 2023 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS.

To model hospital outlier payments for the CY 2023 proposed rule, we applied the overall CCRs from the April 2022 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.974495 to approximate CY 2023 CCRs) to charges on CY 2021 claims that were adjusted (using the proposed charge inflation factor of 1.13218 to approximate CY 2023 charges). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2023 OPPS payments. We estimated that a proposed fixed-dollar threshold of $8,350, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced

OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to Section XIV of the CY 2023 OPPS/ASC proposed rule (87 FR 44726 through 44740).

Comment: Many commenters expressed concern about the proposed CY 2023 fixed-dollar threshold of $8,350 and its large increase from the final CY 2022 fixed-dollar threshold of $6,175. Many commenters were concerned that fewer cases would qualify for OPPS outlier payments, potentially underfunding hospitals, and missing our 1.0 percent target. Commenters also noted that, in the FY 2023 Inpatient Prospective Payment System (IPPS)/Long Term Care Hospital (LTCH) Prospective Payment System final rule, in response to stakeholder comments, we finalized a lower fixed loss amount for IPPS outliers after blending fixed loss amounts that were modeled with COVID inpatient admissions and without COVID inpatient admissions. Commenters recommended that we revisit our methodology for determining the CY 2023 OPPS fixed-dollar threshold to be sure that we meet our 1.0 percent target.

Response: We appreciate the commenters' concerns regarding the large increase in CY 2023 OPPS fixed-dollar threshold from CY 2022. We have reviewed and analyzed our methodology as well as the most up to date CCRs available in the July 2022 OPSF for determining estimated outlier payments. We estimate that the increase in the fixed-dollar threshold from CY 2022 to CY 2023 is largely attributable to an increase in reported charges on

hospital outpatient claims. Holding CCRs constant, an increase in reported charges otherwise increases the charges reduced to cost on hospital outpatient claims. An additional contributing factor is an increase in hospital CCRs in the July 2022 OPSF when compared to the July 2021 OPSF. The increase in hospital CCRs further increases the charges reduced to cost on hospital outpatient claims. We believe the combination of these two factors has increased hospital outpatient costs, thereby allowing more cases to qualify for OPPS outlier payments. To counterbalance these increases, as described in our final calculation below, our modeling estimates a large increase in the OPPS fixed-dollar threshold is required to maintain a 1.0 percent OPPS outlier spending target. As discussed further in section X.D of this final rule with comment period, we believe it is reasonable to assume that there would continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPPS ratesetting, similar to the CY 2021 claims data. As a result, we did not exclude such COVID–19 cases for determining the CY 2023 fixed-dollar threshold.

As described in our final calculation below, we do not believe modification to the underlying methodology is warranted at this time. Therefore, we are finalizing our proposal to determine a fixed-dollar threshold, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, that would allocate 1.0 percent of aggregated total OPPS payments to outlier payments.

3. Final Outlier Calculation

Historically, we have used updated data for the outlier fixed-dollar threshold calculation for the final rule. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63510), we finalized our proposal to not use the most recent CCRs in the OPSF as they may be significantly impacted by the PHE. As we discussed in the CY 2023 OPPS/ASC

proposed rule (87 FR 44533 through 44534), we believe the updated OPSF data for modeling the outlier fixed dollar threshold in the CY 2023 OPPS/ASC proposed rule provides a more accurate data source for estimating CY 2023 aggregate outlier payments. Similarly, we believe using updated OPSF data for this final rule with comment period provides the best source of CCRs for OPPS outlier calculations. For CY 2023, we are applying the overall ancillary CCRs from the July 2022 OPSF file after adjustment (using the CCR inflation adjustment factor 0.974495 to approximate CY 2023 CCRs) to charges on CY 2021 claims that were adjusted using a charge inflation factor of 1.13218 to approximate CY 2023 charges. These are the same CCR adjustment and charge inflation factors that were used to model IPPS outlier payments and to determine the final IPPS fixed-loss threshold for the FY 2023 IPPS/LTCH PPS final rule (87 FR 49427). We simulated aggregated CY 2023 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payment equaled 1.0 percent of aggregated estimated total CY 2023 OPPS payments. We estimated that a fixed-dollar threshold of $8,625 combined with the multiple-threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For example, in CY 2023, if 1.75 times the APC amount is $5,000 and the applicable costs on the claim totaled $10,000 (which also exceeds our CY 2023 fixed-dollar threshold of $8,625), the hospital would receive an outlier payment of

$2,500 (($10,000 - $5,000) * 0.50). However, if the applicable cost on the claim totaled $8,000, which does not exceed our CY 2023 fixed-dollar threshold, no outlier payment would be made.

For CMHCs, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The national unadjusted payment rate is the is payment rate for most APC's before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2023 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B of this final rule with comment period and the relative payment weight described in section II.A of this final rule with comment period. The national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the CMS website) at "https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates" and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available on the CMS website link above) is calculated by multiplying the final CY 2023 scaled weight for the APC by the CY 2023 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this final rule with comment period.

We demonstrated the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1", "J2", "P", "Q1", "Q2", "Q3", "Q4", "R", "S", "T", "U", or "V" (as defined in Addendum D1 to this final rule with comment period, which is available via the Internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. We note that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B

to this final rule with comment period (which are available via the Internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full" national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9807 times the "full" national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2023 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS/ASC final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2023 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) "Lugar" hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We are continuing to apply for the CY 2023 OPPS wage index any adjustments for the FY 2023 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2023 OPPS, we refer readers to section II.C of this final rule with comment period.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108-173. Addendum L to this final rule with comment period (which is available via the Internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2023 IPPS wage index, which are listed in Table 3 associated with the FY 2023 IPPS final rule and available via the Internet on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. (Click on the link on the left side of the screen titled "FY 2023 IPPS Final Rule Home Page" and select "FY 2023 Final Rule Tables.") This step is to

be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The CY 2023 full national unadjusted payment rate for APC 5071 is $648.97. The reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $636.44. This reduced rate is calculated by multiplying the reporting ratio of 0.9807 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the full national unadjusted payment is approximately $389.38 (.60 * $648.97). The labor-related portion of the reduced national adjusted payment is approximately $381.86 (.60 * $636.44).

Step 2 & 3. The FY 2023 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of IPPS 2023 wage index policies, is 1.3329.

Step 4. The wage adjusted labor-related portion of the full national unadjusted payment is approximately $519.00 ($389.38 *1.3329). The wage adjusted labor-related portion of the reduced national adjusted payment is approximately $508.98 ($381.86 * 1.3329).

Step 5. The nonlabor-related portion of the full national unadjusted payment is approximately $259.59 (.40 * $648.97). The nonlabor-related portion of the reduced national adjusted payment is approximately $254.58 (.40 * $636.44).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the full national unadjusted payment is approximately $778.59 ($519.00 + $259.59). The sum of the portions of the reduced national adjusted payment is approximately $763.56 ($508.98 + $254.58).

Full national unadjusted payment rate	Reduced national adjusted payment rate
$778.59	$763.56

We did not receive any public comments on our proposal and therefore, we are finalizing it as proposed.

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national

unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis

as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, "Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests" of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through 2026 (and the corresponding reduction in coinsurance) is 85 percent (with beneficiary coinsurance equal to 15 percent).

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 11101 of the Inflation Reduction Act requires a Part B inflation rebate for a Part B rebatable drug if the ASP of the drug rises at a rate that is faster than the rate of inflation. Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) by adding a new paragraph (9) and subparagraph (F), respectively, that specifies coinsurance under the ASC and OPPS payment systems. Section 1833(i)(9) requires that under the ASC payment system that beneficiary coinsurance for a Part B rebatable drug that is not packaged to be calculated using the inflation-adjusted amount when that amount is less than the otherwise applicable payment amount for the drug furnished on or after April 1, 2023. Section 1833(t)(8)(F) requires that under the OPPS payment system that beneficiary copayment for a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or packaged into the payment for a procedure) is to be calculated using the inflation-adjusted amount when that amount is less than ASP plus 6 percent beginning April 1, 2023. Sections 1833(i)(9) and 1833(t)(8)(F) reference sections 1847A(i)(5) for the computation of the beneficiary coinsurance

and 1833(a)(1)(EE) for the computation of the payment to the ASC or provider and state that the computations would be done in the same manner as described in such provisions. The computation of the coinsurance is described in section 1847A(i), specifically, in computing the amount of any coinsurance applicable under Part B to an individual to whom such Part B rebatable drug is furnished, the computation of such coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount determined under section 1847A(i)(3)(C) for such part B rebatable drug. The calculation of the payment to the provider or ASC is described in section 1833(a)(1)(EE), and the provider or ASC would be paid the difference between the beneficiary coinsurance or copayment of the inflation-adjusted amount and ASP plus 6 percent. We wish to make readers aware of this statutory change that begins April 1, 2023. We wish to make readers of this OPPS/ASC final rule aware of this statutory change. There are no regulatory changes reflecting this provision of the Act in this final rule. Additionally, we refer readers to the full text of the IRA. [5] Additional details on the implementation of section 11101 of the IRA are forthcoming and will be communicated through a vehicle other than the OPPS/ASC regulation.

2. OPPS Copayment Policy

For CY 2023, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period

[5] H.R. 5376 available online at: https://www.congress.gov/bill/117th-congress/house-bill/5376/text

(72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The final national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2023 are included in Addenda A and B to the CY 2023 OPPS/ASC final rule (which are available via the Internet on the CMS website).

As discussed in section XIV.E of the CY 2023 proposed rule (87 FR 44536) and this final rule with comment period, for CY 2023, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.

- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or greater than the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is less than the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.

- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment

percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. In addition, we are finalizing the use of the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The finalized national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2023 are included in Addenda A and B to the CY 2023 OPPS/ASC final rule (which are available via the Internet on the CMS website).

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare

beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $129.79 is approximately 20 percent of the full national unadjusted payment rate of $648.97. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H of this final rule with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*.

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9807.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2023 are shown in Addenda A and B to this final rule with comment period (which are available via the CMS website). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2023 OPD increase factor discussed in section II.B of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLAA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together,

Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit

public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI of this final rule with comment period, specifically, the "CY 2023 Payment Status and Comment Indicators" section, we discuss the various status indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this final rule with comment period.

1. HCPCS Codes That Were Effective for April 2022 for Which We Solicited Public Comments in the CY 2023 OPPS/ASC Proposed Rule

For the April 2022 update, 48 new HCPCS codes were established and made effective on April 1, 2022. Through the April 2022 OPPS quarterly update CR (Transmittal 11305, Change Request 12666, dated March 24, 2022), we recognized several new HCPCS codes for separate payment under the OPPS. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 5 (New HCPCS Codes Effective April 1, 2022) of the CY 2023 OPPS/ASC proposed rule (87 FR 44539-44541), which are also displayed in Table 7.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in April 2022. The comments and our responses are addressed in their respective sections of this final rule with comment period, which include, but are not limited to: sections III.C. (New Technology APCs), III.E. (OPPS APC-Specific

Policies), and IV. (OPPS Payment for Devices). For those April 2022 codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments. We note that several of the temporary HCPCS C-codes have been replaced with permanent HCPCS J-codes, effective January 1, 2023[6]. Their replacement codes are listed in Table 7. In addition, in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 7. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective April 1, 2022, were assigned to comment indicator "NP" in Addendum B to the CY 2023 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the Internet on the CMS website.

TABLE 7: NEW HCPCS CODES EFFECTIVE APRIL 1, 2022

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
A2011	A2011	Supra sdrm, per square centimeter
A2012	A2012	Suprathel, per square centimeter
A2013	A2013	Innovamatrix fs, per square centimeter

[6] HCPCS C-codes are temporary billing codes that describe items and services for hospital outpatient use, including pass-through devices, pass-through drugs and biologicals, brachytherapy sources, new technology procedures, and certain other services. HCPCS J-codes are permanent billing codes that describe drugs.

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
A4100	A4100	Skin substitute, fda cleared as a device, not otherwise specified
A4238	A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9291	A9291	Prescription digital behavioral therapy, fda cleared, per course of treatment
C9090	J2998	Injection, plasminogen, human-tvmh, 1 mg
C9091	J9331	Injection, sirolimus protein-bound particles, 1 mg
C9092	J3299	Injection, triamcinolone acetonide (xipere), 1 mg
C9093	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
C9781	C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed
C9782	C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study
C9783	C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study
J0219	J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0491	J0491	Injection, anifrolumab-fnia, 1 mg
J0879	J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)
J9071	J9071	Injection, cyclophosphamide, (auromedics), 5 mg
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg
J9359	J9359	Injection, loncastuximab tesirine-lpyl, 0.1 mg
K1028	K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
K1029	K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
K1030	K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only
K1031	K1031	Non-pneumatic compression controller without calibrated gradient pressure
K1032	K1032	Non-pneumatic sequential compression garment, full leg
K1033	K1033	Non-pneumatic sequential compression garment, half leg
Q4224	Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
Q4225	Q4225	Amniobind, per square centimeter
Q4256	Q4256	Mlg-complete, per square centimeter
Q4257	Q4257	Relese, per square centimeter
Q4258	Q4258	Enverse, per square centimeter
Q5124	Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
V2525	V2525	Contact lens, hydrophilic, dual focus, per lens
0306U	0306U	Oncology (minimal residual disease [mrd]), next-generation targeted sequencing analysis, cell-free dna, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for mrd
0307U	0307U	Oncology (minimal residual disease [mrd]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free dna, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for mrd
0308U	0308U	Cardiology (coronary artery disease [cad]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [kim-1]), plasma, algorithm reported as a risk score for obstructive cad
0309U	0309U	Cardiology (cardiovascular disease), analysis of 4 proteins (nt-probnp, osteopontin, tissue inhibitor of metalloproteinase-1 [timp-1], and kidney injury molecule-1 [kim-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
0310U	0310U	Pediatrics (vasculitis, kawasaki disease [kd]), analysis of 3 biomarkers (nt-probnp, c-reactive protein, and t-uptake), plasma, algorithm reported as a risk score for kd
0311U	0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)–based antimicrobial susceptibility for each organisms identified
0312U	0312U	Autoimmune diseases (eg, systemic lupus erythematosus [sle]), analysis of 8 igg autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (elisa), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic sle-likelihood assessment
0313U	0313U	Oncology (pancreas), dna and mrna next-generation sequencing analysis of 74 genes and analysis of cea (ceacam5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)
0314U	0314U	Oncology (cutaneous melanoma), mrna gene expression profiling by rt-pcr of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)
0315U	0315U	Oncology (cutaneous squamous cell carcinoma), mrna gene expression profiling by rt-pcr of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a categorical risk result (ie, class 1, class 2a, class 2b)
0316U	0316U	Borrelia burgdorferi (Lyme disease), ospa protein evaluation, urine

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
0317U	0317U	Oncology (lung cancer), four-probe fish (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer
0318U	0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
0319U	0319U	Nephrology (renal transplant), rna expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
0320U	0320U	Nephrology (renal transplant), rna expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
0321U	0321U	Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
0322U	0322U	Neurology (autism spectrum disorder [asd]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (lc-ms/ms), plasma, results reported as negative or positive for risk of metabolic subtypes associated with asd

2. HCPCS Codes That Were Effective July 1, 2021, for Which We Solicited Public Comments in the CY 2023 OPPS/ASC Proposed Rule

For the July 2022 update, 63 new codes were established and made effective July 1, 2022. Through the July 2022 OPPS quarterly update CR (Transmittal 11457, Change Request 12761, dated June 15, 2022), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 6 (New HCPCS Codes Effective July 1, 2022) of the CY 2023 OPPS/ASC proposed rule, which are also listed in Table 8 below.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in July 1, 2022. The comments and our responses are addressed in their respective sections of this final rule with comment period, which include,

but are not limited to: sections III.C (New Technology APCs), III.E (OPPS APC-Specific Policies), and IV (OPPS Payment for Devices). For those July 1, 2022 codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes and one with a HCPCS Q-code. Their replacement codes are listed in Table 8 below. We note that in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 8 below. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective July 1, 2022, were assigned to comment indicator "NP" in Addendum B to the CY 2023 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the Internet on the CMS website.

TABLE 8: NEW HCPCS CODES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
A9596	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9601	A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie
C9094	J1302	Injection, sutimlimab-jome, 10 mg
C9095	J9274	Injection, tebentafusp-tebn, 1 microgram
C9096	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
C9097	J2777	Inj, faricimab-svoa, 0.1 mg
C9098	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
D1708	D1708	Pfizer-BioNTech Covid-19 vaccine administration – third dose
D1709	D1709	Pfizer-BioNTech Covid-19 vaccine administration – booster dose
D1710	D1710	Moderna Covid-19 vaccine administration – third dose
D1711	D1711	Moderna Covid-19 vaccine administration – booster dose
D1712	D1712	Janssen Covid-19 vaccine administration - booster dose
D1713	D1713	Pfizer-BioNTech Covid-19 vaccine administration tris-sucrose pediatric – first dose
D1714	D1714	Pfizer-BioNTech Covid-19 vaccine administration tris-sucrose pediatric – second dose
G0308	G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
G0309	G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
J0739	J0739	Injection, cabotegravir, 1 mg
J1306	J1306	Injection, inclisiran, 1 mg
J1551	J1551	Injection, immune globulin (cutaquig), 100 mg
J2356	J2356	Injection, tezepelumab-ekko, 1 mg
J2779	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2998	J2998	Injection, plasminogen, human-tvmh, 1 mg
J3299	J3299	Injection, triamcinolone acetonide (xipere), 1 mg
J9331	J9331	Injection, sirolimus protein-bound particles, 1 mg
J9332	J9332	Injection, efgartigimod alfa-fcab, 2mg
K1034	K1034	Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count
Q4259	Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Q4260	Signature apatch, per square centimeter
Q4261	Q4261	Tag, per square centimeter
90584	90584	Dengue vaccine, quadrivalent, live, 2 dose schedule, for subcutaneous use
0714T	0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0715T	0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
0716T	0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
0717T	0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs
0718T	0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
0719T	0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
0720T	0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0721T	0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging
0722T	0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)
0723T	0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session
0724T	0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)
0725T	0725T	Vestibular device implantation, unilateral
0726T	0726T	Removal of implanted vestibular device, unilateral
0727T	0727T	Removal and replacement of implanted vestibular device, unilateral
0728T	0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming
0729T	0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming
0730T	0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
0731T	0731T	Augmentative AI-based facial phenotype analysis with report
0732T	0732T	Immunotherapy administration with electroporation, intramuscular
0733T	0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
0734T	0734T	Remote body and limb kinematic measurement-based therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified health care professional, per calendar month
0735T	0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)
0736T	0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter
0737T	0737T	Xenograft implantation into the articular surface
0323U	0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi
0324U	0324U	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug
0325U	0325U	Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug
0326U	0326U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0327U	0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed
0328U	0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service
0329U	0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
0330U	0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
0331U	0331U	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations

3. October 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2023 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we are soliciting comments on the new CPT and Level II HCPCS codes that became effective October 1, 2022 in this final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2022 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2023, we proposed to continue our established policy of assigning comment indicator "NI" in Addendum B to the CY 2023 OPPS/ASC final rule with comment period to those new HCPCS codes that will be effective October 1, 2022, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We invite public comments in this final rule with comment period on the status indicator and APC assignments for these codes, which would be finalized in the CY 2024 OPPS/ASC final rule with comment period.

4. January 2023 HCPCS Codes

a. New Level II HCPCS Codes for Which We Are Soliciting Public Comments in this CY 2023 OPPS/ASC Final Rule with Comment Period

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2023, in this final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and

G-codes listed in Addendum O of the CY 2023 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2023, we proposed to include in Addendum B to the CY 2023 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2023, that would be incorporated in the January 2023 OPPS quarterly update CR. Specifically, for CY 2023, we are finalizing our process of continuing our established policy of assigning comment indicator "NI" in Addendum B to this final rule with comment period to the new HCPCS codes that will be effective January 1, 2023, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We are inviting public comments in this final rule with comment period on the status indicator and APC assignments for these codes, which would be finalized in the CY 2024 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Solicited Public Comments in the CY 2023 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late

for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2023 OPPS update, we received the CPT codes that will be effective January 1, 2023, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator "NP" in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we reminded readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2023 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled "CY 2023 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code," to the proposed rule. We noted that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned comment indicator "NP".

In summary, in the CY 2023 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2023 SI and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2023. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the SI and APC assignments for these codes (with their final CPT code numbers) in the CY 2023 OPPS/ASC final rule with comment period. The proposed SI and APC assignments for these codes were included in Addendum B to the proposed rule (which is available via the Internet on the CMS website).

We received comments on several of the new CPT codes that were assigned to comment indicator "NP" in Addendum B to the CY 2023 OPPS/ASC proposed rule. We have responded

to those public comments in sections III.C (New Technology APCs), III.E (OPPS APC-Specific Policies), and IV (OPPS Payment for Devices) of this final rule with comment period.

The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2023, can be found in Addendum B to this final rule with comment period. In addition, the SI meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2023) to this final rule with comment period. Both Addendum B and D1 are available via the Internet on the CMS website.

Finally, Table 9 below, which is a reprint of Table 7 from the CY 2023 OPPS/ASC proposed rule (87 FR 44548), shows the comment timeframe for new and revised HCPCS codes. Table 9 provides information on our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 9: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
	Level II HCPCS Codes	January 1, 2023	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or

services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3 of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient department services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. In the CY 2023 OPPS/ASC proposed rule (87 FR 44548), for CY 2023, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the

CY 2023 OPPS update will be discussed in the relevant specific sections throughout this final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). For an example of significant procedure codes, refer to the discussion on cardiac computed tomography angiography (CCTA), specifically as it relates to CPT codes 75572 and 75574, which are discussed in section III.E. (Cardiac Computed Tomography Angiography (CCTA) (APC 5571)) of this final rule with comment period. This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that

comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In the CY 2023 OPPS/ASC proposed rule, for CY 2023, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2023 OPPS update, we identified the APCs with violations of the 2 times rule and we proposed changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we proposed a 2 times rule exception) in Addendum B to the CY 2023 OPPS/ASC proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this final rule with comment period. Rather, it is published and made available via the Internet on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we did not propose a 2 times rule exception, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. Refer to section III.E (APC-Specific Policies) of this final rule with comment period for examples of various APC reassignments. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2023 included in the CY 2023 OPPS/ASC proposed rule are related to changes in costs of services that were observed in the CY 2021 claims data available for CY 2023 ratesetting. Addendum B to the CY 2023 OPPS/ASC proposed rule identifies with a comment indicator "CH" those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2022 OPPS Addendum B Update (available via the Internet on the CMS website at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html).

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed to make for CY 2023, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2021 claims data available for the CY 2023 OPPS/ASC proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2023 and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2021 claims data available for the CY 2023 OPPS/ASC proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 10 below. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as

APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 8 of the CY 2023 OPPS/ASC proposed rule listed the 23 APCs for which we proposed to make an exception under the 2 times rule for CY 2023 based on the criteria cited above and claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before December 31, 2021, and CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

Based on the updated final rule CY 2021 claims data used for this CY 2023 final rule with comment period, we found a total of 25 APCs with violations of the 2 times rule. Of these 25 total APCs, 22 were identified in the proposed rule and three are newly identified APCs. The three newly identified APCs with violations of the 2 times rule are the following:

- APC 5341 (Abdominal/Peritoneal/Biliary and Related Procedures)
- APC 5361 (Level 1 Laparoscopy and Related Services)
- APC 5723 (Level 3 Diagnostic Tests and Related Services)

Although we did not receive any comments on Table 8 of the CY 2023 OPPS/ASC proposed rule (87 FR 44550), we did receive comments on APC assignments for specific

HCPCS codes. The comments, and our responses, can be found in section III.D. (OPPS APC-Specific Policies) of this final rule with comment period.

After considering the public comments we received on APC assignments and our analysis of the CY 2021 costs from hospital claims and cost report data available for this CY 2023 OPPS/ASC final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 22 of the 23 proposed APCs from the 2 times rule for CY 2021 and also excepting three additional APCs (APCs 5341, 5361, and 5723) for a total of 25 APCs.

In summary, Table 10 below lists the 25 APCs that we are excepting from the 2 times rule for CY 2023 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2021, and December 31, 2021, that were processed on or before June 30, 2022, and updated CCRs, if available. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

TABLE 10: FINAL CY 2023
APC EXCEPTIONS TO THE 2 TIMES RULE

CY 2023 APC	CY 2023 APC Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5341	Abdominal/Peritoneal/Biliary and Related Procedures
5361	Level 1 Laparoscopy and Related Services
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 3 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5791	Pulmonary Treatment
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are

available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: 1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; 2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and 3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment on the CMS Website and then follow the instructions to access the MEARIS™ system for OPPS New Technology APC applications.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of "S" (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of "T" (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2022, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology - Level 1A ($0-$10)) to the highest cost band assigned to APC 1908 (New Technology - Level 52 ($145,001-$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology – Level 7 ($501 - $600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374). For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on

initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

We note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2023, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to the CY 2023 OPPS/ASC proposed rule (which is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be significant contributors to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a New Technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower

utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we adopted a policy in the CY 2019 OPPS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893).

For purposes of this adjustment, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believed that it was appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has an annual claims volume of fewer than 100 claims (83 FR 58893). Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we also stated that using the median or arithmetic mean rather than the geometric mean (which "trims" the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of "outlier" claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. Also, having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services helps to create a more stable payment rate.

In the CY 2019 OPPS/ASC final rule (83 FR 58893), we implemented a policy that we would seek public comments on which statistical methodology should be used to determine the

payment rate for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we explained that we would use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other interested parties, to determine the most appropriate payment rate. Once we identified the most appropriate payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

In the CY 2022 OPPS/ASC final rule with comment period, we adopted a policy to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to four years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC (86 FR 63529). However, we replaced our specific low-volume New Technology APC policy with the universal low volume APC policy that we adopted beginning in CY 2022. Our universal low volume APC policy is similar to our past New Technology APC low volume policy except that the universal low volume APC policy applies to clinical APCs and brachytherapy APCs as well as low volume procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to assign a procedure with fewer than 100 claims per year to an appropriate New Technology APC. In the CY 2023 OPPS/ASC proposed rule, we proposed to designate three procedures assigned to New Technology APCs as low volume

procedures and use the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to assign such procedures to the appropriate New Technology APCs.

We did not receive any public comments on our proposed methodology for assigning low volume new technology procedures to New Technology APCs and, therefore, we are finalizing our proposal without modification.

3. Procedures Assigned to New Technology APC Groups for CY 2023

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2023, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more

than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

We did not receive any public comments on our proposal to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC, and we are finalizing our proposal without modification. The procedures assigned to the New Technology APCs are discussed below.

a. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. For information on the utilization and payment history of the Argus® II procedure and the Argus® II device through CY 2022, please refer to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529 through 63530).

Early in 2022, we learned that the manufacturer of the Argus® II device discontinued manufacturing the device in 2020. We also contacted the consultant who represented the manufacturer in presentations with CMS, and he confirmed that the Argus® II device is no longer being implanted. A review of OPPS claims data found that there were no claims billed for CPT code 0100T in either CY 2020 or CY 2021. Based on this information, we have determined that the Argus® II device is no longer available in the marketplace and that outpatient hospital providers are no longer performing the Argus® II implantation procedure. Therefore, we proposed to make changes to the OPPS status indicators for HCPCS and CPT codes that are

related to the Argus® II device and the Argus® II implantation procedure to indicate that Medicare payment is no longer available for the device and the implementation procedure as the Argus® II device is no longer on the market and, therefore, is not being implanted. These coding changes would mean that providers could no longer receive payment for performing the Argus® II device or the device implantation procedure. These changes are described in Table 11.

We did not receive any public comments on our proposal and, therefore, we are finalizing our proposal without modification.

TABLE 11: CY 2022 AND 2023 FINAL OPPS STATUS INDICATOR AND APC ASSIGNMENTS FOR THE ARGUS® II DEVICE AND THE ARGUS® II IMPLANTATION PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	E2	N/A
C1841	Retinal prosthesis, includes all internal and external components	N	N/A	D	N/A

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1562)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology – Level 24 ($3001-$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through

85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology – Level 24 ($3001-$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[7] This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, "after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana."

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[8] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed that this new HCPCS code accurately

[7] Luxturna. FDA Package Insert. Available: https://www.fda.gov/media/109906/download
[8] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf

described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that CPT code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C-APC to which CPT code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for CPT code 67036. The placeholder code C97X1 was replaced by HCPCS code C9770. For CY 2021, we finalized our proposal to create HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology –Level 24 ($3001-$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology – Level 24 ($3001-$3500)) using the geometric mean cost of CPT code 67036.

For CY 2023, there are 11 single claims available for ratesetting for HCPCS code C9770. Because this is the first year we have claims data for HCPCS code C9770, we propose to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we proposed to designate HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Using CY 2021 claims, which are the only claims available in our 4-year look back period, we found the geometric mean cost for the service to be approximately $3,326, the arithmetic mean cost to be approximately $3,466, and the median cost to be approximately $3,775. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we proposed to assign HCPCS code C9770 to APC 1562 for CY 2023.

Please refer to Table 12 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9770 for CY 2023. The proposed CY 2023 payment rates can be found in Addendum B to the CY 2023 OPPS/ASC proposed rule (87 FR 44502).

TABLE 12: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1562

Comment: We received a comment in support of the proposal to reassign HCPCS code C9770 to APC 1562 based on the most recent claims data.

Response: We thank this commenter for their support. After consideration of the public comment we received, we are finalizing our policy as proposed. Specifically, we are finalizing our proposal to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. We are also finalizing our proposal to designate HCPCS code C9770 as a low volume procedure under our universal low volume APC

policy and use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on updated claims data available for this final rule with comment period, we have 13 single frequency claims available for ratesetting. Based on this updated claims data, we found the geometric mean cost for the service to be approximately $3,358, the arithmetic mean cost to be approximately $3,489, and the median cost to be approximately $3,770. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we are assigning HCPCS code C9770 to APC 1562 for CY 2023.

Please refer to Table 13 below for the final OPPS New Technology APC and status indicator assignments for HCPCS code C9770 for CY 2023. The final CY 2023 payment rates can be found in Addendum B to this final rule with comment period.

TABLE 13: PROPOSED AND FINAL CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770

HCPCS Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1562	T	1562

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic

guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we again used the claims data from CY 2019 for HCPCS code C9751. Since the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost ($2,693), the arithmetic mean cost ($3,086), and the median cost ($3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501– $4,000)), with a payment rate of $3,750.50 for CY 2022.

There were no claims reported in CY 2020 or CY 2021 for HCPCS code C9751. Thus, for CY 2023, the only available claims for HCPCS code C9751 continue to be from CY 2019, and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2021 and CY 2022 OPPS/ASC final rules with comment period. Therefore, given the low number of claims for this procedure, we proposed to designate this procedure as low volume under our universal low volume policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the procedure to the appropriate New Technology APCs. Because our proposal uses the same claims as we used for CY 2021 and CY 2022, we found the same values for the geometric mean cost, arithmetic mean cost, and the median cost for CY 2023. Once again, the median ($3,708) was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology continues to fall within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we proposed to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a

proposed payment rate of $3,750.50 for CY 2023. Details regarding HCPCS code C9751 are included in Table 14 below.

Comment: One commenter supported our assignment of HCPCS code C9751 to New Technology APC 1562.

Response: We appreciate the support of the commenter for our policy. After consideration of the public comment we received, we are implementing our proposal without modification.

TABLE 14: FINAL CY 2022 AND CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1562	T	1562

d. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520, 1521, and 1523)

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a

payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPPS proposed or final rules. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50 in CY 2021 and CY 2022. Likewise, we continued to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

For CY 2023, we proposed to use CY 2021 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. CPT code 78431 had over 18,000 single frequency claims in CY 2021, which are used to calculate estimated costs for individual services. The geometric mean for CPT code 78431 was approximately $2,509, which is an amount that is above the cost band for APC 1522 (New Technology—Level 22 ($2001–$2500)), where the procedure is currently assigned. We proposed, for CY 2023, that CPT code 78431 be reassigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50. Please refer to Table 15 below for the proposed New Technology APC and status indicator assignments for CPT code 78431.

There were only five single frequency claims in CY 2021 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Although we use up to 4 years of claims data to calculate the appropriate New Technology APC assignment for low volume procedures, for CPT code 78432, the only available claims data are from CY 2021. Our analysis of the data found the geometric mean cost

of the service is approximately $1,747, the arithmetic mean cost of the service is approximately $1,899, and the median cost of the service is approximately $1,481. The arithmetic mean was the statistical methodology that estimated the highest cost for the service. Therefore, we proposed, for CY 2023, to assign CPT code 78432 to APC 1520 (New Technology - Level 20 ($1801-$1900)) with a payment rate of $1,850.50. Please refer to Table 15 for the proposed New Technology APC and status indicator assignments for CPT code 78432.

There were 954 single frequency claims reporting CPT code 78433 in CY 2021. The geometric mean for CPT code 78433 was approximately $1,999, which is an amount that is below the cost band for APC 1523 (New Technology—Level 23 ($2501–$3000)), where the procedure is currently assigned. We proposed, for CY 2023, that CPT code 78433 be reassigned to APC 1521 (New Technology - Level 21 ($1901-$2000)) with a payment rate of $1,950.50.

Comment: Multiple commenters supported the assignment of CPT code 78431 to APC 1523. However, these commenters also requested that CPT codes 78432 and 78433 also be assigned to APC 1523. The commenters felt that the number of claims available to estimate the cost of CPT codes 78432 and 78433 was not enough to accurately calculate the costs of those services, and that the current cost estimates for the services underestimate the services' actual costs.

Response: We appreciate the commenters' support of our assignment of CPT code 78431 to APC 1523. CPT code 78431 has a geometric mean of approximately $2,532 and will continue to be assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)).

Regarding the assignments for CPT codes 78432 and 78433, since CY 2019 we have had in place a policy to estimate the cost of services assigned to new technology APCs with a low volume of claims. The threshold for the low volume policy to apply to a service is 100

separately payable claims. We have identified 1,034 separately payable claims for CPT code 78433, which is well above the threshold for the low volume methodology. Therefore, we use the geometric mean to calculate the cost of the service described by CPT code 78433, and that cost is approximately $1,998. That cost falls in the cost range for APC 1521 of $1,901 to $2,000, and therefore, we believe APC 1521 is the appropriate APC assignment for this service.

Regarding CPT code 78432, there continues to be only five separately payable claims for the service. Therefore, we use the new technology low volume policy to determine the appropriate APC assignment for this service. We use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Although we use up to 4 years of claims data to calculate the appropriate New Technology APC assignment for low volume procedures, for CPT code 78432, the only available claims data are from CY 2021. Our analysis of the data found the geometric mean cost of the service is approximately $1,747, the arithmetic mean cost of the service is approximately $1,900, and the median cost of the service is approximately $1,481. The arithmetic mean was the statistical methodology that estimated the highest cost for the service of approximately $1,900, and therefore, the appropriate APC assignment for the service is APC 1520 (New Technology - Level 20 ($1801-$1900)).

After consideration of the public comments we received, we are implementing our proposal without modification to assign CPT code 78431 to APC 1523, CPT code 78432 to APC 1520, and CPT code 78433 to APC 1521.

TABLE 15: FINAL CY 2022 AND CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final OPPS CY 2023 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1523
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1520
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1521

e. V-Wave Medical Interatrial Shunt Procedure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only

receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology - Level 38 ($10,001-$15,000)).

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for CY 2021 OPPS final rule with comment period. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022.

For CY 2023, there were no claims from CY 2021 billed with HCPCS code C9758. Because there are no claims reporting HCPCS code C9758, we proposed to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2023.

Comment: One commenter supported our assignment of HCPCS code C9758 to APC 1590.

Response: We appreciate the commenter's support for our proposal. After consideration of the public comment we received, we are finalizing our proposal without modification. The final New Technology APC and status indicator assignments for HCPCS code C9758 are shown in Table 16.

TABLE 16: FINAL CY 2022 AND CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal	T	1590	T	1590

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
	echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study				

f. Corvia Medical Interatrial Shunt Procedure (APC 1592)

Corvia Medical has conducted its pivotal trial for its interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and continued through Quarter 3 of CY 2021.[9] On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate payment for the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by

[9] https://clinicaltrials.gov/ct2/show/NCT03088033?term=NCT03088033&rank=1

HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology - Level 41 ($25,001-$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase "or placebo control," from the descriptor. In CY 2022, we used the same claims data as was used in the CY 2021 OPPS final rule to determine the payment rate for HCPCS code C9760 because there were no claims for this service in CY 2019, the year used for ratesetting for CY 2022. Accordingly, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022.

For CY 2023, we proposed to use the claims data from CY 2021 to establish payment rates for services. However, there are no claims with HCPCS code C9760 in the CY 2021 claims data available for ratesetting. Therefore, we proposed to continue to assign HCPCS code C9760 to New Technology APC 1592.

Comment: One commenter, the manufacturer, supported our proposal to assign HCPCS code C9760 to APC 1592.

Response: We appreciate the commenter's support for our proposal. After consideration of the public comment we received, we are finalizing our proposal without modification. The final New Technology APC and status indicator assignments for HCPCS code C9760 are shown in Table 17.

TABLE 17: FINAL CY 2022 AND CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-RANDOMIZED, NON-BLINDED INTERATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592	T	1592

g. Supervised Visits for Esketamine Self-Administration (APCs 1512 and 1516)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by esketamine nasal spray administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate

(NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two devices (for a 56 mg dose) or three devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by esketamine nasal spray administration, and the potential for misuse of the product, Spravato is only available through a restricted distribution system under a REMS, patients must be monitored by a health care provider for at least 2 hours after receiving their esketamine nasal spray dose, the prescriber and patient must both sign a Patient Enrollment Form, and the product must only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology - Level 8 ($601 - $700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. HCPCS code G2083

was assigned to New Technology APC 1511 (New Technology - Level 11 ($901 - $1000)) with a payment rate of $950.50.

For CY 2023, we proposed to use CY 2021 claims data to determine the payment rates for HCPCS codes G2082 and G2083. Therefore, for CY 2023, we proposed to assign these two HCPCS codes to New Technology APCs based on the codes' geometric mean costs. Specifically, we proposed to assign HCPCS code G2082 to New Technology APC 1511 (New Technology - Level 11 ($901 - $1000)) based on its geometric mean cost of $995.47. We also proposed to assign HCPCS code G2083 to New Technology APC 1516 (New Technology - Level 16 ($1401 - $1500)) based on its geometric mean cost of $1,489.93.

Details about the proposed New Technology APC and status indicator assignments for these HCPCS codes are shown in Table 18. The proposed CY 2023 payment rates for these HCPCS codes can be found in Addendum B to the CY 2023 OPPS/ASC proposed rule (87 FR 44502).

TABLE 18: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1511
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the	S	1511	S	1516

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
	supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation				

Comment: Commenters were generally in favor of this proposal. Commenters welcomed efforts to make this treatment more available to beneficiaries and were supportive of CMS's proposed change to reassign HCPCS codes G2082 and G2083 to New Technology APCs 1511 and 1516, respectively.

Response: We thank commenters for their support. After consideration of the public comments we received, for CY 2023, we are finalizing our proposal to assign HCPCS codes G2082 and G2083 to New Technology APCs based on the codes' geometric mean costs. However, we note the geometric mean costs have changed since the proposal rule. Based on updated claims data available for this final rule, the approximate geometric mean cost for HCPCS code G2082 is $1,056. Based on this geometric mean cost, we are assigning HCPCS code G2082 to APC 1512 (New Technology - Level 12 ($1001 - $1100)) for CY 2023. We proposed to assign HCPCS code G2082 to APC 1511 (New Technology - Level 11 ($901 - $1000)) based on the claims data available for the proposed rule, which reflected an approximate geometric mean of $995. Due to updated claims data for this final rule with comment period, we are assigning HCPCS code G2082 to APC 1512 (New Technology - Level 12 ($1001 - $1100) CY 2023.

Based on updated claims data available for this final rule with comment period, the approximate geometric mean cost for HCPCS code G2083 is $1,496. Based on this geometric mean cost, we are finalizing our proposal to assign HCPCS code G2083 to APC 1516 (New Technology - Level 16 ($1401 - $1500)) for CY 2023.

Details about the New Technology APC and status indicator assignments for HCPCS codes G2082 and G2083 are shown in Table 19 below. The final CY 2023 payment rates for these HCPCS codes can be found in Addendum B to this CY 2023 OPPS/ASC final rule with comment period.

TABLE 19: PROPOSED AND FINAL CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1512
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1516	S	1516

h. DARI Motion Procedure (APC 1505)

CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) was effective January 1, 2022. The technology consists of eight cameras that surround a patient. The cameras send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient's clothing or skin. The technology is intended to guide health care providers on pre- and post-operative surgical intervention and on the best course of physical therapy and rehabilitation for patients. In CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology – Level 5 ($301 - $400)), for CY 2022.

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data. Accordingly, for CY 2023 we proposed to continue assigning CPT code 0693T to New Technology APC 1505.

We did not receive any public comments on our proposal and are finalizing our proposal without modification. The final New Technology APC and status indicator assignments for CPT code 0693T are found in Table 20.

TABLE 20: FINAL CY 2022 AND CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	S	1505

i. Histotripsy Service (APC 1575)

CPT code 0686T (Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was effective July 1, 2021. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors. We note that the device that is used in the histotripsy procedure is currently under a Category A IDE clinical study (NCT04573881). The clinical trial is a non-randomized, prospective trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.[10] We note that devices from Category A IDE studies are excluded from Medicare payment. Therefore, payment for CPT code 0686T reflects only the service that is performed each time it is reported on a claim. For CY 2022, we assigned CPT code 0686T to New Technology APC 1575 (New Technology – Level 38 ($10,000 - $15,000) with a payment rate of $12,500.

Since the service became effective in the OPPS in July 2021, there are no claims for this service in the CY 2021 OPPS claims data. Therefore, for CY 2023, we proposed to continue assigning CPT code 0686T to New Technology APC 1575.

We did not receive any public comments on our proposal and are finalizing our proposal without modification. The final New Technology APC and status indicator assignments for CPT code 0686T are found in Table 21.

TABLE 21: FINAL CY 2022 AND CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE HISTOTRIPSY SERVICE

[10] ClinicalTrials.gov. "The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER)." Accessed May 10, 2022. https://clinicaltrials.gov/ct2/show/study/NCT04573881

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575	S	1575

j. Liver Multiscan Service (APC 1511)

CPT code 0648T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ) was effective July 1, 2021. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. The SaaS receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. The SaaS then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. For CY 2022, we assigned CPT code 0648T to New Technology APC 1511 (New Technology – Level 11 ($901 - $1,000) with a payment rate of $950.50.

Since HCPCS code 0648T became effective in the OPPS in July 2021, there has been only one claim from the CY 2021 claims data; but its payment rate appears to be an outlier based

on the service invoice we received from the software developer. Accordingly, for CY 2023, we proposed to continue assigning CPT code 0648T to New Technology APC 1511.

We did not receive any public comments on our proposal and are finalizing continuing to assign CPT code 0648T to New Technology APC 1511. The final New Technology APC and status indicator assignments for CPT code 0648T are found in Table 22.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63542), we finalized that the service represented by CPT code 0649T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure) is a packaged service per the OPPS packaging policy for add-on code procedures. In this final rule with comment period, however, we are adopting a policy that Software as a Service (SaaS) add-on codes are not among the "certain services described by add-on codes" for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18). Instead, SaaS CPT add-on codes will be assigned to identical APCs and have the same status indicator assignments as their standalone codes. Therefore, we are assigning CPT code 0649T to the same APC as CPT code 0648T, specifically, New Technology APC 1511. We direct readers to section X.G. (OPPS Payment for Software as a Service) of this final rule with comment period for a more detailed discussion of our final payment policy for SaaS.

The final New Technology APC and status indicator assignments for CPT codes 0648T and 0649T are found in Table 22. In addition, the final CY 2023 OPPS payment rates for CPT codes 0648T and 0649T can be found in Addendum B to this final rule with comment period. In

addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addenda B and D1 are available via the Internet on the CMS website, specifically at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

TABLE 22: FINAL CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ	S	1511
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

k. Minimally Invasive Glaucoma Surgery (MIGS) (APC 1563)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical

technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

For CY 2022, the AMA's CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 and 66991; deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device; and created a new Category III CPT code, specifically, CPT code 0671T, describing anterior segment aqueous drainage device without concomitant cataract removal.

For CY 2022, we finalized the assignment of CPT codes 66989 and 66991 to New Technology APC 1563 (New Technology - Level 26 ($4001-$4500)). We stated that we believed that the change in coding for MIGS is significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we explained that we did not believe we had the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at that time.

We note that for the CY 2023 OPPS/ASC proposed rule, the proposed payment rates are based on claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before December 31, 2021, and CCRs, if available. Because CPT codes 66989 and 66991 were effective January 1, 2022, and we have no claims data for CY 2022, we proposed to continue assigning CPT codes 66989 and 66991 to New Technology APC 1563 for CY 2023. The proposed New Technology APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 23. Regrettably, we inadvertently misidentified the APC assignment for CPT codes 66989 and 66991 as APC 1526, rather than APC 1563, in the preamble to the proposed rule.

TABLE 23: CY 2022 FINAL AND CY 2023 PROPOSED OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed OPPS CY 2023 APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior	T	1563	T	1563

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed OPPS CY 2023 APC
	segment aqueous drainage device, without extraocular reservoir, internal approach, one or more				
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	T	1563	T	1563

We did not receive any public comments on our proposal and are finalizing our proposal without modification. The final New Technology APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 24.

TABLE 24: CY 2022 FINAL AND CY 2023 FINAL OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final OPPS CY 2023 APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used	T	1563	T	1563

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final OPPS CY 2023 APC
	in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more				
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	T	1563	T	1563

l. Scalp Cooling (APC 1520)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021, to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is

classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around $1,900 to $2,400 associated with calibration and fitting of the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology - Level 20 ($1801-$1900)) with a payment rate of $1,850.50.

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data. Accordingly, for CY 2023, we proposed to continue assigning CPT code 0662T to New Technology APC 1520.

We did not receive any public comments on our proposal and are finalizing our proposal without modification. The final New Technology APC and status indicator assignments for CPT code 0662T are found in Table 25.

TABLE 25: FINAL CY 2022 AND CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520	S	1520

m. Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT code 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) became effective July 1, 2022. The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The risk score is used by the physician to quantify the risk of lung cancer and to help determine whether to refer the patient to a pulmonologist. For CY 2022, we assigned CPT code 0721T to APC New Technology 1508 (New Technology - Level 8 ($601-$700)).

This service became payable under the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data for use in CY 2023 ratesetting. Accordingly, for CY 2023, we proposed to continue to assign CPT code 0721T to New Technology APC 1508 with a status indication of "S". The proposed New Technology APC and status indicator assignments for CPT code 0721T are found in Table 26.

TABLE 26: PROPOSED CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508

Comment: A commenter, the manufacturer of Optellum LCP, requested that we revise the description to the produced risk score to "The physician uses the risk score to quantify the risk of lung cancer and to help determine what the next management step should be for the patient (e.g., CT surveillance versus invasive procedure)." The commenter also supported the continual assignment of CPT code 0721T to New Technology APC 1508 and stated a lower payment would disincentivize its use.

Response: We appreciate the commenter's input on the Optellum LCP produced risk score and agree with the suggested revision.

After consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are assigning CPT code 0721T to APC 1508 for CY 2023.

We note that the Optellum LCP service is also represented by CPT code 0722T, which is an add-on code. In this final rule with comment period, we are adopting a policy that SaaS add-on codes are not among the "certain services described by add-on codes" for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18). Instead, SaaS CPT add-on codes will be assigned to identical APCs and have the same status indicator assignments as their standalone codes. Therefore, we are assigning CPT code 0722T to New Technology APC 1508. We direct readers to section X.G. (OPPS Payment for Software as a Service) of this final rule with comment period for a more detailed.

The final New Technology APC and status indicator assignments for CPT codes 0721T and 0722T are found in Table 27.

The final CY 2023 OPPS payment rates for CPT codes 0721T and 0722T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the

OPPS. Both Addenda B and D1 are available via the Internet on the CMS website, specifically at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

TABLE 27: FINAL CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	S	1508

n. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

CPT code 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session) became effective July 1, 2022. The QMRCP is a Software as a medical Service (SaaS) that performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative

information of biliary tree volume and duct metrics. For CY 2022, we assigned CPT code 0723T to New Technology APC 1511 (New Technology - Level 11($900-$1,000)).

This service became payable under the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data. Accordingly, for CY 2023, we proposed to continue to assign CPT code 0723T to New Technology APC 1511 with a status indicator of "S". The proposed New Technology APC and status indicator assignments for CPT code 0723T are found in Table 28.

TABLE 28: PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	1511

Comment: A commenter, the manufacturer of QMRCP, supported the continual assignment of CPT 0723T to New Technology APC 1511.

Response: We thank the commenter for their input on the assignment of CPT 0723T to New Technology APC 1511.

After consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are assigning CPT code 0723T to APC 1511 for CY 2023.

We note that the QMRCP service is also represented by CPT code 0724T, which is an add-on code. In this final rule with comment period, we are adopting a policy that SaaS add-on

codes are not among the "certain services described by add-on codes" for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18). Instead, SaaS CPT add-on codes will be assigned to identical APCs and have the same status indicator assignments as their standalone codes. Therefore, we are assigning CPT code 0724T to New Technology APC 1511. We direct readers to section X.G. (OPPS Payment for Software as a Service) of this final rule with comment period for a more detailed discussion.

The final New Technology APC and status indicator assignments for CPT codes 0723T and 0724T are found in Table 29.

The final CY 2023 OPPS payment rates for CPT codes 0723T and 0724T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addenda B and D1 are available via the Internet on the CMS website, specifically at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

TABLE 29: FINAL CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	1511

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

o. CardiAMP (APC 1574)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial[11] and the CardiAMP Cell Therapy Heart Failure Trial[12]. The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cells treatment for the following: (1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology - Level 37 ($9,501-$10,000)) with the status indicator "T". We subsequently revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter

[11] ClinicalTrials.gov. "Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia." Accessed May 10, 2022. https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1

[12] ClinicalTrials.gov. "Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure." Accessed May 10, 2022. https://clinicaltrials.gov/ct2/show/NCT02438306

intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix transendocardial injection catheter device in the descriptor. We direct readers to section X.F. (Coding and Payment for Category B Investigational Device Exemption Clinical Devices and Studies) of this final rule with comment period for a more detailed discussion of coding and payment for Category B IDE devices and studies.

Additionally, we determined that APC 1590 (New Technology - Level 39 ($15,001-$20,000)) most accurately accounts for the resources associated with furnishing the procedure described by HCPCS code C9782. We note that a transitional device pass-through application was submitted for the Helix transendorcardial injection catheter device for CY 2023. We direct readers to section IV.A. (Pass-Through Payment for Devices) of this final rule with comment period for a more detailed discussion of the transitional device pass-through applications.

This service became effective in the OPPS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPPS claims data for use in CY 2023 ratesetting. Accordingly, for CY 2023, we proposed to assign HCPCS code C9782 to New Technology APC 1590 with a status indication of “T”.

We did not receive any public comments on our proposal and are finalizing our proposal to assign HCPCS code C9782 to New Technology APC 1590 with a status indication of “T”. The final New Technology APC and status indicator assignments for HCPCS code C9782 are found in Table 30.

TABLE 30: FINAL CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747) we finalized our proposal to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2023 OPPS/ASC proposed rule, CY 2021 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2021 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical

or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to four years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the CY 2023 OPPS/ASC proposed rule, we proposed to designate four brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. The four brachytherapy APCs and 4 clinical APCs meet our criteria of having fewer than 100 single claims in the claims year used for ratesetting (CY 2021 for this CY 2023 OPPS/ASC proposed rule) and, therefore, we propose that they would be subject to our low volume APC policy. These eight APCs were designated as low volume APCs in CY 2022; a ninth APC -- APC 2647 (Brachytherapy, non-stranded, Gold-198) -- was designated as a low volume APC for CY 2022 but did not meet our claims threshold for this CY 2023 OPPS/ASC proposed rule.

Table 31 includes the APC geometric mean cost without the low volume APC designation, that is, if we calculated the geometric mean cost based on CY 2021 claims data available for ratesetting; the median, arithmetic mean, and geometric mean cost using up to four years of claims data based on the APC's designation as a low volume APC; and the statistical methodology we proposed to use to determine the APC's cost for ratesetting purposes for CY 2023. For APC 5494 (Level 4 Intraocular Procedures) and APC 5495 (Level 5 Intraocular

Procedures), we are finalizing an APC cost metric based on the median cost, the greatest of the cost metrics, using up to four years of claims data. For all other Low Volume APCs, we are finalizing an APC cost metric based on the arithmetic mean cost, the greatest of the cost metrics, using up to four years of claims data. As discussed in our CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data we proposed to use to calculate the costs for these APCs are CYs 2017, 2018, 2019, and 2021.

Comment: Some commenters supported our proposed use of the Low Volume APC methodology for the clinical and brachytherapy APCs with fewer than 100 claims available for ratesetting. One commenter was concerned about the proposed payment rate for APC 5495 (Level 5 Intraocular Procedures), which would represent a 32 percent reduction from the CY 2022 payment rate for CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis). The commenter recommended that we use the equitable adjustment authority to apply a cap of 10 percent on the reduction in relative weights for Low Volume APCs in CY 2023. The commenter noted that a similar 10 percent cap on the decline in the relative weight for a Medicare Severity-adjusted Diagnosis-Related Group (MS-DRG) is applied under the IPPS.

Response: We appreciate commenters' support for our proposal to utilize our Low Volume APC methodology for APCs with fewer than 100 claims available for ratesetting. While we acknowledge the CY 2023 payment rate for APC 5495 represents a sizeable reduction from the CY 2022 payment rate, and that CPT code 0308T was the only procedure assigned to this APC in CY 2022, we believe the CY 2023 payment rate represents the historical tendency for this procedure as shown in Table 31 below.

Nonetheless, as discussed in section III.C of this final rule with comment period, we are accepting commenters' recommendation and assigning CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) to APC 5495. The reassignment of CPT code 0616T to APC 5495 increases the CY 2023 APC cost metric from the proposed $16,711.80 to $18,602.90 and increases the OPPS payment rate from $16,564.54 to $18,089.98.

After re-evaluating the APC 5495 cost metric following the reassignment of 0616T to APC 5495, given the increase in the OPPS payment rate from the proposed to the final rule and the historical payment rates for this APC, we are not accepting the commenter's recommendation to limit a Low Volume APC's decline in relative weights to no more than 10 percent. However, given the low claims volume for these APCs, as well as the high cost of many of these APCs, we will continue to monitor the costs and payment rates for procedures assigned to Low Volume APCs to determine if additional changes or refinements to our current policy are needed.

TABLE 31: CY 2017-2022 OPPS PAYMENT RATES FOR CPT CODE 0308T

APC	CY	Payment Rate
5495	2017	$18,991.75
5495	2018	$17,561.29
5494	2019	$16,234.22
5495	2020	$20,675.62
5495	2021	$20,766.56
5495	2022	$24,564.54

After consideration of the public comments we received, based on claims data for this final rule with comment period, for CY 2023, we are finalizing our proposal to continue to use up to 4 years of claims data to calculate Low Volume APCs' costs based on the greater of the median cost, arithmetic mean cost, or geometric mean cost. We note that APC 5881 (Ancillary

Outpatient Services When Patient Dies) had at least 100 claims for ratesetting based on claims data available for this final rule with comment period, whereas for the CY 2023 OPPS/ASC proposed rule only 71 claims were available. Despite not meeting our threshold for fewer than 100 claims, we are finalizing our proposal to designate APC 5881 as a Low Volume APC since stakeholders would not have had an opportunity to comment on the significant change in payment for this APC if we were to not apply our Low Volume APC methodology. Therefore, we are finalizing the APCs described in Table 32 as Low Volume APCs for CY 2023 and determining their payment rates using the Low Volume APC methodology. These four brachytherapy APCs and four clinical APCs are the same eight APCs we proposed to designate as Low Volume APCs in the CY 2023 OPPS/ASC proposed rule (87 FR 44568 through 44569).

TABLE 32: COST STATISTICS FOR PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2023

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	10	$167.11	$31.74	$44.35	$37.26	$44.35
2635	Brachytx, non-str, HA, P-103	28	$130.24	$34.04	$52.09	$43.30	$52.09
2636	Brachy linear, non-str, P-103	0	---*	$49.65	$53.38	$38.80	$53.38
2647	Brachytx, NS, Non-HDRIr-192	14	$144.37	$180.76	$355.64	$141.57	$355.64
5244	Level 4 Blood Product Exchanges and Related Services	74	$46,098.63	$40,581.15	$43,430.85	$38,901.25	$43,430.85.34

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2023 APC Cost
5494	Level 4 Intraocular Procedures	54	$10,747.36	$16,474.43	$15,834.32	$12,384.27	$16,474.43
5495	Level 5 Intraocular Procedures	18	$13,206.61	$18,602.90	$16,572.10	$13,685.48	$18,602.90
5881	Ancillary Outpatient Services When Patient Dies	108	$8,328.77	$7,095.35	$12,589.03	$7,347.98	$12,589.03

* For this final rule with comment period, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) that are available for CY 2023 OPPS/ASC ratesetting.

E. APC-Specific Policies

1. Abdominal Hernia Repair (APCs 5341 and 5361)

For CY 2023, the CPT Editorial Panel deleted 18 abdominal hernia repair codes that were established in 1984 and 2009 and replaced them with 15 new codes. The 18 abdominal hernia repair codes will be deleted December 31, 2022, and replaced with new CPT codes effective January 1, 2023.

As listed in Table 33, the predecessor/deleted codes were assigned to one of the following APCs for CY 2022:

- APC 5341: Abdominal/Peritoneal/Biliary and Related Procedures
- APC 5361: Level 1 Laparoscopy and Related Services
- APC 5362: Level 2 Laparoscopy and Related Services

TABLE 33: 18 ABDOMINAL HERNIA REPAIR CPT CODES THAT WILL BE DELETED DECEMBER 31, 2022

CPT Code	Long Descriptor	CY 2022 OPPS SI	CY 2022 OPPS APC	CY 2022 OPPS Payment Rate
49560	Repair initial incisional or ventral hernia; reducible	J1	5341	$3,249.35
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	J1	5341	$3,249.35
49565	Repair recurrent incisional or ventral hernia; reducible	J1	5361	$5,167.69
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	J1	5361	$5,167.69
49568	Implantation of mesh or other prosthesis for open incisional or ventral hernia repair or mesh for closure of debridement for necrotizing soft tissue infection (List separately in addition to code for the incisional or ventral hernia repair)	N		
49570	Repair epigastric hernia (eg, preperitoneal fat); reducible (separate procedure)	J1	5341	$3,249.35
49572	Repair epigastric hernia (eg, preperitoneal fat); incarcerated or strangulated	J1	5341	$3,249.35
49580	Repair umbilical hernia, younger than age 5 years; reducible	J1	5341	$3,249.35
49582	Repair umbilical hernia, younger than age 5 years; incarcerated or strangulated	J1	5341	$3,249.35
49585	Repair umbilical hernia, age 5 years or older; reducible	J1	5341	$3,249.35
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated	J1	5341	$3,249.35
49590	Repair spigelian hernia	J1	5341	$3,249.35
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible	J1	5361	$5,167.69
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated	J1	5361	$5,167.69
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	J1	5362	$9,096.46
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	J1	5362	$9,096.46
49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible	J1	5362	$9,096.46
49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	J1	5362	$9,096.46

Based on our evaluation of the new codes and because the predecessor codes are not a one-to-one match to the new CPT codes, we proposed to assign the new codes to APC 5341, as shown in Table 34 for CY 2023. Specifically, we proposed to assign six of the 15 new codes to inpatient-only status, one to packaged/bundled status because the code describes an add-on procedure, and eight codes to APC 5341 with a proposed payment rate of $3,235.68. We indicated in the CY 2023 OPPS/ASC proposed rule that the final 5-digit CPT codes were not available when we published the proposed rule, so we included the placeholder codes in OPPS Addendum B. We also note that the predecessor and new codes were included in OPPS Addendum B with only the short descriptors. Because the short descriptors do not adequately describe the complete procedure, we included the 5-digit placeholder codes and long descriptors in Addendum O so that the public could adequately comment on the proposed APC and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled "CY 2023 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code." We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period.

TABLE 34: PROPOSED CY 2023 APC, SI, AND PAYMENT FOR THE NEW ABDOMINAL HERNIA REPAIR CPT CODES EFFECTIVE JANUARY 1, 2023

CPT Code	Placeholder Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment
49591	49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	J1	5341	$3,235.68

CPT Code	Placeholder Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment
49592	49X02	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	J1	5341	$3,235.68
49593	49X03	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	J1	5341	$3,235.68
49594	49X04	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	J1	5341	$3,235.68
49595	49X05	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	J1	5341	$3,235.68
49596	49X06	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other	C		

CPT Code	Placeholder Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment
		prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated			
49613	49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	J1	5341	$3,235.68
49614	49X08	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	J1	5341	$3,235.68
49615	49X09	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	J1	5341	$3,235.68
49616	49X10	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	C		

CPT Code	Placeholder Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment
49617	49X11	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	C		
49618	49X12	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	C		
49621	49X13	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible	C		
49622	49X14	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated	C		
49623	49X15	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic) (List separately in addition to code for primary procedure)	N		

At the August 22, 2022 HOP Panel Meeting, a presenter provided information to the Panel on the APC assignments for the predecessor codes as well as the proposed APC

assignments for the new codes. Based on the information presented at the meeting, the Panel made no recommendation on the APC assignments for the new codes.

Comment: Some commenters disagreed with the proposed assignment to APC 5341 for the eight separately payable codes, and provided their recommendations on the APC reassignments. They stated that the proposed APC assignment for the new codes would be insufficient to cover the cost of furnishing the procedures, and would impact beneficiary access. The commenters stated that the predecessor codes are not a one-to-match to the new codes, and that some of the predecessor codes crosswalk to multiple new codes. They also noted that the geometric mean cost for the predecessor codes exceed the proposed payment rate of $3,235, and assignment of the new codes to APC 5341 would result in significant underpayment for the procedures. Based on the geometric mean cost for the predecessor codes, several of the commenters recommended reassignment of the new codes to the Level 1 and Level 2 laparoscopy APCs, specifically, APCs 5361 and 5362, and noted that many of the new codes are laparoscopic in nature. A few commenters identified the specific codes that should be crosswalked to APCs 5361 and 5362. Other commenters recommended establishing a new APC by grouping the new codes based on the length of the hernia or by length of the hernia, recurrence, and whether the hernia is incarcerated or strangulated. Some commenters suggested reassigning the eight codes to the Level 1 Laparoscopy APC, specifically, APC 5361, while another recommended assignment to New Technology APC 1566 (New Technology - Level 29 ($5501-$6000); proposed payment of $5,750.50). Some commenters favored establishing a new APC for the eight separately payable codes and suggested establishing the cost for the new APC based on the cost data from the predecessor codes. A few commenters specifically suggested establishing a new Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC.

Response: We appreciate the feedback and the many suggestions on the APC reassignments. Of the 15 new codes, 12 codes describe the repair of anterior abdominal hernias, specifically, epigastric, incisional, ventral, umbilical, and spigelian hernias that are performed via an open, laparoscopic, and robotic approach. Based on our review of the new codes, we noted that the eight new codes proposed to APC 5341 have one consistent feature in their code descriptions, specifically, that they are described as either "reducible" or "incarcerated/strangulated." This characteristic of "reducible" and "incarcerated/strangulated" is also present in the predecessor/deleted codes. The descriptions of "reducible" and "incarcerated/strangulated" appear in both the predecessor and new codes, and because we have claims data for the predecessor codes, we believe that establishing the APCs based on this distinction provides us with more appropriate payments for the new codes.

As stated above, the predecessor codes are not a one-to-match to the new codes, however, based on the various recommendations on the APC reassignment, further deliberation on the issue, and input from our medical advisors, we believe that assigning the new codes to APCs 5341 and 5361 is the best option at this time. Consequently, we reconfigured APCs 5341 and 5361 by mapping the predecessor and new codes described as "reducible" to APC 5341 and the more complex and extensive "incarcerated/strangulated" procedures to APC 5361. We note that we mapped predecessor CPT code 49590, which is not described as either "reducible" or "incarcerated/strangulated" to APC 5341 since its geometric mean cost of about $4,134 is more consistent with the geometric mean cost of about $3,642 for APC 5341, rather than the geometric mean cost of approximately $5,360 for APC 5361. Based on our reconfiguration, the geometric mean cost for APC 5341 is approximately $3,642 while the geometric mean cost for APC 5361 is about $5,360. We believe the APC reconfigurations for APCs 5341 and 5361 will result in

more appropriate payments for the new abdominal hernia repair codes and improves the clinical and resource homogeneity within the groupings.

As stated above, we received many suggestions on the APC reassignments for the new codes. We evaluated the recommendations, modeled the suggestions, and analyzed the cost results of each suggestion. Based on our analysis, we believe that assignment of the new codes to APCs 5341 and 5361 is the best option at this time. We note that we review our claims data on an annual basis to establish the OPPS payment rates. We will reevaluate the APC assignments for the eight separately payable codes once we have claims data. The list below provides the various recommendations on the APC reassignments and our concerns associated with each suggestion.

- Suggestion #1: Assign the new CPT codes to APCs based on procedure complexity considering the length of the hernia, recurrence, and whether the hernia is incarcerated/strangulated.

CMS Concern: The predecessor codes, on which we have claims data, do not describe the length of the hernia. This description only applies to the new codes.

- Suggestion #2: Assign the new CPT codes to APCs based on length of hernia.

CMS Concern: The predecessor codes, on which we have claims data, do not describe the length of the hernia. This description only applies to the new codes.

- Suggestion #3: Reassign the new codes to APC 5361 (Level 1 Laparoscopy and Related Services)

CMS Concern: As stated previously, the predecessor codes are not a one-to-one match to the new CPT codes, and many of the predecessor codes on which we have claims data are not laparoscopy-related. However, based on input from our medical advisors, we are reassigning

some of the new codes to APC 5361 from APC 5341, specifically, CPT codes 49592, 49594, and 49614. We note that several of the new codes describe various approaches of the procedure, specifically, they are described as open, laparoscopic, and robotic. Because the new codes are not an exact replacement for the predecessor codes, we believe that we should acquire claims data for the rest of new codes before assigning all eight codes to APC 5361. Once we have claims data, we will determine whether the codes should be reassigned to more appropriate APCs, or whether the establishment of new APCs is necessary.

- Suggestion #4: Reassign the new codes to APC 5361 (Level 1 Laparoscopy and Related Services) and APC 5362 (Level 2 Laparoscopy and Related Services).

CMS Concern: As stated above, the predecessor codes are not a one-to-one match to the new CPT codes, and many of predecessor codes on which we have claims data are not laparoscopy-related. The new codes describe various approaches of the procedure, specifically, they are described as open, laparoscopic, and robotic. Because the new codes are not an exact replacement for the predecessor codes, we do not believe that assigning the new codes to these two APCs would be appropriate. We want to pay accurately for the new codes; however, we believe that we should acquire claims data for the new codes before assigning them to APCs 5361 and 5362. Once we have claims data, we will determine whether the codes should be reassigned to more appropriate APCs, or whether the establishment of new APCs is necessary.

- Suggestion #5: Establish a new APC.

CMS Concern: While we have claims data for several codes, the predecessor codes are not a one-to-one match to the new CPT codes. To ensure that we pay accurately for these new codes, we believe that we should acquire claims data before establishing a new APC.

- Suggestion #6: Reassign the new codes to New Technology APC 1566.

CMS Concern: We do not believe this would be appropriate given that several of the predecessor codes have been in existence since 1984, and we have many years' of claims data for them.

With respect to the concern of beneficiary access, we believe that assignment of the new codes to APCs 5341 and 5361 appropriately provides access to the abdominal hernia repair procedures. In light of the various suggestions on the APC reassignment and because there is not a one-to-one match between the predecessor codes and the new codes, we believe that assignment to APCs 5341 and 5361 is the best approach at this time. We reiterate that we view our claims data on an annual basis to establish the OPPS payment rates. Once we have data, we will reevaluate and, if necessary, reassign the codes to appropriate APCs based on the latest claims data.

After carefully considering all of the comments that we received, we are finalizing our proposal with modification. Specifically, we are finalizing our proposal to assign CPT codes 49591, 49593, 49595, 49613, and 49615 to APC 5341, and assigning CPT codes 49592, 49594, and 49614 to APC 5361. In addition, we are finalizing our proposal for CPT codes 49596, 49616-49618, and 49621-49622, and assigning them to status indicator "C" to indicate that the codes are designated as "inpatient-only" status for CY 2023. Further, we are finalizing our proposal for CPT code 49623 and assigning the code to status indicator "N" for CY 2023 to indicate that the code is packaged since it is an add-on service to the primary code, and its payment is included in the primary service code. Refer to Table 35 for the final APC and SI assignments for the abdominal hernia repair codes for CY 2023. The final payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI)

meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 35: FINAL CY 2023 APC, SI, AND PAYMENT FOR THE 15 NEW ABDOMINAL HERNIA REPAIR CPT CODES EFFECTIVE JANUARY 1, 2023

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2023 OPPS Payment
49591	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	J1	5341	Refer to OPPS Addendum B
49592	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	J1	5361	Refer to OPPS Addendum B
49593	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	J1	5341	Refer to OPPS Addendum B
49594	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	J1	5361	Refer to OPPS Addendum B
49595	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	J1	5341	Refer to OPPS Addendum B
49596	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when	C		

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2023 OPPS Payment
	performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated			
49613	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	J1	5341	Refer to OPPS Addendum B
49614	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	J1	5361	Refer to OPPS Addendum B
49615	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	J1	5341	Refer to OPPS Addendum B
49616	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	C		
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	C		
49618	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	C		

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2023 OPPS Payment
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible	C		
49622	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated	C		
49623	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic) (List separately in addition to code for primary procedure)	N		

2. Administration of Lacrimal Ophthalmic Insert into Lacrimal Canaliculus (APC 5503)

Dextenza, which is described by HCPCS code J1096 (Dexamethasone, lacrimal ophthalmic insert, 0.1 mg), is a drug indicated for "the treatment of ocular inflammation and pain following ophthalmic surgery" and for "the treatment of ocular itching associated with allergic conjunctivitis."[13] Interested parties previously asserted that this drug is administered and described by CPT code 0356T (Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each). Interested parties also previously stated that Dextenza is inserted in a natural opening in the eyelid (called the punctum) and that the drug is designed to deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days. CPT code 0356T was deleted December 31, 2021, and replaced with CPT code 68841 (Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each), effective January 1, 2022.

[13] Dextenza. FDA Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf

For CY 2022, HCPCS code J1096 is assigned to APC 9308 (Dexametha opth insert 0.1 mg) with a status indicator of "G" (Pass-Through Drugs and Biologicals) to indicate that the drug has pass-through status under the OPPS. Refer to section V.A.5. of this final rule with comment period for further information regarding the pass-through status of HCPCS code J1096.

In addition, as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63544 through 63546), because of the clinical similarity between the predecessor CPT code 0356T and its replacement code, specifically, CPT code 68841, we proposed to assign CPT code 68841 to the same APC, status indicator, and payment indicator assignments as CPT code 0356T. In the CY 2022 OPPS/ASC final rule, after taking into consideration commenter feedback, we finalized our proposal to assign CPT code 68841 to APC 5694 (Level 4 Drug Administration) with OPPS status indicator ‘‘Q1’’ for CY 2022. We note that CPT code 68841 was assigned to status indicator ‘‘Q1’’, indicating conditionally packaged payment under the OPPS. Packaged payment applies if a code assigned to status indicator ‘‘Q1’’ is billed on the same claim as a HCPCS code assigned status indicator ‘‘S’’, ‘‘T’’, or ‘‘V’’. Based on the OPPS status indicator assignment, CPT code 68841 was assigned to payment indicator ‘‘N1’’ in the ASC setting, meaning a packaged service/item.

For CY 2023, as indicated in Table 39 (Drugs and Biologicals for Which Pass-through Payment Status or Separate Payment to Mimic Pass-through Payment Will End on December 31, 2022) of the CY 2023 OPPS/ASC proposed rule (87 FR 44628 and 44629), separate payment to mimic pass-through status for Dextenza is expiring December 31, 2022. In addition, as discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44720), we proposed that HCPCS code J1096 is a drug that functions as a surgical supply that meets the criteria described at § 416.174, and we proposed to make separate payment for Dextenza as a non-opioid pain management drug that

functions as a supply in a surgical procedure under the ASC payment system for CY 2023. This means that, effective January 1, 2023, payment for Dextenza will be packaged when furnished in the HOPD but paid separately when furnished in an ASC. We proposed to package HCPCS code J1096 under the OPPS and assign the code to a status indicator of "N" (packaged). This is consistent with our packaging policy outlined at 42 CFR 419.2(b), which lists the types of items and services for which payment is packaged under the OPPS. Specifically, § 419.2(b)(16) includes drugs and biologicals that function as supplies when used in a surgical procedure as packaged costs. Historically, we have stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy (79 FR 66875).

Although we have no data for CPT code 68841 because it is a new code effective January 1, 2022, we have claims data for the predecessor CPT code 0356T. Using cost data for the predecessor code, for CY 2023 we proposed to continue to assign CPT code 68841 to APC 5694 with a proposed payment rate of $338.58. We also proposed to continue to assign CPT code 68841 OPPS status indicator ''Q1'' and an ASC payment indicator of ''N1.''

The issue of payment of CPT code 68841 was brought to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) in 2022 for CY 2023 rulemaking and interested parties requested a new APC placement. At the August 22, 2022 meeting, based on the information presented, the Panel recommended that CMS assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures), with a status indicator (SI) of "J1". We note that for CY 2023, APC 5503 has a proposed payment rate of $2,140.55.

Comment: Several commenters stated that increased payment, and separate payment, for CPT code 68841 was required in order to ensure continued beneficiary access to the drug Dextenza (HCPCS code J1096) in both the HOPD and ASC settings. Some commenters did not make a specific suggestion as to the final APC assignment, but contended that the proposed payment was inadequate. Commenters most frequently recommended assignment to APC 5503 for CPT code 68841. Interested parties believed this would be a clinically appropriate APC assignment as, in their view, the insertion of Dextenza is an extraocular procedure; therefore, it would be appropriate to place CPT code 68841 into APC 5503, which is titled Level 3 Extraocular, Repair, and Plastic Eye Procedures, as this procedure is clinically similar to other extraocular procedures in that APC. Commenters believe this assignment is appropriate given the geometric mean cost for the predecessor CPT code 0356T was $2,227.06 in the proposed rule, which was similar to the proposed rule geometric mean cost of $2,159.58 for APC 5503. Commenters also believed that CMS should assign CPT code 68841 to the same APC as CPT codes 0699T and 66030 because all three procedures involve the delivery of medication to the eye. The commenters cited CPT code 66030 (Injection, anterior chamber of eye (separate procedure); medication) and CPT code 0699T (Injection, posterior chamber of eye; medication), which we proposed to assign to APC 5491 (Level 1 Intraocular Procedures) with a proposed payment rate of $2,201.12, as similar procedures to which CPT code 68841 should be compared. However, commenters recognized that CPT codes 0699T and 66030 were intraocular procedures, so it would not be appropriate to assign CPT code 68841 to the same APC. Since commenters recognized CPT code68841 represented an extraocular procedure, they felt APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) would be an appropriate alternative APC assignment as this APC placement has a comparable payment rate to

APC 5491. Some commenters stated that a ‘‘Q1’’ status indicator was inappropriate, but did not provide an alternative suggestion. However, some other commenters suggested assignment to a “J1” status indicator.

Several commenters pointed to the clinical importance of providing Dextenza to patients, noting that it reduces ocular pain, inflammation, and reduces the burden of topical eyedrop application. Additionally, commenters stated that they usually perform the procedure to administer Dextenza in conjunction with ophthalmic surgeries. Commenters believed the procedure is a distinct surgical procedure that requires additional operating room time and resources. Commenters were concerned that the lack of increased or separate payment may reduce access to Dextenza, particularly in the ASC setting.

Response*:* We thank commenters for their feedback. Based on input from stakeholders, we believe it is appropriate to assign CPT code 68841 to a different APC than the one proposed for CY 2023. After careful consideration of the statements from the commenters, we analyzed available claims data and similar procedures that approximate the clinical resources associated with CPT code 68841. We agree with stakeholders and the HOP Panel that CPT code 68841 should be reassigned to APC 5503. For the CY 2023 OPPS update, based on claims submitted between January 1, 2021, and December 30, 2021, processed through June 30, 2022, our analysis of the latest claims data for this final rule with comment period show a geometric mean cost of approximately $2,079 for predecessor CPT code 0356T based on 122 single claims, which is comparable to the geometric mean cost of about $2,174 for APC 5503. Based on the data, we believe that a reassignment from to APC 5503 for CPT code 68841 is appropriate. However, we continue to believe that assignment of CPT code 68841 to an OPPS status indicator of ‘‘Q1’’ and an associated ASC payment indicator of ‘‘N1’’, is appropriate. We continue to

believe that CPT code 68841 is mostly performed during ophthalmic surgeries, such as cataract surgeries. A status indicator ‘‘Q1’’, indicating a conditionally packaged procedure, describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ‘‘N1’’) under the ASC payment system. Although stakeholders state this is an independent surgical procedure and should not be packaged into the primary ophthalmic procedure in which the drug and drug administration are associated, based on expected clinical patterns as to how the drug is used, we do not agree. We find it appropriate to conditionally package CPT code 68841 under the OPPS based on its clinical use patterns. This is consistent with 42 CFR 419.2(b), which lists the types of items and services for which payment is packaged under the OPPS packaged. The conditional packaging of this code supports our overarching goal to make payments for all services paid under the OPPS and ASC payment system more consistent with those of a prospective payment system and less like those of a per-service fee schedule. We believe that packaging encourages efficiency and is an essential component of a prospective payment system, and that packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service is a fundamental part of the OPPS. We therefore believe packaging of CPT code 68841 is appropriate. After consideration of the public comments, we are finalizing our proposal with modification and reassigning CPT code 68841 from APC 5694 to APC 5503 with OPPS status indicator ‘‘Q1’’ (STV-Packaged Codes) for CY 2023. In addition, based on the OPPS assignments, we are finalizing an ASC payment indicator of ‘‘N1’’ (Packaged service/item; no separate payment made) for CPT code 68841 for CY 2023. For

the final CY 2023 OPPS payment rates, we refer readers to OPPS Addendum B to this final rule with comment period. In addition, we refer readers to OPPS Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. For the final CY 2023 ASC payment rates and payment indicators, we refer readers to Addendum AA and Addendum BB for the ASC payment rates, and Addendum DD1 for the ASC payment indicator and their definitions. The OPPS Addendum B and D1, and ASC Addendum AA, BB, and DD1 are available via the Internet on the CMS website[14].

Refer to Table 36 for the code descriptor, APC assignment, status indicator assignment, and payment indicator assignment for CPT code 68841 for CY 2023.

TABLE 36: FINAL CY 2023 OPPS AND ASC PAYMENT ASSIGMENTS for CPT CODE 68841

HCPCS Code	Descriptor	Final CY 2023 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 ASC PI
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each,	5503	Q1	N1

Similarly, we are finalizing our proposal, without modification, to change HCPCS code J1096 from a status indicator of "G" (pass-through) to "N" (packaged) to indicate that Dextenza is packaged beginning January 1, 2023, as separate payment provision to mimic pass-through status will end on December 31, 2022. We find it appropriate to package HCPCS code J1096 based on its clinical use patterns. Consistent with our clinical review and commenters' input, we believe this drug is mostly performed during ophthalmic surgeries, such as cataract surgeries. The packaging of this drug is consistent with 42 CFR 419.2(b). Specifically, 42 CFR

[14] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS

419.2(b)(16) includes drugs and biologicals that function as supplies when used in a surgical procedure among the items and services for which payment is packaged under the OPPS. Historically, we have stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy (79 FR 66875). The packaging of this code supports our overarching goal to make payments for all services paid under the OPPS and ASC payment system more consistent with those of a prospective payment system and less like those of a per-service fee schedule. We believe that packaging encourages efficiency and is an essential component of a prospective payment system and that packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service is a fundamental part of the OPPS. We therefore believe packaging of HCPCS code J1096 is appropriate in the HOPD setting for CY 2023.

Although packaged under the OPPS, as discussed in section XIII.E (ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies) of this final rule with comment period, we believe Dextenza (HCPCS code J1096), meets the criteria described at § 416.174; and we are finalizing our proposal to make separate payment for Dextenza as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023. For more information on the ASC payment for HCPCS code J1096 for CY 2023, refer to section XIII.E (ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies) of this final rule with comment period.

As a reminder, for OPPS billing, because charges related to packaged services are used for outlier and future rate setting, hospitals are advised to report both CPT code 68841 (administration service) and HCPCS code J1096 (Dextenza drug/product) on the claim whenever Dextenza is provided in the HOPD setting. It is extremely important that hospitals report all HCPCS codes consistent with their descriptors, CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately or is packaged.

Finally, for the final CY 2023 OPPS payment rates, we refer readers to OPPS Addendum B to this final rule with comment period. In addition, we refer readers to OPPS Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. For the final CY 2023 ASC payment rates and payment indicators, we refer readers to Addendum AA and Addendum BB for the ASC payment rates, and Addendum DD1 for the ASC payment indicator and their definitions. The OPPS Addendum B and D1, and ASC Addendum AA, BB, and DD1 are available via the Internet on the CMS website.[15]

3. Artificial Iris Insertion Procedures (APC 5495)

For the July 2020 update, the AMA's CPT Editorial Panel established three CPT codes to describe the CUSTOMFLEX® ARTIFICIALIRIS device implantation procedure. The long descriptors for the codes are listed below.

- 0616T: Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens

[15] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS

- 0617T: Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens
- 0618T: Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange

In addition to the surgical procedure CPT codes, as discussed in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85990 through 85992), we approved the associated device, specifically, the CUSTOMFLEX® ARTIFICIALIRIS for pass-through status effective January 1, 2021, and established a new device category for this device – HCPCS code C1839 (Iris prosthesis). The designation of pass-through status for the device indicates that, under the OPPS, the device is paid separately in addition to the surgical procedure CPT codes. Based on our assessment, we assigned CPT code 0616T to APC 5491 (Level 1 Intraocular Procedures) because, after removing the device costs of the CUSTOMFLEX® ARTIFICIALIRIS for transitional pass-through device status, we believed the insertion of the artificial iris procedure shared similar clinical characteristics and resource costs to the surgical procedures assigned to APC 5491. Similarly, we assigned CPT codes 0617T and 0618T to APC 5492 (Level 2 Intraocular Procedures) because, with the additional implantation of the intraocular lens, we believed CPT codes 0617T and 0618T shared similar clinical characteristics and resource costs to the surgical procedures assigned to APC 5492.

For CY 2023, with the expiration of the pass-through device status for the CUSTOMFLEX® ARTIFICIALIRIS on January 1, 2023, and under our current packaging policies, we proposed to package the device cost associated with HCPCS code C1839 into the primary procedures, specifically, CPT codes 0616T, 0617T, and 0618T. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our

analysis of the claims data available for the proposed rule. For the CY 2023 OPPS/ASC proposed rule, the geometric mean cost of CPT code 0616T was $12,846.69 based on 5 single claims, the geometric mean cost of CPT code 0617T was $17,516.70 based on the 2 claims available for the proposed rule, and the geometric mean cost of CPT code 0618T was $13,257.21 based on 7 claims. With the additional costs from the expired pass-through device, we proposed to reassign CPT codes 0617T and 0618T from APC 5492 to APC 5495 (Level 5 Intraocular APC), which is a Low Volume APC and is discussed in further detail in Section III.D of this final rule with comment period, with a proposed payment amount of $16,564.54. For CPT code 0616T, with the additional costs from the expired pass-through device, we proposed to reassign CPT code 0616T from APC 5491 to APC 5493 (Level 3 Intraocular Procedures) with a proposed payment rate $7,434.16.

Comment: Commenters supported our proposed APC assignment of CPT codes 0617T and 0618T to APC 5495 but disagreed with our proposed assignment of CPT code 0616T to APC 5493 because of the proposed payment rate for that APC. Commenters believed that the proposed payment amount of $7,434.16 for CPT code 0616T would be significantly lower than the procedure's cost and would not adequately cover the cost of the artificial iris device. The commenters recommended that CPT code 0616T be assigned to APC 5495 with a proposed payment rate of $16,564.54 for CY 2023, rather than APC 5493, as the commenters believed the clinical characteristics and resource costs of CPT code 0616T are more similar to CPT codes 0617T and 0618T, which we proposed to assign to APC 5495.

Response: We appreciate the commenters' recommendation and support of our proposal. For this final rule with comment period, based on claims submitted between January 1, 2021, and December 31, 2021, and processed through June 30, 2022, we have 6 claims for CPT code

0616T that yield a geometric mean cost of $14,151.11. Based on our assessment of the updated data, we do not believe a final payment rate of $7,217.54 for APC 5493 would adequately cover the costs associated with CPT code 0616T. Similar to the Level 5 Intraocular Procedures APC, APC 5494 (Level 4 Intraocular Procedures) is a Low Volume APC. The only procedure assigned to APC 5494 is CPT code 67027 (Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous). Therefore, given the clinical similarity of the procedures assigned to APC 5495 when compared to APC 5494 as well as the resource use similarity, we are accepting the commenters' recommendation and reassigning CPT code 0616T to APC 5495 for CY 2023. After reassigning CPT code 0616T to Low Volume APC 5495, as discussed in further detail in Section III.D. of this final rule with comment period, the APC cost of APC 5495 is $18,602.90 and a final payment amount of $18,089.98 for CY 2023.

In summary, after consideration of the public comments, we are finalizing our proposal, with modification, and assigning CPT codes 0616T, 0617T, and 0618T to APC 5495 for CY 2023. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

4. Blood Product Not Otherwise Classified (NOC) (APC 9537)

Providers and interested parties in the blood products field have reported that product development for new blood products has accelerated. They noted there may be several additional new blood products entering the market in the next few years, compared to only one or two new products entering the market over the previous 15 to 20 years. To encourage providers to use these new products, providers and interested parties requested that we establish a new HCPCS

code to allow for payment for unclassified blood products prior to these products receiving their own HCPCS codes. Under the OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family. However, because blood products are each assigned to their own unique APC, the concept of a lowest APC payment level does not exist for blood products.

Starting in CY 2020, we established a new HCPCS code, P9099 (Blood component or product not otherwise classified), which allows providers to report unclassified blood products. For a detailed discussion of the payment history of HCPCS P9099 from CY 2020 through CY 2022, please refer to the CY 2022 OPPS/ASC rule with comment period (86 FR 63546 through 63548).

For CY 2023, we proposed to assign HCPCS code P9099 to APC 9537 (Blood component/product noc) with a proposed payment rate of $56.58. In addition, we proposed to continue our policy of setting a payment rate for HCPCS code P9099 that is equivalent to the lowest cost blood product that is separately payable in the OPPS. The separately payable blood product with the lowest cost at the time of publication of the proposed rule was HCPCS code P9060 (Fresh frozen plasma, donor retested, each unit), with a proposed payment rate of $56.58. Therefore, for CY 2023, we proposed that the payment rate for HCPCS code P9099 would be $56.58, equivalent to the payment rate for HCPCS code P9060.

Comment: Multiple commenters have requested that unclassified blood products assigned to HCPCS code P9099 be paid based on reasonable cost and that HCPCS code P9099 be assigned a status indicator of ‘‘F’’ (paid at reasonable cost). Unclassified blood products paid on the basis of reasonable cost would receive payment based on individual invoices submitted by the provider that detail the actual cost of the unclassified blood products for the provider. The

commenters believe our current policy severely underpays for most unclassified blood products, which limits the ability of providers to use these new products and discourages innovation in the blood products field. Commenters assert that the universe of blood products is very heterogeneous with each product having its own APC and payment rate, and our policy that assigns unclassified clinical services HCPCS codes to the lowest-paying APC in a clinical series is not appropriate for the payment of blood products.

Response: We have concerns about paying unclassified blood products using reasonable cost and assigning HCPCS code P9099 to status indicator ‘‘F’’. Although reasonable cost would likely provide a more granular reflection of the cost of unclassified blood products to providers, there would be no incentive for providers to manage their costs when using unclassified blood products or for the manufacturers to seek individual HCPCS codes for their unclassified blood products. We believe that providers will prefer to receive full cost reimbursement for an unclassified blood product rather than risk receiving a prospective payment that could be less than full cost of the blood product if the blood product is classified and assigned a HCPCS code. Finally, we do not support reasonable cost payment for HCPCS code P9099 because the OPPS is a prospective payment system, and we want to limit rather than expand the types of services paid for under the OPPS that do not receive prospective payment.

Comment: Two commenters supported a different approach to ensure that newly developed blood products can receive payment comparable to the cost of the product until a permanent HCPCS code can be established to describe the new blood products. One of the commenters stated that there is a four to six-month period between the time a new blood product receives FDA approval and clearance and when it is introduced into the market. The commenter suggested that we could evaluate a coding application for a new blood product during this period

before the new blood product enters the market and establish a temporary HCPCS code that would allow the blood product to be payable in both the OPPS and the PFS payment systems. Along with establishing the temporary HCPCS code, the commenter also requests that we establish a payment rate that would be cross-walked to the payment rate of an existing blood product with similar characteristics to the new blood product. The temporary HCPCS code would stay in effect until a permanent HCPCS code is established for the new blood product.

Response: We agree that the process suggested by the commenters is a reasonable approach to ensure new blood products receive payment that better reflects the cost of the product. We previously used this process around 2015 when products, including frozen, pathogen-reduced plasma and pathogen-reduced platelets, were new and required HCPCS codes to receive payment. We currently have the ability to create temporary HCPCS codes for blood products to allow the codes to be used in both the OPPS and the PFS payment systems, and we can assign payment rates that reasonably reflect the cost of the new blood products.

After consideration of the public comments, we are finalizing our proposal without modification. Specifically, we will continue to assign HCPCS code P9099 to status indicator ‘‘R’’ (Blood and Blood Products. Paid under OPPS; separate APC payment.) and pay the code at a rate equal to the lowest paid separately payable blood product in the OPPS that has claims data for CY 2021, which is HCPCS code P9060 with an updated payment rate of $54.74 per unit. Therefore, we are finalizing our proposal, without modification, to continue to assign HCPCS code P9099 to APC 9537 (Blood component/product noc) for CY 2023.

5. Bone Density Tests/Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis and

Digital X-ray Radiogrammetry-Bone Mineral Density (DXR-BMD) Analysis

A bone mineral density test is used to predict fracture risk and detect osteoporosis based on the patient's bone mineral content and bone density of the spine, hip, lower arm, and hands. While the test is performed using x-rays, dual-energy X-ray absorptiometry (DEXA or DXA), and computed tomography (CT), recent advances in technology have introduced newer methods in detecting bone mineral density. These newer technologies have included the use of biomechanical computed tomography (BCT) analysis and digital x-ray radiogrammetry-bone mineral density (DXR-BMD) analysis. A BCT analysis involves the use of a previous CT scan that is used by a computer software program to measure both the bone strength and bone mineral density of the hip or spine region, while a DXR-BMD analysis involves the use of a digital x-ray, that is also used by a computer software, to measure bone mineral density of the hand.

For CY 2023, the CPT Editorial Panel established one new CPT code, specifically, CPT code 0743T to describe the service associated with BCT analysis with concurrent vertebral fracture assessment (VFA), effective January 1, 2023. Because the final CY 2023 CPT code number was not available when we published the proposed rule, the code was listed as placeholder code X012T in OPPS Addendum B of the CY 2023 OPPS/ASC proposed rule. Below is the complete long descriptor for CPT code 0743T.

- 0743T: Bone strength and fracture risk using finite element analysis of functional data and bone mineral density, with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and bone mineral density and classification of any vertebral fractures, with overall fracture risk assessment, interpretation and report

In addition to new CPT code 0743T, there are five existing CPT codes describing BCT analysis that were effective July 1, 2019. The codes and their long descriptors are listed below.

- 0554T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report
- 0555T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data
- 0556T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density
- 0557T: Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report
- 0558T: Computed tomography scan taken for the purpose of biomechanical computed tomography analysis

For CY 2023, the CPT Editorial Panel also established two new CPT codes to describe the services associated with bone mineral density by digital x-ray radiogrammetry, specifically, CPT codes 0749T and 0750T. These services were listed as placeholder codes X031T and X032T in OPPS Addendum B of the CY 2023 OPPS/ASC proposed rule:

- 0749T: Bone strength and fracture risk assessment using digital X-ray radiogrammetry-bone mineral density (DXR-BMD) analysis of bone-mineral density utilizing data from a digital X-ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report

- 0750T: Bone strength and fracture risk assessment using digital X-ray radiogrammetry-bone mineral density (DXR-BMD) analysis of bone-mineral density utilizing data from a digital X-ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report; with single view digital X-ray examination of the hand taken for the purpose of DXR-BMD

We note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled "CY 2023 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code," to the proposed rule. We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period.

On June 24, 1998, we published in the **Federal Register** an interim final rule (IFR) with comment period (63 FR 34320) that specifies the uniform coverage of, and payment for, bone mass measurements for Medicare beneficiaries. This IFR implemented the provisions in section 4106(a) of the Balanced Budget Act of 1997. Currently, Medicare pays for bone density tests when they meet the definition and coverage requirements of bone mass measurement as stated in 42 CFR § 410.31. Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets all of the following conditions:

- Is performed to identify bone mass, detect bone loss, or determine bone quality.

- Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the Food and Drug Administration (FDA) under 21 CFR part 807, or approved for marketing under 21 CFR part 814.
- Includes a physician's interpretation of the results.

Based on our understanding of the services associated with the new codes, BCT and DXR-BMD analysis currently do not meet Medicare's definition of bone mass measurement. Therefore, for CY 2023, we proposed to assign the new codes, specifically, CPT codes 0743T, 0749T, and 0750T, to status indicator "E1" to indicate that they are not covered by Medicare, and not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Similarly, we proposed to assign the existing BCT analysis CPT codes 0554T-0558T to status indicator "E1" for CY 2023.

Comment: Some commenters disagreed with our proposed status indicator assignment of "E1" for the BCT analysis codes, specifically, CPT codes 0554T-0558T, and requested that we continue to pay separately for them. Another commenter stated that the VirtuOst software system that is associated with new CPT code 0743T, is an FDA-cleared Class II bone densitometer medical device. The same commenter stated that BCT analysis of the hip is equivalent to that of DXA (CPT code 77080) while BCT analysis of the spine is similar to that of a qualitative diagnostic CT (CPT code 77078) for osteoporosis identification. Because CPT codes 77078 and 77080 are paid separately under the OPPS, the commenter suggested that the BCT analysis CPT codes should also be paid separately.

Response: As stated above, based on our review and understanding of the service, BCT analysis does not meet Medicare's definition of bone mass measurement, as specified in

§ 410.31(a) that specifies the coverage of, and payment for, bone mass measurements for Medicare beneficiaries . Consequently, for the October 2022 OPPS Update (Transmittal 11594, Change Request 12885, dated September 9, 2022), we revised the status indicator for CPT codes 0554T-0558T to "E1" to indicate that the codes are non-covered because the services described by the codes do not meet Medicare's definition of bone mass measurements (BMMs). As we have stated in every quarterly OPPS Update Change Request (CR), "the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment."

In addition, we remind the commenters that requests for changes to the current BMM definition should be directed to CMS as described in 410.31(f). CMS may determine through the NCD process that additional BMM systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline BMMs. We note that on August 7, 2013, CMS published a **Federal Register** notice (78 FR 48164 through 48169), updating the process used for opening, deciding or reconsidering national coverage determinations (NCDs). Further information on the Medicare coverage determination process, as well how to request a new NCD or revision to an existing NCD, can be found on Medicare's website, specifically, at https://www.cms.gov/Medicare/Coverage/DeterminationProcess.

In summary, after consideration of the public comments, we are finalizing our proposal, and assigning status indicator "E1" to the BCT analysis CPT codes 0554T-0558T and 0743T for

CY 2023. In addition, we received no comments on the codes for DXR-BMD analysis and are finalizing our proposal to assign status indicator "E1" to CPT codes 0748T and 0749T for CY 2023. We note that in the OPPS Addendum B that was released with the CY 2023 OPPS/ASC proposed rule, we inadvertently listed CPT code 0743T (placeholder code X012T) to status indicator "M" (Items and Services Not Billable to the MAC. Not paid under OPPS.) when it should have been listed with status indicator "E1" (Not covered; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type), similar to the status indicator proposed for CPT codes 0749T (placeholder code X031T) and 0750T (placeholder code X032T).

Finally, we remind hospitals that Medicare does pay separately for certain BMM tests under the OPPS. Refer to the Medicare Administrative Contractors (MACs) website for the latest list of covered and payable BMM HCPCS codes. The final CY 2023 payment rates for all codes reported under the OPPS can be found in OPPS Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with for the complete list of status indicators (and definitions) used under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

6. Calculus Aspiration with Lithotripsy Procedure (APC 5376)

For CY 2023, we proposed to continue to assign HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Services) with a proposed payment rate of $8,711.09. The code was effective October 1, 2020, and describes the procedure that uses a sterile, single-use aspiration-irrigation catheter that is designed to assist in the removal of stone fragments during a standard ureteroscopy.

Comment: One commenter urged CMS to maintain the current facility payment rates in both the hospital outpatient department and ambulatory surgery center setting. The commenter

noted that the current payment in both sites of service is appropriate given the procedural complexity involved and stated that performing a steerable renal suction case requires extended operating room (OR) time, multiple technicians, and a full inventory of single-use surgical devices, such as endoscopes, ureteral access sheaths, guidewires, CVAC, and high-energy laser fibers.

Response: HCPCS code C9761 was new in CY 2020, and this is the first year in which we have actual claims data for the procedure. Based on our analysis of the latest CY 2021 claims data available for CY 2023 OPPS ratesetting, the geometric mean cost associated with HCPCS code C9761 is approximately $6,519 based on 24 single claims (out of 24 total claims), which is consistent with the geometric mean cost for APC 5376. We also note that the geometric mean cost for the significant HCPCS codes in APC 5375 (Level 5 Urology and Related Services) ranged between $4,105 and $6,495, which is below the geometric mean cost for HCPCS code C9761. Based on the data, we believe that APC 5376 is the more appropriate assignment rather than APC 5375 for HCPCS code C9761. Therefore, we agree with the commenter, and are maintaining the APC assignment to APC 5376 for CY 2023. Comment: Another commenter made a request to update the long descriptor for HCPCS code C9761 to reduce provider confusion and preserve device cost data integrity. The current long descriptors for CPT code 52356 and HCPCS code C9761 are listed in Table 37. According to the commenter, the 21 facilities in the 2021 claims data that billed procedures with HCPCS code C9761, despite not using a steerable vacuum aspiration catheter, likely did so because of the similarity between the long descriptors for HCPCS code C9761 and CPT code 52356. The commenter explained that the procedure described by HCPCS code C9761 includes all the steps of a conventional laser lithotripsy (CPT code 52356) plus a comprehensive removal of stone fragments from all areas of

the collecting system, including the renal pelvis and all calyces. Table 37 lists the CY 2022 long descriptors for these codes.

TABLE 37: CY 2022 LONG DESCRIPTORS FOR CPT CODE 52356 AND HCPCS CODE C9761

HCPCS Code	Long Descriptor
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, gibbons or double-j type)
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable

To alleviate confusion, the commenter recommended a change in the long descriptor for HCPCS code C9761 to the following: "Steerable vacuum aspiration with continuous irrigation of the kidney following cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including the renal pelvis and all calyces of the collecting system, ureter, bladder, and urethra if applicable." The commenter stated that the suggested revised long descriptor for C9761 moves the device intensive and distinguishing features of the procedure (i.e., "Steerable vacuum aspiration with continuous irrigation of the kidney") to the beginning and more fully describes the complexity of the procedure by calling out the aspiration of the renal pelvis and all calyces.

Response: We do not agree that revising the long descriptor as recommended by the commenter is necessary to provide further clarification on how the procedure is performed. As listed in Table 37, the long descriptors for CPT code 52356 and HCPCS code C9761 do not share substantial similarity. The words "steerable vacuum aspiration" appear in the current long descriptor for HCPCS code C9761. We note that coders are generally aware that they need to read the entire long descriptors, and not rely on short descriptors alone, for the codes they are billing to ensure they are reporting the procedures, services, and items accurately. In addition, it

is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on hospitals and providers to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions and to report services accurately on claims and charges and costs for the services on their Medicare hospital cost report.

Nonetheless, we are sympathetic to the commenter's concern regarding the descriptor, and consequently, we believe that a slight modification to the long descriptor is necessary. Specifically, we are adding the terms "must use a steerable ureteral catheter" to the end of the long descriptor for HCPCS code C9761, as shown in Table 38. The change to the long descriptor for HCPCS C9761 will be included in the January 2023 HCPCS file with an effective date of January 1, 2023. We note that this is the second change to the long descriptor for HCPCS code C9761 since the code was effective on October 1, 2020. Refer to Table 38 for the historical and current descriptor for the code.

TABLE 38: HCPCS CODE C9761 LONG DESCRIPTORS

HCPCS Code	CY	Long Descriptor
C9761	2020	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable
C9761	2021 2022	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable
C9761	2023	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable (must use a steerable ureteral catheter)

In summary, after consideration of the public comments, we are finalizing our proposal for HCPCS code C9761 and assigning the code to APC 5376 for CY 2023. In addition, we are modifying the long descriptor for HCPCS code C9761 to assist HOPDs with reporting the code appropriately.

7. Cardiac Computed Tomography Angiography (CCTA) (APC 5571)

For CY 2023, we proposed to continue to assign the following cardiac CCTA exam codes to APC 5571 (Level 1 Imaging with Contrast) with a proposed payment rate of $183.61. The CPT codes and their long descriptors are listed below.

- 75572: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3d image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
- 75573: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3d image postprocessing, assessment of lv cardiac function, rv structure and function and evaluation of venous structures, if performed)
- 75574: Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3d image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

We received several comments related to our proposed payment for the CCTA codes. Many of the comments, mostly form letters, addressed the same issues that were brought to our attention in the CY 2021 OPPS/ASC final rule (85 FR 85956 through 85959). Below is a

summary of the public comments to the CY 2023 OPPS/ASC proposed rule and our responses to the comments.

Comment: Some commenters expressed concern with the reimbursement and continued assignment to APC 5571 for CPT codes 75572, 75573, and 75574. They stated that the current payment is below the cost of providing the service. Some commenters explained that numerous studies have shown CCTA to have the highest negative predictive value for ruling out coronary artery disease (CAD), and that for certain patients, this is the least invasive test to rule out CAD. They stated that the proposed payment is insufficient to cover the complete cost of furnishing the service, and urged CMS to group the CCTA codes in an appropriate APC with services that are similar based on clinical intensity, resource utilization, and cost. The commenters indicated that the inadequate reimbursement for the service limits Medicare beneficiaries' access to the test. One commenter asserted that CCTA is more complex to perform and requires more time and resources compared to the other tests assigned to APC 5571. The commenters urged CMS to increase the payment for CCTA and suggested revising the assignment from APC 5571 to APC 5572 to adequately compensate hospitals for the cost of providing the service.

Response: The OPPS relies upon historical hospital claims data to establish the annual payment rates, and payments under the OPPS are based on our analysis of the latest available claims and cost report data submitted to Medicare. As we stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85956), we have many years of claims data for CPT codes 75572, 75573, and 75574. The AMA established specific CPT codes for CCTA services beginning in 2006 when they were first described by Category III codes. The Category III CPT codes were subsequently deleted on December 31, 2009, and replaced with Category I CPT codes 75572, 75573, and 75574, which were effective on January 1, 2010. Because OPPS

payments are updated every year based on our analysis of the latest claims data, the payment rates have varied each year based on that data.

For CY 2023, OPPS payments are based on claims submitted between January 1, 2021, through December 31, 2021, that were processed on or before June 30, 2022. Based on our review of the claims data for this final rule, the geometric mean costs for the CCTA codes range between $160 and $238. As shown in Table 39, our analysis reveals a geometric mean cost of approximately $160 for CPT code 75572 based on 19,245 single claims (out of 35,554 total claims), about $238 for CPT code 75573 based on 371 single claims (out of 542 total claims), and approximately $208 for CPT code 75574 based on 46,352 single claims (out of 68,420 total claims). Based on the geometric mean costs for the codes, our data show that the resources associated with providing CCTA services are similar to the costs of other tests assigned to APC 5571. The geometric mean cost for the CCTA codes range between $160 and $238, which are in line with the costs in APC 5571 whose more geometric mean costs for the significant HCPCS codes range between $118 and $247. Based on our claims data, we do not agree that the resource cost for the services in APC 5572 are similar to CCTA because the geometric mean costs for the significant HCPCS codes in APC 5572 are higher with costs ranging between $279 and $523.

As shown in Table 39, we have many years' worth of claims data for CCTA services, and the volume has only increased throughout the years. Based on the volume of claims, we do not believe that Medicare beneficiaries have had access issues. In addition, our current and historical cost data for the CCTA CPT codes demonstrates that the resources of providing CCTA exams are consistent with the cost of the other services assigned to APC 5571. We believe our claims data accurately reflects the resources associated with furnishing CCTA services in the HOPD setting. Because CCTA services have been paid under the OPPS for many years, with payments

based on the latest hospital claims and Medicare cost report data, we believe we are providing a consistent payment methodology that appropriately reflects the hospital costs required to perform CCTA exams.

TABLE 39: VOLUME FOR CCTA EXAMS (CLAIMS SUBMITTED BETWEEN JANUARY 1, 2013 THROUGH DECEMBER 31, 2021)

Final Rule	Claim Submission Timeframe	75572 Single Frequency	75572 Geometric Mean Cost	75573 Single Frequency	75573 Geometric Mean Cost	75574 Single Frequency	75574 Geometric Mean Cost
CY 2015	1/1/2013-12/31/2013	3,855	$205.23	164	$222.17	10,820	$231.29
CY 2016	1/1/2014-12/31/2014	4,188	$196.60	275	$231.58	10,481	$231.45
CY 2017	1/1/2015-12/31/2015	4,905	$195.81	256	$201.90	11,154	$237.58
CY 2018	1/1/2016-12/31/2016	5,703	$185.82	177	$166.19	12,848	$239.04
CY 2019	1/1/2017-12/31/2017	7,256	$185.70	143	$205.35	14,785	$230.69
CY 2020	1/1/2018-12/31/2018	12,299	$158.74	323	$185.26	25,434	$195.62
CY 2021/ CY 2022	1/1/2019-12/31/2019	14,262	$157.27	317	$193.55	32,502	$196.53
CY 2023	1/1/2021-12/31/2021	19,245	$159.60	371	$237.59	46,352	$208.47

We remind the commenters that every year since the implementation of the OPPS on August 1, 2000, we receive many requests from specialty associations, device manufacturers, drug manufacturers, and consultants to increase the payments for codes associated with specific drugs, devices, services, and surgical procedures. Under the OPPS, one of our goals is to make payments that are appropriate for the items and services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and

increases are generally limited to the annual payment update factor. As a budget neutral payment system, the OPPS does not pay the full hospital costs of services, however, we believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services.

Comment: Several commenters requested that we allow hospitals to submit charges for the CCTA CPT codes with revenue codes outside of general CT services, thereby allowing future cost estimates to accurately reflect the true cost of providing CCTA exams.

Response: As we stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85957), it is our standard ratesetting methodology to rely on hospital cost and charge information as it is reported to us through the claims and cost report data. The assignment to APC 5571 for the CCTA CPT codes is consistent with our standard ratesetting methodology, which provides appropriate incentives for efficiency. The OPPS is a prospective payment system that relies on hospital charges on the claims and cost report data from the hospitals that furnish the services in order to determine relative costs for OPPS ratesetting. We believe that the prospective payment rates for CPT codes 75572, 75573, and 75574, calculated based on the costs of those providers that furnished the services in CY 2021, provide appropriate payment to the providers who will furnish the services in CY 2023. We continue to believe that this standard ratesetting methodology accurately provides payment for CCTA exams provided to hospital outpatients.

We further note that hospital outpatient facilities are responsible for reporting the appropriate cost centers and revenue codes. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing, CMS "does not instruct hospitals on the

assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignment of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report." Therefore, HOPDs must determine the most appropriate cost center and revenue code for the CCTA CPT codes 75572, 75573, and 75574.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning the CCTA CPT codes 75572, 75573, and 75574 to APC 5571. The final CY 2023 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

8. Cardiac Contractility Modulation (CCM) Therapy (APC 5232)

CPT code 0408T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed; and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes) was effective January 1, 2016, and since then the code has been paid separately under the OPPS and assigned to APC 5231 (Level 1 ICD and Similar Procedures). For CY 2022, the payment rate for CPT code 0408T (in APC 5231) is $23,550.85; however, for CY 2023, based on our examination of the latest claims data, we believe that reassignment to another APC is more appropriate. Specifically, for CY 2023, we proposed to move CPT code 0408T from APC 5231 to APC 5232 (Level 2 ICD and Similar Procedures) with a proposed payment rate of $32,613.74.

Comment: Several commenters supported the reassignment to APC 5232 for CPT code 0408T. Commenters expressed that the costs clearly demonstrate the appropriateness of the reassignment.

Response: We appreciate the commenters support of the proposed reassignment of CPT code 0408T to APC 5232. Based on our evaluation of the latest claims data for this final rule with comment period, which is based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022, we believe that the reassignment to APC 5232 is appropriate. Our analysis shows a geometric mean cost of about $38,417 based on 115 single claims (out of 116 total claims) for CPT code 0408T, which is comparable to the geometric mean cost of approximately $32,986 for APC 5232, rather than the geometric mean cost of about $23,465 for APC 5231. The data demonstrate that the geometric mean cost for CPT code 0408T is consistent with the geometric mean cost of APC 5232. Therefore, we are increasing the payment for CPT code 0408T and reassigning the code to APC 5232 for CY 2023.

In summary, after our review of the public comments, we are finalizing our proposal without modification to assign CPT code 0408T to APC 5232 (Level 2 ICD and Similar Procedures) for CY 2023. The final CY 2023 payment rate for CPT code 0408T can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS website.

9. Cardiac Magnetic Resonance (CMR) Imaging (APC 5572 and 5573)

For CY 2023, we proposed to continue to assign CPT code 75561 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences) to APC 5572 (Level 2 Imaging with Contrast) with a proposed CY 2023 OPPS payment rate of $375.11. We also proposed to assign CPT code 75563

(Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) to APC 5573 (Level 3 Imaging with Contrast) with proposed CY 2023 OPPS payment rate of $751.54.

Comment: One commenter expressed concern with the fluctuating payment for cardiac MRI services, specifically, those described by CPT codes 75561 and 75563. They believe that these codes should be included with clinically similar services and reassigned to different APCs. The commenter is requesting that CPT code 75561 be reassigned to APC 5573. The commenter is also requesting that CPT code 75563 be reassigned to APC 5593 Level 3 (Nuclear Medicine and Related Services), which had a proposed CY 2023 OPPS payment rate of $1,353.52.

Response: We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. Because payment rates are updated annually based on the latest claims data, OPPS payments for certain services may vary from year to year. We note that we have many years of claims data for CPT codes 75561 and 75563 since these codes were established in 2008. For the CY 2023 OPPS update, based on claims submitted between January 1, 2021, and December 30, 2021, processed through June 30, 2022, our examination of the claims data for this CY 2023 OPPS/ASC final rule with comment period supports the continued assignment of CPT codes 75561 and 75563 to APCs 5572 and 5573, respectively. For CPT code 75561, our claims data reveals a geometric mean cost of approximately $434 based on 21,407 single claims (out of 25,141 total claims), which is comparable to the geometric mean cost of about $379 for APC 5572, rather the geometric mean cost of about $762 for APC 5573. Similarly, for CPT code 75563, our claims data shows a geometric mean cost of approximately $782 based on 3,132 single claims (out of 3,522 total claims), which is consistent with the geometric mean cost of about $762 for APC 5573, rather

than the geometric mean cost of approximately $1,365 for APC 5593. Based on our analysis, CPT codes 75561 and 75563 are appropriately placed in APCs 5572 and 5573, respectively, based on their clinical and resource homogeneity to the services assigned to the APCs.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to assign the cardiac MRI CPT codes 75561 and 75563 to APCs 5572 and 5573, respectively. The final CY 2023 OPPS payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

10. ClariFix Procedure (APC 5165)

CMS established HCPCS code C9771 (Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral)) to describe the technology associated with nasal endoscopy with cryoablation of nasal tissues and/or nerves. HCPCS code C9771 was established based on a New Technology application that was submitted to CMS for New Technology consideration under the OPPS. Based on our evaluation of the New Technology application, we assigned HCPCS code C9771 to APC 5164 (Level 4 ENT Procedures) with a payment rate of $2,736.39 effective January 1, 2021. In CY 2022, we continued to assign the code to APC 5164 with a payment rate of $ 2,793.98. For CY 2023, based on our examination of the latest claims data, we proposed to continue to assign HCPCS code C9771 to APC 5164 with a proposed payment rate of $2,896.26

Comment: We received one comment from the manufacturer requesting that HCPCS code C9771 be reassigned to APC 5165 (Level 5 ENT Procedures), which had a proposed CY 2023 OPPS payment rate of $5,377.70. The commenter believes that assigning HCPCS code

C9771 to APC 5165 would be more appropriate based on CY 2021 claims data and the resource and clinical similarity to the procedures in that APC, specifically CPT codes 30468 (Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)) and 69706 (Nasopharyngoscopy, surgical, with dilation of the eustachian tube (ie, balloon dilation); bilateral).

Response: We thank the commenter for their recommendation. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2023 OPPS update, based on claims submitted between January 1, 2021, and December 30, 2021, and processed through June 30, 2022, our analysis of the latest claims data for this CY 2023 OPPS/ASC final rule supports the reassignment of HCPCS code C9771 to APC 5165. Specifically, our claims data show a geometric mean cost of approximately $6,405 for HCPCS code C9771 based on 123 single claims (out of 125 total claims), which is comparable to the geometric mean cost of approximately $5,491 for APC 5165, rather than to the geometric mean cost of about $2,926 for APC 5164. Based on our review of the CY 2021 claims data for the CY 2023 OPPS ratesetting, we agree that HCPCS code C9771 would be more appropriately placed in APC 5165 based on its clinical and resource homogeneity to the procedures in the APC. Therefore, we are reassigning HCPCS code C9771 to APC 5165.

In summary, after consideration of the public comment, we are finalizing reassigning HCPCS code C9771 to APC 5165 for CY 2023. The final CY 2023 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

11. Cleerly Labs (APC 1511)

Cleerly Labs is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity using Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT). This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

- 0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report
- 0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission
- 0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography
- 0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report

In the CY 2021 OPPS/ASC final rule with comment period, we assigned the above codes to status indicator “E1” to indicate that the codes are not payable by Medicare when submitted

on outpatient claims because the service had not received FDA clearance at the time of the assignment. We note that the codes listed in OPPS Addendum B were in effect as of July 1, 2022, and we requested comments on the OPPS APC and SI assignments.

For the October 2022 update, based on our review of the New Technology application submitted to CMS for OPPS consideration, we evaluated the current status indicator assignments for CPT codes 0623T-0626T. Based on the technology and its potential utilization in the HOPD setting, our evaluation of the service, as well as input from our medical advisors, we assigned CPT code 0625T to a separately payable status. We announced the change to the APC and SI in the October 2022 OPPS update. Specifically, in the October 2022 OPPS Update CR (Change Request 12885, Transmittal 11594, dated September 9, 2022), we reassigned CPT code 0625T to status indicator "S" (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and APC 1511 (New Technology - Level 11 ($900 - $1000)) with a payment rate of $950.50, effective October 1, 2022, following review of the manufacturer's New Technology APC application.

Comment: We received several comments requesting that we reassign CPT code 0625T to status indicator "S" and CPT 0624T to status indicator "N" (packaged). Commenters believed the status indicator assignment of "E1" was an error and that CPT codes 0624T and 0625T are comparable to other services such as HeartFlow, and should be assigned the same status indicators as 0502T and 0503T. Additionally, one commenter, the manufacturer of the technology associated with this service, requested that CPT code 0625T be reassigned to APC 1557 (New Technology – Level 17 ($1500 - $1600).

Response: We thank the commenters for their recommendations. As noted above, CPT code 0625T was reassigned to APC 1511 (New Technology - Level 11 ($900 - $1000)) effective

October 1, 2022. We believe that APC 1511, with a payment rate of $950.50, most accurately accounts for the resources associated with furnishing the procedure described by CPT code 0625T.

We also agree with the commenters that CPT code 0624T should be reassigned to status indicator "N", and note that the technology associated with this service received FDA clearance in October 2020. We are finalizing the reassignment of CPT code 0624T to status indicator "N" effective January 1, 2023. Additionally, we are reassigning CPT codes 0623T and 0626T to status indicator "M" to indicate that these codes are not payable under the OPPS.

In summary, after consideration of the public comments, we are finalizing our proposal, with modification, to reassign CPT code 0624T to status indicator "N" and reassign CPT codes 0623T and 0626T to status indicator "M" for CY 2023. We are also continuing to assign 0625T to APC 1511 (New Technology - Level 11 ($900 - $1000)) for CY 2023. The final APC assignment and status indicators for CPT codes 0623T-0626T can be found in OPPS Addendum B. We refer readers to Addendum B of the final rule with comment period for the final payment rates for all codes reportable under the OPPS. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and Addendum D1 are available via the Internet on the CMS website.

12. Coflex® Interlaminar Implant Procedure (APC 5116)

For CY 2023, we proposed to continue to assign CPT code 22867 (Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level) to APC 5116.

CPT code 22867 describes the procedure associated with an open surgical decompression with interlaminar stabilization of the lumbar region.

Comment: One commenter agreed with the proposed assignment to APC 5116 and asked CMS to finalize the proposal.

Response: CPT code 22867 was effective January 1, 2017, and since its inception, the code has been assigned to APC 5116. For the CY 2023 OPPS update, the payment rates are based on claims submitted between January 1, 2021, through December 31, 2021, that were processed on or before June 30, 2022. Our analysis of the claims data for this final rule shows 582 single claims (out of 584 total claims) with a geometric mean cost of approximately $15,504, which falls within the range of the geometric mean cost for the significant HCPCS codes in APC 5116. The range of the geometric mean cost is between approximately $15,504 and $27,978. Based on the claims data for this final rule, we are finalizing our proposal and assigning CPT 22867 to APC 5116. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

In summary, after consideration of the public comment, we are finalizing our proposal to assign CPT code 22867 to APC 5116. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, the complete list of status indicator meanings for the OPPS payment system can be found in Addendum D1 to this final rule with comment period. Both Addendum B and Addendum D1 are available via the Internet on the CMS website.

13. Colonic Lavage (APC 5721)

The CPT Editorial Panel created CPT code 0736T (Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter) effective July

1, 2022. For CY 2023, we proposed to assign the code to APC 5733 (Level 3 Minor Procedures) with status indicator "Q1", indicating conditionally packaged payment under the OPPS with a proposed 2023 payment rate of $58.50.

Comment: We received one comment from the manufacturer requesting the reassignment of CPT code 0736T to APC 5694 (Level 4 Drug Administration). The commenter stated that the assignment of CPT code 0736T to APC 5694 is more appropriate based on resource and clinical coherence with other codes within that APC. Because the code is new and we have no claims data, the commenter provided invoices for the equipment, supplies, and staff required to perform this procedure.

Response: We appreciate the additional information provided by the commenter. Based on our understanding of the procedure and input from our medical advisors, we do not agree that the service associated with CPT code 0736T shares significant clinical or resource similarity with the services included in APC 5694 (Level 4 Drug Administration). We note that the long descriptor for the code describes a service that utilizes water and involves inserting a device, specifically, a rectal catheter, and does not describe the administration of a drug. Consequently, we do not believe that assignment to APC 5694 would be appropriate. However, based on the clinical characteristics of the procedure, we believe that the service should be reassigned to another more appropriate APC. Based on the nature of the procedure and the additional information provided to us, we believe that the service associated with CPT code 0736T is more appropriate in APC 5721 (Level 1 Diagnostic Tests and Related Services). Moreover, based on our assessment, we believe that the service described by HCPCS code 0736T shares similar resource and clinical characteristics with some of services included in APC 5721. Therefore, for

CY 2023, we are revising the assignment for CPT code 0736T to APC 5721, which is assigned to status indicator "S".

In summary, after consideration of the public comment, we are finalizing the APC assignment for CPT code 0736T with modification. Specifically, we are revising the APC assignment for CPT code 0736T to APC 5721 and assigning the code to status indicator "S" for CY 2023. The final CY 2023 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website. As we do every year, we will reevaluate the APC assignment for CPT code 0736T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

14. CoverScan (APC 5523)

CPT code 0697T (Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs) describes a procedure that generates metrics for multiple organs from a single, non-contrast MRI scan. CPT code 0697T was established effective January 1, 2022, and since its establishment, the code has been assigned to APC 5523 (Level 3 Imaging without Contrast). Under the OPPS, we review our claims data on an annual basis to determine the payment rates. For CY 2023, the OPPS payment rates are based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Because the code was new in 2022, we have no claims data at this time. However, we note that with all new codes for which we lack pricing

information, our policy has been to assign the service to an existing APC based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the service to existing procedures, input from CMS medical advisors, and review of all other information available to us. The OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. For CY 2022, based on our evaluation, we assigned CPT code 0697T to APC 5523. We believe the service associated with CPT code 0697T shares similar clinical characteristics to the services assigned to APC 5523. For CY 2023, we proposed continuing to assign CPT code 0697T to APC 5523 with a payment rate of $238.24.

Comment: One commenter requested that CPT code 0697T be reassigned to New Technology APC 1523 (New Technology - Level 23 ($2501-$3000)) with a payment rate of $2,750.50. The commenter noted that the procedure described by CPT code 0697T captures images and provides metrics on multiple organs, however, the code for the service is assigned to an APC whose payment rate is much lower in comparison to similar procedures that only capture images and generate metrics for a single organ.

Response: The developer of the service described by CPT code 0697T recently submitted an application for consideration as a new technology service through the CMS OPPS New Technology APC process. Because we are currently reviewing the application, we are not making any changes to the APC assignment for CPT code 0697T at this time. After our evaluation of the application, we will determine whether a change to the APC assignment is necessary.

After consideration of the public comment, we are finalizing our proposal without modification to continue to assign CPT code 0697T to APC 5523 for CY 2023. The final CY

2023 payment rate for CPT code 0697T can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS website.

15. COVID-19 Vaccine and Monoclonal Antibody Administration Services

a. Statutory and Regulatory Background

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L 116-136, March 27, 2020) provides for coverage of the COVID-19 vaccines under Part B of the Medicare program without any beneficiary cost sharing. Specifically, section 3713 added the COVID–19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. Additionally, section 3713(e) of the CARES Act authorizes CMS to implement the amendments made by section 3713 "through program instruction or otherwise." The changes to section 1861(s)(10)(A) of the Act were effective on the date of enactment, that is, March 27, 2020, and apply to a COVID–19 vaccine beginning on the date that such vaccine is licensed under section 351 of the PHS Act (42 U.S.C. 262).

We discussed our implementation of section 3713 in the interim final rule with comment period titled, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," published in the November 6, 2020 **Federal Register** (85 FR 71145 through 71150). In that rule, we stated that, while section 3713(e) of the CARES Act authorizes us to implement the amendments made by that section through program instruction or otherwise, we believed it was important to clarify our interpretation of section 3713 and announce our plans to ensure timely Medicare Part B coverage and payment for the COVID-19 vaccine and its administration. We anticipated that payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would

inform the payment rates for administration of COVID-19 vaccines. In the same interim final rule, we stated that, as soon as practicable after the authorization or licensure of each COVID-19 vaccine product by FDA, we would announce the interim coding and a payment rate for its administration (or, in the case of the OPPS, an APC assignment for each vaccine product's administration code), taking into consideration any product-specific costs or considerations involved in furnishing the service. We further stated that the codes and payment rates would be announced through technical direction to the Medicare Administrative Contractors (MACs) and posted publicly on the CMS website.

In December 2020, we publicly posted the applicable CPT codes for the Pfizer-BioNTech and Moderna COVID–19 vaccines and initial Medicare payment rates for administration of these vaccines upon FDA's authorization of them. We announced an initial Medicare payment rate for COVID–19 vaccine administration of $28.39 to administer single-dose vaccines. For a COVID–19 vaccine requiring a series of two or more doses—for example, for both the Pfizer-BioNTech and Moderna products—we announced a payment rate for administration of the initial dose(s) of $16.94, which was based on the Medicare payment rate for administering the other preventive vaccines under section 1861(s)(10) of the Act. We also announced a payment rate for administering the second dose of $28.39.[16] On March 15, 2021, we announced an increase in the payment rate for administering a COVID–19 vaccine to $40 per dose, effective for doses administered on or after March 15, 2021. For additional information, on timing and payment rates for COVID-19 vaccine administration, please see the CMS website:

[16] Medicare COVID-19 Vaccine Shot Payment. CMS Website. https://www.cms.gov/medicare/preventive-services/covid-19-services-billing-coverage/covid-19/medicare-covid-19-vaccine-shot-payment#:~:text=%2416.94%20for%20the%20initial%20dose,final%20dose%20in%20the%20series

https://www.cms.gov/medicare/preventive-services/covid-19-services-billing-coverage/covid-19/medicare-covid-19-vaccine-shot-payment.

b. Payment for COVID-19 Vaccine Administration Services Under the OPPS and Use of Alternative Site-Neutral Methodology to Update Payment Rates for COVID-19 Vaccine Administration Services for CY 2023

Under the OPPS, separate payment is made for the COVID-19 vaccine product and its administration. Except when the provider receives the COVID-19 vaccine for free (as has been the case to date), providers are paid for COVID-19 vaccine products at reasonable cost, as is the case with influenza and pneumococcal vaccines.[17] The HCPCS codes associated with the vaccine products are assigned OPPS status indicator "L" to indicate that they are paid at reasonable cost and are exempt from coinsurance and deductible payments under sections 1833(a)(3) and 1833(b) of the Act.

While COVID-19 and other preventive vaccine products are paid based on reasonable cost under the OPPS, the payment rates for the COVID-19 vaccine administration HCPCS codes are based on the APCs to which the codes are assigned. Because COVID-19 vaccination can involve more than one dose, we established APCs 9397 (COVID-19 Vaccine Admin Dose 1 of 2) and 9398 (COVID-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) to appropriately identify and pay for the administration of the COVID-19 vaccines. In CY 2021, we announced the establishment of APCs 9397 and 9398 for the COVID-19 vaccine administration codes through the April 2021 OPPS Update CR (Transmittal 10666, Change Request 12175 dated March 8, 2021). Prior to March 15, 2021, APC 9397 for the first dose of the COVID-19 vaccine was assigned a payment rate of $16.94; and APC 9398 for the second

[17] COVID-19 Vaccines and Monoclonal Antibodies. CMS Website. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

dose was assigned a payment rate of $28.39. As described above, we changed the payment rate to $40 per dose for the primary series and booster dose(s) of the COVID-19 vaccine effective March 15, 2021.

For CYs 2021 and 2022, we maintained the payment rate of $40 for the APCs to which the COVID-19 vaccine administration services are assigned. For further information, please see Addendum B to the CY 2021 and 2022 OPPS/ASC final rules with comment period on the CMS OPPS website. As of July 1, 2022, there are approximately 18 COVID–19 vaccine administration HCPCS codes. We note that the latest list of HCPCS codes for COVID–19 vaccine products and vaccine administration, along with their effective dates and payment rates, is available on the CMS COVID–19 Vaccines and Monoclonal Antibodies website at https://www.cms.gov/ medicare/medicare-part-b-drug-averagesales-price/covid-19-vaccines-andmonoclonal-antibodies. Based on our review of CY 2021 claims data associated with the COVID-19 vaccine administration HCPCS codes, we explained in the proposed rule that the geometric mean cost for APC 9397 is $25.86 and the geometric mean cost for APC 9398 is $36.80. We are generally using CY 2021 claims data to set CY 2023 payment rates for APCs at the geometric mean costs for the APCs based on that data. We note, however, that CY 2021 utilization of the COVID-19 vaccine administration codes in the outpatient hospital setting was very high, with nearly 7 million claims for these codes in that year, which may not be reflective of future year utilization. Because we do not know if demand for COVID-19 vaccine administration in the outpatient hospital setting will be significantly different in CY 2023 than CY 2021 because CY 2021 was the first complete year for which we had COVID-19 vaccine administration claims data, and because we do not know if the PHE for COVID-19 will be in effect in CY 2023, we explained in the proposed rule that we believe that we should maintain the

$40 per dose payment rate for the COVID-19 administration HCPCS codes in CY 2023 until we have an additional year of claims data on which to base the payment rate. Therefore, although the geometric mean costs for the APCs to which we assigned the COVID-19 vaccine administration codes are lower than $40, for CY 2023 we proposed to use the equitable adjustment authority in section 1833(t)(2)(E) of the Act to maintain the payment rate of $40 for each of the COVID-19 vaccine administration APCs: APC 9397 and APC 9398. We believe maintaining the current, site neutral payment rate is necessary to ensure equitable payments during the continuing PHE and at least through the end of CY 2023.

We noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44575) that we do not pay under the OPPS for monoclonal antibody products used to treat COVID-19 and their administration using the COVID-19 vaccine administration APCs. Rather, the OPPS payment rates for administration of COVID-19 monoclonal antibody products under the Part B preventive vaccine benefit are set at the midpoint of the cost bands for the New Technology APCs to which the monoclonal antibody administration services are assigned under the OPPS. We assigned COVID-19 monoclonal antibody administration services to New Technology APCs based on estimated costs for these services. For further discussion of payment for COVID-19 monoclonal antibody administration see section III.E.15.d below in this final rule with comment period.

Under current policy, the payment rates for COVID-19 vaccine administration services are site-neutral across most outpatient and ambulatory settings. We requested comment on whether we should continue a site-neutral payment policy for COVID-19 vaccine administration for CY 2023, and what alternative approaches (including under our equitable adjustment authority at section 1833(t)(2)(E) of the Act) may be appropriate to update the OPPS payment rates for the COVID-19 vaccine administration HCPCS codes (including the in-home add-on

HCPCS code M0201) while continuing to ensure site-neutral payment for these services. For example, in the CY 2023 PFS proposed rule that was included in the July 29, 2022 **Federal Register** (87 FR 46221 through 46222), we proposed to update the payment rate for the administration of preventive vaccines (other than for services paid under other payment systems such as the OPPS) using the annual increase to the Medicare Economic Index (MEI). We requested public comments on whether, as an alternative to our proposal to maintain current OPPS payment rates for COVID-19 vaccine administration using our equitable adjustment authority at section 1833(t)(2)(E) of the Act, we should instead use the rate finalized through PFS rulemaking that generally applies under the preventive vaccine benefit, or an alternative method commenters suggest, to determine the appropriate payment rates for preventive vaccine administration under the OPPS, which would likely also require use of our equitable adjustment authority.

For more information on the payment rates for the administration of preventive vaccines, including the proposal to update the payment rate by the annual increase to the MEI, we referred readers to the CY 2023 PFS proposed rule that was included in the July 29, 2022 **Federal Register** (87 FR 46218 through 46228).

We also sought comment on whether to use the rate finalized through PFS rulemaking generally as it applies under the preventive vaccine benefit, or an alternative method commenters suggest, to set the CY 2023 payment rate for HCPCS code M0201 (COVID-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID-19 vaccine administration is performed at the patient's home).

In summary, for CY 2023, we proposed to continue to pay $40 per dose for the administration of the COVID–19 vaccines provided in the HOPD setting, and an additional

$35.50 for the administration of the COVID-19 vaccines when provided under certain circumstances in the patient's home. Additionally, we requested comments on whether, as an alternative to maintaining the CY 2022 OPPS payment rates for COVID-19 vaccine administration services in CY 2023, we should use a different approach, including relying on our equitable adjustment authority in section 1833(t)(2)(E) of the Act to base the payment rate for COVID-19 vaccine administration under the OPPS in CY 2023 on the payment rate for the COVID-19 vaccine administration under the preventive vaccine benefit under Part B as finalized in PFS rulemaking, or employing another alternate methodology to set CY 2023 payment rates for these services.

Comment: Commenters supported our proposal to continue to pay $40 per dose for the administration of the COVID–19 vaccines provided in the HOPD setting, and an additional $35.50 for the administration of the COVID-19 vaccines when provided under certain circumstances in the patient's home for CY 2023. One commenter recommended that CMS maintain these payment rates beyond CY 2023.

One commenter expressed concerns over site-neutral payment policies for both COVID-19 vaccine administration when furnished in facilities and COVID-19 vaccine administration furnished in the patient's home. These commenters stated that site-neutral policies may make it more challenging for different settings to offer certain services when reimbursement does not adequately reflect the different costs involved in providing care.

One commenter stated that adjustments to the payment rate for COVID-19 vaccine administration should be made based on the MEI and GAF, consistent with the proposal in the CY 2023 PFS proposed rule. This commenter stated that they believe that both updates could be adopted using CMS's equitable adjustment authority under section 1833(t)(2)(E) of the Act.

Response: We continue to believe that the resources associated with COVID-19 vaccine administration do not vary across settings of care and are largely consistent across physician office and hospital outpatient department settings. We agree that, for CY 2023, the payment rates for COVID-19 vaccine administration should be consistent across settings of outpatient care, and we are concerned that a higher payment rate in the physician office setting could create financial incentives to furnish COVID-19 vaccines in that setting, rather than the hospital setting. Therefore, for CY 2023, we are finalizing adoption of the PFS payment rates for COVID-19 vaccine administration using our equitable adjustment authority at section 1833(t)(2)(E) of the Act. We believe that our goal to promote broad and timely access to COVID-19 vaccines will be better served if our policies with respect to payment for these products continue until the EUA declaration pursuant to section 564 of the FD&C Act covering these products is terminated. Therefore, we are finalizing payment rates for APCs 9397 and 9398 of $41.52 if the EUA declaration[18] persists into CY 2023 and $31.14 if the EUA declaration is terminated in CY 2022. We note that we will display a payment rate of $41.52 in Addendum B of the CY 2023 OPPS Final Rule with comment period and if needed will update the APC payment rates to $31.14 through sub regulatory guidance. We are also finalizing creation of a new APC, APC 9399 (Covid-19 vaccine home administration), with a payment rate of $36.85 and are reassigning HCPCS code M0201 so as to effectuate the same payment amount for at-home COVID-19 vaccine administration when billed by both hospitals and physician offices. We will consider whether to implement permanent site-neutral payment rates in future rulemaking.

c. Comment Solicitation on the Appropriate Payment Methodology for Administration of Preventive Vaccines

[18] 85 FR 18250

Currently under the OPPS, the codes describing the administration of the influenza, pneumococcal, and hepatitis b vaccines are assigned to APC 5691 (Level 1 Drug Administration), with a payment rate of about $40. However, given that the statutory benefit for Medicare Part B preventive vaccines and their administration is based on 1861(s)(10) of the Act, we are seeking comments on whether we should adopt a different methodology to make payment when these services are furnished by a HOPD other than the one for covered OPD services under section 1833(t) of the Act. Therefore, we sought comments on the appropriate payment methodology for the administration of Part B preventive vaccines, including the COVID-19 vaccine post-PHE.

Comment: Several commenters stated that, while they support a site-neutral payment policy for vaccines in general because the resource costs of administering a vaccine are consistent across settings of care, they believe the OPPS payment rate is more accurate than the PFS rate and encouraged CMS to continue to use OPPS ratesetting for the Part B preventive vaccine administration services as the OPPS methodology is updated each year by new cost data based on OPPS claims, which is a more reliable source of current hospital costs for services.

Response: We thank commenters for their input and will consider any changes to the payment methodology for preventive vaccines in future rulemaking.

d. COVID-19 Monoclonal Antibody Products and Their Administration Services Under OPPS

Subsequent to the November 6, 2020 IFC and as discussed in the CY 2022 PFS final rule (86 FR 65190 through 65194), when monoclonal antibody products for COVID-19 treatment were granted EUAs during the PHE for COVID-19, we made the determination to cover and pay for them under the Part B vaccine benefit in section 1861(s)(10) of the Act.

Regarding the availability of COVID-19 monoclonal antibody products, we noted in the CY 2023 OPPS/ASC proposed rule that as of the date of publication of that proposed rule, there were no monoclonal antibody products approved for the treatment or prevention of COVID-19. There are five authorized monoclonal antibody COVID-19 products; four are authorized for the treatment or post-exposure prophylaxis for prevention of COVID-19 and one is authorized as pre-exposure prophylaxis for prevention of COVID-19.[19] We note that at the time of publication of this Final Rule with comment period, none of the four monoclonal antibody products for treatment or post-exposure prevention of COVID-19 that have been granted an EUA are authorized for use in geographic regions where infection was likely caused by a non-susceptible variant. Due to data indicating decreased activity for three of these treatments against Omicron variants currently in wide circulation, only one of these treatments is currently authorized in any U.S. region until further notice by FDA.

Consistent with how we pay for COVID-19 vaccine products and their administration under the OPPS, we pay separately for COVID-19 monoclonal antibodies and their administration. Except when the provider receives the COVID-19 monoclonal antibody product for free, providers are paid for these products at reasonable cost.[20] The HCPCS codes associated with the COVID-19 monoclonal antibody products are assigned to OPPS status indicator "L" to indicate that they are paid at reasonable cost and are exempt from coinsurance and deductible payments under sections 1833(a)(3) and 1833(b) of the Act.

While the COVID-19 monoclonal antibody products are paid based on reasonable cost under the OPPS, the payment rates for the COVID-19 monoclonal antibody product

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[19] Viewed 5/6/2022. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[20] COVID-19 Vaccines and Monoclonal Antibodies. CMS Website. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

administration depends on the route of administration and whether the product is furnished in a healthcare setting or in the beneficiary's home. As discussed in more detail in the CMS COVID-19 Monoclonal Toolkit,[21] payment for administration of monoclonal antibodies can range from $150.50 to $750.00. The HCPCS codes associated with the COVID-19 monoclonal antibody product administration are assigned to New Technology APCs 1503, 1504, 1505, 1506, 1507, and 1509 with an OPPS status indicator "S" (Procedure or Service, Not Discounted When Multiple, separate APC assignment) to indicate that the administration of monoclonal antibodies is paid separately under the OPPS.

For CYs 2021 and 2022, we maintained the payment rates for the COVID-19 monoclonal antibody product administration services by maintaining their New Technology APC assignments. For further information, please see Addendum B to the CY 2021 and 2022 OPPS/ASC final rules with comment period. For CY 2023, we proposed to use the equitable adjustment authority at section 1833(t)(2)(E) of the Act to maintain the CY 2022 New Technology APC assignments (specifically, New Technology APCs 1503, 1504, 1505, 1506, 1507, or 1509) and corresponding payment rates for each of the COVID-19 monoclonal antibody product administration HCPCS codes for as long as these products are considered to be covered and paid under the Medicare Part B vaccine benefit so that, if the PHE ends, the benefit category and corresponding payment methodology under the OPPS will remain site neutral.

We noted that, once these products are no longer considered to be covered and paid under the Medicare Part B vaccine benefit, we would expect the COVID-19 monoclonal antibody product administration services to be paid similar to monoclonal antibody products used in the treatment of other health conditions – to be "biologicals". For more background on Medicare

[21] https://www.cms.gov/monoclonal

Part B payment for COVID-19 monoclonal antibody products and their administration, and for proposals regarding such payment, we referred readers to the CY 2023 PFS proposed rule that was included in the July 29, 2022 **Federal Register** (87 FR 46224 through 46228). In particular, the CY 2023 PFS proposed rule proposed to clarify that the COVID-19 monoclonal antibody products would be covered and paid for under the Medicare Part B vaccine benefit until the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act for drugs and biological products is terminated. Additionally, we proposed to continue the existing policy to pay for monoclonal antibody products used as pre-exposure prophylaxis for prevention of COVID-19 and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization.

Comment: We did not receive any comments on our proposal to continue existing policy to pay for monoclonal antibody COVID-19 pre-exposure prophylaxis products under the Part B vaccine benefit after the EUA declaration is terminated, provided those products have market authorization. Commenters stated that while they appreciated CMS's efforts to provide consistent payment policy for monoclonal antibodies and their administration during the PHE, they encouraged the agency to continue to work with providers to ensure that the payment rates are accurate, even if they vary by setting of care.

Response: We thank commenters for their input and will consider any changes to payment policy for monoclonal antibodies and their administration in future rulemaking.

Comment: Commenters encouraged CMS to work with providers as we scale back or wind down any PHE-specific flexibilities so that the agency provides clear guidance on how payment policies may be changing, and the impact that will have on providers.

Response: We appreciate these comments and will consider how best to provide guidance on any policy changes either during the PHE or after.

After consideration of public comments, we are finalizing our proposal to use the equitable adjustment authority at section 1833(t)(2)(E) of the Act to maintain the CY 2022 New Technology APC assignments (specifically, New Technology APCs 1503, 1504, 1505, 1506, 1507, or 1509) and corresponding payment rates for each of the COVID-19 monoclonal antibody product administration HCPCS codes. We are also finalizing our proposal that this policy would continue to apply for OPPS payment for monoclonal antibody products used as pre-exposure prophylaxis for prevention of COVID-19 and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization.

16. Duplex Scan of Extracranial Arteries (APC 5523)

For CY 2023, we proposed to continue to assign CPT code 93880 (Duplex scan of extracranial arteries; complete bilateral study) to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment rate of $238.24.

Comment: One commenter disagreed with the proposed payment amount and recommended that CPT code 93880 be reassigned from APC 5523 to APC 5524 (Level 4 Imaging without Contrast) with a proposed payment rate of $512.73 for CY 2023. The commenter stated that CPT code 93880 should be reassigned due its clinical and resource similarity to CPT code 93306 (Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral

doppler echocardiography, and with color flow doppler echocardiography), which is assigned to APC 5524.

Response: We are not accepting this recommendation. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2023 OPPS update, based on claims submitted between January 1, 2021, and December 30, 2021, and processed through June 30, 2022, our analysis of the claims data for this final rule with comment period supports the continued assignment of CPT code 93880 to APC 5523 based on its clinical and resource homogeneity to the procedures and services in the APC. Specifically, our claims data show a geometric mean cost of approximately $225 based on 444,369 single claims (out of 514,044 total claims) for CPT code 93880, which is consistent with the geometric mean cost of about $240 for APC 5523, rather than the geometric mean cost of approximately $517 for APC 5524. We believe the resource requirements for CPT code 93880 are more similar to procedures found in APC 5523 rather than in APC 5524. Therefore, for CY 2023, we will continue to assign CPT code 93880 to APC 5523.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT code 93880 to APC 5523 for CY 2023. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

17. Endoscopic Submucosal Dissection (ESD) Procedure (APC 5303)

CMS established HCPCS code C9779 (Endoscopic submucosal dissection (ESD), including endoscopy or colonoscopy, mucosal closure, when performed) effective October 1,

2021, to describe the endoscopic submucosal dissection (ESD) performed during an endoscopy or colonoscopy. HCPCS code C9779 was established based on a New Technology application that was submitted to CMS for New Technology consideration under the OPPS. Based on our assessment, we assigned the code to APC 5313 (Level 3 Lower GI Procedures) because we believe the ESD procedure has similar clinical characteristics and resource costs as the surgical procedures assigned to APC 5313. We announced the assignment to APC 5313 in the October 2021 OPPS quarterly update CR (Transmittal 10997, Change Request 12436, dated September 16, 2021) with a payment rate of $2,443.39. In CY 2022, we continued to assign the code to APC 5313 with a payment rate of $2,495.04. For CY 2023, we proposed to continue to assign HCPCS code C9779 to APC 5313 with a proposed payment rate of $2,611.51.

Comment: Some commenters disagreed with the proposed payment amount and requested that HCPCS code C9779 be reassigned from APC 5313 to APC 5303 (Level 3 Upper GI Procedures) with a proposed payment rate of $3,319.29 for CY 2023. Commenters stated that the ESD procedure's resource requirements and geometric mean cost of $4,049 are more similar to the resource requirements and geometric mean costs of procedures found in APC 5303. Further, commenters noted that the ESD procedure is technically more demanding, requires advanced skills to perform, and is clinically similar to CPT code 43497 (Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])), which is currently assigned to APC 5303.

Response: Based on the comments received, further evaluation of the surgical procedure, and input from our medical advisors, we agree with the commenters that the resource requirements for HCPCS code C9779 may be more similar to the procedures assigned to APC

5303. Therefore, we are accepting the commenter's recommendation and reassigning HCPCS code C9779 to APC 5303 for CY 2023.

In summary, after consideration of the public comments, we are finalizing reassigning HCPCS code C9779 to APC 5303 for CY 2023. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

18. Endovenous Femoral-Popliteal Arterial Revascularization (APC 5193)

For CY 2023, we proposed to continue to assign CPT code 0505T (Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion) to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment rate of $10,760.97.

Comment: One commenter requested the reassignment of CPT code 0505T to APC 5194 (Level 4 Endovascular Procedures). The commenter provided utilization claims data and asserted that CPT code 0505T is currently being studied in an IDE clinical trial and that the claims are not currently representative of the full cost of the procedure. The commenter stated that CPT code

0620T (Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed), which is assigned to APC 5194, is clinically similar to CPT code 0505T.

Response: Based on our review of the cost data and input from our clinical advisors, we disagree with the suggestion that CPT code 0505T should be assigned to APC 5194. We also do not agree that CPT code 0505T is comparable to CPT 0620T. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS. Based on our analysis of the claims data for this CY 2023 OPPS/ASC final rule with comment period, our data shows a geometric mean cost of about $14,264 for CPT code 0505T based on 22 single claims (out of 22 total claims), which is in line with the geometric mean cost of $10,916 for APC 5193. In contrast, the geometric mean cost for CPT code 0620T is significantly higher at approximately $26,468, which is based on 9 single claims (out of 9 total claims). Our data demonstrates that the resource cost associated with CPT code 0505T is significantly lower than the cost of CPT code 0620T. We believe that the procedure described by CPT code 0505T is more clinically similar to the procedures assigned to APC 5193 (Level 3 Endovascular Procedures) and that the costs of other procedures in this APC more accurately compare to the costs associated with CPT code 0505T.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to assign CPT code 0505T to APC 5193. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we

refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website. For additional discussion regarding the commenter's request to add CPT code 0505T to the ASC covered procedures list (CPL), refer to section XIII. (ASC Payment System).

19. External Electrocardiographic (ECG) Recording (APC 5732)

For CY 2023, we proposed to assign CPT code 93242 (External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)) to APC 5732 (Level 2 Minor Procedures) with a proposed payment rate of $34.61. The code was new in CY 2021 with an effective date of January 1, 2021. Prior to CY 2021, the code was reported with CPT code 0296T (External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)), which was active between January 1, 2012, and December 31, 2020.

Comment: We received a comment requesting that we assign CPT code 93242 to APC 5733 or 5734 (Level 4 Minor Procedures). The commenter stated that the resource cost associated with furnishing the service described by CPT code 93242 is not reflected in the payment rate for APC 5732.

Response: We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our review of the latest claims data. For the CY 2023 OPPS update, based on claims submitted between January 1, 2021, and December 30, 2021, processed through June 30, 2022, our analysis of the latest claims data for this CY 2023 OPPS/ASC final rule supports the assignment of CPT code 93242 to APC 5732 based on its clinical and resource homogeneity to the procedures and services in the APC. Specifically, our data shows a geometric

mean cost of approximately $25 based on 15,603 single claims (out of 31,034 total claims) for CPT code 93242, which is consistent with the geometric mean cost of about $35 for APC 5732 rather than the geometric cost of about $59 for APC 5733 or the geometric mean cost of approximately $119 for APC 5734. Based on our data, the cost associated with furnishing CPT code 93242 is significantly less than the cost associated with the services assigned to APC 5733 or APC 5734. We believe that CPT code 93242 accurately fits in APC 5732 based on its clinical and resource homogeneity to the procedures in the APC.

In summary, after consideration of the public comment, we are finalizing our proposal without modification, and assigning CPT code 93242 to APC 5732 for CY 2023. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

20. Eye Procedures (APCs 5502 and 5503)

For CY 2023, we proposed to continue to assign CPT code 65426 (Excision or transposition of pterygium; with graft) to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) with a proposed payment rate of $2,140.55. In addition, we proposed to continue to assign CPT 65778 (Placement of amniotic membrane on the ocular surface; without sutures) to APC 5502 (Level 2 Extraocular, Repair, and Plastic Eye Procedures) with a proposed payment rate of $882.12.

Comment: A commenter requested the reassignment of CPT code 65426 to APC 5504 (Level 4 Extraocular, Repair, and Plastic Eye Procedures) and CPT 65778 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures). The commenter stated that the inclusion of

"grafts" in CPT 65426 code descriptor leads to billing discrepancies and underreported device and supply costs. The commenter believes that the device offset for CPT 65426 and CPT 65778 is not truly reflective of the cost of the graft as a result of the underreported device and supply costs. Additionally, the commenter cited CPT 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured) and CPT 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) as two examples of procedures paid for under the OPPS that use the same graft as CPT code 65426 but are assigned to APC 5504, with CPT 65779 having a device offset amount of $1,242.53.

Response: Based on our review of the cost data and input from our clinical advisors, we disagree with commenters that CPT code 65426 should be assigned to APC 5504. For CY 2023, based on claims submitted between January 1, 2021, through December 31, 2021, that were processed on or before June 30, 2022, our analysis of the latest claims data for this final rule continues to support the assignment to APC 5503 for CPT code 65426. Specifically, our claims data reveal a geometric mean cost of approximately $2,474 for CPT code 65426 based on 1,092 single claims (out of 1,101 total claims), which is consistent with the geometric mean cost of about $2,174 for APC 5503, rather than the geometric mean cost of $3,595 for APC 5504. Similarly, we do not agree that CPT code 65778 should be reassigned to APC 5503. Our claims data show a geometric mean cost of approximately $1,349 for CPT code 65778 based on 190 single claims (out of 443 total claims), which is consistent with the geometric mean cost of about $897 for APC 5502, rather than the geometric mean cost of approximately $2,174 for APC 5503. We believe that assigning CPT code 65778 to APC 5503 would overpay for the procedures. In addition, we do not believe that CPT code 65426 is comparable to CPT code 65779 or CPT code 65780. Based on our review of the clinical characteristics of the procedure, and input from our

medical advisors, we believe CPT code 65426 is more similar to the procedures assigned to APC 5503 and CPT code 65778 is more similar to the procedures assigned to APC 5502, and these payment rates better account for the cost of the procedures as well as the resources used.

With respect to the issue of billing discrepancies, based on our review of the claims data for CPT codes 65426 and 65778, we have no reason to believe that the procedures are miscoded. Based on our analysis of the claims data for this final rule with comment period, we are unable to determine whether hospitals are misreporting the procedures. Moreover, it is generally not our policy to judge the accuracy of provider coding and charging for purposes of OPPS ratesetting. We rely on hospitals and providers to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to report services accurately on claims and charges and costs for the services on their Medicare hospital cost report.

In summary, after consideration of the public comments, we are finalizing our proposal without modification, and assigning CPT code 65426 to APC 5503 and CPT 65778 to APC 5502. The final CY 2023 payment rate for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website. For additional discussion regarding the commenter's request to increase the device offset of CPT code 65426 and CPT code 65779, refer to section IV. C. (Device-Intensive Procedures).

21. Eye-Movement Analysis Without Spatial Calibration (APC 5734)

The CPT Editorial Panel established CPT code 0615T (Eye-movement analysis without spatial calibration, with interpretation and report), effective July 1, 2020, to describe eye-movement analysis without spatial calibration that involves the use of the EyeBOX system as an

aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI). The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without a concussion.

For CY 2023, we proposed to continue to assign CPT code 0615T to APC 5734 (Level 4 Minor Procedures) with status indicator "Q1" (conditionally packaged) and a proposed CY 2023 OPPS payment rate of $118.32.

Comment: A commenter requested a change in the status indicator for CPT code 0615T to "S" to make it separately payable to provide adequate reimbursement and to treat it similarly to other SaaS procedures. The commenter also stated that packaging payment for use of the EyeBox into payment for the clinic or emergency department visit produces insufficient reimbursement, just as CMS's current approach to the other packaged SaaS codes fails to provide appropriate payment for those services. The manufacturer also urged CMS to assign the procedure to an APC with a payment rate of at least $200 to ensure that hospitals are adequately reimbursed for this procedure.

Response: Although HCPCS code 0615T was effective July 1, 2020, we have no claims data for the code. We note that for the CY 2023 OPPS update, payments are based on claims submitted between January 1, 2021, through December 31, 2021, and processed through June 30, 2022. Because we have no claims data, we believe that we should continue to assign CPT code 0615T to APC 5734 for CY 2023. We note that we review, on an annual basis, the APC

assignments for all services and items paid under the OPPS. As a result, we will reevaluate the placement for CPT code 0615T for the next rulemaking cycle.

In addition, as listed in OPPS Addendum D1 of the CY 2023 OPPS/ASC proposed rule, codes assigned to status indicator "Q1" may be packaged, assigned to a composite APC, or paid separately under the OPPS. Specifically, a "Q1" status indicator may indicate a:

- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator “S”, “T”, or “V"; or
- Composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services; or
- In other circumstances, payment is made through a separate APC payment

After reviewing the procedure with our medical advisors, we believe that, similar to several other SaaS procedures, it is appropriate for the procedure described by CPT code 0615T to be paid separately. Therefore, we are revising the status indicator for the code from "Q1" (conditionally packaged) to "S" (Procedure or Service, Not Discounted When Multiple) to indicate that the service is paid separately.

After consideration of the public comment, we are finalizing our proposal with modification. Specifically, we are finalizing the assignment to APC 5734 for CPT code 0615T and revising the status indicator from “Q1” (conditionally packaged) to “S” (separately payable), consistent with the CY 2023 payment methodology for other SaaS procedures.

22. Fecal Microbiota Procedure (APC 5301)

For January 1, 2023, the AMA’s CPT Editorial Panel established new CPT code 0780T (Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract). We

note that CPT code 0780T was listed as placeholder code X041T in the OPPS Addendum B of the CY 2023 OPPS/ASC proposed rule. The CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, so we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled "CY 2023 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code," to the proposed rule. We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period. For CY 2023, we proposed to assign CPT code 0780T to status indicator "B", indicating that this code is not paid under OPPS and an alternate code that is recognized by OPPS may be available.

Comment: We received one comment from the manufacturer requesting that CMS assign CPT code 0780T to status indicator "T" and APC 5301 (Level 1 Upper GI Procedures) with a proposed payment rate of $841.07. The commenter stated that CPT code 0780T should be assigned to APC 5301 based on its clinical and resource homogeneity to procedures in this APC. The commenter also expressed concern that the lack of payment for CPT code 0780T under the OPPS would negatively impact Medicare beneficiaries' access to procedure.

Response: We thank the commenter for their feedback. The fecal microbiota procedure has been in existence for several years now, and although CPT code 0780T is a new code effective January 1, 2023, the procedure is already described by existing codes, specifically, HCPCS code G0455 and CPT code 44705. Since 2013, Medicare has paid separately for HCPCS code G0455 under the OPPS. Table 40 lists the long descriptors for all three codes. We note that

CPT code 44705 was effective January 1, 2013, however, as we stated in both the CY 2013 PFS final rule (77 FR 69052) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 74978-74979), we did not recognize the CPT code, and instead established HCPCS code G0455, effective January 1, 2013. We note that the payment for the preparation and instillation of fecal microbiota is included in HCPCS code G0455. As stated in the CY 2013 PFS final rule, Medicare's payment for the preparation of the donor specimen is only made if the specimen is ultimately used for the treatment of a beneficiary because Medicare is not authorized to pay for the costs of any services not directly related to the diagnosis and treatment of a beneficiary (77 FR 69052). For the fecal microbiota procedure, the only code payable under the OPPS is HCPCS code G0455 for this procedure.

For CY 2023, we proposed to continue to assign HCPCS code G0455 to status indicator Q1 (conditionally packaged) and APC 5301 (Level 1 Upper GI Procedures), which had a proposed CY 2023 OPPS payment rate of $841.07. Because HCPCS code G0455 exists to describe the fecal microbiota procedure, both CPT codes 44705 and 0780T are assigned to status indicator "B" (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) to indicate that the codes are not recognized under OPPS, and instead, should be reported with another HCPCS code. In this case, the appropriate code that should be reported to Medicare under the OPPS is HCPCS code G0455 for the fecal microbiota procedure.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT code 0780T to status indicator “B”. In addition, we note that we received no comments on CPT code 44705 or HCPCS code G0455 and are finalizing our proposals with respect to those codes without modification. Table 40 list the long

descriptors for the fecal microbiota HCPCS and CPT codes and their OPPS SI and APC assignments for CY 2023. We refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addendum D1 is available via the Internet on the CMS website.

TABLE 40: FINAL CY 2023 SI AND APC FOR THE FECAL MICROBIOTA PROCEDURE

HCPCS/ CPT Code	Placeholder Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2023 OPPS APC Group
G0455		Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen	Q1	5301	Level 1 Upper GI Procedures
44705		Preparation of fecal microbiota for instillation, including assessment of donor specimen	B		
0780T	X041T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract	B		

23. Fractional Flow Reserve Derived from Computed Tomography (FFRCT) (APC 5724)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow service is indicated for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is,

a coronary angiogram). In 2018, the CPT Editorial Panel established CPT code 0503T to describe the service associated with HeartFlow. Below is the long description for the CPT code:

- 0503T: Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that we should pay separately for HeartFlow because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. Based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500, in CY 2018, we assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology - Level 16 ($1,401 - $1,500)), with a payment rate of $1,450.50. Because the CPT code was new in 2018, we did not have Medicare claims data in CY 2019; and we continued to assign the service to New Technology APC 1516 with a payment rate of $1,450.50.

CY 2020 was the first year for which we had Medicare claims data to calculate the cost of HCPCS code 0503T. We note that for CY 2020, the OPPS payment rates were based on claims submitted between January 1, 2018, and December 31, 2018, processed through June 30, 2019. For the CY 2020 OPPS/ASC final rule with comment period, there were 957 claims reported with CPT code 0503T, of which 101 were single frequency claims that were used to

calculate the geometric mean of the procedure. We planned to use the geometric mean to determine the cost of HeartFlow for purposes of determining the appropriate APC assignment for the procedure. However, the number of single claims for CPT code 0503T was below the New Technology APC low-volume payment policy threshold for the proposed rule, and this number of single claims was only two claims above the threshold for the New Technology APC low-volume policy for the final rule. Therefore, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our New Technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12, and the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean, which fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. The arithmetic mean also helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean. Therefore, in CY 2020, we assigned CPT code 0503T to New Technology APC 1511.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T. Specifically, using CY 2019 data, we identified 3,188 claims billed with

CPT code 0503T including 465 single frequency claims. These totals were well above the threshold of 100 claims for a procedure to be evaluated using the New Technology APC low-volume policy. Therefore, we used our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T. Based on the CY 2019 claims data used for the CY 2021 OPPS ratesetting, we found that the geometric mean cost decreased from the previous year. Specifically, our analysis found that the geometric mean cost for CPT code 0503T was $804.35, which was consistent with the geometric mean cost for New Technology APC 1510 (New Technology—Level 10 ($801–$900)). However, providers and other stakeholders noted that the cost to furnish FFRCT services is approximately $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

We noted that HeartFlow was one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services (85 FR 85943). This especially appeared to be the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, in CY 2021, we decided it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to New Technology APC 1511, which is the same APC assignment as in CY 2020, in order to provide payment stability and equitable payment for providers as they continued to become familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. Accordingly, we continued to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

For CY 2022, we used claims data from CY 2019 to estimate the cost of the HeartFlow service. Because we were using the same claims data as in CY 2021, these data continued to reflect that providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services. Therefore, we continued to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021: New Technology APC 1511 (New Technology—Level 11 ($901–$1000)), with a payment rate of $950.50 for CY 2022, which was the same payment rate for the service as in CY 2020 and CY 2021.

Since 2018, CPT code 0503T has been paid separately under the OPPS. We now have several years' worth of claims data. Based on the historical claims data for the past three years, specifically, from CY 2018, CY 2019, and CY 2021, and based on the claims data for the CY 2023 OPPS/ASC proposed rule, we stated that we believe that CPT code 0503T should be reassigned from a New Technology to a clinical APC. First, we explained that we have sufficient single frequency claims from these three years to have a reliable estimate of the cost of the service. There were 101 single frequency claims in CY 2018, 465 single frequency claims in CY 2019, and 1,681 single frequency claims in CY 2021. The estimated cost of 0503T has been reasonably consistent over the same three years as well. The estimated cost of HeartFlow was around $768 in CY 2018, about $808 in CY 2019, and approximately $827 in CY 2021. Since the cost data have been stable for HeartFlow for the past several years, we stated that we believe it is appropriate to reassign the service to a clinical APC using our regular process of using the most recent year of claims data for a procedure. Based on our analysis of the claims data for the proposed rule, the geometric mean cost for CPT code 0503T is $826.52 based on 1,681 single claims. HeartFlow is a diagnostic service, and based on its geometric mean cost, we believe that

the cost of furnishing the FFRCT service is similar to the other services within APC 5724 (Level 4 Diagnostic Tests and Related Services), whose geometric mean cost is $960.98. We further believe that CPT code 0503T appropriately fits in APC 5724 based on its clinical and resource homogeneity to the procedures in the APC. Therefore, for CY 2023, we proposed to reassign CPT code 0503T to clinical APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of $952.52.

Comment: Multiple commenters, including the developer of HeartFlow, expressed support for our proposal to assign CPT code 0503T to clinical APC 5724. The commenters believe APC 5724 is an appropriate APC assignment that reflects most of the costs of the HeartFlow service. The commenters also appreciated the payment stability for the service that will occur since HeartFlow is assigned to a clinical APC rather than a new technology APC.

Response: We appreciate the support of our proposal from the commenters. We note that analysis of the latest claims data for this final rule with comment period further supports the assignment to APC 5724. Specifically, our analysis reveals a geometric mean cost of about $824 for CPT code 0503T based on 1,844 single claims (out of 6,660 total claims), which is comparable to the geometric mean cost of approximately $961 for APC 5724.

After consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT code 0503T to clinical APC 5724 (Level 4 Diagnostic Tests and Related Services) for CY 2023. Table 41 shows the current status indicator and APC assignment for CPT code 0503T for CY 2022, and the finalized status indicator and APC assignment for CPT code 0503T for CY 2023. We refer readers to Addendum B of this CY 2023 OPPS/ASC final rule for the payment rates for all codes reportable under the OPPS. Addendum B is available via the Internet on the CMS website.

TABLE 41: FINAL CY 2022 AND FINAL CY 2023 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0503T

CPT Code	Long Descriptor	CY 2022 OPPS SI	CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0503T	Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model	S	1511	S	5724

24. Gastrointestinal Motility (APC 5722)

Gastrointestinal (GI) motility codes describe procedures that assesses the motor activity and muscle contractions of the colon or large intestine. For CY 2023, we proposed to assign CPT code 91117 (Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, e.g., meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report) and CPT code 91122 (Anorectal manometry) to APC 5371 (Level 1 Urology and Related Services), with a proposed payment rate of $224.14.

Comment: Commenters expressed concerns with the proposed CY 2023 geometric mean cost of APC 5371. Specifically, they are concerned that the decrease in the geometric mean cost for APC 5371 will adversely impact the payment rate for two GI motility codes, specifically, CPT codes 91117 and 91122. The commenters also contended that the two GI motility codes, currently assigned to APC 5371, do not share similar clinical characteristics with the urological services assigned to APC 5371 as this APC series is designated for urology and related services.

The commenters further pointed out that these services are more similar, clinically and with regard to resource utilization, to three other GI motility codes: CPT code 91037 (Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation;), CPT code 91120 (Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)), and CPT code 91132 (Electrogastrography, diagnostic, transcutaneous;), which are currently assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services), with a proposed payment rate of $285.63. The commenters argued that the proposed geometric mean cost of $324.49 for CPT code 91122 is in line with the geometric mean cost for the three GI motility codes (CPT codes 91037, 91120, and 91132) currently assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services). The commenter further stated that the low volume of CPT code 91117 is primarily due to the procedure being performed in the pediatric population.

Response: We agree with the commenters that CPT codes 91117 and 91122 are clinically similar to CPT codes 91037, 91120, and 91132, which assess the GI motility. In terms of resource utilization, our analysis of the latest CY 2021 claims data for this CY 2023 OPPS/ASC final rule with comment period, yielded zero single claims for CPT code 91117, therefore we have no data for its geometric mean cost. However, we observed 3,741 single claims for CPT code 91122 with a geometric mean cost of about $324.83. Therefore, we agree with the commenters that CPT code 91122 has a similar resource utilization to the procedures assigned to APC 5722, which include CPT code 91037 (geometric mean cost: $207.23), CPT code 91120 (geometric mean cost: $213.02), and CPT code 91132 (geometric mean cost: $326.53). However, we note that APC 5722 is not limited to CPT codes 91037, 91120, and 91132, but instead, includes a myriad of diagnostic tests besides GI motility procedures. We

analyzed our claims data for this final rule with comment period, and the geometric mean cost for four of the five motility codes, specifically, 91037, 91120, 91122, and 91132, range between $207 and $327, which is in line with the geometric mean cost of about $288 for APC 5722. Although we have no claims data for CPT code 91117, because the service is clinically similar to the services described by CPT codes 91037, 91120, 91122, and 91132, both from a clinical and resource perspective, we believe that assignment to APC 5722 for the five codes is appropriate. We agree that assignment of these services to APC 5722 would improve the clinical and resource homogeneity of the services within the APC.

In summary, after consideration of the public comments, we are finalizing the reassignment of CPT codes 91117 and 91122 to APC 5722. The final APC and status indicator assignments for CPT codes 91117 and 91122 are found in Table 42 below. The final CY 2023 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addenda B and D1 are available via the Internet on the CMS website.

TABLE 42: FINAL CY 2023 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CPT COLON MOTILITY STUDY AND ANORECTAL MANOMETRY

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report	T	5722
91122	Anorectal manometry	T	5722

25. Gastrointestinal Myoelectrical Activity Study (APC 5723)

For CY 2023, the CPT Editorial Panel created CPT code 0779T (Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and report) to describe the procedure associated with the G-Tech Wireless Patch System, which collects electrical signals from the stomach, intestine, and colon over multiple days, which are then transmitted to a phone that stores the transmissions in the cloud, where they are then processed by an algorithm that generates a report based on the transmitted information.

CMS proposed to assign CPT code 0779T to APC 5733 (Level 3 Minor Procedures) with a proposed payment rate of around $59. We note that CPT code 0779T was listed as placeholder code X069T in Addendum B of the proposed rule. The CPT and Level II HCPCS code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item. Therefore, we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the proposed rule so that the public could adequately comment on the proposed APCs and SI assignments. Because CPT code 0779T is a new code effective January 1, 2023, we included the 5-digit placeholder code and long descriptor in Addendum O. We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period.

Comment: We received several comments on this proposal. Commenters, including the device manufacturer, stated that the payment rate associated with APC 5733 does not capture all of the costs associated with providing the service described by CPT code 0779T. They indicated that the G-Tech Wireless Patch System itself costs around $950. They recommended that CMS reassign CPT code 0779T to either APC 5312 (Level 2 Lower GI Procedures) with a proposed

payment rate of $1,059.06 or APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of $939.61.

Response: While we agree with commenters that the proposed payment rate for APC 5733 does not accurately capture the costs associated with CPT code 0779T, we disagree with the APC assignments recommended by commenters. Because the code is new, we have no historical cost information on which to base an accurate payment for CPT code 0779T. As with all new codes for which we lack pricing information, our policy has been to assign the service to an existing APC based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the service to existing procedures; input from CMS medical advisors; and review of all other information available to us. After further evaluation, we believe CPT code 0779T is more similar to CPT codes 91022 (Duodenal motility (manometric) study) and 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed), both of which are assigned to APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment rate of $493.29. Because we believe that CPT code 0779T has similar clinical and resource characteristics as CPT codes 91022 and 91040, we are reassigning the assignment to APC 5723 for CY 2023.

In summary, after consideration of the public comments, we are finalizing the reassignment of CPT code 0779T to APC 5723. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI)

meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

26. Hemodialysis Arteriovenous Fistula Procedures (APC 5194)

For CY 2019, based on two New Technology applications received by CMS for hemodialysis arterviovenous fistula creation, CMS established two new HCPCS codes to describe the surgical procedures associated with the two technologies as no specific CPT codes existed. Specifically, CMS established HCPCS codes C9754 for the Ellipsys System and C9755 for the WavelinQ System effective January 1, 2019. For the July 2020 update, we deleted HCPCS codes C9754 and C9755 on June 30, 2020, and replaced them with G-codes effective July 1, 2020, to enable physicians to report the procedures when performed in the physician office setting. Specifically, HCPCS code C9754 was deleted and replaced with HCPCS Code G2170 (Percutaneous arteriovenous fistula creation (avf), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed) effective July 1, 2020. Similarly, HCPCS code C9755 was deleted and replaced with HCPCS Code G2171 (Percutaneous arteriovenous fistula creation (avf), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed). In the CY 2021 OPPS/ASC final rule with comment period (85

FR 85954 through 95955), we assigned HCPCS codes G2170 and G2171 to APC 5194 (Level 4 Endovascular Procedures) for CY 2021. We continued this APC assignment for CY 2022.

For the January 2023 update, the AMA's CPT Editorial Panel established CPT code 36836 (Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation) to describe the Ellipsys System. In addition to CPT code 36836, for the January 2023 update, the AMA's CPT Editorial Panel established CPT code 36837 (Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation) to describe the WavelinQ System. With the implementation of new CPT codes 36836 and 36837, we are deleting HCPCS codes G2170 and G2171 effective January 1, 2023. Based on claims data available for the CY 2023 OPPS/ASC proposed rule, the geometric mean cost of predecessor codes G2170 and G2171 was $12,055.90 and $13,486.08, respectively. For the CY 2023 proposed rule, based on our assessment of the geometric mean cost and APC assignment of the predecessor codes, we proposed to assign CPT codes 36836 and 36837 to the same APC as the predecessor codes, APC 5194, with a proposed payment amount of $17,495.14 for CY 2023. We note that CPT code 36836 was listed as placeholder code 368X1 in the OPPS Addendum B of the CY 2023 OPPS/ASC proposed rule. Additionally, CPT code 36837 was listed as placeholder code 368X2 in the OPPS Addendum B of CY 2023 OPPS/ASC proposed rule. Because the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe

the complete procedure, service, or item described by the CPT code, we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled "CY 2023 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code," to the proposed rule. We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period.

Comment: One commenter supported our proposal and recommending finalizing our assignment to APC 5194 for CPT codes 36836 and 36837.

Response: We thank the commenter for their support. Based on our review of claims data available for this final rule with comment period, we believe an assignment to APC 5194 for CPT codes 36836 and 36837 is appropriate for CY 2023.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT codes 36836 and 36837 to APC 5194 for CY 2023. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

27. IB-Stim Application Service (APC 5724)

For the July 2022 update, the CPT Editorial Panel established CPT code 0720T (Percutaneous electrical nerve field stimulation, cranial nerves, without implantation) to describe the service associated with the IB-Stim device, which received FDA De Novo marketing

approval in June 2019. The device is placed behind the patient's ear rather than implanted, and is intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS). For CY 2023, we proposed to assign CPT code 0720T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of $285.63. We note that CPT code 0720T is a new code effective July 1, 2022.

At the August 22, 2022 HOP Panel Meeting, a presenter provided information to the Panel on the description of the service, the cost of the IB-Stim kit, and the estimated total procedure cost. According to the presenter, the total cost of the procedure is approximately $1,323, which includes the cost of the IB-Stim kit ($1,195) At the conclusion of the presentation, the presenter advised the Panel to request that CMS reassign CPT code 0720T from APC 5722 to one of the following APCs:

- 5431: Level 1 Nerve Procedures (proposed payment rate $1,829.84)
- 5312: Level 2 Lower GI Procedures (proposed payment rate $1,102.72)
- 1515: New Technology - Level 15 ($1301 - $1400) (proposed payment rate $1,350.50)

Based on the information presented at the meeting, the Panel recommended that CMS revise the payment and assign CPT code 0720T to APC 1515 to account for the costs and resource utilization of providing the service.

Comment: A commenter disagreed with the proposed assignment to APC 5722 and requested that CMS assign CPT code 0720T to APC 1515, as recommended by the HOP Panel. The commenter stated that the IB-Stim service is not similar, with respect to clinical and resource homogeneity, to the procedures assigned to APC 5722. The commenter explained that the IB-Stim service is therapeutic in nature, while the procedures in APC 5722 are primarily diagnostic. In addition, the resource cost associated with the procedures in APC 5722 is not as

significant as that of CPT code 0720T. The commenter noted that the IB-Stim application code involves the use of an expensive device, which is in contrast to the procedures in APC 5722 that have almost no device costs. The commenter reiterated the cost information provided at the August 22, 2022 HOP Panel Meeting and stated that the estimated procedure cost for the service is approximately $1,323, which includes the cost of the IB-Stim kit ($1,195). The commenter added that the most clinically appropriate assignment is APC 5461 (Level 1 Neurostimulator and Related Procedures), however, the proposed geometric mean cost of the APC is high at $3,491. Because the code is new and there is not an appropriate APC, both from a clinical and cost perspective, the commenter stated that assignment to New Technology APC 1515 would be the best option until claims data becomes available, consistent with the recommendation of the HOP Panel at the August 22, 2022 meeting.

Response: We rely upon historical hospital claims data to establish the annual payment rates under the OPPS. Because the code is new, we have no historical cost information on which to base an accurate payment for CPT code 0720T. Also, it should be noted that with all new codes for which we lack pricing information, our policy has been to assign the service to an existing APC based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the service to existing procedures; input from CMS medical advisors; information from interested specialty societies; and review of all other information available to us. The OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. Based on our assessment, we believe that the IB-Stim application service shares similar clinical characteristics to the services assigned to APC 5722. Consequently, we assigned CPT code 0720T to APC 5722 effective July 1, 2022.

As stated above, at the August 22, 2022 HOP Panel meeting, in lieu of APC 5722, the presenter requested a reassignment to either APC 5431, APC 5312, or APC 1515, whose proposed payment rate ranged between approximately $1,103 and $1,830. During the meeting, the Panel recommended that CMS reassign the code to New Technology APC 1515 with a payment of approximately $1,351. Based on the HOP Panel recommendation and comment, we reviewed the appropriateness of the existing APC assignment and determined that New Technology APC 1515 may overpay for the service. Consequently, we are not accepting the Panel's recommendation to assign the code to APC 1515. We still believe that CPT code 0720T has similar clinical characteristics as the services in APC 5722; however, we acknowledge the estimated device cost of $1,195 for the IB-Stim kit, and we believe that APC 5724 (Level 4 Diagnostic Tests and Related Services) with a geometric mean cost of about $961, is the more appropriate assignment at this time. Therefore, we are revising the APC assignment for CPT code 0720T from APC 5722 to APC 5724.

We note that every year, since the implementation of the OPPS on August 1, 2000, we receive many requests from specialty associations, device manufacturers, drug manufacturers, and consultants to increase the reimbursement and ensure full payment for codes associated with specific drugs, devices, services, and surgical procedures. Under the OPPS, one of our goals is to make payments that are appropriate for the items and services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are generally limited to the annual payment update factor. As a budget neutral payment system, the OPPS does not pay the full hospital costs of services. Nevertheless, we believe that our payment rates generally reflect the costs that are associated with providing

care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services.

In summary, after consideration of the public comment, we are finalizing assignment of CPT code 0720T to APC 5724. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

28. IDx-DR: Artificial Intelligence System To Detect Diabetic Retinopathy (APC 5733)

For CY 2023, we proposed to continue to assign CPT code 92229 (Imaging of retina for detection or monitoring of disease; with point-of care automated analysis with diagnostic report; unilateral or bilateral) to APC 5733 (Level 3 Minor Procedures) with a proposed payment rate of $58.50.

Comment: One commenter supported the continued assignment to APC 5733 with a status indicator of "S" and praised CMS for recognizing the value of the service.

Response: We thank the commenter for their support.

After consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are finalizing our proposal and assigning CPT code 92229 to APC 5733. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the complete list of status indicator meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

29. Insertion of Bioprosthetic Valve (APC 5184)

For CY 2023, we proposed to assign CPT code 0744T (Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (e.g., polyester, ePTFE, bovine pericardium), when performed) to APC 5184 (Level 4 Vascular Procedures) with a proposed payment rate of $5,220.31. CPT code 0744T was listed as placeholder code 0X13T in Addendum B of the proposed rule. The CPT and Level II HCPCS code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item. Therefore, we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the proposed rule so that the public could adequately comment on the proposed APCs and SI assignments. Because CPT code 0744T is a new code effective January 1, 2023, we included the 5-digit placeholder code and long descriptor in Addendum O. We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period.

Comment: We received a single comment supporting our proposed APC assignment.

Response: We thank the commenter for their support.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT code 0744T (placeholder code 0X13T) to APC 5184. The final CY 2023 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

30. InSpace Subacromial Tissue Spacer Procedure (APC 5115)

For CY 2023, we proposed to continue to assign HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression acromioplasty, and biceps tenodesis when performed) to APC 5114 (Level 4 Musculoskeletal Procedures) with a proposed payment rate of $6,721.24.

Comment: We received several comments from providers and the device manufacturers requesting the reassignment of HCPCS code C9781 to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed payment rate of $13,274.06. The device manufacturer alternatively requested the reassignment of HCPCS code C9781 to APC 1575 (New Technology Level 38), with a proposed payment rate of $12,500.50 or APC 5115 in order to better reflect the costs of the procedure and resources used in the procedure, including the cost of the implant. The device manufacturer stated that the invoice for the device exceeds the proposed payment of $6,397, and that the combined cost for both the procedure and device is over $13,000. The device manufacturer asserted that the complete procedure was not described by a CPT code prior to the creation of HCPCS code C9781 and that HCPCS code C9781 includes multiple complex procedures, including: CPT code 29823 (Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])) and CPT code 29828 (Arthroscopy, shoulder, surgical; biceps tenodesis). The manufacturer stated that the cost of CPT codes 29823 and 29828 plus the cost of the InSpace implant align closely with the costs of other services in APC 5115. In support of this assertion, the device manufacturer submitted additional cost data, including numerous invoices.

Additionally, commenters stated that HCPCS code C9781 is clinically similar to the reverse shoulder reconstruction and repair procedures assigned to APC 5115.

Response: We thank the commenters for their recommendations. After further evaluation of HCPCS code C9781, and additional review of the clinical characteristics of the procedure, input from our medical advisors, and the resources required to perform the procedure, we believe it is appropriate to reassign HCPCS code C9781 to APC 5115 (Level 5 Musculoskeletal). Based on our evaluation of the additional information provided to CMS on the cost of the device, we believe that the resource cost associated with HCPCS code C9781 is higher than the proposed payment for APC 5114. Therefore, we are revising the APC assignment for HCPCS code C9781 for CY 2023.

In summary, after consideration of the public comments, we are finalizing reassigning HCPCS code C9781 to APC 5115. The final CY 2023 OPPS payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website. For additional discussion regarding the commenter's request to increase the device offset, please refer to section IV. C. (Device-Intensive Procedures).

31. Intervertebral Disc Allogenic Cellular and/or Tissue-Based Product Percutaneous Injection (APC 5115)

For the January 2021 update, the AMA's CPT Editorial Panel established four CPT codes to describe the VIA Disc NP procedure. The long descriptors for the codes are listed below.

- 0627T: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
- 0628T: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (list separately in addition to code for primary procedure)
- 0629T: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; first level
- 0630T: Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; each additional level (list separately in addition to code for primary procedure)

In the CY 2021 OPPS/ASC final rule with comment period, we finalized an APC assignment to APC 5115 (Level 5 Musculoskeletal Procedures) for CPT codes 0627T and 0629T. Additionally, we finalized a status indicator of "J1" for CPT codes 0627T and 0629T. CPT codes 0628T and 0630T were assigned to status indicator "N" (packaged) to indicate that payment for the add-on service described by the codes is packaged. As discussed in the CY 2014 OPPS/ASC final rule (78 FR 74942), add-on codes are generally packaged under the OPPS. We continued these APC assignments and status indicator assignments in CY 2022. For CY 2023, we proposed to continue to assign CPT codes 0627T and 0629T to APC 5115 with a status

indicator of "J1". Additionally, we proposed to continue to assign a status indicator of "N" to CPT codes 0628T and 0630T.

Comment: One commenter supported our proposed APC assignment of CPT codes 0627T and 0629T. The commenter also recommended that we assign device-intensive status to CPT code 0629T.

Response: We appreciate the commenter's recommendation and support of our proposal. We refer readers to section IV.B of this final rule with comment period for a discussion on device-intensive status designations under the OPPS and section XIII.C.1.b of this final rule with comment period for a discussion on device-intensive status designations under the ASC payment system. Based on our review of claims data available for this final rule with comment period, we believe an assignment to APC 5115 for CPT codes 0627T and 0629T is appropriate for CY 2023.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT codes 0627T and 0629T to APC 5115 for CY 2023. We are also finalizing our proposal to assign status indicator "N" under the OPPS to CPT codes 0628T and 0630T as the OPPS packaging policy packages the cost of an add-on codes into the primary procedure. The final CY 2023 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

32. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APC 5463)

CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) describes MRgFUS procedures for the treatment of essential tremor. Since CY 2021, CPT code 0398T has been assigned to APC 5463 (Level 3 Neurostimulator and Related Procedures). For CY 2023, we proposed to continue to assign CPT code 0398T to APC 5463 with a proposed payment rate of $12,866.05.

Comment: Multiple commenters, including the manufacturer, requested a higher paying APC for CPT code 0398T because the current payment rate for APC 5463 of $12,866.05 is substantially lower than the geometric mean cost of the service. According to the commenters, the geometric mean cost for CPT code 0398T has steadily increased from $10,136 in CY 2018 to $18,119 in CY 2021.

Response: We appreciate the concerns of the commenters about the level of payment for CPT code 0398T. However, the OPPS is a prospective payment system and it is expected that any individual service may be paid more or less than the geometric mean cost of the service. For CY 2023, the OPPS payment rates are based on our examination of the claims data for this final rule. Based on claims submitted between January 1, 2021, and December 30, 2021, and processed through June 30, 2022, our analysis supports the continued assignment of CPT code 0398T to APC 5463 based on its clinical and resource homogeneity to the procedures and services in the APC. Specifically, our data show a geometric mean cost of approximately $13,773 for CPT code 0398T based on 551 single claims (out of 551 total claims), which is comparable to the geometric mean cost of about $12,291 for APC 5463, rather than the geometric mean cost of about $6,791 for APC 5462 or the geometric mean cost of approximately $22,125 for APC 5464. We note that CPT code 0398T is grouped with other neurostimulator and

related procedures that have clinical and resource similarity to the MRgFUS; and, based on our analysis of the claims data, we believe that the code is appropriately placed in APC 5463.

In summary, after consideration of the public comments, we are finalizing our proposal without modification and assigning CPT code 0398T to APC 5463 for CY 2023. The final CY 2023 payment rate for CPT code 0398T can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS website.

33. Medical Physics Dose (APC 5723)

For CY 2023, we proposed to continue to assign CPT code 76145 (Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report) to APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation) with a proposed payment rate of $365.15. We previously discussed in the CY 2022 OPPS/ASC final rule with comment period that we believed APC 5612 was an appropriate placement for CPT code 76145, as APC 5612 contains CPT code 77307 (Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)), which we believed was clinically similar to CPT code 76145 in that CPT code 77307 describes the work of a medical physicist and dosimetrist. The full details of this assignment are discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63557 through 63558).

We note that the issue of payment for this code was brought to the Advisory Panel on Hospital Outpatient Payment (also known as HOP Panel) in 2022 for the CY 2023 rulemaking, and a new APC placement was requested by interested parties. At the August 22, 2022 meeting, the Panel recommended that CMS assign HCPCS code 76145 to APC 1505 (New Technology - Level 5 ($301 - $400)).

Comment*:* Generally, commenters disagreed with the assignment to APC 5612 and requested a reassignment to APC 5724 (Level 4 Diagnostic Tests and Related Services), with a proposed payment rate of $952.52. Commenters further described the clinical process associated with this code and stated that the services assigned to APC 5724 require similar resource use as CPT code 76145. Commenters also stated that APC 5724 contains a range of services that are clinically similar to CPT code 76145 and asserted that CPT code 76145 is not a radiation oncology code. Commenters also pointed to the Medicare Physician Fee Schedule proposed CY 2023 payment of $907.65 for this service.

Commenters agreed with the HOP Panel that it would also be appropriate to assign CPT code 76145 to a New Technology APC; however, interested parties believe assignment to APC 1510 (New Technology Level 10 ($801-$900) would be more appropriate than the HOP Panel's recommended APC placement.

Response*:* For CY 2023, the OPPS payment rates are based on claims submitted between January 1, 2021, and December 30, 2021, processed through June 30, 2022. CPT code 76145 was effective January 1, 2021, however, based on our review, we have no claims data for the code. After consideration of the comments, further evaluation of the service associated with CPT code 76145, and input from our medical advisors, we believe a revision of the APC assignment is appropriate. We agree that assignment to APC 5612 is not appropriate based on commenters' clinical description of the code, and instead, agree with interested parties that the Diagnostic Tests and Related Procedures APC series is appropriate. However, absent any claims data, we do not believe that assignment to APC 5724 is appropriate. Based on our assessment, we believe that CPT code 76145 fits more appropriately in APC 5723, rather than APC 5724 or a New Technology APC. Consequently, we are not accepting the HOP Panel recommendation because

we believe that APC 5723 is the more appropriate APC assignment. Therefore, we are assigning CPT code 76145 to APC 5723 for CY 2023. We note that we review our data on an annual basis. Once we have claims data, we will determine whether a change in the APC assignment is necessary.

In summary, after consideration of the public comments, we are finalizing the reassignment of CPT code 76145 to APC 5723 for CY 2023. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

34. Minimally Invasive Glaucoma Surgery (MIGS) (APC 5491)

For CY 2023, we proposed to continue to assign CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more) to APC 5491 (Level 1 Intraocular Procedures). Prior to CY 2022, this procedure was described by CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

Comment: We received several comments requesting that we reassign CPT code 0671T to APC 5492 (Level 2 Intraocular Procedures) based on the claims data and APC assignment for its predecessor code, CPT code 0191T. Commenters also argued that CPT code 0671T is clinically similar to several procedures in APC 5492. Additionally, this issue was presented at the 2022 HOP Panel, with the Panel recommending CPT code 0671T be reassigned to APC 5492.

Response: We thank commenters for their feedback. We note that, although CPT code 0191T has a geometric mean cost of $4,972.24 and was placed in APC 5492, CPT code 0191T was predominantly reported with CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) and 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation). We believe that some of the costs of the concurrent cataract removal may be reflected in the geometric mean cost for CPT code 0191T. CPT code 0671T describes insertion of intraocular lens without concurrent cataract removal and would never be billed alongside the cataract removal procedures resulting in an overall reduction in resource costs compared to CPT code 0191T. Based on our review of the clinical characteristics of the procedure and input from our medical advisors, we continue to believe that this service is more similar to the other services in APC 5491 and that the resource cost for this standalone procedure cannot be accurately compared to CPT code 0191T. Consequently, we are not accepting the HOP Panel's recommendation to reassign the code to APC 5492, and instead, we will continue to assign the code to APC 5491 for CY 2023.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to continue to assign CPT code 0671T to APC 5491. The final CY 2023 OPPS payment rates for these codes can be found in Addendum B to this final rule with

comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

35. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments to utilize prospective payment packages, we consolidated these individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary. In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requested changes to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for the CY 2023 OPPS/ASC proposed rule, we continued to believe that the six level APC structure for the Musculoskeletal Procedures APC series is appropriate and we proposed to maintain it for the CY 2023 OPPS update.

Comment: One commenter requested that CPT codes 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method) and 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) be reassigned from APC 5114 to APC 5115. The commenters noted that these procedures would cause two times rule violations if the codes were cost significant, which the commenters believed they might be at the time of the final rule.

Response: We appreciate the commenter's recommendation regarding the APC assignment of CPT 28297 and 28740. CPT codes 28297 and 28740 are currently assigned to APC 5114 (Level 4 Musculoskeletal Procedures). We note that APC 5114 does not currently have a 2 times rule violation in the final rule data. In addition, both CPT codes 28297 and 28740 do not meet the requirements for cost significance for 2 times rule purposes, under the requirements described in section III.B.2. of this final rule with comment period. We have reviewed the codes' geometric mean cost based on the available CY 2021 claims data as well as their clinical similarity to other codes within APC 5114 and believe that their current APC assignment continues to be appropriate.

Comment: A commenter requested that CMS reassign CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))) from APC 5115 to APC 5116, based on the hospital resources associated with the procedure as well as its estimated cost.

Response: CPT code 23472 had a proposed CY 2023 OPPS assignment to APC 5115. In the claims data available for final CY 2023 OPPS ratesetting, APC 5115 has a range of HCPCS geometric mean costs for cost significant codes from approximately $10,554.18 to $17,441.14. While we note that the geometric mean cost of this CPT code is at the higher end of the cost range, we believe that its placement in APC 5115 remains appropriate based on its clinical similarity to other codes in the APC. As a result, we are finalizing the proposed assignment of CPT code 23472 to APC 5115. However, we will continue to review the claims and cost data for these APCs.

After consideration of the comments, we are finalizing our proposal without modification. The final CY 2023 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

36. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. Since CY 2015, the four-level APC structure for the series has remained unchanged. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule with comment period, we also made the Levels 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS/ASC final rule with comment period, we also made the Level 1 Neurostimulator and Related Procedure APC (APC 5461) a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for the CY 2021 OPPS/ASC proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between what were then the Levels 2 and 3 APCs. Creating this APC allowed for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). In addition to creating the new level, we also assigned CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC (85 FR 85970).

Some interested parties have requested that we create a Level 6 Neurostimulator and Related Procedures APC, due to their concerns around clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedures APC. Based on our review of the data available for the CY 2023 OPPS/ASC proposed rule, we believed that the five-level structure for the Neurostimulator and Related Procedures APC series remains appropriate. The proposed geometric mean cost for the Level 5 Neurostimulator and Related Procedures was $30,198.36 with the geometric means of cost significant codes in Level 5 ranging from approximately $28,000 to $36,000, which is well within the range of the 2 times rule. In addition, a review of the clinical characteristics of the services in the APC suggests that the current structure was appropriate. Finally, as discussed in the CY 2021 OPPS/ASC final rule with comment period, we reiterate that the OPPS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of any individual service within

the APC may be higher or lower than the APC's geometric mean. As a result, in the OPPS any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs. (85 FR 85968).

While we did not propose any changes in the CY 2023 OPPS/ASC proposed rule to the 5-level structure of the Neurostimulator and Related Procedures APC series, we recognized the interested parties' concerns regarding the granularity of the current APC levels and their request to create an additional level to address such concerns. Accordingly, we solicited comments on the potential creation of a new Level 6 APC from the current Level 5 within the Neurostimulator and Related Procedures APC series, which would include the following codes:

- 0266T: Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
- 0268T: Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)
- 0424T: Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)
- 0431T: Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only

- 64568: Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

In summary, for CY 2023, we proposed to maintain the current 5-level structure for the Neurostimulator and Related Procedure APC series. However, we also solicited comment on the creation of an additional Level 6 APC in the series from the current Level 5 APC.

Comment: Several commenters supported the creation of a Level 6 Neurostimulator and Related Procedures APC, believing that doing so would provide better payment specificity and support access to those procedures. However, others commenters recommended that we maintain the current 5 level APC structure, believing that it continues to remain appropriate and sufficient until claims data suggest otherwise. Several commenters also requested that HCPCS code 0424T be temporarily assigned to New Technology APC 1581, which has a proposed and final OPPS payment rate of $55,000.50. These commenters believed that doing so would provide appropriate and consistent payment and support beneficiary access for the new procedure until such time as sufficient claims data were available for ratesetting purposes. Finally, a commenter requested that there be transparency around the ratesetting methodology so that the public can also reproduce the OPPS rates.

Response: We appreciate the concerns of the commenters and the different issues that they have raised. In reviewing the claims data available for OPPS ratesetting in this final rule, we continue to believe that the 5-level APC structure remains appropriate based on clinical and cost characteristics. However, we also recognize that for CPT code 0424T there remains a significant difference between its geometric mean cost and that of the APC. As a result, we agree that a temporary placement in New Technology APC 1581, which has a CY 2023 OPPS payment rate of $50,000.50, is appropriate. We note that we will continue to monitor the claims data available

for CPT code 0424T as well as the APC more broadly and reevaluate and potentially reconfigure it as is appropriate.

With regard to transparency around the ratesetting process, we do make several data files related to each proposed and final rulemaking cycle available via the Internet on the CMS web site. We also refer readers to the claims accounting narrative(s) under supporting documentation for the proposed and final rules on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html to the CY 2022 OPPS/. That document describes the process through which we establish the OPPS rates for each proposed and final rulemaking cycle.

After consideration of the public comments we received, we are finalizing our proposal to maintain the 5-level structure of the Neurostimulator and Related Procedure APC series and reassigning CPT code 0424T to New Tech APC 1581 in the CY 2023 OPPS. Table 43 list the final geometric mean cost for the Neurostimulator and Related Procedures APCs.

TABLE 43: FINAL CY 2023 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Final CY 2023 APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,339.76
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,791.09
5463	Level 3 Neurostimulator and Related Procedures	J1	$12,291.48
5464	Level 4 Neurostimulator and Related Procedures	J1	$22,125.38
5465	Level 5 Neurostimulator and Related Procedures	J1	$30,190.88

37. Optilume Cystourethroscopy (APC 5374)

The Optilume cystourethroscopy is intended to treat urethral stricture disease. The procedure, represented by CPT code 0499T (Cystourethroscopy, with mechanical dilation and

urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed), became effective in January 2018. The procedure involves the use of a semi-compliant inflatable balloon that expands to create micro-fissures in the stricture to deliver the drug paclitaxel. Paclitaxel works as an anti-proliferative drug that stops new tissue growth and prevents fibrotic scarring that may result in stricture recurrence.

For CY 2023, we proposed to delete CPT code 0499T. We note that in the OPPS Addendum B of the CY 2023 OPPS/ASC proposed rule, the code is assigned to status indicator "D" (Discontinued Codes) to indicate that the code would be deleted at the end of the year. For CY 2022, the code is assigned to APC 5374 (Level 4 Urology and Related Services).

Comment: A commenter explained that CPT code 0499T would be deleted on December 31, 2022, with no replacement code. The commenter requested that CMS establish a new temporary HCPCS C-code to replace CPT code 0499T and expressed concern that the lack of a specific HCPCS code would disrupt payment for the cystourethroscopy procedure. The commenter also requested the reassignment of CPT code 0499T to APC 5375 (Level 5 Urology and Related Services; proposed payment rate of $4,783.70), and argued that the current payment for APC 5374 does not reimburse the facility for the cost of furnishing the procedure. The commenter estimated that the total cost to perform the Optilume cystourethroscopy is about $5,454 and the device alone is $2,395. The commenter contended that the device was not commercially available until January 2022, so the current cost data reflected in the proposed rule only reflects the clinical costs of the Optilume pivotal clinical trial and not the actual cost of providing the procedure in the HOPD setting.

Additionally, the commenter requested a device offset adjustment of 50 percent of APC 5375, citing a device cost of $2,395, which exceeds the 31 percent device offset threshold. The

commenter further added that, based on the assignment to APC 5374, the device cost is more than 76 percent of the procedure cost.

Response: The CPT Editorial Summary of Panel Actions September 2022, which was published on October 14, 2022 on the AMA website indicates that the CPT Editorial Panel rescinded the sunset of 0499T, therefore negating the necessity of a temporary HCPCS code for 0499T for CY 2023.

While we are sympathetic to the commenter's argument that the current data reflect the clinical costs of the Optilume pivotal clinical trial, we believe that the current assignment to APC 5374 is appropriate. Our analysis of the claims data for this final rule with comment period reveal a geometric mean cost of about $2,583 based on 16 single claims (out of 16 total claims) for CPT code 0499T, which is consistent with the geometric mean cost of about $3,296 for APC 5374, rather than the geometric mean cost of approximately $4,836 for APC 5375. For the device offset amount for CPT 0499T, we direct readers to section IV.B of this final rule with comment period for a more detailed discussion.

In summary, after consideration of the public comment, we are finalizing our proposal without modification, and assigning CPT code 0499T to APC 5374 for CY 2023. The final APC and status indicator assignment for CPT code 0499T is found in Table 44. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addenda B and D1 are available via the Internet on the CMS website.

TABLE 44: FINAL CY 2023 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTILUME CYSTOURETHROSCOPY

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	J1	5374

38. Pathology Services (APC 5672)

The CPT Editorial Panel created CPT code 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology) to describe in situ hybridization testing using urine samples, effective January 1, 2011. For CY 2023, we proposed to reassign CPT code 88121 from APC 5673 (Level 3 Pathology) to APC 5672 (Level 2 Pathology) with a proposed payment rate of $160.44.

Comment: Some commenters emphasized that the proposed change represents a 46 percent decrease in the payment amount. While not reflected in the OPPS cost data, commenters assert that the costs associated with the service reported for CPT code 88121 is nearly three times the cost of an APC 5672 "Level 2 Pathology" service, based on physician fee schedule technical component cost differences. Commenters state that this proposed reassignment creates a resource cost rank order anomaly with other physician services, and the technical costs will not be fully recovered from each unit of service. Another commenter expressed concern that flawed data led to this change in APC level for CPT code 88121. The commenters requested that CMS maintain the assignment of CPT code 88121 to APC 5673 for CY 2023 and preserve access to this test that is used to detect bladder cancer for Medicare beneficiaries.

Response: Based on our analysis of the claims data for this CY 2023 OPPS/ASC final rule with comment period, our data reveals a geometric mean cost of about $175.28 for CPT code 88121 based on 1,423 single claims (out of 1,834 total claims), which is in line with the geometric mean cost of $161.71 for APC 5672 rather than the geometric mean cost of $333.29 for APC 5673. We believe that continuing to assign CPT code to APC 5673 would significantly overpay for the procedure.

With respect to the flawed data issue, we rely upon historical hospital claims data to establish the annual payment rates under the OPPS. Based on our review of the claims data associated with CPT code 88121, we have no reason to believe that the service is miscoded. In addition, based on our analysis of the CY 2023 claims data used for this final rule with comment period, we are unable to determine whether facilities are misreporting the service. It is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on hospitals and providers to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions and to report services accurately on claims and charges and costs for the services on their Medicare hospital cost report.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to assign CPT code 88121 to APC 5672. The final CY 2023 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

39. Percutaneous Arthrodesis of the Sacroiliac Joint (APC 5116)

In 2015, the CPT Editorial Panel established CPT code 27279 to describe the procedure associated with a percutaneous arthrodesis of the sacroiliac joint that involves placement of a transfixing device. Prior to 2015, the procedure was reported with CPT code 0334T (Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized), when performed, includes image guidance when performed (eg, ct or fluoroscopic)), which was effective July 1, 2013, and deleted December 31, 2014, when it was replaced with CPT code 27279 effective January 1, 2015.

For CY 2023, the CPT Editorial Panel established new CPT code 0775T, effective January 1, 2023, to describe a percutaneous arthrodesis of the sacroiliac joint that involves placement of an intra-articular implant, such as a bone allograft or synthetic device(s). The long descriptors for both CPT code 27279 and 0775T are listed in Table 45. The CPT 2023 code book clarifies the reporting of the new code, specifically, CPT code 0775T, and states that the new code should be reported when the procedure involves an implantable device that "does not transfix the sacroiliac joint," while existing CPT code 27279 should be reported in cases that involve an implantable device that does transfix the sacroiliac joint. The CPT code book further states that the unlisted CPT code 27299 (Unlisted procedure, pelvis or hip joint) should be reported when the percutaneous arthrodesis of the sacroiliac joint involves the use of both a transfixation device and an intra-articular implant(s).

As listed in Table 45, for CY 2023, we proposed to continue to assign CPT code 27279 to APC 5116 (Level 6 Musculoskeletal Procedures). We also proposed to assign new CPT code 0775T, which was listed as placeholder code X034T in Addendum B of the CY 2023 OPPS/ASC proposed rule, to the same APC. We note that the CPT and Level II HCPCS code descriptors that

appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item. Therefore, we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the proposed rule so that the public could adequately comment on the proposed APCs and SI assignments. Because CPT code 0775T is a new code effective January 1, 2023, we included the 5-digit placeholder code and long descriptor in Addendum O. We further stated in the proposed rule that the final CPT code numbers would be included in this CY 2023 OPPS/ASC final rule with comment period. We received some comments on the proposed APC assignment for CPT code 0775T.

TABLE 45: PROPOSED CY 2023 SI AND APC FOR CPT CODES 27279 AND 0775T

CPT Code	Placeholder Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment Rate
27279	N/A	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	J1	5116	$22,303.35
0775T	X034T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])	J1	5116	$22,303.35

Comment: A few commenters disagreed with the proposed assignment to APC 5116 for CPT code 0775T. They indicated that the resources to perform the procedure are not as significant as the procedure described under existing CPT code 27279, and suggested lowering the payment for the procedure by reassigning the code to APC 5115 (Level 5 Musculoskeletal Procedures), which has a proposed payment of $13,274.06. The commenters added that until

CMS has sufficient claims data, APC 5115 is the more appropriate assignment for CPT code 0755T, and that finalizing the proposal to APC 5116 would result in overpayment for the procedure. One commenter listed the clinical differences between the two procedures, specifically with regard to procedure time, anesthesia, staffing requirements, recovery time, and device costs. The commenter stated that CPT code 27279 is a procedure that often takes 60 minutes to perform, requires a 3-5 cm incision, involves the use of general anesthesia, uses up to three implants, may require both assistants at surgery and co-surgeons, and requires several hours of post-operative recovery for pain control and mobilization. In contrast, CPT code 0775T is a procedure that takes between 20 to 30 minutes to perform, requires a 1-2 cm incision, involves local anesthesia, requires only a single bone allograft or implant, does not require co-surgeons or assistants at surgery, and typically involves minimal to no post-operative recovery period. Based on these differences, the commenter strongly urged CMS to lower the payment for the procedure and modify the assignment for CPT code 0775T from APC 5116 to APC 5115.

Alternatively, several commenters reported that the new code, specifically, CPT code 0775T (posterior approach), shares similar resources and characteristics with existing CPT code 27279 (lateral approach), and, therefore, should be placed in the same APC. The commenters explained that prior to the establishment of CPT code 0775T, the procedure was reported for more than five years with CPT code 27279. The same commenters stated that CPT code 0775T utilizes the same pre, post, and intra operative resources as the procedure described under existing CPT code 27279. According to the commenters, CPT code 0775T shares these similar characteristics with existing CPT code 27279: requires 1 to 1.5 hours of procedure time, involves the use of general anesthesia or MAC sedation, utilizes the same fluoroscopy time under indirect visualization, involves the same anatomical space (SI joint for fusion), and utilizes similar sites

of service--both are performed in the HOPD and ASC settings. The commenter added that the estimated cost to perform the surgery associated with CPT code 0775T is approximately $14,379. Based on its similarity to existing CPT code 27279, the commenters urged CMS to finalize the proposal to APC 5116 for CPT code 0775T.

Response: Based on the information submitted to CMS for CPT codes 27279 and 0775T, and based on our understanding of the procedures, we believe that we should assign CPT code 0775T to APC 5116. While we are unable to confirm whether the service described by CPT code 0775T was previously billed with CPT code 27279, we believe that the new code (CPT code 0775T) does share some clinical similarities to the procedures assigned to APC 5116. Therefore, we believe it would be appropriate to assign CPT code 0775T to APC 5116. We note that if a procedure, service, or item is not described by any specific code, the unlisted code should be reported. In the case of new CPT code 0775T, if it was not described by any specific HCPCS code prior to its establishment, we believe that HOPD facilities would have likely reported the procedure under an unlisted code (e.g., 22899, 27299, etc.).

Because the code is new for 2023, we currently do not have any claims data for CPT code 0775T. However, as we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. We will review our claims data in the next rulemaking cycle, and if appropriate, revise the APC assignment for CPT code 0775T.

In summary, after consideration of the public comments, we are finalizing our assignment to APC 5116 for CPT code 0775T. We did not receive any comments on the APC or SI assignment for CPT code 27279, therefore, we are finalizing our proposal for the code. Table 46

lists the final APC and SI assignments for CPT codes 27279 and 0775T for CY 2023. The final CY 2023 payment rates for both codes can be found in Addendum B to the CY 2023 OPPS/ASC proposed rule with comment period. In addition, we refer readers to Addendum D1 of the CY 2023 OPPS/ASC final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 46: FINAL CY 2023 SI AND APC FOR CPT CODES 27279 AND 0775T

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Final CY 2023 OPPS Payment Rate
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	J1	5116	Refer to OPPS Addendum B
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])	J1	5116	Refer to OPPS Addendum B

40. Placement of Breast Localization Devices (APCs 5071 and 5072)

For CY 2023, we proposed to assign CPT code 19281 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance)) to APC 5072 (Level 2 Excision/ Biopsy/ Incision and Drainage Procedures) with a proposed payment rate of $1,520.37 and proposed to continue to assign CPT codes 19283 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance), 19285 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle,

radioactive seeds), percutaneous; first lesion, including ultrasound guidance), and code 19287 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance) to APC 5071 (Level 1 Excision/ Biopsy/ Incision and Drainage Procedures) with a proposed payment rate of $659.86.

Comment: Several commenters shared their support for the reassignment of CPT code 19281 to APC 5072 while also requesting the reassignment of CPT codes 19283-19287 to APC 5072 in order to maintain clinical and resource homogeneity with CPT code 19281. The commenters stated that the procedures varied only by the type of guidance utilized and argued that reassigning these services to APC 5072 would avoid discrepancies in imaging guidance driven by payment assignments. Commenters also stated that CPT codes 19281 through 19287 were clinically similar to a series of percutaneous image-guided breast biopsy procedures that also vary by type of guidance, CPT codes 19081 (Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance) through 19086 (Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)).

Response: We thank the commenters for their support of our reassignment of CPT code 19281 to APC 5072. CPT code 19281 was reassigned due to a violation of the 2 times rule in APC 5071, as it met the criteria required for an exception under the 2 times rule. More specifically, to address the violation of the 2 times rule and improve clinical and resource

homogeneity, we proposed to reassign CPT code 19281 to APC 5072 to optimize clinical and resource cost homogeneity, given the available claims data.

Based on our review of the cost and utilization data and input from our clinical advisors, we disagree with the suggestions to reassign CPT code 19283, CPT code 19285, and CPT code 19287 to APC 5072 and believe that APC 5071 better accounts for the cost of the procedure as well as the resources used. Our claims data for CPT codes 19283, 19285, and 19287, demonstrate that their geometric mean cost is consistent with APC 5071, whose geometric mean cost ranges between $476 and $1,032, rather than with APC 5072, whose geometric mean cost ranges between $1,192 and $2,372. Specifically, our data shows a geometric mean cost of approximately $1,032 for CPT code 19283 based on 1,167 single claims, a geometric mean cost of about $1,027 for CPT code 19285 based on 8,204 single claims, and a geometric mean cost of about $715 for CPT code 19287 based on 62 single claims. As we do every year, we will review the APC assignments for all services and items paid under the OPPS. Consequently, we will continue to monitor the claims data for APC 5071 and APC 5072 as they become available.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to assign CPT code 19281 to APC 5072 and CPT code 19283, CPT code 19285, and CPT code 19287 to APC 5071. The final CY 2023 payment rate for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

41. ProSense Cryoablation Procedure (APC 5091)

For CY 2023, we proposed to continue to assign CPT code 0581T (Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed,

unilateral) to status indicator "E1" to indicate that the code is not covered by Medicare and not paid by Medicare when submitted on outpatient claims (any outpatient bill type).

Comment: A commenter disagreed with the proposed status indicator and requested a reassignment to APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures) with a proposed payment rate of $6,027.41. The commenter reported that the device (ProSense™ Cryoablation System) associated with the procedure received FDA 510(k) marketing approval on December 20, 2019, and also received FDA Breakthrough Device Designation on March 31, 2021. The commenter reported an estimated cost of approximately $7,016 for the procedure, which includes the cost of the $2,200 single-use cryoprobe device. Based on the estimated cost for the procedure, the commenter suggested assigning the code to APC 5092 rather than APC 5091 since the resource costs are comparable to APC 5092.

Response: For CY 2023, we did not include the claims data in our ratesetting process because CPT code 0581T was previously assigned to status indicator "E1" under the OPPS. We do note that the FDA 510(k) marketing approval (K183213) for the device associated with CPT code 0581T indicates that the device is used in a wide variety of surgical applications. Specifically, the FDA marketing approval indicates that the device is indicated for use in "general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology." Because of its variable applicability to other procedures unrelated to breast cryotherapy, and the 2019 FDA approval, we believe that the device cost may already be reflected in our payment for the other procedures. CPT code descriptors are general in nature and not specific to a particular product, so the device may be used in surgical procedures that are described by existing cryotherapy and cryoablation procedures CPT codes (e.g., 20983, 32994, 47383, 50593, etc.). Consequently, we do not believe

that assignment to APC 5092 would be appropriate. However, based on our analysis of the estimated resource cost, as well as our review of the clinical characteristics of the procedure and input from our medical advisors, we believe that CPT code 0581T should be assigned to APC 5091 (Level 1 Breast/Lymphatic Surgery and Related Procedures Contrast) because of its clinical similarity to the procedures in the APC. We believe that assignment to APC 5091 is more appropriate than assignment to APC 5092, and adequately reflects the resources associated with providing the service. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS. We will reevaluate the APC assignment for CPT code 0581T once we have hospital outpatient claims data and, if appropriate, reassign and/or restructure the APC assignment.

In summary, after consideration of the public comment, we are finalizing assignment of CPT code 0581T to APC 5091 for CY 2023. The final CY 2023 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings used under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

42. Pulmonary Rehabilitation Services (APC 5731)

For CY 2023, we proposed to continue to assign HCPCS codes G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring)) and G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring)) to APC 5731 (Level 1 Minor Procedures) with a proposed payment rate of $14.00. We also proposed to exclude claims data from C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2)

(coronavirus disease [covid-19]), any specimen source) from the calculation of the rate for APC 5731 as it is a high-volume but temporary code for the duration of the Public Health Emergency for COVID-19. However, we inadvertently included the claims data in ratesetting for the CY 2023 OPPS/ASC proposed rule, and so the proposed CY 2023 OPPS payment rate did not properly reflect that proposal.

At the August 22, 2022 HOP panel meeting a presenter requested that CMS split APC 5731 into two separate APC categories to ensure a more representative payment for the pulmonary rehabilitation services described by HCPCS codes G0237 and G0238. The presenter stated that the payment rate associated with APC 5731 did not accurately capture the resources associated with HCPCS codes G0237 and G0238, which have a geometric mean cost of $28.76 and $26.91, respectively.

The HOP Panel supported removing HCPCS code C9803 from APC 5731 and recommended recalculating the payment rates for the remaining services in APC 5731.

Comment: A few commenters expressed concern over the proposed payment rate for APC 5731, noting that the presence of claims data for HCPCS code C9803 distorts the overall rate associated with APC 5731. These commenters noted that one solution would be to exclude the claims data associated with HCPCS code C9803 from the calculation of the payment rate for APC 5731. However, they also expressed concern that keeping HCPCS code C9803 in APC 5731 while excluding the claims data associated with this service from the calculation of the payment rate would result in a significant overpayment for HCPCS code C9803. Another option according to commenters would be to split APC 5731 into two APCs. These commenters were concerned over the impact the payment rate for APC 5731 would have on pulmonary rehabilitation services.

Response: We thank commenters for their concerns and refer them to section X.D. (Use of Claims Data for CY 2023 OPPS and ASC Payment System Ratesetting) of this final rule with comment period for a discussion of our finalized policy to exclude claims data associated with HCPCS code C9803 from the calculation of the payment rate for APC 5731.

In summary, after consideration of the public comments, we are finalizing our proposal without modification. Specifically, we are continuing to assign HCPCS codes G0237 and G0238 to APC 5731. The final CY 2023 payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

43. Remote Physiologic Monitoring Services

For CY 2023, we proposed to continue to assign a status indicator of “B” to CPT codes 99457 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes) and 99458 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)).

Comment: We received a comment requesting that CMS revise the status indicators for these two services to "S" (Procedure or Service, Not Discounted When Multiple) and assign them to either APC 5821 (Level 1 Health and Behavior Services) or 5822 (Level 2 Health and Behavior Services) with proposed payment rates of $30.21 or $76.98, respectively. These

commenters stated that making these services separately payable will increase access to RPM in the HOPD setting.

Response: As stated in the CY 2021 OPPS/ASC final rule with comment period, we assigned CPT codes 99457 and 99458 to status indicator ‘‘B’’ (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x). Not paid under OPPS.) effective March 1, 2020, to enable Critical Access Hospitals (CAHs) to bill under CAH’s Method II for the service so that claims with this code would process appropriately in the Integrated Outpatient Code Editor (IOCE) (85 FR 85977-85979). We continue to believe that, since CPT code 99457 primarily describes the work associated with the billing of professional services, which would not be paid separately under the OPPS, and CPT code 99458 describes an add-on service to CPT code 99457, neither service is appropriate for separate payment under the OPPS. Therefore, we will continue to assign these codes to status indicator "B" for CY 2023.

In summary, after consideration of the public comment, we are finalizing our proposal without modification. Specifically, we are continuing to assign HCPCS codes 99457 and 99458 to status indicator "B" for CY 2023. We refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Addendum D1 is available via the Internet on the CMS website.

44. Repair of Nasal Valve Collapse (APC 5165)

For CY 2023, the CPT Editorial Panel created a new code, CPT code 30469 (Repair of nasal valve collapse with low-energy, temperature-controlled based (i.e., radiofrequency) subcutaneous/submucosal remodeling), effective January 1, 2023, to describe minimally-invasive coagulation of soft tissue in the nasal airway to treat nasal airway obstruction. For CY 2023, we proposed to assign CPT code 30469 to a status indicator of "S" (Procedure or Service,

Not Discounted When Multiple) and to APC 5164 (Level 4 ENT Procedures) with a proposed payment rate of $2,896.26. We note that CPT code 30469 was listed as placeholder code 37X01 in Addendum B of the CY 2023 OPPS/ASC proposed rule. In addition, the CPT and Level II HCPCS code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item. Therefore, we included the 5-digit placeholder codes and long descriptors for the new CY 2023 CPT codes in Addendum O to the CY 2023 OPPS/ASC proposed rule so that the public could adequately comment on the proposed APCs and SI assignments. Because CPT code 30469 is a new code effective January 1, 2023, we included the 5-digit placeholder code and long descriptor in Addendum O. We further stated in the proposed rule that the final CPT code numbers would be included in this final rule with comment period.

Comment: We received several comments on the proposed APC assignment for CPT code 30469. These commenters requested that CMS reassign CPT code 30469 to APC 5165 (Level 5 ENT Procedures), which has a proposed payment rate of $5,377.70. Commenters stated that CPT code 30469 is clinically similar to CPT code 30468 (Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant) in that both procedures involve the bilateral repair of nasal valve collapse with similar surgical approaches, and, when performed in the hospital outpatient setting, virtually identical non-physician staffing, preparation, operating room requirements, supplies, trays, scopes, anesthesia, post-operative care, and other costs. Commenters also stated that CPT code 30469 is comparable to CPT code 69705 (Nasopharangoscopy, surgical, with dilation of eustachian tube; unilateral) in that CPT code 69705 involves a similar surgical approach, similar hospital setting resource requirements (such

as non-physician staffing, operating room resources, anesthesia and supplies), and reliance on a single-use medical device. Both CPT codes 30468 and 69705 are assigned to APC 5165.

Response: CPT code 30469 is effective January 1, 2023, and because the code is new, we have no historical cost information on which to base an accurate payment. However, it should be noted that with all new codes for which we lack pricing information, our policy has been to assign the service to an existing APC based on input from a variety of sources, including, but not limited to, review of the clinical similarity of the service to existing procedures; input from CMS medical advisors; and review of all other information available to us. We note that CMS received an invoice suggesting that the device described by CPT code 30469 costs around $1,950. Based on the additional information provided to CMS and advice from our medical advisors, we agree that the surgical procedure described by CPT code 30469 does share similar clinical and resource characteristics with the procedures described by CPT codes 30468 and 69705. We agree with the commenters that the two comparison codes provided are closer in terms of resource costs and clinical characteristics to the service described by CPT code 30469 and that, inclusive of the costs of the device, APC 5165 would be a more accurate APC assignment. Analysis of our claims data for this final rule with comment period shows that the geometric mean cost for CPT code 30468 is approximately $5,987 based on 362 single claims (out of 368 total claims) and the geometric mean cost for CPT code 69705 is approximately $4,846 based on 263 single claims (out of 265 total claims). Because we agree that the clinical and resource costs are similar to CPT codes 30468 and 69705, we are assigning CPT code 30469 to APC 5165 for CY 2023.

In summary, after consideration of the public comments, we are finalizing assignment of CPT code 30469 (placeholder code 37X01) to APC 5165. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we

refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

45. Single-Use Disposable Negative Pressure Wound Therapy (dNPWT) (APC 5052)

For CY 2023, we proposed to continue to assign CPT codes 97607 and 97608 to status indicator "T" (Procedure or Service, Multiple Procedure Reduction Applies) and APC 5052 (Level 2 Skin Procedures) with a proposed payment rate of $379.94. Below are the long descriptors for the codes:

- 97607: Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
- 97608: Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

Comment: One commenter requested that we change the status indicator for the codes to "S" so there would be no discounting involved when the service is performed with other procedures on the same day. The commenter further stated that the change in the status indicator would result in the OPPS payment completely covering the cost of the service, thus improving the quality of care for Medicare beneficiaries.

Response: A procedure or service is assigned to status indicator "T" to indicate that

that it is subject to multiple procedure discounting when the service is performed with other services on the same day to reflect the savings associated with providing the service. We believe there are savings achieved when more than one service is performed on the same day or during a single operative session, as in the case of surgical procedures. The patient has to be prepared only once, and the costs associated with staff, anesthesia, operating and recovery room use, and other services required for the second procedure are incremental. We note that the reduced payment for the multiple procedures applies to both the beneficiary coinsurance and Medicare payment amounts, so this policy benefits beneficiaries.

We disagree that CPT codes 97607 and 97608 should not be discounted when they are performed with other procedures on the same day. As stated above, there are savings associated with providing multiple services on the same day. We expect hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. We do not agree that the Medicare beneficiary should be subject to the full coinsurance amount when there are savings achieved for multiple procedures performed on the same day/session. We believe it is in the best interest of the Medicare program to continue to assign procedures and services to the multiple procedure discounting methodology when appropriate.

We note that we reviewed the CY 2021 OPPS claims data for this final rule with comment period and found that the geometric mean costs for both codes demonstrate that the assignment to APC 5052 with a status indicator of "T" is appropriate. Specifically, our data show a geometric mean cost of approximately $259 for CPT code 97607 based on 8,059 single claims (out of 10,921) and a geometric mean cost of about $310 for CPT code 97608 based on 435 single claims (out of 769 total claims). The costs of $259 and $310 for CPT codes 97607 and 97608, respectively, are consistent with the geometric mean cost of approximately $384 for APC

5052, rather than the geometric mean cost of APC 5053, which is approximately $597. Based on our data, the assignment to status indicator "T" has not impacted the payment for the services inappropriately; rather, we believe the payment amounts for these services are adequate to ensure access.

In summary, after consideration of the comment received, we are finalizing our proposals for CPT codes 97607 and 97608 without modification. Specifically, we are maintaining their assignment to APC 5052 (Level 2 Skin Procedures) and status indicator to "T" (Procedure or Service, Multiple Procedure Reduction Applies) for CY 2023. The final CY 2023 OPPS payment rates for CPT codes 97607 and 97608 can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

46. Surfacer® Inside-Out® Access Catheter System (APC 1534)

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance) describes the procedure associated with the use of the Surfacer® Inside-Out® Access Catheter System that is designed to address central venous occlusion. HCPCS code C9780 was established on October 1, 2021, and since its establishment the code has been assigned to New Technology APC 1534 (New Technology - Level 34 ($8001-$8500)). For CY 2023, the OPPS payment rates are based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Although the code was effective October 1, 2021, we have no claims data at this time. We note that under the OPPS, we review on an annual basis our claims data to determine the payment rates. Because we have no claims data, for CY 2023, we proposed

continuing to assign HCPCS code C9780 to APC 1534 with a proposed payment rate of $8,250.50.

Comment: Multiple commenters, including the developer, requested that HCPCS code C9780 be reassigned to New Technology APC 1575 (New Technology - Level 38 ($10,001-$15,000)) with a proposed payment rate of $12,500.50. The developer stated that the payment rate should be changed because the cost of the procedure has increased since they submitted their initial New Technology application to CMS. The developer noted that the increase in inflation has increased the costs of supplies, contrast agents, and labor used to perform the procedure. The developer also explained that data from hospitals that have performed the procedure described by HCPCS code C9780 have reported substantially longer operating room time and recovery room time for the procedure than what was anticipated when the initial service code application was submitted.

Response: We reviewed the request from the commenters, and we believe that it would be premature to revise the APC assignment for the service at this time. Because we have no claims data on which to base an accurate payment assignment, it is difficult to determine whether the costs of the procedure are substantially higher than what was anticipated when the developer made their initial request for this procedure to receive a unique HCPCS code. We review our claims data annually to establish the OPPS payment rates. Once we have claims data for HCPCS code C9780, we will reevaluate and determine whether an APC reassignment is necessary. For CY 2023, we believe that the assignment to New Technology 1534 is appropriate.

After consideration of the public comments, we are finalizing our proposal without modification to continue to assign HCPCS code C9780 to New Technology APC 1534 for CY

2023. The final CY 2023 payment rate for HCPCS code C9780 can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS website.

47. Total Ankle Replacement Procedure (APC 5116)

CPT code 27702 (Arthroplasty, ankle; with implant (total ankle)) describes the total ankle replacement (TAR) procedure. Between CY 2000 and CY 2020, the code was assigned to inpatient-only status under the OPPS. In CY 2021, based on public comments and our evaluation of the procedure in an evolving healthcare environment, we removed the code from the inpatient-only list and paid separately for the procedure by assigning the code to APC 5115 (Level 5 Musculoskeletal Procedures) effective January 1, 2021. We continued with this APC assignment in CY 2022, with a payment rate of $12,593.29.

Under the OPPS, we review our claims data on an annual basis to set the payment rates. For the CY 2023 OPPS/ASC proposed rule, we identified approximately 1,733 paid claims for CY 2021 with a geometric mean cost of $22,501.63. Based on our examination of the proposed rule data, we revised the APC assignment for CPT code 27702. For CY 2023, we proposed to move CPT code 27702 from APC 5115 to APC 5116 (Level 6 Musculoskeletal Procedures) with a proposed payment rate of $22,303.35.

Comment: Several commenters supported the reassignment from APC 5115 to APC 5116 for CPT code 27702. Commenters stated that the reassignment of outpatient TAR cases from APC 5115 to APC 5116 is consistent with Medicare's IPPS policy and would appropriately recognize the clinical complexity of these procedures. Commenters noted that the geometric mean cost of approximately $25,906 for CPT 27702 exceeds the geometric mean cost of approximately $22,502 for APC 5116. They expressed concern that the cost does not reflect the total costs hospitals incur in furnishing TAR procedures in the HOPD setting, but that it would

mitigate the significant shortfall currently associated with performing this procedure when it is assigned to APC 5115 and help preserve patient access to outpatient TAR surgery.

Response: We appreciate the commenters' support of the reassignment of CPT code 27702 to APC 5116. Based on our evaluation of the latest claims data for this final rule with comment period, which is based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022, we believe that the reassignment to APC 5116 is appropriate. Specifically, our analysis reveals a geometric mean cost of about $26,036 based on 1,884 single claims (out of 1,904 total claims) for CPT code 27702, which is in line with the geometric mean cost of approximately $22,519 for APC 5116, rather than the geometric mean cost of about $13,418 for APC 5115. We note that the geometric mean cost for CPT code 27702 falls within the range of the geometric mean cost for the significant HCPCS codes within APC 5116, which is between approximately $15,504 and $27,978. Based on the data, the geometric mean cost of about $26,036 for CPT code 27702 is consistent with the geometric mean cost of APC 5116. Therefore, for CY 2023, we believe it is appropriate to increase the payment for the TAR procedure described by CPT code 27702 and reassign the code to APC 5116.

In summary, after consideration of the public comments, we are finalizing our proposal without modification to assign CPT code 27702 to APC 5116 (Level 6 Musculoskeletal Procedures) for CY 2023. The final CY 2023 payment rate for CPT code 27702 can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS website.

48. Transcatheter Implantation of Coronary Sinus Reduction Device (APCs 5193 and 5194)

For the July 2022 update, we created HCPCS code C9783 (Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including

vascular access and closure, right heart catheterization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study) to describe the blinded arm of COSIRA-II clinical trial. We assigned this code to APC 5193 (Level 2 Endovascular Procedures) with a proposed payment rate of $10,760.97. In addition, we proposed to assign CPT code 0645T (Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed) to status indicator "E1" (Not covered. Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)), as use of the device in a non-blinded clinical trial had not been approved by the FDA for inclusion in an IDE study.

Comment: We received a few public comments, including a comment from the device manufacturer, stating that as of July 21, 2022, the device manufacturer had revised the protocol for their clinical trial to add a single arm nonrandomized cohort to accommodate specified patients who do not qualify for the randomized arm of the trial. They stated that for patients in this cohort, the blinded code will not accurately describe the procedure, and instead, CPT code 0645T will need to be used to report the procedure. They requested that CPT code 0645T be assigned to APC 1591 (New Technology -- Level 40 ($20,001 - $25,000)) with a proposed payment rate of $22,500.50. Information provided to CMS by the manufacturer indicates that the estimated cost of the device is around $15,500.

Response: We thank commenters for their responses. However, we believe that CPT code 0645T fits more appropriately in a clinical APC rather than a new technology APC. We believe that the procedure to implant the COSIRA-II device is most accurately described by CPT code

93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Based on our analysis of the latest claims data for this final rule with comment period, the geometric mean cost for CPT code 93451 is approximately $2,287. When the geometric mean cost of CPT code 93451 is added to the cost of the device, the total cost of the procedure described by CPT code 0645T is around $18,000, which is in line with the geometric mean cost of about $17,665 for APC 5194 (Level 4 Endovascular Procedures). Based on the cost, we believe that CPT code 0645T is more appropriate in APC 5194 rather than New Technology APC 1591. As we do every year, we will reevaluate the APC assignment for CPT code 0645T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are assigning CPT code 0645T to APC 5194 for CY 2023. In addition, we did not receive any comments on the APC assignment for HCPCS code C9783 and are finalizing our proposal to assign the code to APC 5193. The final CY 2023 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

49. Transnasal Esophagogastroduodenoscopy (EGD) Procedure (APC 5301 and 5302)

As shown in Table 47, we proposed to continue to assign CPT codes 0652T and 0653T to APC 5301, and 0654T to APC 5302 for CY 2023. We also proposed to continue to assign device category HCPCS code C1748 to APC 2029 with a status indicator of "H" to indicate that the device is on pass-through status under the OPPS.

TABLE 47: PROPOSED CY 2023 SI AND APC ASSIGNMENTS FOR CPT CODES 0652T, 0653T, 0654T AND HCPCS CODE C1748

HCPCS Code	Long Descriptor	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	APC Group Title	Proposed CY 2023 OPPS Payment
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic including collection of specimen(s) by brushing or washing, when performed (separate procedure)	T	5301	Level 1 Upper GI Procedures	$841.07
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	T	5301	Level 1 Upper GI Procedures	$841.07
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	J1	5302	Level 2 Upper GI Procedures	$1,768.53
C1748	Endoscope, single-use (i.e., disposable), upper GI, imaging/illumination device (insertable)	H	2029	Endoscope, single, UGI	

Comment: Some commenters expressed concern with the proposed APC assignments for CPT codes 0652T, 0653T, and 0654T. They stated that the pass-through status for device HCPCS code C1748 will expire on June 30, 2023, and consequently, HOPDs will no longer receive additional payment for the device beginning July 1, 2023. The commenter explained that the EvoEndo® Model LE Single-Use Gastroscope, which is a device used in the procedure, has an invoice price of $2,000. They also stated that the device cost is not reflected in our claims data because it just received FDA 510(k) marketing clearance on February 14, 2022 and they indicated that the cost of the device exceeds the proposed payment rate for both APC 5301 and APC 5302. In addition, despite the lack of data for the EvoEndo device, the commenters acknowledged that the five claims for CPT code 0654T suggest a change in the APC assignment from APC 5302 to APC 5303 is necessary. Specifically, they explained that the geometric mean cost of approximately $2,795 for CPT code 0654T included in the proposed rule shows that the

cost to perform the procedure is similar to the procedures in APC 5303, whose geometric mean cost is about $3,349, rather than the geometric mean cost of approximately $1,784 for APC 5302. Based on our claims data, and because the proposed payment rates for the procedure codes do not account for the cost of the EvoEndo® Model LE Single-Use Gastroscope, the commenters requested a reassignment from APC 5301 to APC 5302 for CPT codes 0652T and 0653T, and from APC 5302 to APC 5303 with a proposed payment rate of $3,319.29 for CPT code 0654T effective July 1, 2023, when the device pass-through status expires for HCPCS code C1748.

Response: Based on the information submitted to CMS, the cost of the EvoEndo® Model LE Single-Use Gastroscope, and the recent 510(k) FDA approval, we believe that we should modify the APC assignments for these procedure codes. As listed in Table 47, the proposed CY 2023 OPPS payment rates are $841.07 for CPT codes 0652T and 0653T and $1,768.53 for CPT code 0654T, which, according to the commenter, are below the cost of the EvoEndo® Model LE Single-Use Gastroscope. We note that for CY 2023, the OPPS payment rates are based on claims submitted between January 1, 2021, through December 31, 2021, that were processed on or before June 30, 2022. Our analysis of the data for this final rule shows that we have no claims data for CPT codes 0652T and 0653T, however, because the cost of the device exceeds the proposed payment rate for APC 5301, we believe that we should reassign both codes to APC 5302. In addition, as mentioned by the commenters, we have some data for CPT 0654T, which is consistent with the geometric mean cost for APC 5303. Specifically, our claims for this final rule with comment period reveal 5 single claims (out of 5 total claims) with a geometric mean cost of approximately $2,804 for CPT code 0654T. Based on this data, we believe a reassignment for CPT code 0654T to APC 5303 is appropriate. Therefore, effective July 1, 2023, we are reassigning CPT codes 0652T and 0653T from APC 5302 to APC 5303, and

CPT code 0654T from APC 5303 to APC 5304. As we do every year, we will reevaluate the APC assignments for CPT codes 0652T, 0653T, and 0654T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. First, for the January 1, 2023 update, we are finalizing our proposal without modification for CPT codes 0652T, 0653T, 0654T and HCPCS code C1748. Secondly, effective July 1, 2023, we are revising the APC assignments for CPT codes 0652T, 0653T, and 0654T to the APCs listed in Table 48. We note that the pass-through status for device category HCPCS code C1748 will expire on June 30, 2023, and at that time, the status indicator will change from "H" (device pass-through) to "N" (packaged) effective July 1, 2023. Table 48 below list the final SI and APC assignments for CY 2023. The final CY 2023 payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the Internet on the CMS website.

TABLE 48: FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0652T, 0653T, 0654T AND HCPCS CODE C1748 EFFECTIVE JANUARY 1, 2023 AND JULY 1, 2023

HCPCS Code	Long Descriptor	Jan 1, 2023 OPPS SI	Jan 1, 2023 OPPS APC	July 1, 2023 OPPS SI	July 1, 2023 OPPS APC
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic including collection of specimen(s) by brushing or washing, when performed (separate procedure)	T	5301	J1	5302
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	T	5301	J1	5302

0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	J1	5302	J1	5303
C1748	Endoscope, single-use (i.e., disposable), upper GI, imaging/illumination device (insertable)	H	2029	N	

50. Unlisted Dental Procedure/Service (APC 5871)

For CY 2022, CPT code 41899 (Unlisted procedure, dentoalveolar structures) is assigned to APC 5161 (Level 1 ENT Procedures). Unlisted codes, like CPT 41899, do not describe any specific procedure or service, so they lack the specificity needed to describe the resources used. As a reminder, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that the drug, device, procedure, or service is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment based on other statutory or regulatory restrictions. Unlisted codes provide a way for providers to report services for which there is no HCPCS code that specifically describes the service furnished. Because of the lack of specificity, unlisted codes are generally assigned to the lowest level APC within the most appropriate clinically related APC group under the OPPS. However, we stated in the proposed rule that we believe APC 5161 (Level 1 ENT Procedures) is not the most clinically appropriate APC series for this code. While APC 5161 includes some dental services, we explained that we believe CPT code 41899 is more closely aligned clinically to the dental services in APC 5871 (Dental Procedures), which is the sole APC where dental procedures described by the Current Dental

Terminology (CDT) reside. Therefore, for CY 2023, we proposed to reassign CPT code 41899 to clinical APC 5871, which is the only, and therefore lowest, APC group that specifically describes dental procedures.

In the CY 2023 OPPS proposed rule, we stated that, while we do not consider costs for services described by unlisted codes for rate setting purposes, based on both our established policy of generally assigning these codes to the lowest level APC within the most appropriate, clinically related APC group, and our inability to determine the specific services the unlisted code describes, the geometric mean cost for CPT code 41899 is more closely aligned with the geometric mean cost of other dental procedures in APC 5871 than with its current APC assignment. Specifically, in our annual review of the CY 2021 claims submitted between January 1, 2021, through December 31, 2021, and processed on or before December 31, 2021, the geometric mean cost for CPT code 41899 was $2,310.42 while the geometric mean cost of the code's current APC assignment, APC 5161, was$212.05. In contrast, the geometric mean cost of APC 5871 (Dental Procedures) was$1,973.71. Table 49 below shows the current and proposed status indicator and APC assignment for CPT code 41899.

TABLE 49: CY 2023 PROPOSED OPPS APC AND STATUS INDICATOR FOR CPT CODE 41899

CPT Code	Long Descriptor	CY 2022 OPPS SI	CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
41899	Unlisted procedure, dentoalveolar structures	T	5161	S	5871

The following summaries describe the public comments we received on our proposal.

Comment: Commenters expressed concern that patients with disabilities and children have limited access to dental care under general anesthesia in an operating room. Several commenters explained the importance of having access to this type of sedated dental care for vulnerable patient populations, especially patients with disabilities and other special health care needs. For example, one commenter explained that general anesthesia can lessen the trauma caused during dental exams or procedures to patients with special needs and sensory issues. Similarly, another commenter stated that the least traumatic option for children with disabilities and severe dental issues, is often full mouth dental rehabilitation under general anesthesia in a hospital setting. A comment from a dental association further highlighted the need for patient access to dental rehabilitation services in an operating room under anesthesia. The dental association explained that many patients' dental health deteriorated during the COVID-19 pandemic, due to changing eating habits, declining mental health, diminishing daily routines, and deferred elective health care procedures during quarantine. The commenter explained that an overwhelming number of patients, especially children, subsequently presented with rampant tooth decay and a dire need for sedation services, and will oftentimes face a waiting period of up to six months due lack of access to operating rooms. During this extended waiting period, the commenter explained that patients' dental health may further deteriorate; abscesses are more likely to develop and teeth that may initially have warranted crowns need to be emergently extracted via dental rehabilitation surgery. Per the commenter, the optimal care setting to address the oral health care needs for many patients who require complex dental services under general anesthesia, including dental rehabilitation surgery, is often in a hospital or another surgical setting, such as an ambulatory surgical center (ASC). This commenter further recommended that CMS create an oral rehabilitation code that would enable these services to be prioritized by

hospitals and ensure patient access. We also received comments from several family members of adults and children with disabilities who require anesthetized dental care in an operating room and are unable to access it for their family members. These commenters explained they are often on waiting lists, have to travel long distances to receive care, or only have one provider in their area that could provide needed dental care for their family member. Similarly, we received comments from dentists struggling to reserve operating rooms to provide dental care to vulnerable patients that require general anesthesia in this setting. One dentist commented that the local children's hospital only provided a few operating room days per month, causing a backlog of over 1,500 patients, mostly Medicaid beneficiaries, unable to receive dental services in an operating room. Commenters explained that dentists often need to provide surgical dental services and non-surgical dental services for vulnerable patient populations in operating rooms under general anesthesia given the time involved for these procedures, the often complex equipment and anesthesia required, and the complexity of the services required for high-risk patients.

Response: We thank the commenters for expressing their concerns on this important issue. We appreciate hearing about firsthand experiences from dentists and family members of patients in vulnerable populations who are unable to access dental care as their perspectives help us to better understand the issue. While we appreciate that the commenters have brought awareness to an important dental issue impacting health equity that needs to be addressed, we note that there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. Services must meet Medicare coverage requirements to be paid by Medicare, regardless of patient necessity. Therefore, while we understand that commenters believe that finalizing our proposal without modification would improve access to needed dental services for

vulnerable populations, we are clarifying that the policies in this final rule apply only to hospital outpatient department services covered by Medicare Part B and paid under the OPPS.

Comment: Commenters stated that they generally bill CPT code 41899 to describe the provision of dental services in the outpatient setting, and that the code's CY 2022 OPPS payment rate is too low to cover facility costs and incentivize hospitals to reserve operating rooms for dentists to provide needed dental care for patients with disabilities under general anesthesia. All commenters were supportive of the proposed reassignment of CPT 41899 to APC 5871 (Dental Procedures) and explained that the resulting increase in Medicare payment for covered dental procedures under CPT code 41899 would have the potential to mitigate the current reimbursement obstacles to operating room access. One commenter in particular was supportive of our proposal because they believed the CY 2022 APC assignment of CPT 41899 to APC 5161 (Level 1, ENT Procedures) was not an accurate representation of the resource costs associated with the range of dental surgical services for which CPT code 41899 is billed.

Response: We thank the commenters for their support of our proposal. As we noted in our proposal, we do not consider costs for services described by unlisted codes for rate setting purposes, based on both our established policy of generally assigning these codes to the lowest level APC within the most appropriate, clinically related APC group, and our inability to determine the specific services the unlisted code describes. While we understand that finalizing our proposal without modification would have the effect of increasing the payment rate for CPT 41899, and that commenters believe the increased payment rate may improve access to needed dental procedures for vulnerable populations, we reiterate that CMS has a longstanding policy of assigning unlisted codes, like CPT 41899, to the lowest level APC within the most appropriate, clinically related APC group, without consideration of resource costs.

Comment: Several commenters suggested that our proposal may improve access to dental care for Medicaid beneficiaries with disabilities, especially children. For example, one commenter stated that they hoped that state Medicaid systems would follow the proposed payment rate increase for unlisted code CPT code 41899.

Response: While we understand that state Medicaid programs often use Medicare payment rates for their own rate-setting purposes, we are clarifying that the payment rates and APC assignments in this final rule with comment period only apply to the hospital outpatient department services paid under the hospital outpatient prospective payment system (OPPS) under Medicare Part B.

Comment: One commenter requested that we review the fee schedule for anesthesiologists providing dental care sedation.

Response: We note that this final rule with comment period does not set Medicare payment rates for physicians and other practitioners. The Medicare fee schedule for practitioners is provided annually in the Physician Fee Schedule (PFS) proposed and final rules.

Comment: Some commenters referenced the dental proposals in the CY 2023 PFS proposed rule as evidence that there will be a significant, and potentially expanding, number of dental procedures that will be covered by Medicare. One commenter stated that the CY 2023 PFS proposed rule implicitly supports an approach that would make individual CDT codes payable in the HOPD and ASC settings. Another commenter stated they suspected that dental surgical procedures that require anesthesia would be covered by Medicare.

Response: We are clarifying that Medicare payment under the OPPS will be made for dental services that are covered by Medicare. As we stated in the proposed rule, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the

OPPS does not mean that the service is covered by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. Therefore, even if a code describing a dental service is assigned to an APC, which has an associated payment rate, Medicare will make payment for the service if it meets coverage requirements. This means that dental services billed with CPT code 41899 will be paid by Medicare if they are covered. We are further clarifying that this policy does not serve as a coverage determination for dental services under general anesthesia. We direct readers to the CY 2023 PFS final rule for additional discussion of Medicare coverage and payment for dental services. We note the CY 2023 PFS final rule is scheduled to be issued within a few days of this final rule with comment period

Finally, regarding the addition of other dental codes to the OPPS and the ASC CPL, CMS has not proposed to assign any additional codes describing specific dental services to an APC or to the ASC CPL for CY 2023. We will address APC assignments for codes describing dental procedures that are described by the dental policy discussed in the CY 2023 PFS final rule in future rulemaking, as appropriate, and as part of our annual review and revision of the APC groups.

Comment: Several commenters requested that CMS cover and pay for dental surgeries furnished in the ASC setting. Commenters explained that not having dental surgical procedures on the ASC CPL severely impedes access to potential sites of service for Medicare and Medicaid beneficiaries, given that Medicaid typically follows Medicare coverage and payment guidelines. Additionally, some commenters requested we add CDT code D9420 (Hospital or Ambulatory Surgical Center Call) to the ASC CPL.

Response: First, we reiterate that Medicare Part B pays for dental services when they meet our coverage requirements. In the CY 2023 PFS final rule, CMS clarified and codified certain dental services that may be covered and paid for under Medicare Part B. As a result, there may be at least some additional dental services that meet coverage requirements as outlined in the CY 2023 PFS final rule. As previously stated, the fact that a service is assigned a HCPCS code and a payment rate under the OPPS does not mean the service is covered by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. If a dental service is covered under Medicare Part B and meets the criteria for the ASC CPL (42 CFR 416.66), then it may be added to the ASC CPL. There are currently dental-related procedures on the ASC CPL that are described by CPT codes (i.e., 41800, 41805, 41806, 41820-41828, 41830, 41850, 41870, 41872, and 41874), but no additional dental-related procedures were proposed for CY 2023. We thank the commenters for their suggestions and will consider this issue for future rulemaking.

Comment: Several commenters requested that CMS expand its proposal to the ASC setting and add CPT 41899 to the ASC CPL. One commenter stated that some state Medicaid plans only make payments to ASCs for procedures found on the Medicare ASC CPL, which causes access issues if CPT 41899 is not on the ASC CPL.

Response: We thank the commenters for their suggestion. However, our current regulations preclude the inclusion of procedures that can only be reported using unlisted CPT code on the ASC CPL (42 CFR 416.166(c)(7)), as it would not be possible to evaluate whether procedures reported using unlisted codes meet the relevant criteria at 42 CFR 416.166 to be included on the ASC CPL. As a reminder, under §§ 416.2 and 416.166 of the Medicare

regulations, subject to certain exclusions, Medicare covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, are not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Covered surgical procedures in an ASC do not include those surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, commonly require systemic thrombolytic therapy, are designated as requiring inpatient care under § 419.22(n), only able to be reported using a CPT unlisted surgical procedure code, and are otherwise excluded under § 411.15. For further discussion on ASC CPL, refer to section XIII.C.1.d (Additions to the List of ASC Covered Surgical Procedures) of this CY 2023 OPPS/ASC final rule with comment period.

Based on the comments received, we are finalizing the following coding policy for dental services that meet Medicare coverage requirements as specified in the CY 2023 PFS final rule. First, we are creating a new code, HCPCS code G0330, to describe facility services for dental rehabilitation procedure(s) furnished to patients who require monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care)) and use of an operating room. We are adopting this code based on extensive public comments expressing the need for a coding and payment mechanism to improve access to covered dental procedures under anesthesia, especially dental rehabilitation procedures, an issue that commenters explained is caused by barriers to securing sufficient operating room time to furnish these services. HCPCS code G0330 will be assigned to APC 5871 (Dental Procedures), the APC to which we proposed to assign CPT code 41899. Due to public comments detailing the lack of access to appropriate facilities to receive

dental services under anesthesia, we are creating this code to enable HOPDs to bill the technical, facility-fee component of Medicare-covered dental rehabilitation services only. We further note that HCPCS G0330 is only billable under the OPPS and must only be used to describe facility fees for dental rehabilitation services that meet Medicare coverage requirements as interpreted in the CY 2023 PFS final rule. Therefore, G0330 cannot be used to describe or bill the facility fee for non-covered dental professional services.

Second, we are clarifying that the use of unlisted CPT code 41899 should be limited to procedures that are not otherwise described by other, more specific dental codes. We stated in the CY 2005 OPPS final rule (70 FR 68515-68980) that the assignment of unlisted codes to the lowest level APC in the clinical category specified in the code descriptor provides a reasonable means for interim payment until such time as there is a code that specifically describes what is being paid. We stated that this policy encourages the creation of codes where appropriate and mitigates the risk of overpayment for services that are not clearly identified on the claim. That is why we are creating HCPCS code G0330 for providers to use to bill for facility services for dental rehabilitation procedures performed on patients who require monitored anesthesia in an operating room. We believe this new code is more clinically appropriate and would more accurately pay facility fees for covered dental rehabilitation services furnished to patients who require monitored anesthesia in an operating room rather than unlisted CPT code 41899, which is non-specific. Therefore, we are clarifying that unlisted CPT code 41899 may be used more broadly to describe other dental or dental-related procedures on the teeth and gums, not otherwise described by other HCPCS codes currently assigned to APCs, such as those performed in the clinical dental scenarios as described in the CY 2023 PFS final rule, as well as covered non-surgical dental services and surgical dental services provided to patients who do not require

monitored anesthesia and the use of an operating room. In accordance with existing billing practices, providers will continue to use existing, specific CDT codes already assigned to APCs when available.

After consideration of the public comments we received, we are not finalizing the proposed APC assignment for CPT code 41899 of APC 5871 (Dental Procedures). We believe that because we are creating a new code that describes facility fees for dental rehabilitation services for patients that require hospital facilities and monitored anesthesia, unlisted code CPT 41899 should instead be used to identify other dental or dental-related services, and remain assigned to APC 5161 (Level 1, ENT Procedures), the lowest-level, clinically appropriate APC. The new G-code we are establishing, HCPCS code G0330, will be assigned to APC 5871 (Dental Procedures) for CY 2023. HCPCS code G0330 describes facility services for dental rehabilitation procedures performed on patients who require monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care)) and use of an operating room. While the new G-code is not payable in the ASC setting for CY 2023, we will consider adding it to the ASC CPL in future rulemaking. We reiterate that payment will be made for services identified with unlisted CPT code 41899 or HCPCS code G0330 when those services meet Medicare coverage requirements. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS, including CPT code 41899 and G0330. Addendum B is available via the Internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates. We note that HCPCS code G0330 is assigned to comment indicator "NI" in Addendum B to indicate that comments will be accepted on the interim APC assignment.

51. Urology and Related Services (APCs 5371 through 5378)

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85984 through 85986), we finalized a reorganization of the Urology and Related Services APCs from what was previously a seven-level series of related APCs into an eight-level series. In addition to creating the Urology and Related Services APC 5378 (Level 8 Urology and Related Services) and finalizing the reassignment of several urology procedures, we also revised the APC assignment for CPT code 53440 (Male sling procedure) and CPT code 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from APC 5376 to APC 5377. We believed the CY 2021 reorganization appropriately addressed the resource costs for the procedures whose geometric mean costs were between APC 5376 and APC 5377. Since CY 2021, the eight-level APC structure for the series has remained unchanged.

In our review of the latest claims data for this final rule with comment period, specifically, claims submitted between January 1, 2021, through December 31, 2021, and processed on or before June 30, 2022, we examined the procedures assigned to the Urology Procedures APCs. In the CY 2022 final rule with comment period (86 FR 63565), we stated that we received comments requesting that CPT code 55880 be reassigned from APC 5375 (Level 5 Urology and Related Services) to APC 5376 (Level 6 Urology and Related Services). We remind readers that, for the CY 2022 ratesetting, we used CY 2019 claims data due to the PHE. For CY 2022, we did not finalize any APC reassignment for the urology-related procedures because our data analysis using the CY 2019 claims did not support the reassignment based on the geometric mean cost of these codes and the impact across the Urology and Related services' APC's.

For the CY 2023 ratesetting, we proposed to use CY 2021 claims data. Using the CY 2021 claims data, we identified eight procedures (listed below) that were potentially appropriate to move from APC 5375 to APC 5376 because the geometric mean cost for the procedures ranged between the two APCs. Specifically, the proposed geometric mean cost of these services was closer to the geometric mean cost of $8,788.53 for APC 5376, rather than the geometric mean cost of $4,826.23 for APC 5375. This reassignment to APC 5376 would improve the resource cost and clinical homogeneity for the procedures within APC 5375 and APC 5376. Below is a list of the procedures and their geometric mean costs that we proposed to reassign from APC 5375 to APC 5376 for CY 2023.

- CPT 50576: Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy (proposed geometric mean cost: $11,137.98)
- HCPCS C9769: Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (proposed geometric mean cost: $7,742.45)
- CPT 51860: Cystorrhaphy, suture of bladder wound, injury or rupture; simple (proposed geometric mean cost: $7,548.83)
- CPT 53452 (0549T): Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance (Proposed geometric mean cost: $7,337.54)
- CPT 53449: Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff (proposed geometric mean cost: $7,109.79)

- CPT 54344: Repair of hypospadias complication(s) (ie, fistula, stricture, diverticula); requiring mobilization of skin flaps and urethroplasty with flap or patch graft (proposed geometric mean cost: $7,005.64)
- CPT 54316: Urethroplasty for second stage hypospadias repair (including urinary diversion) with free skin graft obtained from site other than genitalia (proposed geometric mean cost: $7,069.06)
- CPT 55880: Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance (proposed geometric mean cost: $7,015.62)

Comment: A commenter supported our proposal to reassign the above codes from APC 5375 to APC 5376. The commenter agreed that the reassignment improves the resource cost and homogeneity for the procedures within APC 5375 and APC 5376.

Response: We thank the commenter for the input.

Based on our examination of the latest claims data for this final rule with comment period, we continue to believe the reassignment of the above set of urological procedures improves the resource cost and clinical homogeneity for the procedures within APC 5375 and APC 5376.

Comment: Commenters supported our proposal to reassign CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance) back to level 6 Urology and Related Services (APC 5376). They stated that the CY 2019 assignment of HIFU to the level 5 Urology and Related Services APC, specifically, APC 5375, limited Medicare beneficiaries' access to HIFU because the facility would have to absorb the cost for the procedure since the payment rate for APC 5375 does not reflect the cost

of the service. Commenters believe the HIFU reassignment to APC 5376 would increase access for African American men who are diagnosed with prostate cancer. One commenter requested CMS apply the 31 percent default device offset for HIFU.

Response: Our analysis of the latest claims data used for this final rule with comment period supports the reassignment from APC 5375 to APC 5376. Specifically, our review reveals a geometric mean cost of approximately $7,134 for CPT code 55880 based on 345 single claims (out of 348 total claims), which is consistent with the geometric mean cost of about $8,800 for APC 5376, rather than the geometric mean cost of approximately $4,836 for APC 5375. The data indicates that the resource costs associated with CPT code 55880 are consistent with the services assigned to APC 5376. Therefore, we believe it would be appropriate to reassign the code from APC 5375 to APC 5376 for CY 2023. However, based on the latest data available, we have no evidence that supports applying the default 31 percent device offset for HIFU (CPT 55880).

Comment: A commenter supported the reassignment of HCPCS code C9769 (Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts) to APC 5376 (Level 6 Urology and Related Services). Additionally, the commenter supported the device offset percentage of 75.06 percent for HCPCS code C9769.

Response: We examined our claims data for this final rule with comment period, and our analysis of the latest claims data shows that the geometric mean cost for HCPCS code C9769 is approximately $7,656 based on 13 single claims (out of 13 total claims), which is in line with the geometric mean cost of about $8,800 for APC 5376 rather than the geometric mean cost of approximately $4,836 for APC 5375. The geometric mean cost for HCPCS code C9769 demonstrates that its resource cost is consistent with the resources of the services assigned to APC 5376. Consequently, we believe that the assignment to APC 5376 for HCPCS code C9769

is appropriate. Additionally, based on the available evidence, we believe it is appropriate to adjust the device offset percentage to 75.06 percent for CY 2023.

In addition to the above codes, we also received a comment related to CPT code 53452. For CY 2023, we proposed to continue to assign CPT code 53452 (Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance) to APC 5375 (Level 5 Urology and Related Services) with a proposed payment of $4,783.70.

Comment: A commenter requested the reassignment of CPT code 53452 to APC 5376 (Level 6 Urology and Related Services). The commenter also stated that prior to CY 2022, CPT code 53452 was billed as CPT code 0549T (Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy).

Response: We agree that CPT code 53452 has been replaced with CPT code 0549T. We note that CPT codes 0549T and 53452 are assigned to the same APC. As noted above, the CY 2023 OPPS payment rates are based on our analysis of the claims data submitted between January 1, 2021, through December 31, 2021, and processed on or before June 30, 2022. Our analysis of the claims data for this final rule shows a geometric mean cost of about $7,315 for the predecessor CPT code 0549T based on 6 single claims (out of 6 total claims), which is consistent with the geometric mean cost of approximately $8,800 for APC 5376, rather than the geometric mean cost of about $4,836 for APC 5375. Based on the data, we believe that the resource costs associated with CPT code 53452 (previously billed as CPT code 0549T) are similar to the other surgeries assigned to APC 5376. We believe the reassignment of CPT code 53452 is appropriate and improves both the resource cost and clinical homogeneity of the procedures within APC 5376.

In summary, after consideration of the public comments, we are finalizing our proposal and reassigning the eight urology-related procedures discussed above from APC 5375 to APC 5376. In addition, we are finalizing our proposal with modification for CPT code 53452 and reassigning the code from APC 5375 to APC 5376 for CY 2023. Table 50 below shows the final geometric mean cost for each APC within the Urology and Related Services grouping.

TABLE 50: FINAL CY 2023
UROLOGY AND RELATED SERVICES APCs

APC	Group Title	SI	Final CY 2023 Geometric Mean Cost
5371	Level 1 Urology and Related Services	J1	$220.96
5372	Level 2 Urology and Related Services	J1	$643.07
5373	Level 3 Urology and Related Services	J1	$1,907.46
5374	Level 4 Urology and Related Services	J1	$3,296.00
5375	Level 5 Urology and Related Services	J1	$4,835.50
5376	Level 6 Urology and Related Services	J1	$8,800.17
5377	Level 7 Urology and Related Services	J1	$12,369.11
5378	Level 8 Urology and Related Services	J1	$19,828.41

52. Waterjet Prostate Ablation (APC 5376)

The AquaBeam® System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The waterjet prostate ablation procedure is represented by CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)). The procedure involves resection of the prostate to relieve symptoms of urethral compression. The resection is performed robotically using a high velocity, nonheated sterile saline water jet (in a procedure called Aquablation). The procedure utilizes real-time intra-operative ultrasound

guidance to allow the surgeon to precisely plan the surgical resection area of the prostate and then the system delivers Aquablation therapy to accurately resect the obstructive prostate tissue without the use of heat. The AquaBeam® device, represented by HCPCS code C2596, received device transitional pass-through payment status beginning in CY 2020.

For CY 2023, we proposed to continue to assign CPT code 0421T to APC 5376 (Level 6 Urology and Related Services) based on the CY 2021 claims. Our analysis of the CY 2021 claims data for the CY 2023 OPPS/ASC proposed rule with comment period, which was based on claims data submitted between January 1, 2021, through December 31, 2021, and processed through December 31, 2021, yielded 1,016 single claims for CPT code 0421T with a proposed geometric mean cost of about $8,754.54.

Comment: A commenter supported the continued assignment of CPT code 0421T to APC 5376 (Level 6 Urology and Related Services) based on its clinical and resource comparability to the procedures within the APC. The commenter noted that the transitional pass-through status for the AquaBeam® device, (HCPCS code C2596) expires on December 31, 2022, and urged CMS to package the device cost into the waterjet ablation procedure (CPT code 0421T). Additionally, the commenter stated that the proposed device offset of 35 percent is artificially low and argued that the PHE has exacerbated omissions in device coding. The commenter requested a device offset of 66 percent.

Response: We thank the commenter for the input. Based on our analysis of the updated claims data for this final rule with comment period, which is based on claims submitted between January 1, 2021, through December 31, 2021, processed through June 30, 2022, we believe the assignment of CPT code 0421T to APC 5376 is appropriate based on its resource cost and clinical homogeneity to the procedures within APC 5376. Specifically, our claims data shows a

geometric mean cost of approximately $8,677 based on 1,121 single claims (out of 1,128 total claims), which is consistent with the geometric mean cost of about $8,800 for APC 5376. We note that upon expiration of the device transitional pass-through at the end of December 2022, the cost of the AquaBeam® device, represented by HCPCS C2596, will be packaged into the waterjet ablation procedure (0421T). Additionally, based on the available data, we believe the device offset percentage of 35 percent is appropriate for CPT code 0421T.

In summary, after consideration of the public comment, we are finalizing our proposal without modification and assigning CPT code 0421T to APC 5376. The final APC and status indicator assignments for CPT codes 0421T is found in Table 51. The final CY 2023 OPPS payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Both Addenda B and D1 are available via the Internet on the CMS website, specifically, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

TABLE 51: FINAL CY 2023 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR THE WATERJET ABLATION PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)	J1	5376

53. ZOLL µCor™ Heart Failure Management System Service (HFSM) Monitoring

The Heart Failure Management System Service (HFMS) is designed to help clinicians improve outcomes and reduce hospitalizations for heart failure patients with potential fluid-management problems by providing monitoring for pulmonary fluid levels, an early indicator for heart failure decompensation. The system uses a non-invasive, water-resistant sensor, which can be worn by patients 24 hours a day, and novel radiofrequency technology to monitor pulmonary fluid levels. Proprietary algorithms analyze patient-specific trends in the incoming data, allowing for early detection of deterioration in the patient's condition by the Independent Diagnostic Testing Facility (IDTF). Actionable clinical parameters recorded and available to clinicians include the thoracic fluid index, heart rate, respiration rate, activity, posture, and heart rhythm (ECG). Notifications relating to the condition of each patient are provided to the treating physician; data in the notifications aid the physician in the diagnosis and identification of various clinical conditions, events, or trends, allowing for timely intervention by the physician with the goal of avoiding a hospital readmission.

The CPT Editorial Panel established CPT codes 0607T and 0608T to describe the HFSM monitoring effective July 1, 2020. For CY 2023, we proposed to continue to assign CPT code 0607T (Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency- derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment) to status indicator "V" (clinic or emergency department visit) and APC 5012 (Clinic Visits and Related Services) with a proposed payment rate of $122.82. We also proposed to continue to assign CPT code 0608T (Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration

rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center;) to status indicator "S" (procedure or service, not discounted when multiple) and APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment rate of $35.96.

Comment: The manufacturer stated that the services associated with CPT codes 0607T and 0608T are not performed in the HOPD setting and are exclusively IDFT services. The manufacturer further added that the APC assignment for these codes under the OPPS has resulted in confusion that impedes availability of the HFMS to Medicare patients. The manufacturer requested that CMS revise the status indicators for CPT codes 0607T and 0608T to either "A", "B", or "M" to indicate that the services are not payable under the OPPS.

The commenter explained that the HFMS services are provided only through ZOLL Laboratory Services, a Joint Commission, Medicare-enrolled IDTF and indicated that no hospital in the United States possesses the HFMS technology. In addition, the commenter noted that there have been no OPPS claims for CPT codes 0607T or 0608T because hospitals do not provide this service. This same commenter added that CPT codes 0607T and 0608T are currently contractor-priced by Medicare Administrative Contractors (MACs) under the PFS.

Response: We thank the commenter for the feedback. Since the HFMS services are provided only through ZOLL's IDTF and no hospital in the U.S. has the technology to offer the service, we are accepting the recommendation and finalizing a change in the status indicators for these codes to "A" to indicate that the services associated with CPT codes 0607T and 0608T are contractor-priced. Status indicator "A" means that items or services are paid under another fee schedule or payment system or are contractor-priced by MACs. Because CPT codes 0607T and

0608T are contractor-priced by MACs under PFS, we are assigning these services to status indicator "A".

We refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through

eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.[22]

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not

[22] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act (PRA). This collection (CMS-10052) has an OMB control number of 0938-0857 and an expiration date of 11/30/2022. The application is currently undergoing the PRA reapproval process, which has notice and comment periods separate from this proposed rule. The 60-day notice was published in the **Federal Register** on April 29, 2022 (87 FR 25488).

more than 3 years. Currently, there are 14 device categories eligible for pass-through payment. These devices are listed in Table 52 where we detail the expiration dates of pass-through payment status for each of the 14 devices currently receiving device pass-through payment.

In the CY 2022 OPPS/ASC final rule with comment period we used CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting (86 FR 63755). As a result, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). A full discussion of this finalized policy is included in section X.F of the CY 2022 OPPS/ASC final rule with comment (86 FR 63755). In section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), we proposed to resume the regular update process of using claims from the year 2 years prior to the year for which we are setting rates, specifically CY 2021 outpatient claims for CY 2023 OPPS ratesetting. Based on CMS's policy proposal in section X.D, we did not propose to provide any additional quarters of separate payments for any drug, biological or device category whose pass-through payment status will expire between December 31, 2022 and September 30, 2023. We solicited comment on how the circumstances for CY 2023 are similar to those in CY 2022, when we adopted the equitable adjustment to mimic continued pass-through status for drugs, biologicals, and a device category with pass-through payment status that expired between December 31, 2021 and September 30, 2022. We note that in section I.V of the CY 2023 OPPS/ASC proposed rule (87 FR 44578) CMS proposed not to provide additional pass-through payments for any device

categories expiring in CY2023. We were silent on the issue of providing additional pass-through payments for drugs and biologicals in both section I.V of the CY 2023 OPPS/ASC proposed rule (87 FR 44578) and section (87 FR 44626 through 44627). However, consistent with the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755), where we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, we believe it is appropriate to address not only the comments received with respect to drugs and biologicals as they relate to providing additional quarters of pass-through status payments, but also the impact of CMS' finalized decision to resume the regular update process of using claims from the year 2 years prior to the year for which we are setting rates on drug and biological pass-through status payments.

Comment: Many commenters noted that the Covid-19 PHE persisted through 2021 and into 2022, impacted beneficiary access to certain drugs, biologicals, and devices, and disrupted product utilization. Commenters expressed concern that the general reduction in utilization of devices and services will be reflected in the 2021 claims data, similar to what occurred with the 2020 data, and as such, the rationale for continuing separate payments for pass-through technologies impacted by the Covid-19 PHE remains just as pertinent for the CY 2023 OPPS/ASC final rule as it was in CY 2022 OPPS/ASC final rule. Commenters expressed further concern that using the 2021 claims data as proposed will result in insufficient claims data, inaccurate rate-setting, lower reimbursement rates that do not accurately reflect provider costs, and improper APC assignments.

We received many comments specific to providing additional quarters of separate payments for drugs and biologicals whose pass-through payment status will expire between December 31, 2022 and December 30, 2023. One commenter stated that there continue to be major distortions in the claims data impacting numerous specialties and that these distortions significantly impacted the CY 2021 claims data used for the CY 2023 rate-setting. Another commenter requested that CMS use its equitable adjustment authority to extend the pass-through period for all radiopharmaceuticals impacted by the ongoing COVID-19 public health emergency (PHE), including the pass-through period for A9590 (Iodine I-131, iobenguane). This commenter recommended that this pass-through period extension continue as long as necessary to enable CMS to use three full years of claims data *outside of the PHE period* to capture radiopharmaceutical costs that will be packaged into nuclear medicine APC payments after pass-through status ends. Several commenters requested that CMS extend pass-through through December 31, 2024 for Detectnet, which was granted pass-through status beginning January 2021 and, in addition to COVID-19 challenges, commenters cited claims processing issues during CY 2021 that impacted utilization.

Response: We thank the commenters for their input. While we appreciate the concerns expressed by the commenters, we do not agree that the circumstances for CY 2023 are similar to those in CY 2022 when we adopted the equitable adjustment to mimic continued pass-through status for drugs, biologicals, and a device category with pass-through status that expired between December 31, 2021 and September 30, 2022. Based on CMS' decision to finalize the proposal to resume the regular update process of using claims from the year 2 years prior to the year for which we are setting rates, specifically CY 2021 outpatient claims for CY 2023 OPPS ratesetting, we believe that the data collected for CY 2023 ratesetting will result in the necessary

cost data being collected and incorporated into the costs for these drugs, biologicals, and devices into the procedure APC rate. Therefore, we believe that the claims data used in CY 2023 OPPS ratesetting for procedures including these drugs, biologicals, and devices with expiring pass-through status is sufficient and an additional extension of separate payment to mimic pass-through status is neither necessary nor appropriate. Due to clear improvement between the CY 2020 claims data and the CY 2021 claims data and CMS' return to the regular update process, we do not believe that the circumstances that resulted in CMS utilizing our equitable adjustment authority at section 1833(t)(2)(E) of the Act are similar to the circumstances in CY 2022. Therefore, we are finalizing our proposal to not provide any additional quarters of separate payments for any drug, biological, or device category whose pass-through payment status will expire between December 31, 2022 and December 30, 2023. We direct readers to section X.B of this final rule with comment period for a full discussion of use of claims data for CY 2023 OPPS/ASC payment system ratesetting due to the PHE.

Comment: Many commenters stated their opposition to CMS's proposal to not provide any additional quarters of separate payments for any device category whose pass-through payment status will expire between December 31, 2022 and September 30, 2023 for CY 2023. These commenters encouraged CMS to use its legal authority under section 1833(t)(2)(E) of the Act to extend pass-through payments for devices an additional four quarters through CY 2023 due to a historic decline in utilization during the COVID–19 pandemic.

Response: We thank the commenters for their input. Consistent with the statute and regulations, under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category is eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years, but not more than 3 years (81 FR 79655). Once a device category has received transitional

pass-through payments for 2 to 3 years, the device category is no longer eligible for pass-through payments and we utilize the established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). We note that device pass-through payment status is intended to be temporary and we consider the cost data to be included in the payment rates regardless of whether the technology's use in the Medicare population has been frequent or infrequent during the time period under which a device was receiving transitional pass-through payments.

Recognizing some of the more acute effects of the Covid-19 PHE on the utilization of devices with pass-through status in CY 2020, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). However, we do not believe that it is appropriate to adopt similar measures in CY 2023 based on CMS' decision to finalize the proposal to resume the regular update process of using claims from the year 2 years prior to the year for which we are setting rates, specifically CY 2021 outpatient claims for CY 2023 OPPS ratesetting. We believe that the data collected for CY 2023 ratesetting will result in the necessary

cost data being collected and incorporated into the costs for these devices into the procedure APC rate. Therefore, in this final rule with comment period, we are finalizing our proposal to not provide any additional quarters of separate payments for any device category whose pass-through payment status will expire between December 31, 2022 and September 30, 2023 for CY 2023. Again, we direct readers to section X.B of the this final rule with comment period a full discussion use of claims data for CY 2023 OPPS/ASC payment system ratesetting due to the Covid-19 PHE.

Comment: We received a comment from Stryker requesting that the pass-through status for SpineJack® (C1062, *Intravertebral body fracture augmentation with implant (e.g., metal, polymer)*) continue through CY 2024. Stryker noted concerns that there are unique considerations that support extending the SpineJack® period through CY 2024, including erroneous CMS National Correct Coding Initiative (NCCI) claims edits, commercial Medicare claims submission software errors, and insufficient CMS guidance on charging for the components of the associated bone preparation kit. As such, Stryker recommended that CMS use its equitable adjustment authority under 1833(t)(2)(E) to provide four quarters of additional separate pass-through payment for SpineJack® /C1062, through December 31, 2024.

Response: We thank Stryker for providing information related to SpineJack®. SpineJack® currently has pass-through status through 2023. We note that the pass-through status for SpineJack® expires on December 31, 2023 and will remain effective throughout the OPPS CY 2023 final rule with comment period, as such we will take the recommendations provided into consideration in the CY 2024 rulemaking.

Comment: We received a number of comments seeking clarification on whether several device category codes were omitted from Table 30 (Devices with Pass-Through Status (or

Adjusted Separate Payment) Expiring at the End of the Fourth Quarter of 2022, in 2023, or in 2024) in the proposed rule.

Response: We appreciate the comments. In section IV.4.A.1 of the CY 2023 OPPS/ASC proposed rule, we stated that, "Currently, there are currently 11 device categories eligible for pass-through payment. These devices are listed in Table 30 where we detail the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment." While we correctly included the amount of 11 device categories and included all of those device categories in the CY 2023 proposed estimate of pass-through spending, we erroneously omitted two device categories from Table 30 in the proposed rule (84 FR 44579). The two device category codes that should have been included are C1832 (Autograft suspension, including cell processing and application, and all system components) and C1833 (Monitor, cardiac, including intracardiac lead and all system components (implantable)). See Table 52 for the updated list of 14 device category codes where we detail the expiration dates of pass-through payment status for each of the 14 devices currently receiving device pass-through payment. Note that Table 52 includes the eight (8) device category codes included in the proposed estimate of pass-through spending with expiration dates in both 2023 and 2024, which includes the device code C1831 that received preliminary approval upon quarterly review effective October 1, 2021 and had pass-through payment status in CY 2022. In addition, Table 52 includes three (3) device category codes finalized in this final rule with comment period for a total of 11 device categories receiving pass-through payments effective January 1, 2023.

Comment: We received a number of comments noting discrepancies in the dates provided in Table 30 of the CY 2023 OPPS/ASC proposed rule. Specifically, commenters noted that six (6) HCPCS codes included in Table 30 with a December 31, 2022 expiration date were later

identified as estimated expenditures for CY 2023 in section VI. B., Proposed Estimate of Pass-Through Spending for CY 2023 (87 FR 44660), which suggested that the pass-through status for these codes continued in CY 2023. These six (6) HCPCS codes with CY 2022 expiration dates were identified as C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), C1824 (Generator, cardiac contractility modulation (implantable)), C1982 (Catheter, pressure-generating, one-way valve, intermittently occlusive), C1839 (Iris prosthesis), C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)), and C2596 (Probe, image-guided, robotic, waterjet ablation).

Response: We thank the commenters for their feedback. While those six (6) HCPCS codes listed in Table 30 contained correct CY 2022 expiration dates (87 FR 44579), we inadvertently included these codes in section VI. B., Proposed Estimate of Pass-Through Spending for CY 2023 (87 FR 44660). The six (6) HCPCS codes that were inadvertently included in the estimate of pass-through spending for CY 2023 were C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), C1824 (Generator, cardiac contractility modulation (implantable)), C1982 (Catheter, pressure-generating, one-way valve, intermittently occlusive), C1839 (Iris prosthesis), C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)), and C2596 (Probe, image-guided, robotic, waterjet ablation).

In addition, consistent with the final approval for device-pass through payment status of C1831 (Personalized, anterior and lateral interbody cage (implantable)), as described in section IV.2.b.1 of this final rule with comment period, we have added C1831 to Table 52 in this final rule with comment period. We inadvertently did not include C1831 in Table 30 in the CY 2023 OPPS/ASC proposed rule. However, as the device code received preliminary approval upon

quarterly review effective October 1, 2021 and had pass-through payment status in CY 2022, the device HCPCS code should have been included in Table 30 in the CY 2023 OPPS/ASC proposed rule. Table 52 has been updated to reflect the inclusion of C1831. Finally, HCPCS codes C1832 (Autograft suspension, including cell processing and application, and all system components) and C1833 (Monitor, cardiac, including intracardiac lead and all system components (implantable)) were included in the proposed estimate of pass-through spending for CY 2023 (87 FR 44660) but did not appear in Table 30 in the CY 2023 OPPS/ASC proposed rule. Both C1832 and C1833 have been added to Table 52 in this final rule. These device categories were approved for device pass-through effective January 1, 2022. As such, device category HCPCS codes C1831, C1832, and C1833 that were omitted from Table 30 in the proposed rule have been added to Table 52 in this final rule with comment period, and the six (6) HCPCS codes discussed above that were inadvertently included in the estimate of pass-through spending for CY 2023 have been removed to accurately reflect the final estimate of pass-through spending as part of the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023.

We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters in CY 2022 for C1823, as its pass-through payment status expired on December 31, 2021 (86 FR 63570). Separate payment for HCPCS code C1823 under our equitable adjustment authority will end on December 31, 2022. Table 52 includes this date for the device described by HCPCS code C1823 and includes the specific expiration dates for devices with pass-through status expiring at the end of the fourth quarter of 2022, in 2023, or in 2024.

TABLE 52: DEVICES WITH PASS-THROUGH STATUS (OR ADJUSTED SEPARATE PAYMENT) EXPIRING AT THE END OF THE FOURTH QUARTER OF 2022, IN 2023, OR IN 2024

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2022*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/22	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/22	12/31/2024

* We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 for C1823 whose pass-through payment status expired on December 31, 2021. Adjusted separate payment for HCPCS code C1823 will end on December 31, 2022.

2. New Device Pass-Through Applications for CY 2023

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of

devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and

- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results

published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/HospitalOutpatientPPS/passthrough_payment.html, in the "Downloads" section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Status for CY 2023

We received eight complete applications by the March 1, 2022 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2023 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2021, one of the applications in the third quarter of 2021, two of the applications in the fourth quarter of 2021, and five of the applications in the first quarter of 2022. One of the applications was approved for device pass-through status during the quarterly review process: the aprevo™ Intervertebral Body Fusion, which received quarterly approval under the alternative pathway effective October 1, 2021. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, aprevo™ Intervertebral Body Fusion is discussed in section IV.2.b.1 of this final rule with comment period.

Applications received for the later deadlines for the remaining 2022 quarters (the quarters beginning June 1, September 1, and December 1 of 2022), if any, will be discussed in the CY 2024 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

Discussions of the applications we received by the March 1, 2022 deadline are included below.

1. Alternative Pathway Device Pass-through Applications

We received two device pass-through applications by the March 2022 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore are eligible to apply under the alternative pathway.

(1) aprevo™ Intervertebral Body Fusion Device

Carlsmed, Inc. submitted an application for a new device category for transitional pass-through payment status for aprevo™ Intervertebral Fusion Device (aprevo™) for CY 2023. Per the applicant, the device is an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. The applicant stated that the implant device is custom made for patient-specific features using patient computed tomography (CT) scans to create 3D virtual models of the deformity to be used during anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion procedures. The aprevo™ device is additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and has a cavity intended for the packing of bone graft. In addition, the applicant explained that aprevo™ is used with supplemental fixation devices and bone graft packing. Per the applicant, the device was formerly known as "Corra™."

According to the applicant, the surgical correction plan for adult patients with spinal deformity is significantly more complex than performing a spine fusion for a degenerative spinal condition. The applicant further described that these deformity correction plans require numerous

complex measurements and calculations that consider a multitude of relationships between each area of the spine (cervical, thoracic, lumbar), the 33 individual levels of the spine, the pelvis, hips, and other reference points in relation to normal values based on the patient's age. The applicant stated that achieving the proper balance between these factors has been shown to directly contribute to improved clinical outcomes and increased patient satisfaction. Despite the use of sophisticated planning tools, surgeons are frequently unable to obtain the planned correction, and this is often because stock devices, which are not patient-specific, do not match the specific geometry that is required to realign each level of the individual patient's spine. The applicant claimed that aprevo™ devices provide the precise geometry to match the planned surgical correction for a spinal deformity patient, and they maintain this precise position while the bones fuse together in their new alignment.

According to the applicant, aprevo™ devices are surgically placed between two vertebral levels of the spine. The approach may be from the front, side, or back of the patient. The surgeon will gently clear away the disc material (which is often degenerated) before placing the device. Bone graft is placed inside a central opening of the interbody device. This allows the patient's bone to integrate with the graft material and form a bony bridge.

The applicant asserted that there are no other devices in the market like aprevo™. Per the applicant, other stock devices do not match the anatomy of each patient precisely. The applicant stated, in contrast, aprevo™ utilizes 3D generated reconstructions of each level of the patient's lumbar spine that match the anatomy of the patient. Per the applicant, the device's upper and lower surfaces match the topography of the patient's bone as this is important because the surfaces of the vertebral endplates can be extremely bumpy or wavy and sometimes thin and fragile. Per the applicant, by having a fit that matches these contours, the high loads that result

from body weight are more evenly distributed across the surface. The applicant stated that this contributes to faster healing of the bone and lessens the risk of having high stress points that could result in a stock interbody device breaking through the thin endplate.

Aprevo™ is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an Oswestry Disability Index (ODI) >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had 6 months of non-operative treatment. The devices are intended to be used with autologous and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

With respect to the newness criterion at § 419.66(b)(1), aprevo™ received FDA Breakthrough Device designation under the name "Corra" on July 1, 2020 for the Corra Anterior, Corra Transforaminal, and Corra Lateral Lumbar Fusion System interbody device which is intended for use in anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion under this designation. The applicant received 510(k) clearance from FDA for the Intervertebral Body Fusion Device (anterior lumbar interbody fusion and aprevo™ lateral lumbar interbody fusion devices) on December 3, 2020. The applicant also received 510(k) clearance from FDA for the Transforaminal Intervertebral Body Fusion (IBF) device on June 30, 2021. We received the application for a new device category for transitional pass-through payment status for aprevo™ on May 27, 2021, which is within 3 years of the date of the initial FDA marketing authorization of both indications. We solicited public comment on whether aprevo™ meets the newness criterion.

We did not receive public comments regarding whether aprevo™ meets the newness criterion at § 419.66(b)(1). Because we received the aprevo™ pass-through application on May 27, 2021, which is within 3 years of July 1, 2020, December 3, 2020, and June 30, 2021, the dates of FDA Breakthrough Device designation and 510(k) clearance, we have concluded that aprevo™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, aprevo™ is integral to the service provided, is used for one patient only, comes in contact with human tissue and is surgically inserted in a patient until the procedure is completed. The applicant also claimed that aprevo™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We solicited public comments on whether aprevo™ meets the eligibility criteria at § 419.66(b).

Response: The applicant submitted a comment reiterating that aprevo™ meets the eligibility criteria at § 419.66(b)(3) and § 419.66(b)(4). Based on the information we have received and our review of the application, we agree with the applicant that aprevo™ is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, and therefore meets the requirements in § 419.66(b)(3). We also agree that aprevo™ meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Based on this assessment we have determined that aprevo™ meets the eligibility criteria at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes aprevo™ as an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. Per the applicant, no previous device categories for pass-through payment have encompassed the device. In addition, per the applicant, the possible existing pass-through codes: C1821 (Interspinous process distraction device (implantable)), C1776 (Joint device (implantable)), C1734 (Orthopedic/device/drug matrix for opposing bone-to- bone or soft tissue-to-bone), and C1062 (Intravertebral body fracture augmentation with implant (e.g., metal, polymer)) do not appropriately describe aprevo™ because none of the existing codes pertain to a patient-specific spinal interbody fusion device and, therefore, do not encompass aprevo™.

We stated in the CY 2023 OPPS/ASC proposed rule that we had not identified an existing pass-through payment category that describes aprevo™ and we solicited public comment on whether aprevo™ meets the device category criterion.

We did not receive any comments on whether aprevo™ meets the criteria for establishing new device categories specified at § 419.66(c)(1). We continue to believe that there is not an existing pass-through payment category that describes aprevo™ because none of the existing codes pertain to a patient-specific spinal interbody fusion device. Based on this information we have determined that aprevo™ meets the device category eligibility criterion at § 419.66(c)(1). The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS

determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61295). Aprevo™ has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement. We note that the applicant was granted new technology add-on payments under the Alternative Pathway for Breakthrough Devices in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45132 through 45133).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that aprevo™ would be reported with HCPCS codes in Table 53.

TABLE 53: HCPCS Codes Reported with Aprevo™ Intervertebral Fusion Device

HCPCS Code	Long Descriptor	SI	APC
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)	N	N/A
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5115, which had a CY 2021 payment rate of $12,314.76 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 22633 had a device offset amount of $6,851.93 at the time the application was received. According to the applicant, the cost of aprevo™ is $26,000.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $26,000 for aprevo™ is 211.13 percent of the applicable APC payment amount for the service related to the category of devices of $12,314.76 (($26,000 /$12,314.76) x 100 = 211.13 percent). Therefore, we stated in the CY 2023 OPPS/ASC proposed rule that we

believe aprevo™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $26,000 for aprevo™ is 379.46 percent of the cost of the device-related portion of the APC payment amount for the related service of $6,851.93 (($26,000/$6,851.93) x 100 = 379.46 percent). Therefore, we stated in the CY 2023 OPPS/ASC proposed rule that we believe aprevo™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $26,000 for aprevo™ and the portion of the APC payment amount for the device of $6,851.93 is 155.49 percent of the APC payment amount for the related service of $12,314.76 ((($26,000 - $6,851.93)/ $12,314.76) x 100 = 155.49 percent). Therefore, we stated in the CY 2023 OPPS/ASC proposed rule that we believe that aprevo™ meets the third cost significance requirement.

We solicited public comment on whether aprevo™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: The applicant provided a comment reiterating that aprevo™ meets the cost significance requirements.

Response: We thank the applicant for reiterating that aprevo™ meets the cost significance requirements specified at § 419.66(d). Based on our findings from the first, second, and third cost significant tests, we believe that aprevo™ meets the cost significance criterion specified at § 419.66(d).

Comment: The applicant commented on the cost criteria calculations and requested that CMS evaluate and adjust the device offset amount associated with the use of the aprevo™ interbody device to reflect only the interbody device-related costs for the procedure. Specifically, the applicant noted that CMS used APC 5115 for the calculations, which had a CY 2021 payment rate of $12,314.76 at the time the application was received, and a device-related portion of the APC payment amount for the related service of $6,851.93.

The applicant requested that we also consider that the applicable HCPCS code used in this analysis (22633: Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace lumbar), describes a procedure requiring both the posterior interbody fusion and posterolateral fusion. The posterolateral fusion is performed using screws, rods and bone graft. The applicant asserted that aprevo™ does not replace all existing technologies used in this procedure because the interbody device is not applicable to the posterolateral fusion.

Response: We appreciate the applicant's input and additional information regarding the device criterion and associated offset. We have evaluated the information provided by the applicant and agree that we should adjust the off-set amount associated with the use of the

aprevo™ interbody device to $0. We refer the reader to Addendum B of this CY 2023 OPPS/ASC with comment period for APC payment rates.

Comment: We received one comment in support of finalizing pass-through payment status for aprevo™. The commenter stated that with new developments in personalized medicine moving forward, the innovation in products uniquely suited to an individual patient's anatomy offers a promising future for patient care.

Response: We appreciate the commenter's support.

After considering the public comments we received and our review of the device pass-through application, we are finalizing approval of device pass-through payment status for aprevo™ under the alternative pathway for devices that have an FDA Breakthrough Device designation and FDA market authorization for the indication for which the device has Breakthrough Device designation. Therefore, we will continue the device pass-through payment status for aprevo™.

Comment: We received comments from the applicant requesting that we change the device descriptor for C1831 to include the posterior/transforaminal approach. In addition, we received a request from the applicant to remove CPT code 22612 as an applicable code with which to bill devices described by C1831. Aprevo™ was granted multiple FDA clearances, all of which collectively cover the different approaches in which the device can be implanted into the patient (from the front, side, or back of the patient). Aprevo™ received FDA Breakthrough Device designation under the name "Corra" on July 1, 2020 for the Corra Anterior, Corra Transforaminal, and Corra Lateral Lumbar Fusion System interbody device which is intended for use in anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion under this designation. The applicant received 510(k) clearance from

FDA for the Intervertebral Body Fusion Device (anterior lumbar interbody fusion and aprevo™ lateral lumbar interbody fusion devices) on December 3, 2020. In addition, the applicant received 510(k) clearance from FDA for the Transforaminal (posterior) Intervertebral Body Fusion (IBF) device on June 30, 2021. We received a new device category for transitional pass-through payment status application for aprevo™ on May 27, 2021. Aprevo™ was approved for device pass-through payment during the quarterly review process and received fast-track approval under the alternative pathway effective October 1, 2021.

Aprevo™ was temporarily assigned the HCPCS code C1831 (Personalized, anterior and lateral interbody cage (implantable)). The associated MLN Matters October 2021 publication provided the following instruction: "Always bill the device(s) in the category described by HCPCS code C1831 with 1 of the primary CPT codes 22558, 22586, 22612, 22630, or 22633 and add-on code 22853 or 22854." Subsequent to C1831 being created, CMS added CPT codes 22558 and 22586 (the anterior and lateral implant placement procedures) to the inpatient only list (IPO). As such, C1831 can no longer be billed with CPT codes 22558 and 22586 as an OPPS service. However, C1831 may be billed with CPT codes 22612, 22630 and 22633 (the posterior/ transforaminal implant placement procedures).

In response to this, the applicant requested that CMS take two actions: First, the applicant requested that CMS modify the current C1831 long descriptor, "Personalized, anterior and lateral interbody cage (implantable)" to read "Personalized posterior interbody cage (implantable)." The applicant stated that the current long descriptor includes "anterior and lateral" both of which are now on the IPO list, but does not include the posterior/transforaminal approach, which is not on the IPO list. The applicant provided that the aprevo™ device utilized for the

posterior/transforaminal approach received FDA 510(k) clearance on June 30, 2021, and as such, the posterior/transforaminal approach should be included in the long descriptor.

Second, the applicant asserts that the inclusion of CPT code 22612 in the *October 2021 MLN Matters* article as an applicable code with which to bill devices described by C1831 is incorrect. As such, the applicant requested that CPT code 22612 be removed as an applicable code with which to bill devices described by C1831. The applicant asserts that that 22612 is not an interbody fusion procedure because, while it describes a posterolateral fusion, it is different from a posterior interbody fusion. The posterolateral fusion, 22612, involves fusing the back area of the spine, along the sides of the vertebrae, without doing an interbody fusion.

Response: We thank the applicant for their comments. We agree with the applicant that the long descriptor for C1831 should be updated to include the posterior interbody implant device which is surgically placed through the posterior/transforaminal approach. However, we believe that the anterior and lateral implant devices should remain in the long descriptor at this time in the event that the surgical procedures for their placement are removed from the IPO list in the future. As such, we will revise the long descriptor for C1831 effective January 1, 2023 to read: "Interbody cage, anterior, lateral or posterior, personalized (implantable)." We believe this description addresses all potential approaches. We also agree with the applicant that CPT code 22612 was incorrectly included in the *October 2021 MLN Matters* article as an applicable code with which to bill devices described by C1831. Therefore, CMS will provide updated instructions in the *January 2023 MLN Matters* article reflecting the removal of CPT code 22612 as applicable code with which to bill devices described by C1831. In addition, we have determined that CPT code 22632 and CPT code 22634 are applicable codes with which to bill devices described by C1831. As such, CMS will provide updated instructions in the *January*

2023 MLN Matters article reflecting the addition CPT code 22632 and CPT code 22634 as applicable codes with which to bill devices described by C1831.

(2) MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System)

MicroTransponder, Inc. submitted an application for a new device category for transitional pass-through payment status for the ViviStim® Paired VNS System (Vivistim® System) for CY 2023. Per the applicant, the Vivistim® System is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

According to the applicant, the Vivistim® System is an active implantable medical device that is comprised of four main components: (1) an Implantable Pulse Generator (IPG), (2) an implantable Lead, (3) Stroke Application & Programming Software (SAPS), and (4) a Wireless Transmitter (WT). The IPG and Lead comprise the implantable components; the SAPS and WT comprise the non-implantable components.

The applicant asserts that the key feature of the biochemical process that underlies neural pathway development is called neuroplasticity. The applicant describes neuroplasticity as a complex biochemical process that is necessary for establishing new synaptic connections. The applicant further states it is widely understood that vagus nerve stimulation triggers the brain to release a burst of neuromodulators, such as acetylcholine and norepinephrine, which are enablers of neuroplasticity. In addition, the applicant further states it is understood that pairing neuromodulator bursts with events increases brain plasticity, which in turn increases the

formation of new neural connections.[23] Per the applicant, the use of the external paired stimulation controller to precisely pair VNS with rehabilitation movements is essential to creating neuroplasticity in patients who have upper limb deficits, and this "event-pairing" of movement with VNS that generates long-lasting plasticity in the motor and sensory cortex leads to the restored motor function observed in clinical studies.[24]

The applicant specifies the SAPS and WT are non-implantable and are collectively called the External Paired Stimulation Controller. The applicant specifies the IPG and implantable Lead are implantable components. Per the applicant, the External Paired Stimulation Controller allow the implanted components (the IPG and Lead) to stimulate the vagus nerve while rehabilitation movement occurs through the following process: (1) The implantable Lead electrodes are attached to the left vagus nerve in the neck; (2) The implantable Lead is tunneled from the neck to the chest where it is connected to the IPG; (3) The IPG is placed subcutaneously (or sub-muscularly) in the pectoral region; (4) Following implantation of the IPG and stimulation Lead, the External Paired Stimulation Controller enables real-time "event-pairing" of vagus nerve stimulation and rehab movements; (5) The IPG and the implantable Lead stimulate the vagus nerve while rehabilitation movements occur; and (6) A therapist initiates the stimulation using a USB push-button or mouse click to synchronize the vagus nerve stimulation with rehabilitation movements to maximize the clinical effect. Patients undergo in-clinic rehabilitation, where vagus nerve stimulation is actively paired with rehabilitation by a therapist. Following in-clinic rehabilitation paired with vagus nerve stimulation, the patient can continue using the device at home. When directed by a physician, the patient can initiate at-home use by swiping a magnet

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[23] Meyers EC, Solorzano BR, James J, Ganzer PD, Lai ES, Rennaker RL 2nd, Kilgard MP, Hays SA. Vagus Nerve Stimulation Enhances Stable Plasticity and Generalization of Stroke Recovery. Stroke. 2018 Mar;49(3):710-717.
[24] Hays SA, Rennaker RL, Kilgard MP. Targeting plasticity with vagus nerve stimulation to treat neurological disease. Prog Brain Res. 2013;207:275-299. doi:10.1016/B978-0-444-63327-9.00010-2

over the IPG implant site which activates the IPG to deliver stimulation while rehabilitation movements are performed

With respect to the newness criterion at § 419.66(b)(1), Vivistim® System was granted FDA Breakthrough Device Designation effective February 10, 2021 for use in stimulating the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The applicant states the Vivistim® System received FDA premarket approval (PMA) on August 27, 2021 as a Class III implantable device for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Vivistim® System on September 1, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comment on whether the Vivistim® System meets the newness criterion.

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that Vivistim® System received FDA marketing authorization on August 27, 2021. The applicant also noted that a manufacturing delay prevented market availability of the device until April 29, 2022. The applicant requested that CMS begin the newness period for the Vivistim® System using the latter market availability date of April 29, 2022.

Response: We appreciate the commenter's input. Because we received Vivistim® System's pass-through application on September 1, 2021, which is within 3 years of August 27, 2021, the date of FDA premarketing approval, we agree that the Vivistim® System meets the newness criterion, and as such we do not need to consider using the date on which the Vivistim® System was first marketed, April 29, 2022.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, VNS System is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) into the patient. We noted that the external components SAPS and WT were not implanted in a patient and do not come in contact with the human tissue as required by § 419.66(b)(3). The applicant claimed that Vivistim® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, we noted that the external non-implantable components SAPS and WT may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered and may be considered depreciable assets as described in § 419.66(b)(4). We solicited public comments on whether Vivistim® System meets the eligibility criteria at § 419.66(b).

Comment: In response to our concern that the external components SAPS and WT are not implanted in a patient and do not come in contact with the human tissue as required by § 419.66(b)(3), the applicant provided that, like other implantable neurostimulator systems, the Vivistim® System includes implantable components and external components. The applicant stated that Vivistim® System (the IPG and Lead) is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) into the patient. The applicant further noted the following: the external components communicate remotely with the implantable pulse generator, are integral to the function of the Vivistim® System, and the implanted components (the IPG and Lead) cannot work as intended without the external paired stimulation controller and vice versa.

In addition, the applicant asserted that the existence of external components within an FDA-approved neurostimulator system does not negate eligibility under § 419.66(b)(3). The applicant further provided that the FDA approval for the Vivistim® System does not acknowledge a distinction between implanted and non-implanted components, which are collectively approved as a "device." The applicant clarified that this is not unique to the Vivistim® System since each of the neurostimulator systems for which a new device category was previously created (C1820, C1822, C1823, C1825) are provided with a reusable clinical interface (i.e., remedē® System Programmer Model 1102A1; Nevro® HF10 Clinician Programmer PG20002; CVRx® Programmer System Model 90103). The applicant asserted that the existence of reusable, external clinical interfaces does not, and has not, historically been construed to negate eligibility under § 419.66(b)(4).

In response to our concern that the external non-implantable components SAPS and WT may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered and may be considered depreciable assets as described in § 419.66(b)(4), the applicant again clarified that existence of a reusable clinical user interface is neither unique to the Vivistim® System nor negates eligibility under § 419.66(b)(4). The applicant stated the Vivistim® System external paired stimulation controller is provided at no cost under a loaner agreement, where ownership of the device is retained by the manufacturer

Response: We appreciate the additional information from the applicant with respect to whether the device meets the criteria in § 419.66(b)(3) and § 419.66(b)(4). Based on the information we have received and our review of the application, we agree with the applicant that the applicable components of the device are used for one patient only, come in contact with human tissue, and are surgically implanted or inserted. As such, we agree that Vivistim® System

meets the eligibility criterion specified at § 419.66(b)(3)). While we agree that Vivistim® System meets the eligibility criterion specified at § 419.66(b)(3)), we note that the criteria FDA utilizes to grant medical device approvals differ from the criteria CMS has established to evaluate device eligibility for OPPS device pass-through payments.

Based on the clarification provided by that applicant that they retain and maintain the Vivistim® System external paired stimulation controller (the reusable hardware components) at no charge to the providers via a loaner agreement, and ownership of the device is retained by the manufacturer, we agree with the applicant that the applicable components meet the device eligibility requirements of § 419.66(b)(4) because they are not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and they are not a supply or material furnished incident to a service. We agree and conclude that the Vivistim® System device meets the eligibility requirements at § 419.66(b)(4).

Based on this assessment we have determined that the Vivistim® System meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

According to the applicant, there are several device categories that are similar to or related to the proposed device category. The applicant stated that there are five HCPCS device category codes describing neurostimulation devices that are similar to the Vivistim® System, listed in the Table 54.

TABLE 54: HCPCS CODES REPORTED WITH THE VIVISTIM® SYSTEM

HCPCS Code	Long Descriptor	Status Indicator	APC
C1767	Generator, neurostimulator (implantable), non-rechargeable	N	N/A
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	N	N/A
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	N	N/A
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	H	2993
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	H	2030

Per the applicant, the codes in Table 54 do not encompass the Vivistim® System because none of the codes feature an external paired stimulation controller to actively pair stimulation with rehabilitation by a clinician, which is integral to the function and clinical benefit of the device, and the Vivistim® System does not include a rechargeable battery or charging system. The following paragraphs include the applicant's description of each related device category, the distinguishing device features and/or accessories of devices included in each of these categories, and the applicant's rationale for why the Vivistim® System device is not encompassed by these existing device categories.

Per the applicant, the Vivistim® System and similar device category codes that have preceded it (C1820, C1822, C1823, C1825) are distinct from the C1767 device category because of distinguishing device features and/or accessories not currently described by C1767.

The applicant stated that the C1767 was created in 2000 and was the first category for non-rechargeable neurostimulator generators. Per the applicant, the C1767 code currently describes multiple non-rechargeable neurostimulator generator devices that are approved to treat

a wide variety of conditions. The applicant stated it is aware of currently marketed implantable, non-rechargeable vagus nerve stimulation devices, such as the VNS Therapy® System (LivaNova, PLC) which are described by C1767. Further, the applicant stated it is aware that CMS does not acknowledge indication for use alone as a reasonable basis to establish a new device category. According to the applicant, the VNS Therapy® System (LivaNova, PLC) has different device components and therapy delivery than the Vivistim® System. Per the applicant, the LivaNova VNS Therapy® System implantable neurostimulators differ from the Vivistim® System in a number of ways. Specifically, according to the applicant, VNS Therapy® System neurostimulators are "always on" and send periodic pulses to deliver therapy over the life of the device, whereas the Vivistim® System is actively paired with rehabilitation movements by a clinician to deliver therapy. In addition, the applicant stated the VNS Therapy® System is used to treat neurological disorders such as epilepsy and treatment resistant depression, whereas the Vivistim® System is used to treat upper limb motor deficits in ischemic stroke survivors. The applicant concluded C1767 does not encompass the Vivistim® System.

Per the applicant, C1820 describes an implantable neurostimulator that includes a rechargeable battery and charging system. The applicant stated it is aware of several marketed devices that are described by device category C1820 which was created in CY 2006. The applicant concluded C1820 does not encompass the Vivistim® System. Per the applicant, C1822 describes an implantable neurostimulator, which delivers "high-frequency" stimulation (10 kHz) and is provided with a rechargeable battery and charging system. The applicant stated it is aware of only one currently marketed device that is described by this device category, the HF10® Spinal Cord Stimulator (Nevro Corp.). The applicant stated the Vivistim® System is not a "high-frequency" stimulator as described by C1822. The applicant stated the paired stimulation using

the Vivistim® System is delivered at a maximum of 30 Hz, whereas spinal cord stimulation using the HF10® (Nevro Corp.) is delivered at 10 kHz. The applicant concluded C1822 does not encompass the Vivistim® System.

According to the applicant, C1823 describes an implantable neurostimulator, which is nonrechargeable and includes transvenous sensing and stimulation leads. The applicant stated that it is aware of only one currently marketed device that is described by C1823, the remedē System® Phrenic Nerve Stimulator (Respicardia, Inc.). This device category code does not encompass the Vivistim® System. According to the applicant, the stimulation lead included in the Vivistim® System is placed onto the vagus nerve and is not transvenously placed to stimulate the phrenic nerve. In addition, the applicant asserted the Vivistim® System does not include a sensing lead. The applicant concluded C1823 does not encompass the Vivistim® System.

Per the applicant, C1825 describes an implantable neurostimulator which is nonrechargeable and includes a carotid sinus baroreceptor lead. The applicant stated it is aware of only one currently marketed device that is described by C1825, the BaroStim Neo™ (CVRx, Inc.). According to the applicant, the stimulation lead included in the ViviStim® System is placed onto the vagus nerve and is not placed on the carotid sinus. The applicant concluded C1825 does not encompass the Vivistim® System.

The applicant has asserted that the Vivistim® System is distinct from HCPCS codes C1820, C1822, C1823 and C1825 due to distinguishing features unique to these codes. These unique features include rechargeable batteries, high frequency stimulation, transvenous sensors and stimulators and unique placement of stimulators. With respect to C1767, however, the applicant's argument is that the Vivistim® System is not "always on" and is paired to an external

stimulation controller to allow for clinician-controlled stimulation during rehabilitation, and therefore is unlike the non-rechargeable implantable neurostimulator of the VNS Therapy® System (LivaNova, PLC), which is described by C1767. We noted that it was our understanding, however, that implantable neurostimulators for epilepsy and depression are not "always on," but are programmed to turn on and off in specific cycles as determined by a clinician. Furthermore, in the case of treatment for epilepsy, a neurostimulator can be turned on by the patient with a hand-held magnet if an impending seizure is sensed, and the neurostimulator can similarly be turned off by the patient during certain activities, such as speaking, exercising, or eating. As per the application, the IPG of the Vivistim® System can also be patient-engaged with a magnetic card, allowing the patient to continue therapy at home. In this context, we believe the Vivistim® System may be similar to the devices currently described by C1767, and therefore the Vivistim® System may also be appropriately described by C1767. We solicited public comment on whether the Vivistim® System meets the device category criterion.

Comment: In response to our concern that the Vivistim® System may be appropriately described by C1767, the applicant sought to clarify the characterization provided in the application of the VNS Therapy® System (LivaNova, PLC) as an "always-on" stimulation delivery system. The applicant stated that this description was not meant to imply that the VNS Therapy® System is delivering continuous stimulation or that it lacks programmable stimulation features. Rather, the applicant stated that it intended to communicate that, in normal mode, the VNS Therapy® System is designed to deliver stimulation at preprogrammed intervals throughout the day and night (typically 5 minutes off, 30 seconds on) and normal mode settings result in approximately 130 minutes of stimulation daily at 1.5 mA. Further, the applicant noted that while in normal mode, the patient controller allows for the patient to turn off the system

during certain activities such as speaking, exercise or eating, or to deliver a burst of stimulation when an impending seizure is sensed. However, outside of these circumstances, the VNS Therapy® System (LivaNova, PLC) is designed to deliver stimulation at regular intervals throughout the day and night (e.g., "always on"). Conversely, in comparison to its device, the applicant stated that the Vivistim® System is not set to deliver stimulation on a pre-defined schedule, but to pair stimulation with specific movements during in-clinic therapy. The applicant reiterated that no current category appropriately describes a neurostimulator that is actively paired with movement during rehabilitation by a skilled therapist where she/he instructs the patient to perform upper limb rehabilitation exercises and delivers stimulation using a push-button feature of the external paired stimulation controller (i.e., the face-to-face, manual delivery of stimulation by a skilled therapist is necessary to pair stimulation with the specific time point when it will be most effective), and this "event-pairing" of stimulation delivery that has been shown in clinical studies to deliver 2-3X the clinical benefit of intense rehabilitation alone. For example, the applicant stated that the circuitry of the Vivistim® System implantable pulse generator is uniquely designed to communicate at a distance with the external paired stimulation controller. The applicant specifically noted that the Vivistim® System IPG uses a medical implant communication system (MICS 403 MHz) with an effective range of 1-2 meters from the patient's body. The applicant asserted that this feature allows the external paired stimulation controller to communicate with the IPG from a greater distance, while the patient is actively moving. The applicant stated the VNS Therapy® devices (LivaNova, PLC) contain circuitry that communicates by inductive link communication, a different communication protocol, which limits the effective communication range to ~3-4 cm from the patient's body and utilizes a slower data transfer rate. The applicated further provided that during in-clinic therapy,

stimulation is only delivered at a precise time-point by a skilled therapist to maximize the clinical effect. The applicant stated as a result, the Vivistim® System delivers only 9 minutes of stimulation at 0.8 mA during a typical in-clinic therapy session day.

In response to our concern that IPG of the Vivistim® System can also be patient-engaged with a magnetic card, allowing the patient to continue therapy at home using the Vivistim® System and therefore, may be appropriately described by C1767, the applicant agreed patient-engaged features are common to neurostimulator devices. However, the applicant asserted that the existence of common features in the device should not negate the novelty of an in-clinic paired therapeutic delivery by a skilled therapist. In addition, the applicant clarified that the unique feature of the Vivistim® System is the external paired stimulation controller, not the patient-engaged features of the device. As such, the applicant asserted the Vivistim® System meets the first criterion for establishing a new device category at § § 419.66(c)(1) because there are no existing categories established for device TPT that describe the Vivistim® System.

Response: After consideration of the public comment that we received from the applicant, we agree there is no existing pass-through payment category that appropriately describes the Vivistim® System because no current category appropriately describes a neurostimulator that is actively paired with movement during rehabilitation by a skilled therapist where she/he instructs the patient to perform upper limb rehabilitation exercises and delivers stimulation using a push-button feature of an external paired stimulation .

Based on this information, we have determined that Vivistim® System meets the first eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has

demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61295). The Vivistim® System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement. We note that the applicant has also submitted an application for IPPS New Technology Add-on payments for FY 2023 Payment under the Alternative Pathway for Breakthrough Devices (87 FR 48975 through 48977).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the insertion procedure for the Vivistim® System implantable pulse generator (IPG) and stimulation lead would be reported with the HCPCS Level I CPT code

64568 (Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator).

To meet the cost criteria for device pass-through payment status, a device must pass all three tests of the cost criteria for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criteria, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5465 Level 5 Neurostimulator and Related Procedures, which had a CY 2021 payment rate of $29,444.52 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 64568 had a device offset amount of $25,236.9 at the time the application was received. According to the applicant, the cost of the Vivistim® System is $36,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $36,000.00 for Vivistim® System is 122.26 percent of the applicable APC payment amount for the service related to the category of devices of $29,444.52 (($36,000.00 /$29,444.52) × 100 = 122.26 percent). Therefore, we stated that we believe Vivistim® System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related

portion of the APC found on the offset list). The estimated average reasonable cost of $36,000.00 for Vivistim® System is 142.65 percent of the cost of the device-related portion of the APC payment amount for the related service of $25,236.90 (($36,000.00 /$25,236.90) × 100 = 142.65 percent). Therefore, we stated that we believe that Vivistim® System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $36,000.00 for Vivistim® System and the portion of the APC payment amount for the device of $25,236.90 is 36.55 percent of the APC payment amount for the related service of $29,444.52 (($36,000.00 - $25,236.90)/$29,444.52) × 100 = 36.55 percent). Therefore, we stated that we believe that Vivistim® System meets the third cost significance requirement.

We solicited public comment on whether Vivistim® System meets the device pass-through payment criteria discussed in this section, including the cost criteria for device pass-through payment status.

We did not receive any comments with regard to any of the cost significance requirements specified at § 419.66(d). Based on our findings from the first, second, and third cost significant tests, we believe that the Vivistim® System meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the Vivistim® System meets the requirements for device pass-through payment status described at § 419.66. As stated previously, devices that

are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, and we believe Vivistim® System meets those other criteria. Therefore, effective beginning January 1, 2023, we are finalizing approval for device pass-through payment status for Vivistim® System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

2. Traditional Device Pass-through Applications

(1) The BrainScope TBI (model: Ahead 500)

BrainScope Company Inc. submitted an application for a new device category for transitional pass-through payment status for the BrainScope Ahead 500 system (hereinafter referred to as the BrainScope TBI) for CY 2023. The BrainScope TBI is a handheld medical device and decision-support tool that uses artificial intelligence (AI) and machine learning technology to identify objective brain-activity based biomarkers of structural and functional brain injury in patients with suspected mild traumatic brain injury (mTBI). According to the applicant, the BrainScope TBI is an FDA-cleared, portable, non-invasive, point-of-care device and disposable headset intended to provide results and measures to aid in the rapid, objective, and accurate diagnosis of mTBI. Per the applicant, the BrainScope TBI is intended to be used in emergency departments (ED), urgent care centers, clinics, and other environments where used by trained medical professionals under the direction of a physician.

According to the applicant, the BrainScope TBI is comprised of two elements: (1) the Ahead 500, a disposable forehead-only 8-electrode headset temporarily applied to the patient's

skin to assess brain injury (the wounded area) which records electroencephalogram (EEG) signals; and (2) a reusable handheld device (hereinafter "Handheld Device"), which includes a standard commercial off-the-shelf handheld computer connected to a custom manufactured Data Acquisition Board (DAB) via a permanently attached cable. The applicant stated that the BrainScope software (including proprietary BrainScope algorithms) and a kiosk mode application running on Android are loaded onto an off-the-shelf handheld computer configuration. The disposable headset is attached to the DAB, which collects the EEG signal and passes it as a digital signal to the Handheld Device to perform the data processing and analysis.

According to the applicant, the BrainScope TBI device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (qEEG) parameters from frontal locations on a patient's forehead. Patient information is transferred to electronic health records via USB connected to a computer. The BrainScope TBI calculates and displays raw measures for the following standard qEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. The applicant asserts that these raw measures are intended to be used for post-hoc analysis of EEG signals for interpretation by a qualified user. Per the applicant, the device can be used as a screening tool and aid in determining the medical necessity of head computerized tomography (CT) scanning.

With respect to the newness criterion at § 419.66(b)(1), on September 11, 2019, the applicant received 510(k) clearance from FDA for the BrainScope TBI as a Class II device for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion/mild traumatic brain injury (mTBI)). We received the application for a new device category for transitional pass-through payment status for the BrainScope TBI on

February 23, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether the BrainScope TBI meets the newness criterion.

We did not receive public comments in regard to whether the BrainScope TBI meets the eligibility criteria at § 419.66(b)(1). Based on the fact that the BrainScope TBI application was received on February 23, 2022, within 3 years of the date of the initial FDA marketing authorization, we agree with the applicant that the BrainScope TBI meets the criteria of § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the BrainScope TBI is integral to the service provided and is used for one patient only. Per the applicant, the Ahead 500 component records EEG signals via a disposable forehead-only 8-electrode headset and is temporarily applied to the patient's skin to assess brain injury. We noted that while the Ahead 500 component is used for one patient only and is temporarily applied to the patient's skin, the device is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by 42 CFR 418.66(b)(3). We further noted that the other component of the BrainScope TBI, the Handheld Device, does not come in contact with the patient's tissue, and the device is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by § 418.66(b)(3). Per the applicant, the Handheld Device is used by multiple patients. We further questioned whether this device may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered in accordance with the device eligibility requirements of § 419.66(b)(4). The applicant did not indicate if the BrainScope TBI is a supply or material furnished incident to a service. We

solicited public comments on whether the BrainScope TBI meets the eligibility criteria at § 419.66(b).

We did not receive public comments regarding whether the BrainScope TBI meets the eligibility criteria at § 419.66(b)(3) or § 419.66(b)(4). With respect to the eligibility criterion at § 419.66(b)(3), in the proposed rule, we noted that the Ahead 500 component of BrainScope TBI is not surgically implanted or inserted or applied in or on a wound or other skin lesion. In addition, we noted that the other component of the BrainScope TBI, the Handheld Device, is used by multiple patients, does not come in contact with the patient's tissue, and is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by 42 CFR 418.66(b)(3).

With respect to the eligibility criterion at § 419.66(b)(4), based on the information provided in the application, we have determined that the Handheld Device component of the BrainScope TBI is an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered in accordance with the device eligibility requirements in the proposed rule and, as such, does not meet the eligibility criteria at § 419.66(b)(4).

BrainScope TBI does not meet the eligibility criteria to be considered a device for transitional pass-through payment. Therefore, we did not evaluate the product on the other criteria required for transitional pass-through payment for devices, including, existing or previous categories, the substantial clinical improvement criterion, and the cost criteria. We are not approving BrainScope TBI for transitional pass-through payment status for CY2023 because the product does not meet the eligibility criteria to be considered a device.

We note that we received public comments with regard to the cost criteria for this device, but, because we have determined that the device does not meet the eligibility criteria and

therefore, is not eligible for approval for transitional pass-through payment status for CY 2023, we are not summarizing comments received or making a determination on those criteria in this final rule.

(2) NavSlim™ and NavPencil

Elucent Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the NavSlim™ and NavPencil (referred to collectively as "the Navigators"). The applicant described the Navigators as single-use (disposable) devices for real-time, stereotactic, 3D navigation for the excision of pre-defined soft tissue specimens.

According to the FDA 510(k) Summary (K183400) provided by the applicant,[25] the Navigators are a component of the applicant's EnVisio™ Navigation System[26] which is intended only for the non-imaging detection and localization (by navigation) of a SmartClip™ Soft Tissue Marker (SmartClip™) that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.[27] We noted in CY 2023 OPPS/ASC proposed rule that the applicant submitted a separate application for pass-through payment status for the SmartClip™ for CY 2023, as discussed in a subsequent section. The applicant explained that the sterile, single-use Navigators affix to an electrocautery (surgical cutting) tool and, in combination with the other EnVisio™ Navigation System components and the SmartClip™, provide real-time intraoperative 3D navigation to the tumor and margin. The applicant explained that, at the time

[25] As explained later in this section, the applicant received FDA 510(k) clearance for the EnVisio™ Navigation System, which includes the Navigators.
[26] The FDA 510(k) Summary for the EnVisio™ Navigation System states that the EnVisio™ Navigation System "equipment components" are the Console, Heads Up Display, Patient Pad and Foot Pedal. The Navigator is listed as a separate, sterile, non-patient contacting, single-use system component. The applicant submitted an application for pass-through payment status only for the Navigator component of the EnVisio™ Navigation System.
[27] The SmartClip™ has a separate FDA 510(k) clearance. Based on the FDA 510(k) Summary for the EnVisio™ Navigation System, the SmartClip™ does not appear to be part of the EnVisio™ Navigation System.

of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System activate the implanted SmartClip™ within a 50cm x 50cm x 35cm volume. The applicant further explained that the SmartClip™ contains an application-specific integrated circuit (ASIC) which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision. The applicant asserted that this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D. According to the applicant, the Navigators enable intraoperative visualization by displaying real-time stereotactic 3D guidance from the tip of the surgical tool enabling minimally invasive removal of pre-defined tissue specimen (tumor and margin). The applicant stated that surgeons are able to visualize the directional distances to make excisional plane of each margin in-situ without using conventional imaging (e.g., ultrasound).

The applicant stated that there are two types of Navigators: (1) the NavSlim™ (which the applicant described as a lightweight model that allows integration with a broader range of electrosurgical tools, with or without smoke evacuation); and (2) the NavPencil (which, according to the applicant, incorporates a small screen in the surgical sightline that mimics the EnVisio™ Navigation System operating room monitor). The applicant also asserted that the integration of the Navigators with the single use, sterile electrocautery tool enables a single, light weight tool that can be utilized in situ for a minimally invasive surgery without infection risk. According to the applicant, the Navigators reduce the risk of tumor microenvironment caused by tissue disruption of non-targeted tissue. The applicant stated that the patient populations that can benefit from this technology are those that have biopsy proven cancers in organs that lack anatomic landmarks like breast, abdomen, and head and neck.

The applicant stated that the Navigators are the first devices to provide precise real-time navigation with a large patient volume of 50cm x 50cm x 35cm (per the applicant, encompassing > 99 percent of breast cancer patient habitus and > 90 percent of lung cancer patient habitus). In addition, the applicant asserted several other clinically differentiating features from prior products. First, the applicant stated that the Navigators process 240 simultaneous data streams solving for location 16 times per second with millimeter level of accuracy and display it to the surgeon based upon actual location of the defined lesion as it is manipulated in situ, not based on imaging that occurred days or weeks before. The applicant asserted that as the tissue is moved or manipulated during a surgical intervention, the location is instantaneously updated. According to the applicant, this allows for intelligent, real-time, intraoperative visualization and guidance for the surgeon, enabling precise removal of a defined tissue specimen (including tumor and margin). Furthermore, the applicant asserted that the accurate and real-time wireless location eliminates any potential registration errors that are typically found in devices that use pre-procedure imaging for guidance. The applicant explained that no static pre-procedure imaging is necessary eliminating the potential of mis-registration due to patient or tissue movement. In addition, the applicant stated that the Navigators provide 3D guidance – medial/lateral, inferior/superior and anterior/posterior, as well as the most direct path, and asserted that this is increasingly important in treating lobular and deep tumors. The applicant also claimed that because the guidance is from the tip of the cutting tool, exact measurements can be taken in situ at the exact cutting location. In addition, per the applicant, the Navigators allow for an oncoplastic[28] approach – the applicant stated that because the location is not tethered or

[28] According to Columbia University Irving Medical Center, oncoplastic breast surgery combines the techniques of traditional breast cancer surgery with the cosmetic advantages of plastic surgery. https://columbiasurgery.org/conditions-and-treatments/oncoplastic-breast-surgery

constrained in any way, the surgeon can choose the best cutting approach to achieve the optimal oncoplastic outcome. Finally, the applicant added that the Navigators provide the ability to distinctly identify and navigate up to three separate lesions in the same patient.

With respect to the newness criterion at § 419.66(b)(1), on March 22, 2019, the applicant received 510(k) clearance from FDA to market the EnVisio™ Navigation System (which, as explained previously, includes the Navigators) for the non-imaging detection and localization (by navigation) of a SmartClip™ that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Navigators on February 28, 2022, which is within 3 years of the date of the initial FDA marketing authorization. In the CY 2023 OPPS/ASC proposed rule, we solicited public comments on whether the Navigators meet the newness criterion.

Comment: The applicant stated that the pass-through payment application for the Navigators was submitted within 3 years of the date of the initial FDA marketing authorization.

Response: We appreciate the applicant's input. Because we received the Navigator pass-through payment application on February 28, 2022, which is within 3 years of March 22, 2019, the date of FDA premarketing approval, we agree that the Navigators meet the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Navigators are an integral part of the service furnished and are used for one patient only. However, the applicant did not specifically indicate whether the Navigators come in contact with human tissue and are surgically implanted or inserted or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3).[29] The FDA 510(k) Summary (K183400) states that the

[29] In the proposed rule, we noted that by contrast, the SmartClip™, discussed in the next section of this preamble, is inserted into human tissue.

Navigator is a sterile, non-patient contacting, single-use device. In the CY 2023 OPPS/ASC proposed rule, we stated that we would welcome comments on whether the Navigators meet the requirements of § 419.66(b)(3). The applicant also did not indicate whether the Navigators meet the device eligibility requirements at § 419.66(b)(4), which provide that the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). In the CY 2023 OPPS/ASC proposed rule, we solicited public comments on whether the Navigators met the eligibility criteria at § 419.66(b).

Comment: The applicant stated that the Navigators are single use devices intended for one patient only, and that without the Navigators, real-time surgical navigation using the Elucent system cannot be performed. The applicant asserted that, after attachment of a Navigator to the electrocautery tool, the surgeon runs a calibration step which allows the system to provide the precise location of the electrocautery tool tip relative to the SmartClip™ marker (implanted in or around the intended target). According to the applicant, this enables precise navigation to the tissue and surgeon-identified margins for excision. The applicant further stated the Navigator is inserted into the patient (generally into a surgical wound) as the surgeon uses the electrocautery tool to perform each component of the tissue excision, during which the Navigators come into temporary contact with patients' tissue. The applicant noted that the safety of this temporary contact has been confirmed through biocompatibility testing in accordance with ISO 10993.

In addition, the applicant stated that the Navigators meet eligibility requirements of § 419.66(b)(4) in that the Navigators are not (1) pieces of equipment, instruments, apparatus, implements, or items for which depreciation and financing expenses are recovered as depreciable

assets (the applicant noted that the Navigators are single use patient devices); (2) materials or supplies furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). The applicant noted that the Navigators are utilized for real time three-dimensional surgical navigation.

Response: We appreciate the applicant's input. Based on the information we have received and our review of the application, we agree with the applicant that the Navigators are integral to the service provided, used for one patient only, come in contact with human tissue, and are surgically implanted or inserted or applied in or on a wound or other skin lesion. In addition, we agree with the applicant that the Navigators meet the device eligibility requirements of § 419.66(b)(4) because they are not equipment, instruments, apparatus, implements, or items for which depreciation and financing expenses are recovered, and they are not supplies or materials furnished incident to a service. Therefore, based on the public comments we have received and our review of the application, we have determined that the Navigators meet the eligibility criteria at § 419.66(b)(3) and (b)(4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant stated that it was not aware of an existing pass-through payment category that describes the Navigators and listed an existing device category that it considered for comparison to the Navigators – specifically, HCPCS code C1748 (Endoscope, single-use (i.e., disposable), upper GI, imaging/illumination device (insertable)). The applicant stated that the Navigators are designed to meet the demands within the clinical environment for a

single-use (i.e., disposable) device to decrease infection rate, similar to the recent advancements of "disposable" endoscopes to address clinical demands for single-use to eliminate risks of cross contamination and improper sterilization. HCPCS code C1748 is a current pass-through payment category, effective beginning July 1, 2020. The applicant did not specifically differentiate the Navigators from devices in HCPCS code C1748. We stated in the CY 2023 OPPS/ASC proposed rule that, upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Navigators. We solicited public comments on whether the Navigators meet the device category criterion.

Comment: The applicant asserted that the Navigators are not currently described by any existing categories or any category previously in effect and were not being paid as an outpatient service as of December 31, 1996. The applicant clarified that in its application it sought to compare the Navigators to single use duodenoscopes for descriptive purposes only. According to the applicant, both products are designed to offer high performance in a single patient use device and provide clinical guidance during a medical procedure, and that both products reduce infection rates that may be a result of improper reprocessing. In addition, the applicant stated that both products provide guidance to diseased targeted tissue and demonstrate the precise location for targeted tissue removal. However, the applicant emphasized that the products are completely different in form and reflect different clinical uses. Per the applicant, the duodenoscope is an endoscope used endoluminally in the GI tract (vs. surgically for Navigators) for different clinical conditions (removal of gallstones, endoscopic retrograde cholangiopancreatography (ERCP), evaluation of the bile and pancreatic ducts with potential interventions). In contrast, the applicant stated that the Navigators are attached to an electrocautery device and are intended to guide

physicians to surgical margins through an open surgical wound during excision of diseased or malignant tissue.

Response: We agree with the applicant that the Navigators can be differentiated from devices in HCPCS code C1748, including single use duodenoscopes, and that there is no current or previously in effect category that describes the Navigators. After consideration of the public comments we received, we continue to believe that there is not a current or previously existing pass-through payment category that describes the Navigators, and therefore, the Navigators meet the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the use of the Navigators results in substantial clinical improvement over existing technologies by (1) reducing positive margin and re-excision rates, thereby decreasing the rate of subsequent therapeutic interventions; (2) reducing the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach (surgeons are not tethered to the best radiological approach, and the incision can be placed in the ideal location resulting in better oncoplastic results, less complex path to the lesion, and better visualization during

surgery). The applicant provided articles and case reports for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that use of the Navigators reduce positive margin and re-excision rates, the applicant submitted an abstract of a study performed to assess the impact of electromagnetic seed localization (ESL) using the EnVisio™ Navigation System and SmartClip™ compared to wire localization (WL) on operative times, specimen volumes, margin positivity, and margin re-excision rates.[30] Between August 2020 and August 2021, 97 patients underwent excisional biopsy (n=20), or lumpectomy with (n=53) or without (n=24) sentinel lymph node biopsy (SLNB) using ESL guidance at a single institution by 5 surgeons. The study authors matched these patients, one-to-one, with WL patients undergoing surgery between 2006 and 2021 based on surgeon, procedure type with stratification for those having and not having nodal procedures, and pathologic stage or benign pathology. When greater than one WL match was found, selection was randomized. The authors compared continuous variables (operative times, specimen volumes, excess volume excised) between patients undergoing ESL and WL using Wilcoxon rank sums tests. The authors compared categorical variables (positive margin rates, re-excision rates) using Fisher's exact tests. Median operative time for ESL versus WL for lumpectomy with SLNB was 66 versus 69 minutes (p=0.76) and without SLNB was 40 versus 34.5 minutes (p=0.17). Median specimen volume was 55cm^3 with WL versus 36cm^3 with ESL (p=0.0012). In those with measurable tumor volume, excess tissue excised was larger with WL compared to ESL (median=73.2cm^3 versus 52.5cm^3, p=0.017). Main segment margins were positive in 18 of 97 (19 percent) WL patients compared to 10 of 97 (10 percent) ESL patients

[30] Jordan R, Rivera-Sanchez L, Kelley K, O'Brien M, et al. The Impact of an Electromagnetic Seed Localization Device as Versus Wire Localization on Breast Conserving Surgery: A Matched Pair Analysis. Abstract presented at: 23rd Annual Meeting of The American Society of Breast Surgeons; April 6-10, 2022. https://www.breastsurgeons.org/meeting/2022/docs/2022_Official_Proceedings_ASBrS.pdf

(p=0.17). In the WL group, 13 of 97 (13 percent) had margin re-excision at a separate procedure, compared to 6 of 97 (6 percent) in the ESL group, (p=0.15). The authors concluded that ESL is superior to WL because it provided more accurate localization, evidenced by smaller specimen volume with less excess tissue excised, despite similar operative times. In addition, the authors reported that, although not statistically significant, ESL resulted in lower positive margin rates and lower margin re-excision rates compared to WL. The authors further noted that ESL allows for preoperative localization, eliminating same day operative delays, and single tool 3D localization. The authors concluded that further studies comparing ESL to other non-wire localization techniques are required to refine which localization technology is most advantageous in breast conservation surgery.

The applicant provided a second article consisting of a clinical paper from the Moffitt Cancer Center that, per the applicant, is pending publication.[31] The paper presented three cases from the Moffitt Cancer Center, including radiographic and other images, employing three different methods of breast mass localization: (1) SmartClip™, (2) SAVI SCOUT® radar reflector localizer, and (3) traditional wire localizer. The authors stated that the purpose of the paper was to educate the audience about the technological advances regarding breast mass localization and to discuss the advantages and disadvantages of SmartClip™ localizers, SAVI SCOUT® localizers, and wire localizers.

The authors first discussed wire localization, stating that wire localization involves image-guided insertion of a guidewire into a targeted mass and that the use of multiple wires allows for bracketing of multiple lesions or a large lesion. The authors asserted that, while effective in localization, this procedure has drawbacks such as wire breakage, patient discomfort,

[31] Ibanez J, Wotherspoon T, Mooney B, Advances in Image Guided Breast Mass Localization Techniques (undated). Submitted by the applicant with its application on February 28, 2022.

wire migration while moving or transporting the patient, and the need to surgically remove the wire the same day that it is placed due to this risk of migration.

The authors also discussed radar reflector localizers such as SAVI SCOUT®, which are small devices that can be placed into a targeted mass at any time prior to lumpectomy. The authors explained that once a surgeon gains a general idea of the mass' location by looking at the post localizer placement mammogram, this localizer is "hunted" for intraoperatively using a special handheld device which provides auditory feedback but does not provide location details until it is found via the auditory feedback. The authors cited a retrospective study at the Moffitt Cancer Center which, according to the authors, indicated that localization using SAVI SCOUT ® was successful for 125 out of 129 patients (97 percent, 95 percent Confidence Interval 92-99 percent) and showed that in comparison to wire localization, SAVI SCOUT® provides improved patient comfort and eliminates the need to perform the surgery on the same day as the localization procedure.[32]

Finally, the authors discussed localization using the SmartClip™. The authors noted that the SmartClip™ is the first device to provide three-plane localization information. The authors stated that a monitor displays the approximate position of the SmartClip™ allowing everyone in the operating room to assist with the localization of the SmartClip™ and provide knowledge of its location prior to and throughout the surgery. They further noted that the SmartClip™ localizer can be visualized on a small screen mounted on the electrocautery tool which, similar to the monitor, depicts the direction and depth to the SmartClip™. According to the authors, this provides real-time visual feedback to surgeons as the electrocautery tool moves and allows them

[32] Falcon S, Weinfurtner RJ, Mooney B, Niell BL. SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting. Clin Imaging. 2018 Nov-Dec; 52:280-286. doi: 10.1016/j.clinimag.2018.07.008. Epub 2018 Jul 24. PMID: 30193186.

to find the clip without having to look up at the operating room monitor. The authors asserted that the three-axis visualization eliminated the need to search for the clip since the location is always known, and that the availability of the SmartClip™ in three colors with different signals eases differentiation between localizers and allows for bracketing of masses.

The authors concluded that wire localization has drawbacks such as wire breakage, patient discomfort, high chances of migration, and narrow placement timeframes, which have been mitigated over the past decade by various soft tissue localizers such as SAVI SCOUT® (radar reflector localizer). The authors concluded that the SmartClip™, which they refer to as a new localizer, may potentially resolve other difficulties encountered with the soft tissue localizers that they currently use. Finally, the authors noted that a clinical study is currently underway at the Moffitt Cancer Center to evaluate the advantages of using the SmartClip™ in clinical practice.

In addition, the applicant provided two physician case reports, each describing the use of the EnVisio™ Navigation System and SmartClip™ in a single patient (62 and 59-year-old female breast cancer patients). Each case report described the patient's history, diagnostic tools utilized, pre-operative, peri-operative, and/or post-operative course, pathology results, as well as the physician's perceptions of the SmartClip™ or EnVisio™ Navigation System. In the first surgical case report,[33] the surgeon noted that the foot pedal activation of the EnVisio™ Navigation System allowed toggling between two SmartClip™ devices, allowing complete dissection around the periphery of the mass to obtain a precise margin. The surgeon asserted that with one marker, there would have been a higher risk of a positive margin. In the second surgical

[33] Kruper, Laura, Bracketing Lobulated Breast Lesion with the EnVisio™ Navigation System using Differentiated SmartClip™.

case report,[34] the surgeon similarly noted that the EnVisio™ Navigation System helped her to map out and be more precise in her incision location and lumpectomy dissection.

The applicant also submitted several articles in general support of its application, which we summarized in the CY 2023 OPPS/ASC proposed rule as follows. An article from the Mayo Clinic concluded that intraoperative pathologic assessment with frozen-section margin evaluation of all neoplastic breast specimens allows for immediate re-excision of positive or close margins during the initial operation and results in an extremely low reoperation rate of <2%.[35] Another article addressed the relationship between post-surgery infection and breast cancer recurrence and concluded that there is association between surgical site infection and adverse cancer outcomes, but the cellular link between them remains elusive.[36] Furthermore, a study from the Mayo Clinic concluded there was no reduction in the surgical site infection rate among patients who received postoperative antibiotic prophylaxis after breast surgery.[37] In addition, a study from Washington University School of Medicine concluded that surgical site infection (SSI) after breast cancer surgical procedures was more common than expected for clean surgery and more common than SSI after non-cancer-related breast surgical procedures.[38] A review article from the Department of Radiation Oncology, Case Western Reserve University and University Hospitals in Cleveland surmised that precision medicine holds the promise of

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[34] Henkel, Dana, Single SmartClip™ Case.
[35] Racz JM, Glasgow AE, Keeney GL, Degnim AC, Hieken TJ, Jakub JW, Cheville JC, Habermann EB, Boughey JC. Intraoperative Pathologic Margin Analysis and Re-Excision to Minimize Reoperation for Patients Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2020 Dec;27(13):5303-5311. doi: 10.1 245/s10434-020-08785-z. Epub 2020 Jul 4. PMID: 32623609.
[36] O'Connor RÍ, Kiely PA, Dunne CP. The relationship between post-surgery infection and breast cancer recurrence. J Hosp Infect. 2020 Nov;106(3):522-535. doi: 10.1016/j.jhin.2020.08.004. Epub 2020 Aug 13. PMID: 32800825.
[37] Throckmorton AD, Boughey JC, Boostrom SY, Holifield AC, Stobbs MM, Hoskin T, Baddour LM, Degnim AC. Postoperative prophylactic antibiotics and surgical site infection rates in breast surgery patients. Ann Surg Oncol. 2009 Sep;16(9):2464-9. doi: 10.1245/s10434-009-0542-1. Epub 2009 Jun 9. PMID: 19506959.
[38] Olsen MA, Chu-Ongsakul S, Brandt KE, Dietz JR, Mayfield J, Fraser VJ. Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg. 2008 Jan;143(1):53-60; discussion 61. doi: 10.1001/archsurg.2007.11. PMID: 18209153.

truly personalized treatment which provides every individual breast cancer patient with the most appropriate diagnostics and targeted therapies based on the specific cancer's genetic profile as determined by a panel of gene assays and other predictive and prognostic tests.[39] An abstract on the subject of prognostic factors for surgical margin status and recurrence in partial nephrectomy concluded that (1) surgical margin positivity after partial nephrectomy is not significantly associated with tumor characteristics and anatomical scoring systems, (2) surgical indication for partial nephrectomy has a direct influence on positive surgical margin rates, and (3) tumor size and stage after partial nephrectomy are valuable parameters in evaluating the recurrence risk.[40] Lastly, a study examining the significance of resection margin in hepatectomy for hepatocellular carcinoma concluded that the width of the resection margin did not influence the postoperative recurrence rates after hepatectomy for hepatocellular carcinoma.[41]

Based on the evidence submitted with the application, we noted the following concerns in the CY 2023 OPPS/ASC proposed rule. We noted that the first study appeared to be unpublished, and it was not clear whether it had been submitted for publication in a peer-reviewed journal. In addition, we stated that the study involved a sample of 97 patients from one institution and appeared to be written as a feasibility study for a potentially larger randomized control trial. Notably, the authors of this study stated that further studies are required to compare ESL to other non-wire localization techniques to refine which localization technology is most advantageous in breast conservation surgery. Furthermore, we indicated that the authors did not

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[39] Eleanor E. R. Harris, "Precision Medicine for Breast Cancer: The Paths to Truly Individualized Diagnosis and Treatment", International Journal of Breast Cancer, vol. 2018, Article ID 4809183, 8 pages, 2018. https://doi.org/10.1155/2018/4809183.

[40] Demirel HC, Çakmak S, Yavuzsan AH, Yeşildal C, Türk S, Dalkılınç A, Kireççi SL, Tokuç E, Horasanlı K. Prognostic factors for surgical margin status and recurrence in partial nephrectomy. Int J Clin Pract. 2020 Oct;74(10):e13587. doi: 10.1111/ijcp.13587. Epub 2020 Jul 14. PMID: 32558097.

[41] Poon, R. T., Fan, S. T., Ng, I. O., & Wong, J. (2000). Significance of resection margin in hepatectomy for hepatocellular carcinoma: A critical reappraisal. *Annals of surgery*, *231*(4), 544–551. https://doi.org/10.1097/00000658-200004000-00014.

report the sex or age of the study participants. Additionally, the authors reported that the differences in positive margin and re-excision rates between ESL and WL groups were not statistically significant. We also noted a potential concern regarding practice/selection effects bias inherent in the methodology presented.

In addition, we noted that the second article was an undated,[42] unpublished descriptive clinical paper comparing three different breast mass localization techniques in three cases from one institution. The applicant stated that this paper is pending publication but provided no further details regarding the status of the paper. We also explained that the paper did not systematically compare the techniques across any measurable variables and the authors indicated that a clinical study was underway at the institution to evaluate the SmartClip™ in clinical practice. Similarly, we noted that the physician case reports were solely descriptive in nature – they presented each physician's anecdotal experience using the EnVisio™ Navigation System and SmartClip™. Furthermore, we noted that the applicant provided several additional articles that, while informative, did not involve the Navigators and did not appear to directly support the applicant's claim of substantial clinical improvement. We stated that we would welcome additional information and evidence from larger, multi-center studies that provide comparative outcomes between the Navigators and existing technologies.

In the CY 2023 OPPS/ASC proposed rule, we further stated that none of the articles and case reports provided conclusive evidence that the use of the Navigators reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant. In addition, we indicated that the articles and case reports provided by the applicant described the use of the subject devices only in breast cancer surgery cases. As reported by the applicant, the Navigators

[42] Although the applicant reported the date of the study as January 2021, the copy of the study provided by the applicant was not dated.

can also be used for patients that have biopsy proven cancers in other organs that lack anatomic landmarks like the abdomen and head and neck. We stated in the proposed rule that we would welcome additional evidence of substantial clinical improvement in cases related to non-breast cancer related procedures.

We solicited public comments on whether the Navigators meet the substantial clinical improvement criterion.

Comment: All commenters addressing the substantial clinical improvement criterion offered support for approval of the application.

Some commenters, including the applicant, noted that for many years, the standard of care for breast conservation surgery has been wire localization and that little progress has been made. Such commenters noted that compared to the investments and advances that have been made in surgical technologies for other types of cancer (including male-predominant cancers such as prostate cancer) to reduce positive margin rates and increase quality of life, the tools for breast cancer surgery have remained limited. According to commenters, advances in surgical technologies for other types of cancer have included minimally invasive approaches inclusive of laparoscopic as well as robotic surgery, image-fusion, and advanced navigation. Such commenters considered the under-resourcing of breast surgery to be an equity issue due to the fact that breast surgery is primarily performed on women, and one commenter noted, in particular, that the downstream impacts of repeat surgeries (increased disfigurement, anxiety, infection risk, economic costs, time away from work and family) are particularly impactful to working women, especially those of child-bearing age and lower socio-economic status. In addition, a commenter noted that breast tissue, unlike the liver or lungs, can be variably thick or dense versus fatty depending on the age and genetics of the patient, and that this makes the

localization of abnormalities or cancers in a breast difficult as each case can be different depending on the amount of fat versus dense tissue and the patient's breast size. These commenters believed that advances in technology are needed in breast surgery to improve surgical results.

Several commenters described numerous drawbacks and difficulties associated with wire localization techniques, including the following: (1) some patients require up to 4 wires to "bracket" an abnormality in the breast; (2) trauma and pain associated with having wires placed and then extruding from a breast on the morning of surgery; (3) scheduling difficulties associated with wire placement on the day of surgery; (4) movement or displacement prior to or during surgery; (5) wires can be cut or "lost" during the procedure, especially if the cautery or bovie gets too close to them during the procedure; and (6) wires are designed to have a small "thicker" portion placed at the site of the tumor or abnormality; this small thick portion is difficult to place accurately and if it migrates slightly can change the orientation of the excision. In addressing difficulties in localizing the wires, a commenter explained that surgeons attempt to localize the tumor by "following the wire," palpation, and educated guesses as to where to resect tissue. Several commenters noted that these difficulties in accurate tumor localization have resulted in high re-excision rates. A commenter noted that over 15-20% of patients annually require a second surgery to remove more breast tissue because the localization was inexact at the time of the first surgery. A second commenter stated that a recent meta-analysis showed an average 22% re-excision rate for inadequate margins after primary lumpectomy. This commenter asserted that the human and health care costs of this failure rate are high and fall disproportionately on women. In addition, a commenter reported that when using an alternative wire-free solution with a radar detection marker, surgeons at his institution reported an increase in re-excision rates,

nearly doubling that of wires. Commenters asserted that, as a result of difficulties and complications with wire techniques, new technologies for localizing a breast and/or lymph node abnormality requiring excision in the operating room are needed.

Several commenters described clinical and surgical benefits of using the Navigator and SmartClip™ based on experience using this technology. Most of these commenters stated that using this technology decreases positive surgical margin and re-excision rates. A commenter noted that the system not only localizes the actual tumor targeted for removal, but also shows the surgeon suggested margins. That commenter added that with the Navigators and SmartClip™, the specimens are more circumferential and consistent at a fixed (but surgeon selected) distance from the implanted clip which has resulted in fewer positive margins, reducing the need for a second surgery. Other commenters explained that the technology allows the surgeon to track the position of the implanted clip during surgery in 3D with real-time updates, allowing the surgeon to have an objective view of the tip of the surgical instrument with respect to the SmartClip™, which according to commenters, can result in decreases in both positive margin and re-excision rates.

In addition, a few commenters noted that the technology results in removal of less normal breast tissue, with one commenter noting that early data from major cancer centers is starting to show that less normal tissue is being removed when the Elucent technology is used. Commenters noted that this has major implications for post-surgical pain, deformity, oncoplastic reconstructions, and complications. A commenter asserted that it is unusual for a device to simultaneously decrease deformity, pain and suffering, health care costs, and cancer metrics like positive margin and re-excision rates.

Furthermore, a commenter noted that, in their anecdotal experience, the use of the Navigators and SmartClip™ saves overall operating room time compared to the hook-wire technique. This commenter asserted that this decreases costs and anesthesia time and enables more efficient use of operating rooms for other cases. Another commenter reported that with the Navigators and SmartClip™, there is less need for synchronization with radiology for localization procedures. This commenter asserted that in the past, the need to have tumors localized in radiology before coming to the operating room caused a number of problems such as displaced wires, operating room delays, long patient waiting times with wires protruding from the breast, and decreased efficiency.

Some commenters described additional technical and operational advantages to using the Navigators and SmartClip™. These commenters noted that the Navigators and SmartClip™ are unique because they allow the surgeons to track the position of the SmartClip™ during surgery in 3D with real time updates. A few commenters specifically noted that the SmartClip™ contains an ASIC chip which is activated at surgery once the patient lays on the operative table. A commenter further asserted that the field of navigation is over 30cm and can enable identification in a large or small breast or one that is wide or narrow. This commenter claimed that the most important component of the system is the NavSlim and NavPencil which enable navigation in real time without using another device or probe. According to this commenter, the NavSlim and Pencil are placed onto the operative tool or cautery and do not have to be picked up intermittently.

Another commenter stated a significant technical advantage of the technology is that a 3D readout is generated as a graphic representation of the clip relative to the tip of the handpiece (compared to an audio signal only) as a reflection of distance, which per the commenter, is a

more intuitive way to understand the device localization. This commenter further stated that, perhaps most important to a surgeon, the detector portion of the handpiece is fixed to the cautery. According to this commenter, having the navigation portion of the system within the operative field for real-time detection significantly improves identification of the clip and the lesion, even when working in a small space or in detection of a very small target, as division or retraction of the tissue often causes the target to move in surgery. This commenter noted that with real-time and nearly continuous detection, loss or disorientation of the target is minimized while performing the operation.

A few commenters described clinical outcome data from their experience using the Navigators and SmartClip™. A commenter reported that he has decreased his re-excision rate from 16% in 2019 prior to the COVID pandemic to 5% in 2021. This commenter stated that he performs an average of 200 breast conservation surgeries per year. This commenter also added that the adoption of the Elucent technology has resulted in fewer operative interventions for his patients undergoing breast conservation, improved cosmesis with one surgery, improved oncoplastic approaches as well as less anxiety and fewer delays in oncologic care. A second commenter stated that in the five months that they have implemented the technology, they have seen re-excision rates drop to approximately 1.5%. Another commenter stated that his institution is in the process of analyzing its clinical outcomes data, which the commenter asserted illustrates the significant clinical impact of implementing the SmartClip™ and Navigator across six healthcare facilities and 235 surgical procedures.

Finally, a few commenters acknowledged the need for additional research and larger clinical trials to support the preliminary positive outcomes data, including the data indicating that the Navigators and SmartClip™ decrease re-excision rates in breast conservation surgery for

patients with breast malignancy. These commenters asserted that approval of pass-through payment for the Navigators and SmartClip™ would enable greater access to patients which will allow the surgical community to conduct additional studies and collect more comprehensive and multi-center data to further substantiate the clinical outcomes seen in early research studies.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in making our final determination of the substantial clinical improvement criterion, discussed below.

Comment: The applicant submitted comments in response to many of the concerns we expressed regarding the study abstract referenced in the proposed rule, which assessed the impact of ESL using the EnVisio Navigation System and SmartClip™ compared to wire localization. In response to our concern that the study was unpublished, the applicant stated that it submitted a manuscript for peer-review and potential publication. In response to our concern that this study appeared to be a feasibility study for a potentially larger randomized controlled trial, the applicant stated that the study authors did not make this statement and noted that prospective randomized controlled trials are exceedingly rare in this space and not considered necessary for adoption of a particular guidance technology. The applicant further claimed that the study referenced in the abstract has a rigorous cohort-matched design and a patient population size which is far beyond a feasibility study. In response to our concern about the lack of gender and age information, the applicant noted that this was an IRB-approved matched cohort analysis (1:1) of 194 patients (n=97 in both the study and control groups). The applicant further stated that the age in the ESL group was 64 versus 61 in the WL group (p=.015) (the applicant did not indicate whether these were average ages, median ages, or otherwise). The applicant added that the matched sample set included 190 females and four males. The applicant reiterated that the study

authors matched patients, one-to-one, based on surgeon, procedure type with stratification for those having or not having nodal procedures, and pathologic stage or benign pathology, and restated the numerical results from the study abstract (which we summarized in the CY 2023 OPPS/ASC proposed rule (87 FR 44593)).

In response to our concern that the differences in positive margin and re-excision rates between the ESL and WL groups were not statistically significant, the applicant asserted that the lack of statistical significance for re-excisions was driven solely by the sample size of the study. The applicant further noted that the retrospective cohort-matched design prioritized patient matching over sample size and the study was not prospectively powered for re-excision rates as the authors had no *a priori* knowledge that this would be an outcome of interest. The applicant claimed that, in hindsight, reasonably achievable increases in sample size would have made statistical conclusions possible. Specifically, the applicant claimed that with a sample size of 150 (rather than 97) in each group, and assuming identical re-excision rates, the difference between the ESL and WL groups becomes statistically significant (p=0.049, Fisher's exact test). The applicant further noted that ESL results were from the initial cases performed with ESL at the study center and included a learning curve, whereas the control wire localization cases were performed at a time where the learning curve had been overcome and surgeons had decades of experience with thousands of wire localization cases. In addition, the applicant asserted that its system is being used predominantly for the treatment of breast cancer, and that the early results demonstrate lower positive margin rates and removal of less normal tissue resulting in lower rates of re-excision by >50%.

The applicant also noted other clinical impacts of the Navigators and SmartClip™ in supporting its claim of substantial clinical improvement. The applicant claimed that the

electromagnetic navigation allows for more precise and accurate tissue localization, resulting in 34.5% less normal functioning tissue being removed at the time of surgery with ESL compared to WL. According to the applicant, this results in less deformity and simpler oncoplastic reconstructions and may decrease complications and post-procedure pain. The applicant noted that the amount of excess (i.e., unnecessary) tissue removed was statistically significant between the WL and ESL groups in the study abstract it referenced, and that even with less tissue removed, the re-excision rate decreased for the ESL group. According to the applicant, the removal of less normal functioning non-neoplastic tissue during surgery when using the Navigator compared to WL will cause less tissue deformity, pain, and suffering and, in and of itself, is evidence of substantial clinical improvement under § 419.66(c)(2) – specifically, that the removal of less normal functioning tissue substantially improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

In response to our concern that the applicant had not provided conclusive evidence that use of the Navigators reduces surgical site infection rates, the applicant explained that this study was not specifically powered to address surgical site infections, but stated that when compared to wires, there are several surgical principles that should contribute to lower SSI rates in adequately powered studies. The applicant noted that the protrusion of the wire from the patient is an infection risk because the wire is placed prior to surgery (often hours) in a separate physical location from the operating room (often radiology) and the patient is then transported to the operating room with a semi-sterile dressing. The applicant added that the wire is a further infection risk due to the added tissue trauma associated with removal of larger volumes of tissue to minimize positive margins and future additional procedures.

In response to our concern that the applicant had not provided conclusive evidence that use of the Navigators reduces risk of tissue marker migration, the applicant claimed that there is currently no standard to determine tissue marker migration other than the histopathological results. The applicant stated that migration of the marker clip would result in an increase in positive margins and re-excisions as well as an increase in the volume of tissue excised due to uncertainty as to the exact position of the target, but that neither of these findings was seen in the study. The applicant noted that the lower re-excision rates and lower positive margins seen in the ESL group are evidence of lack of tissue marker migration, in addition to the smaller specimens and excess tissue excised.

Finally, the applicant asserted that breast cancer is the second leading cause of cancer mortality in women, and that the current standard localization technique (hook-wire) is both insufficient and has not changed for many decades, despite high positive margin rates. The applicant noted that in contrast to this, during this same time period, larger investments in advanced technologies have been made to decrease positive margin rates and increase quality of life in male-predominant tumors such as prostate cancer. Thus, the applicant asserted that technology-driven improvements in patient outcomes are particularly important in breast cancer.

Response: We appreciate the applicant's responses to our questions as well as the other comments we received about the Navigators. However, we maintain the concerns we articulated in the proposed rule. The provided published studies did not demonstrate a statistically significant difference in positive margin and re-excision rates between the ESL and WL technologies or provide evidence that SmartClip™ reduces surgical site infection rates or risk of tissue marker migration. Although the applicant noted that the amount of excess tissue removed was statistically significant between the WL and ESL groups in the study abstract it referenced,

we do not agree that this result, in and of itself, is evidence of substantial clinical improvement under § 419.66(c)(2) – that is, we do not believe that this result, in itself, is evidence that the technology substantially improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part. We continue to believe that additional information and evidence is necessary from larger, multi-center published studies (including studies involving non-breast cancer related procedures) that provide comparative outcomes between the Navigators and existing technologies. Because of these concerns, we do not believe that the Navigators represent a substantial clinical improvement relative to currently existing technologies. After consideration of the public comments we received, and our review of the device pass through application, we are not approving the Navigators for transitional pass-through payment status in CY 2023 because the device does not meet the substantial clinical improvement criterion. Because we have determined that the Navigators do not meet the substantial clinical improvement criterion, we are not evaluating in this final rule whether the device meets the cost criterion.

(3) SmartClip™

Elucent Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the SmartClip™ Soft Tissue Marker (SmartClip™). The applicant described the SmartClip™ as an electromagnetically activated, single-use, sterile soft tissue marker used for anatomical surgical guidance. According to the applicant, the SmartClip™ is the only soft tissue marker that delivers independent coordinates of location when used in conjunction with the applicant's EnVisio™ Navigation System (which includes the Navigators discussed previously in this final rule. Per the applicant, at the time of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System

activate the implanted SmartClip™ within a 50cm x 50cm x 35cm volume. The applicant further explained that the SmartClip™ contains an application-specific integrated circuit (ASIC), customized for use with the EnVisio™ Navigation System, which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision.[43] The applicant asserted that this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D.

The applicant stated that the SmartClip™ is assembled into a hermetically sealed, Parylene C coated glass cylinder and provided pre-loaded into a 15-gauge introducer needle available in various lengths (5cm, 7.5cm, 10cm). Per the applicant, using the introducer needle, the SmartClip™ is implanted directly into a tumor at the time of biopsy or during a separate procedure in advance of surgery. According to the FDA 510(k) Summary (K180640), the SmartClip™ can be implanted into various types of soft tissue, such as lung, gastrointestinal system, and breast, and can subsequently be detected using the EnVisio™ Navigation System or by means of radiography (including mammographic imaging), ultrasound, and magnetic resonance imaging (MRI). Per the applicant, it is utilized frequently in breast conserving surgery, lymph nodes, and head/neck cancers.

According to the applicant, up to three SmartClips™, each with a unique electromagnetic signature, can be implanted in a patient to mark and provide continuous location of multiple targets (for example, 3 lesions, or 2 lesions/1 lymph node) or to bracket either a large lesion or microcalcifications. The applicant claimed that the SmartClip™ enables the surgeon to choose

[43] Based on the FDA 510(k) Summary for the EnVisio™ Navigation System, the SmartClip™ does not appear to be a component of the EnVisio™ Navigation System; the SmartClip™ has a separate FDA 510(k) clearance as discussed later in this section.

the safest, least disfiguring (oncoplastic) approach and path to the tumor before the surgery. According to the applicant, providing surgical planning and excision lessens the impact of the disruption of non-targeted tissue. In addition, the applicant stated that the SmartClip™ enables the surgeon to measure and record specimen size post excision.

The applicant further asserted that the SmartClip™ is a significantly advanced version of an interstitial implant device, such as a gold fiducial marker, that is placed into a tumor directly to guide the surgeon to the location of a malignant lesion. The applicant claimed that the SmartClip™ has characteristics that differentiate it from conventional fiducial markers. First, the applicant stated that the SmartClip™ location is expressed relative to the patient's position – medial/lateral, inferior/superior, anterior/posterior with 2mm precision. Second, according to the applicant, the SmartClip™ location is instantaneous and updated 16 times per second reflecting any location change due to tissue manipulation and allowing alterations in the patient's position with no compromise in accuracy. Furthermore, the applicant asserted that the SmartClip™ provides seamless, real-time navigation, maintaining the 3D position of the lesion within the surgical space and relative to the surgical tools. The applicant added that the SmartClip™ is not subject to registration errors often seen with navigation that utilizes pre-procedure imaging for guidance. Furthermore, the applicant asserted that the SmartClip™ is ideal for minimally invasive procedures in that it does not require line of sight. The applicant also stated that the SmartClip™ does not utilize any radioactive materials or contain any ionizing radiation. Per the applicant, the SmartClip™ does not require a separate imaging modality, however, if another imaging modality is utilized, the SmartClip™ is radiopaque. Finally, the applicant stated that the SmartClip™ provides the following advantages compared to current localization methods (including preoperative wire localization): (1) no migration of the SmartClip™; (2) no depth

limitation, addressing broader patient population clinical needs; (3) no limitations on clinical approach for placement or surgical excision; (4) permanently implantable, should continuum of care change; (5) no risks for multifocal or extensive lesion markings for complex cases; (6) no required workflow changes for varied surgical tools; (7) can be placed remote from surgery (days or weeks) at the patient's convenience; (8) nothing protruding from the skin so there is no mechanical pathway for bacterial contamination; and (9) puncture is healed at the time of surgery.

With respect to the newness criterion at § 419.66(b)(1), on June 4, 2018, the applicant received 510(k) clearance from FDA to market the SmartClip™ for radiographic marking of sites in soft tissue and in situations where the soft tissue site needs to be marked for future medical procedures. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the SmartClip™ on February 28, 2022, which is more than 3 years from the date of the initial FDA marketing authorization. We note that in accordance with 42 CFR 419.66(b)(1), the pass-through payment application for a medical device must be submitted within 3 years from the date of the initial FDA approval or clearance, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case we will consider the pass-through payment application if it is submitted within 3 years from the date of market availability. The applicant asserted that the SmartClip™ could not be marketed until May 2019 because it is utilized in conjunction with the EnVisio™ Navigation System and FDA clearance for the EnVisio™ Navigation System was required prior to use of the SmartClip™ (as mentioned previously, the applicant received FDA clearance for the EnVisio™ Navigation System on March 22, 2019). We note that, according to the FDA 510(k) Summary and Indications for Use for the SmartClip™

(K180640) and the EnVisio™ Navigation System (K183400), the SmartClip™ also can be located and surgically removed through the use of imaging guidance such as x-ray, mammography, ultrasound, and MRI. According to the applicant, the EnVisio™ Navigation System enables the SmartClip™ as an intelligent interstitial soft tissue marker utilizing electromagnetic waves to display precise coordinates in each of three planes. The applicant further asserted that the SmartClip™ was designed to provide the surgeon the precise coordinates for target tissue removal and that this function requires the utilization of the electronic field generated by the EnVisio™ Navigation System. The applicant noted that while the SmartClip™ is visible and can be located using imaging guidance (such as ultrasound, MRI, or radiography), such imaging guidance would typically only be used in the removal of the targeted tissue should the SmartClip™ ASIC fault, so as to ensure patient care is not compromised. The applicant further stated that it did not consider pursuing marketability of the SmartClip™ as an unintelligent interstitial marker as the applicant believed that the action would not have resulted in meeting the unmet healthcare need for substantial clinical improvements. In addition, the applicant claimed that due to the impact of the COVID-19 pandemic, ambulatory surgical centers and outpatient facilities were restricted in performing breast cancer surgery, resulting in a verifiable delay. The applicant requested that CMS utilize the FDA clearance date for the EnVisio™ Navigation System (March 22, 2019) as the applicable date for the SmartClip™'s initial marketability. In the CY 2023 OPPS/ASC proposed rule, we solicited public comments on whether the SmartClip™ meets the newness criterion.

Comment: The applicant asserted that the COVID-19 pandemic, which started in the spring of 2020, and the subsequent halting of elective surgeries, screening mammography, and company access to hospitals substantially delayed the clinical implementation of the

SmartClip™ as well as the follow-on research necessary to file a successful pass-through application. The applicant stated that, in light of the COVID-19 global pandemic resulting in the suspension of both research and elective surgical care, it believes the newness criterion, which it stated is measured by available time on market, is achieved.

Response: We appreciate the applicant's input. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the SmartClip™ on February 28, 2022, which is more than 3 years from the date of the initial FDA marketing authorization (June 4, 2018). We do not agree that the COVID-19 pandemic created a basis for claiming a verifiable delay in U.S. market availability of the SmartClip™. The applicant received 510(k) clearance from FDA to market the SmartClip™ on February 4, 2018, which was well before the beginning of the pandemic and thus we do not believe the pandemic created a verifiable delay. In addition, in its application, the applicant requested that we utilize the FDA clearance date for the EnVisio™ Navigation System (March 22, 2019) as the applicable date for the SmartClip™'s initial marketability (which also was before the onset of the COVID-19 pandemic). In its application, the applicant asserted that it could not market the SmartClip™ until May 2019 because it is utilized in conjunction with the EnVisio™ Navigation System and FDA clearance for the EnVisio™ Navigation System was required prior to use of the SmartClip™. However, we note that, according to the FDA 510(k) Summary and Indications for Use for the SmartClip™ (K180640) and the EnVisio™ Navigation System (K183400), the SmartClip™ also can be located and surgically removed through the use of imaging guidance such as x-ray, mammography, ultrasound, and MRI. Thus, we do not believe the March 22, 2019, FDA clearance date for the EnVisio™ Navigation System created a verifiable delay in the market availability of the SmartClip™. Accordingly, we do not believe the applicant has

provided a basis for a verifiable delay in U.S. market availability. Finally, in response to the applicant's assertion that the newness criterion is measured by available time on the market, we note that where there is a documented, verifiable delay in market availability, under § 419.66(b)(1), CMS assesses compliance with the newness criterion by measuring amount of time from the date of market availability, not available time on the market; that is, where there is a verifiable delay, CMS will consider a pass-through application if it is submitted within three years from the date of market availability. After consideration of the public comments we received, and our review of the device pass through application, we have determined that the SmartClip™ does not meet the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the SmartClip™ is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. The applicant did not indicate whether the SmartClip™ meets the device eligibility requirements of § 419.66(b)(4), which provide that the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). In the CY 2023 OPPS/ASC proposed rule, we solicited public comments on whether the SmartClip™ meets the eligibility criteria at § 419.66(b).

Comment: The applicant asserted that the SmartClip™ meets eligibility requirements of § 419.66(b)(4) in that (1) it is not a piece of equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered as depreciable assets (the applicant noted that the SmartClip™ is a permanently implantable single use device), and (2) it

is not a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). The applicant noted that the SmartClip™ is utilized for real time three-dimensional surgical navigation. As such, the applicant asserted that the SmartClip™ meets the eligibility criteria at § 419.66(b).

Response: Based on the information we have received and our review of the application, we agree with the applicant that the SmartClip™ is integral to the service provided, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. In addition, we agree with the applicant that the SmartClip™ meets the device eligibility requirements of § 419.66(b)(4) because it is not a piece of equipment, instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Therefore, based on the public comments we have received and our review of the application, we have determined that the SmartClip™ meets the eligibility criteria at § 419.66(b)(3) and (b)(4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant stated that it was not aware of an existing pass-through payment category that describes the SmartClip™.

The applicant identified three devices or device categories that it believes are most closely related to the SmartClip™: (1) hook-wire systems (the applicant did not provide an associated code, but listed Kopans (Bard and McKesson) and Dualok (McKesson) as types of such systems); (2) HCPCS code A4648 (Tissue marker, implantable, any type, each); and (3)

HCPCS code 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (Smartpill™)).[44]

Although HCPCS code A4648 is not an existing pass-through payment category, we noted in the CY 2023 OPPS/ASC proposed rule that a previous equivalent code, HCPCS code C1879 (Tissue marker (implantable)), was a pass-through payment category in effect between August 1, 2000 and December 31, 2002.[45] Pursuant to Change Request 8338, CMS deleted temporary HCPCS code C1879 on June 30, 2013, because this category of devices was described by permanent HCPCS code A4648. We stated in the Change Request that effective July 1, 2013, when using implantable tissue markers with any services provided in the OPPS, providers should report the use and cost of the implantable tissue marker with HCPCS code A4648 only.[46] According to the applicant, tissue markers described by HCPCS code A4648 are passive mechanical localization devices. The applicant explained that such tissue markers are generally made of gold or other radiographically opaque substances (usually metal). Per the applicant, compared to the SmartClip™, such tissue markers do not provide margin or 3D information, do not update in real-time, and require advanced radiographic capability (computed tomography, fluoroscopy, ultrasound) to be detected and localized. According to the applicant, these markers are only useful because they are visible either radiographically or to the naked eye. The applicant identified two types of gold fiducial markers – generic gold fiducial marker (IZI Medical) and

[44] HCPCS code 91112 is not a current or previous pass-through payment category. According to the applicant, the Smartpill™ is an ingestible pill that is tracked using a wearable device for short term pH and pressure testing for intestinal tract diagnostics. By contrast, the applicant noted that the SmartClip™ is permanently implantable within soft tissue to direct a surgeon for the purposes of removal of a lesion and margin.
[45] Medicare Claims Processing Manual, Ch. 4, section 60.4.2.
[46] Change Request 8338, June 7, 2013. The Medicare Claims Processing Manual further defines the devices encompassed by HCPCS code C1879 as material that is placed in subcutaneous or parenchymal tissue (may also include bone) for radiopaque identification of an anatomic site and adds that these markers are distinct from topical skin markers, which are positioned on the surface of the skin to serve as anatomical landmarks. Medicare Claims Processing Manual, Ch. 4, section 60.4.3.

generic soft tissue gold marker (Civco). The applicant explained that the SmartClip™ is an advanced interstitial implant that substantially improves upon both generic gold fiducial markers and common hook-wire localization systems. According to the applicant, passive mechanical tissue markers such as gold fiducial markers and hook-wire systems are related devices created for roughly the same purpose as the SmartClip™, but neither can be considered an adequate comparator due to the highly advanced technology embedded in the SmartClip™. In contrast to both generic gold fiducial markers and hook-wire systems, the applicant asserted that the SmartClip™ contains an ASIC which is activated at a specific frequency and provides location information regarding both the SmartClip™ and the surgical margins to the operating physician in near real-time. The applicant claimed that it is not aware of any other device that has this functionality. The applicant added that this data is calibrated relative to the tip of an electrocautery device or other operating instrument and is displayed in 3D so that the surgeon has an objective method of obtaining a negative concentric margin. According to the applicant, this is particularly useful for posterior and deep margins for which passive localization devices provide no information. The applicant asserted that it does not believe that the SmartClip™ is described by HCPCS code A4648.

We solicited public comments on whether the SmartClip™ meets the device category criterion.

Comment: A commenter stated that the SmartClip™ meets the criterion at § 419.66(c)(1) and can be differentiated from other tissue markers. The commenter stated that the SmartClip™ soft tissue marker has replaced the hook-wire, and other non-directional, wire-free localization "tissue markers" across multiple sites at his institution since early March of 2022. The commenter asserted that because the SmartClip™ offers the uniqueness of integrated intelligence

of precise location, he supported the claim that the SmartClip™ is the first and only soft tissue marker that provides the technical and clinical benefit of knowing the exact location within a three-dimensional space. The commenter added that the SmartClip™ is unique in that radiologists can approach the placement of the marker in any direction without any limitations on the depth, distance, or location of the targeted tissue. The commenter also asserted that the enhanced differentiation of the SmartClip™'s unique signature further allows placement that benefits complete removal of the tissue of concern. Per the commenter, the removal of complex lesions with the distant disease has been an area of concern for which improved localization markers have not been able to meet the clinical need. The commenter reported that his practice has explored alternative techniques and technologies, which increased re-excision rates, resulting in patients having to repeat the various procedures for localization and removal of additional tissue from the breast. The commenter added that since implementing the SmartClip™ soft tissue marker, his facilities have seen a significant reduction in the need for patients to return for additional interventions.

Another commenter noted that in the proposed rule, the applicant identified HCPCS code 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (SmartPill)) as one of the device categories it believed was most closely related to the SmartClip™ and indicated that the SmartClip™ is used in procedures described by HCPCS code 91112. The commenter disagreed with the applicant's statement that these procedures would be reported with the SmartClip™ device. Per the commenter, the SmartClip™ and SmartPill, an endoluminal capsule used in the diagnosis of GI disorders, are not related devices used for similar purposes. The commenter stated that while the SmartClip™ is implanted in soft tissue and is used as a surgical marker, the SmartPill capsule is

ingested, captures information as it moves through the GI tract, and passes naturally throughout the GI tract. According to the commenter, the SmartPill is intended to measure pH, pressure, and temperature throughout the GI tract, along with four different GI transit times. The commenter asserted that because the SmartClip™ and SmartPill, are not functionally related devices and have vastly different indications for use, it is unlikely that a surgical procedure to place a fiducial marker in soft tissue using the SmartClip™ device would be reported with the diagnostic procedure limited to the GI tract and described by CPT code 91112. The commenter requested that CMS remove reference to SmartPill from considerations related to the SmartClip™ pass-through application.

Response: We appreciate the information provided by the commenters and have taken this into consideration in making our final determination below regarding the criterion at § 419.66(c)(1).

Comment: The applicant stated that it does not believe the SmartClip™ is described by HCPCS code A4648 and explained that it can be differentiated from the passive tissue markers identified within HCPCS code A4648. According to the applicant, inert metal biopsy markers, gold fiducial markers, magnetic seeds, radioactive seeds, and hook-wires are used in conjunction with some form of detector to provide a localizable marker at the known site of disease. The applicant stated that these types of markers provide a visual location under imaging or are locatable with various types of detectors and are palpable at the time of surgery. The applicant added that, like the inert metal markers, the radioactive and magnetic markers are also passive, but can be located in the presence of a magnetic or radioactive detector. Per the applicant, the markers do not contain any computing capability within the marker itself, and thus no 3D data can be communicated. The applicant asserted that the SmartClip™ soft tissue marker is unique in

that it is designed to contain an ASIC. According to the applicant, this circuit is passive until it is in the presence of a specific radiofrequency at which time the SmartClip™ actively communicates with the Navigator to relay 3D coordinates to the surgeon at a rate of 16x per second. The applicant stated that the three different models (i.e., colors) of the SmartClip™ operate at slightly different frequencies so that they can be uniquely identified, individually located, and color coded for presentation to the surgeon.

Response: We appreciate the commenters' input. For the reasons specified by the commenters, we agree that the SmartClip™ can be differentiated from the passive tissue markers identified within HCPCS code A4648. We agree that passive mechanical tissue markers such as gold fiducial markers and hook-wire systems are related devices created for roughly the same purpose as the SmartClip™, but that neither can be considered an adequate comparator due to the highly advanced technology (ASIC) embedded in the SmartClip™ which can be activated at a specific radiofrequency and communicate 3D coordinates to the surgeon in real time.

In addition, we agree with the commenter who noted that the SmartClip™ and SmartPill are not functionally related devices and have vastly different indications for use. We further agree that it is unlikely that a surgical procedure to place a fiducial marker in soft tissue using the SmartClip™ device would be reported with the diagnostic procedure limited to the GI tract and described by CPT code 91112.

After consideration of the public comments we received, we believe that there is not a current or previously existing pass-through payment category that describes the SmartClip™, and therefore, the SmartClip™ meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has

demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

The applicant claimed that the use of the SmartClip™ results in substantial clinical improvement over existing technologies by, (1) reducing positive margin and re-excision rates, thereby decreasing the rate of subsequent therapeutic interventions; (2) reducing the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach (surgeons are not tethered to the best radiological approach, and the incision can be placed in the ideal location resulting in better oncoplastic results, less complex path to the lesion, and better visualization during surgery). The applicant provided articles and case reports for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that use of the SmartClip™ reduces positive margin and re-excision rates, the applicant submitted an abstract of a study performed to assess the impact of electromagnetic seed localization (ESL) using the EnVisio™ Navigation System and SmartClip™ compared to wire localization (WL) on operative times, specimen volumes, margin positivity, and margin re-excision rates.[47] Between August 2020 and August 2021, 97 patients

[47] Jordan R, Rivera-Sanchez L, Kelley K, O'Brien M, et al. The Impact of an Electromagnetic Seed Localization Device as Versus Wire Localization on Breast Conserving Surgery: A Matched Pair Analysis. Abstract presented at: 23rd Annual Meeting of The American Society of Breast Surgeons; April 6-10, 2022. https://www.breastsurgeons.org/meeting/2022/docs/2022_Official_Proceedings_ASBrS.pdf

underwent excisional biopsy (n=20), or lumpectomy with (n=53) or without (n=24) sentinel lymph node biopsy (SLNB) using ESL guidance at a single institution by 5 surgeons. The study authors matched these patients, one-to-one, with WL patients undergoing surgery between 2006 and 2021 based on surgeon, procedure type with stratification for those having and not having nodal procedures, and pathologic stage or benign pathology. When greater than one WL match was found, selection was randomized. The authors compared continuous variables (operative times, specimen volumes, excess volume excised) between patients undergoing ESL and WL using Wilcoxon rank sums tests. The authors compared categorical variables (positive margin rates, re-excision rates) using Fisher's exact tests. Median operative time for ESL versus WL for lumpectomy with SLNB was 66 versus 69 minutes (p=0.76) and without SLNB was 40 versus 34.5 minutes (p=0.17). Median specimen volume was 55cm^3 with WL versus 36cm^3 with ESL (p=0.0012). In those with measurable tumor volume, excess tissue excised was larger with WL compared to ESL (median=73.2cm^3 versus 52.5cm^3, p=0.017). Main segment margins were positive in 18 of 97 (19 percent) WL patients compared to 10 of 97 (10 percent) ESL patients (p=0.17). In the WL group, 13 of 97 (13 percent) had margin re-excision at a separate procedure, compared to 6 of 97 (6 percent) in the ESL group, (p=0.15). The authors concluded that ESL is superior to WL because it provided more accurate localization, evidenced by smaller specimen volume with less excess tissue excised, despite similar operative times. In addition, the authors reported that, although not statistically significant, ESL resulted in lower positive margin rates and lower margin re-excision rates compared to WL. The authors further noted that ESL allows for preoperative localization, eliminating same day operative delays, and single tool, 3D localization. The authors concluded that further studies comparing ESL to other non-wire

localization techniques are required to refine which localization technology is most advantageous in breast conservation surgery.

The applicant provided a second article consisting of a clinical paper from the Moffitt Cancer Center that, per the applicant, is pending publication.[48] The paper presented three cases from the Moffitt Cancer Center, including radiographic and other images, employing three different methods of breast mass localization: (1) SmartClip™, (2) SAVI SCOUT® radar reflector localizer, and (3) traditional wire localizer. The authors stated that the purpose of the paper was to educate the audience about the technological advances regarding breast mass localization and to discuss the advantages and disadvantages of SmartClip™ localizers, SAVI SCOUT® localizers, and wire localizers.

The authors first discussed wire localization, stating that wire localization involves image-guided insertion of a guidewire into a targeted mass and that the use of multiple wires allows for bracketing of multiple lesions or a large lesion. The authors asserted that, while effective in localization, this procedure has drawbacks such as wire breakage, patient discomfort, wire migration while moving or transporting the patient, and the need to surgically remove the wire the same day that it is placed due to this risk of migration.

The authors also discussed radar reflector localizers such as SAVI SCOUT®, which are small devices that can be placed into a targeted mass at any time prior to lumpectomy. The authors explained that once a surgeon gains a general idea of the mass' location by looking at the post localizer placement mammogram, this localizer is "hunted" for intraoperatively using a special handheld device which provides auditory feedback but does not provide location details until it is found via the auditory feedback. The authors cited a retrospective study at the Moffitt

[48] Ibanez J, Wotherspoon T, Mooney B, Advances in Image Guided Breast Mass Localization Techniques (undated). Submitted by the applicant with its application on February 28, 2022.

Cancer Center which, according to the authors, indicated that localization using SAVI SCOUT ® was successful for 125 out of 129 patients (97 percent, 95 percent Confidence Interval 92-99 percent) and showed that in comparison to wire localization, SAVI SCOUT® provides improved patient comfort and eliminates the need to perform the surgery on the same day as the localization procedure.[49]

Finally, the authors discussed localization using the SmartClip™. The authors noted that the SmartClip™ is the first device to provide three-plane localization information. The authors stated that a monitor displays the approximate position of the SmartClip™ allowing everyone in the operating room to assist with the localization of the SmartClip™ and provide knowledge of its location prior to and throughout the surgery. They further noted that the SmartClip™ localizer can be visualized on a small screen mounted on the electrocautery tool which, like the monitor, depicts the direction and depth to the SmartClip™. According to the authors, this provides real-time visual feedback to surgeons as the electrocautery tool moves and allows them to find the clip without having to look up at the operating room monitor. The authors asserted that the three-axis visualization eliminated the need to search for the clip since the location is always known, and that the availability of the SmartClip™ in three colors with different signals eases differentiation between localizers and allows for bracketing of masses.

The authors concluded that wire localization has drawbacks such as wire breakage, patient discomfort, high chances of migration, and narrow placement timeframes, which have been mitigated over the past decade by various soft tissue localizers such as SAVI SCOUT® (radar reflector localizer). The authors concluded that the SmartClip™, which they refer to as a

[49] Falcon S, Weinfurtner RJ, Mooney B, Niell BL. SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting. Clin Imaging. 2018 Nov-Dec;52:280-286. doi: 10.1016/j.clinimag.2018.07.008. Epub 2018 Jul 24. PMID: 30193186.

new localizer, may potentially resolve other difficulties encountered with the soft tissue localizers that they currently use. Finally, the authors noted that a clinical study is currently underway at the Moffitt Cancer Center to evaluate the advantages of using the SmartClip™ in clinical practice.

In addition, the applicant provided three physician case reports (two by surgeons and one by radiologists), each describing the use of the SmartClip™ in a single patient (62, 59, and 53-year-old female breast cancer patients). Each case report described the patient's history, diagnostic tools utilized, pre-operative, peri-operative, and/or post-operative course, pathology results, as well as the physician's perceptions of the SmartClip™ or EnVisio™ Navigation System. In the first surgical case report,[50] the surgeon noted that the foot pedal activation of the EnVisio™ Navigation System allowed toggling between two SmartClip™ devices, allowing complete dissection around the periphery of the mass to obtain a precise margin. The surgeon asserted that with one marker, there would have been a higher risk of a positive margin. In the second surgical case report,[51] the surgeon similarly noted that the EnVisio™ Navigation System helped her to map out and be more precise in her incision location and lumpectomy dissection. Finally, in the radiologists' case report,[52] ultrasound guided SmartClip™ localization was ordered for definitive surgical management. The radiologists noted the visibility of the SmartClip™ relative to the coil clip, mass, and surrounding tissue, as well as the ease of the deployment.

The applicant also submitted several articles in general support of its application, which we summarized in the CY 2023 OPPS/ASC proposed rule as follows. An article from the Mayo

[50] Kruper, Laura, Bracketing Lobulated Breast Lesion with the EnVisio™ Navigation System using Differentiated SmartClip™.
[51] Henkel, Dana, Single SmartClip™ Case.
[52] Lee, Marie C., Mooney, Blaise, Right Breast IDC/DCIS.

Clinic concluded that intraoperative pathologic assessment with frozen-section margin evaluation of all neoplastic breast specimens allows for immediate re-excision of positive or close margins during the initial operation and results in an extremely low reoperation rate of <2 percent.[53] Another article addressed the relationship between post-surgery infection and breast cancer recurrence and concluded that there is association between surgical site infection and adverse cancer outcomes, but the cellular link between them remains elusive.[54] Furthermore, a study from the Mayo Clinic concluded there was no reduction in the surgical site infection rate among patients who received postoperative antibiotic prophylaxis after breast surgery.[55] In addition, a study from Washington University School of Medicine concluded that surgical site infection (SSI) after breast cancer surgical procedures was more common than expected for clean surgery and more common than SSI after non-cancer-related breast surgical procedures.[56] A review article from the Department of Radiation Oncology, Case Western Reserve University and University Hospitals in Cleveland surmised that precision medicine holds the promise of truly personalized treatment which provides every individual breast cancer patient with the most appropriate diagnostics and targeted therapies based on the specific cancer's genetic profile as determined by a panel of gene assays and other predictive and prognostic tests.[57] An abstract on

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[53] Racz JM, Glasgow AE, Keeney GL, Degnim AC, Hieken TJ, Jakub JW, Cheville JC, Habermann EB, Boughey JC. Intraoperative Pathologic Margin Analysis and Re-Excision to Minimize Reoperation for Patients Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2020 Dec;27(13):5303-5311. doi: 10.1245/s10434-020-08785-z. Epub 2020 Jul 4. PMID: 32623609.

[54] O'Connor RÍ, Kiely PA, Dunne CP. The relationship between post-surgery infection and breast cancer recurrence. J Hosp Infect. 2020 Nov;106(3):522-535. doi: 10.1016/j.jhin.2020.08.004. Epub 2020 Aug 13. PMID: 32800825.

[55] Throckmorton AD, Boughey JC, Boostrom SY, Holifield AC, Stobbs MM, Hoskin T, Baddour LM, Degnim AC. Postoperative prophylactic antibiotics and surgical site infection rates in breast surgery patients. Ann Surg Oncol. 2009 Sep;16(9):2464-9. doi: 10.1245/s10434-009-0542-1. Epub 2009 Jun 9. PMID: 19506959.

[56] Olsen MA, Chu-Ongsakul S, Brandt KE, Dietz JR, Mayfield J, Fraser VJ. Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg. 2008 Jan;143(1):53-60; discussion 61. doi: 10.1001/archsurg.2007.11. PMID: 18209153.

[57] Eleanor E. R. Harris, "Precision Medicine for Breast Cancer: The Paths to Truly Individualized Diagnosis and Treatment", International Journal of Breast Cancer, vol. 2018, Article ID 4809183, 8 pages, 2018. https://doi.org/10.1155/2018/4809183.

the subject of prognostic factors for surgical margin status and recurrence in partial nephrectomy concluded that (i) surgical margin positivity after partial nephrectomy is not significantly associated with tumor characteristics and anatomical scoring systems, (ii) surgical indication for partial nephrectomy has a direct influence on positive surgical margin rates, and (iii) tumor size and stage after partial nephrectomy are valuable parameters in evaluating the recurrence risk.[58] Lastly, a study examining the significance of resection margin in hepatectomy for hepatocellular carcinoma concluded that the width of the resection margin did not influence the postoperative recurrence rates after hepatectomy for hepatocellular carcinoma.[59]

Based on the evidence submitted with the application, we noted the following concerns in the CY 2023 OPPS/ASC proposed rule. We noted that the first study appeared to be unpublished, and it was not clear whether it had been submitted for publication in a peer-reviewed journal. In addition, we stated that the study involved a sample of 97 patients from one institution and appeared to be written as a feasibility study for a potentially larger randomized control trial. Notably, the authors of this study stated that further studies are required to compare ESL to other non-wire localization techniques to refine which localization technology is most advantageous in breast conservation surgery. Furthermore, we indicated that the authors did not report the sex or age of the study participants. Additionally, the authors reported that the differences in positive margin and re-excision rates between ESL and WL groups were not statistically significant. We also noted a potential concern regarding practice/selection effects bias inherent in the methodology presented.

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[58] Demirel HC, Çakmak S, Yavuzsan AH, Yeşildal C, Türk S, Dalkılınç A, Kireççi SL, Tokuç E, Horasanlı K. Prognostic factors for surgical margin status and recurrence in partial nephrectomy. Int J Clin Pract. 2020 Oct;74(10):e13587. doi: 10.1111/ijcp.13587. Epub 2020 Jul 14. PMID: 32558097.

[59] Poon, R. T., Fan, S. T., Ng, I. O., & Wong, J. (2000). Significance of resection margin in hepatectomy for hepatocellular carcinoma: A critical reappraisal. *Annals of surgery*, *231*(4), 544–551. https://doi.org/10.1097/00000658-200004000-00014.

In addition, we noted that the second article was an undated,[60] unpublished descriptive clinical paper comparing three different breast mass localization techniques in three cases from one institution. The applicant stated that this paper is pending publication but provided no further details regarding the status of the paper. We explained that the paper did not systematically compare the techniques across any measurable variables, and the authors indicated that a clinical study was underway at the institution to evaluate the SmartClip™ in clinical practice. Similarly, we noted that the physician case reports were solely descriptive in nature – they presented each physician's anecdotal experience using the EnVisio™ Navigation System and/or SmartClip™. Furthermore, we noted that the applicant provided several additional articles that, while informative, did not involve the SmartClip™ and did not appear to directly support the applicant's claim of substantial clinical improvement. We stated that we would welcome additional information and evidence from larger, multi-center studies that provide comparative outcomes between the SmartClip™ and existing technologies.

In the CY 2023 OPPS/ASC proposed rule, we further stated that none of the articles and case reports provided conclusive evidence that the use of the SmartClip™ reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant. In addition, we indicated that the articles and case reports provided by the applicant described the use of the subject devices only in breast cancer surgery cases. As reported by the applicant, the SmartClip™ is utilized frequently in breast conserving surgery, lymph nodes, and head/neck cancers. We stated in the proposed rule that we would welcome additional evidence of substantial clinical improvement in cases related to non-breast cancer related procedures. We

[60] Although the applicant reported the date of the study as January 2021, the copy of the study provided by the applicant was not dated.

solicited public comments on whether the SmartClip™ meets the substantial clinical improvement criterion.

Comment: All commenters addressing the SCI criterion offered support for approval of the SmartClip™ application. Some commenters, including the applicant, noted that for many years, the standard of care for breast conservation surgery has been wire localization and that little progress has been made. Such commenters noted that compared to the investments and advances that have been made in surgical technologies for other types of cancer (including male-predominant cancers such as prostate cancer) to reduce positive margin rates and increase quality of life, the tools for breast cancer surgery have remained limited. According to commenters, advances in surgical technologies for other types of cancer have included minimally invasive approaches inclusive of laparoscopic as well as robotic surgery, image-fusion, and advanced navigation. Such commenters considered the under-resourcing of breast surgery to be an equity issue due to the fact that breast surgery is primarily performed on women, and one commenter noted, in particular, that the downstream impacts of repeat surgeries (increased disfigurement, anxiety, infection risk, economic costs, time away from work and family) are particularly impactful to working women, especially those of child-bearing age and lower socio-economic status. In addition, a commenter noted that breast tissue, unlike the liver or lungs, can be variably thick or dense versus fatty depending on the age and genetics of the patient, and that this makes the localization of abnormalities or cancers in a breast difficult as each case can be different depending on the amount of fat versus dense tissue and the patient's breast size. These commenters believed that advances in technology are needed in breast surgery to improve surgical results.

Several commenters described numerous drawbacks and difficulties associated with wire localization techniques, including the following: (1) some patients require up to 4 wires to "bracket" an abnormality in the breast; (2) trauma and pain associated with having wires placed and then extruding from a breast on the morning of surgery; (3) scheduling difficulties associated with wire placement on the day of surgery; (4) movement or displacement prior to or during surgery; (5) wires can be cut or "lost" during the procedure, especially if the cautery or bovie gets too close to them during the procedure; and (6) wires are designed to have a small "thicker" portion placed at the site of the tumor or abnormality; this small thick portion is difficult to place accurately and if it migrates slightly can change the orientation of the excision. In addressing difficulties in localizing the wires, a commenter explained that surgeons attempt to localize the tumor by "following the wire," palpation, and educated guesses as to where to resect tissue. Several commenters noted that these difficulties in accurate tumor localization have resulted in high re-excision rates. A commenter noted that over 15-20% of patients annually require a second surgery to remove more breast tissue because the localization was inexact at the time of the first surgery. A second commenter stated that a recent meta-analysis showed an average 22% re-excision rate for inadequate margins after primary lumpectomy. This commenter asserted that the human and health care costs of this failure rate are high and fall disproportionately on women. In addition, a commenter reported that when using an alternative wire-free solution with a radar detection marker, surgeons at his institution reported an increase in re-excision rates, nearly doubling that of wires. Commenters asserted that, as a result of difficulties and complications with wire techniques, new technologies for localizing a breast and/or lymph node abnormality requiring excision in the operating room are needed.

Several commenters described clinical and surgical benefits of using the Navigator and SmartClip™ based on experience using this technology. Most of these commenters stated that using this technology decreases positive surgical margin and re-excision rates. A commenter noted that the system not only localizes the actual tumor targeted for removal, but also shows the surgeon suggested margins. That commenter added that with the Navigators and SmartClip™, the specimens are more circumferential and consistent at a fixed (but surgeon selected) distance from the implanted clip which has resulted in fewer positive margins, reducing the need for a second surgery. Other commenters explained that the technology allows the surgeon to track the position of the implanted clip during surgery in 3D with real-time updates, allowing the surgeon to have an objective view of the tip of the surgical instrument with respect to the SmartClip™, which according to commenters, can result in decreases in both positive margin and re-excision rates.

In addition, a few commenters noted that the technology results in removal of less normal breast tissue, with one commenter noting that early data from major cancer centers is starting to show that less normal tissue is being removed when the Elucent technology is used. Commenters noted that this has major implications for post-surgical pain, deformity, onco-plastic reconstructions, and complications. A commenter asserted that it is unusual for a device to simultaneously decrease deformity, pain and suffering, health care costs, and cancer metrics like positive margin and re-excision rates.

Furthermore, a commenter noted that, in their anecdotal experience, the use of the Navigators and SmartClip™ saves overall operating room time compared to the hook-wire technique. This commenter asserted that this decreases costs and anesthesia time and provides the ability to more efficiently use operating rooms for other cases. Another commenter reported

that with the Navigators and SmartClip™, there is less need for synchronization with radiology for localization procedures. This commenter asserted that in the past, the need to have tumors localized in radiology before coming to the operating room caused a number of problems such as displaced wires, operating room delays, long patient waiting times with wires protruding from the breast, and decreased efficiency. This commenter and another noted that the SmartClip™ can be implanted at virtually any time prior to the surgery at the patient's convenience, thus avoiding delay or wire displacement on the day of surgery.

Some commenters described additional technical and operational advantages to using the Navigators and SmartClip™. These commenters noted that the Navigators and SmartClip™ are unique because they allow the surgeons to track the position of the SmartClip™ during surgery in 3D with real time updates. A few commenters specifically noted that the SmartClip™ contains an ASIC chip which is activated at surgery once the patient lays on the operative table. A commenter further asserted that the field of navigation is over 30cm and can enable identification in a large or small breast or one that is wide or narrow. This commenter claimed that the most important component of the system is the NavSlim and NavPencil which enable navigation in real time without using another device or probe. According to this commenter, the NavSlim and Pencil are placed onto the operative tool or cautery and do not have to be picked up intermittently.

Another commenter stated a significant technical advantage of the technology is that a 3D readout is generated as a graphic representation of the clip relative to the tip of the handpiece (compared to an audio signal only) as a reflection of distance, which per the commenter, is a more intuitive way to understand the device localization. This commenter further stated that, perhaps most important to a surgeon, the detector portion of the handpiece is fixed to the cautery.

According to this commenter, having the navigation portion of the system within the operative field for real-time detection significantly improves identification of the clip and the lesion, even when working in a small space or in detection of a very small target, as division or retraction of the tissue often causes the target to move in surgery. This commenter noted that with real-time and nearly continuous detection, loss or disorientation of the target is minimized while performing the operation.

Furthermore, a commenter provided comments based on his personal experiences placing the SmartClip™ and direct observation of his colleagues' use of SmartClip™. The commenter first noted that all non-wire /non-radioactive localization methods have some common benefits to patients, in that they allow for flexibility with scheduling, are generally less painful than wires, have less chance of dislodgment /migration after placement, can be used to localize targets in the axilla and non-palpable targets which are too superficial or too deep for a wire, and when operating room cases are unexpectedly cancelled or delayed, no harm comes to patients. The commenter asserted that the SmartClip™ has several unique benefits, observed at his institution, that demonstrate that it meets the criterion at § 419.66(c)(2). First, the commenter stated that the utilization of the SmartClip™ provides the ability to localize targets deep in the breast and deep in the axilla, beneath overlying dense tissue such as muscle. The commenter noted that the 35cm detection depth available with the SmartClip™ soft tissue marker exceeds that of other types of markers such as the SaviScout, which the commenter stated are often not detectable when the target is deeper than 4 cm of normal breast tissue or beneath dense tissue, such as muscle encountered in axilla. The commenter stated that this causes the surgeon to have to "cut down" through tissue until the clip is detected, resulting in a less optimal approach, longer operating room time, and potential damage to the clip with electrocautery devices.

According to this commenter, a second important benefit the SmartClip™ provides is the ability to localize targets surrounded by blood products/hematomas. Per the commenter, the ASIC computer chip within the SmartClip™ is not affected by surrounding human tissue, including hematomas. The commenter stated that in contrast, other tissue markers are often not detectable if a hematoma is present. The commenter noted that if a hematoma limits the signal and detection of a localizing clip, the result is delay in surgery or a prolonged, less accurate surgical excision and need for radiology staff to come to the operating room to assist the surgeon localizing the target using ultrasound technology/fluoroscopy.

Third, the commenter stated that in his experience, the SmartClip™ provides more specific bracketing ability with 3 differentiated clip signatures, due to the ASIC computer chip that delivers precise coordinates of the individual SmartClip™ signals and their locations. According to the commenter, this has resulted in smaller, more accurate surgical specimens.

Fourth, the commenter noted that if there is migration of a localizing clip, a second clip must be placed, and asserted that because the SmartClip™ has 3 unique signals, this complication is easily remedied. Per the commenter, other clips which lack unique signals must be placed far enough from the migrated clip, resulting in time consuming imaging and communication to ensure the proper area is surgically excised, as well as more time, more radiation, and more tissue being removed as surgeons must make larger incisions.

In addition, the commenter noted that when a patient undergoes neoadjuvant chemotherapy, the cancer must be localized before chemotherapy treatment to ensure the correct area is removed, and that response to treatment is often measured with MRI. Per the applicant, the SmartClip™ has less MRI artifact than other clips, which allows for accurate assessment of response to therapy. The commenter also stated that the SmartClip™ is highly visible clip with

ultrasound. The commenter asserted that the ultrasound visibility makes placement easy for radiologists, as the SmartClip™ looks significantly larger and brighter than the biopsy clips which are already in the target tissue being localized. Additionally, the commenter stated that in the unexpected event that the SmartClip™ must be localized with ultrasound intraoperatively, the highly visible nature of the SmartClip™ makes this easier when compared to searching for other clips which are less echogenic.

This commenter also described some technical advantages of the SmartClip™. First, the commenter stated that the SmartClip™ is easy to deploy. The commenter specifically noted that the needle is available in different lengths, specifically noting the second-generation needle called "SmartClip™ Lite." The commenter stated that the bevel of this needle is longer than other needles, which makes cutting through dense tissue easier. The commenter added that the bevel is also etched and highly echogenic, and that when the bevel is pointed "up" towards the ultrasound probe, the SmartClip™ is very easy to see. The commenter explained that this allows the radiologist and ultrasound technologist to readily distinguish between structures in the breast, existing biopsy clips, and the tip of the deployment needle. Additionally, the commenter asserted that the thumb button and forward movement is intuitive and familiar to breast radiologists and can all be done with one hand (no need to put the ultrasound probe down to "unlock" the deployment needle). The commenter also stated that the needle is lightweight, but extremely sharp, and that the shape of the SmartClip™ makes ultrasound deployment easy. In addition, per the commenter, the clip is smooth with no external antennas or protrusions to get caught in tissue or bend in dense tissue. The commenter stated that, to date, they have not bent any needles or had any needles self-deploy. However, the commenter acknowledged that they have had two unsuccessful deployments due to an issue which has since been rectified, but the commenter

stated that each of these situations was solved simply with the deployment of a second SmartClip™ without patient harm or delayed treatment. The commenter stated that the applicant has communicated an improved quality control process to prevent future incidents going forward.

A few other commenters described clinical outcome data from their experience with the Navigators and SmartClip™. A commenter reported that he has decreased his re-excision rate from 16% in 2019 prior to the COVID pandemic to 5% in 2021. This commenter stated that he performs an average of 200 breast conservation surgeries per year. This commenter also added that the adoption of the Elucent technology has resulted in fewer operative interventions for his patients undergoing breast conservation, improved cosmesis with one surgery, improved oncoplastic approaches as well as less anxiety and fewer delays in oncologic care. A second commenter stated that in the five months that they have implemented the technology, they have seen re-excision rates drop to approximately 1.5%. Another commenter stated that his institution is in the process of analyzing its clinical outcomes data, which the commenter asserted illustrate the significant clinical impact of implementing the SmartClip™ and Navigator across six healthcare facilities and 235 surgical procedures.

Finally, a few commenters acknowledged the need for additional research and larger clinical trials to support the preliminary positive outcomes data, including the data indicating that the Navigators and SmartClip™ decrease re-excision rates in breast conservation surgery for patients with breast malignancy. These commenters asserted that approval of pass-through payment for the Navigators and SmartClip™ would enable greater access to patients which will allow the surgical community to conduct additional studies and collect more comprehensive and multi-center data to further substantiate the clinical outcomes seen in early research studies.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in making our final determination of the substantial clinical improvement criterion, discussed below.

Comment: The applicant submitted comments in response to many of the concerns we expressed regarding the study abstract referenced in the proposed rule, which assessed the impact of ESL using the EnVisio Navigation System and SmartClip™ compared to wire localization. In response to our concern that the study was unpublished, the applicant stated that it submitted a manuscript for peer-review and potential publication. In response to our concern that this study appeared to be a feasibility study for a potentially larger randomized controlled trial, the applicant stated that the study authors did not make this statement and noted that prospective randomized controlled trials are exceedingly rare in this space and not considered necessary for adoption of a particular guidance technology. The applicant further claimed that the study referenced in the abstract has a rigorous cohort-matched design and a patient population size which is far beyond a feasibility study. In response to our concern about the lack of gender and age information, the applicant noted that this was an IRB-approved matched cohort analysis (1:1) of 194 patients (n=97 in both the study and control groups). The applicant further stated that the age in the ESL group was 64 versus 61 in the WL group (p=.015) (the applicant did not indicate whether these were average ages, median ages, or otherwise). The applicant added that the matched sample set included 190 females and four males. The applicant reiterated that the study authors matched patients, one-to-one, based on surgeon, procedure type with stratification for those having or not having nodal procedures, and pathologic stage or benign pathology, and restated the numerical results from the study abstract (which we summarized in the CY 2023 OPPS/ASC proposed rule (87 FR 44593)).

In response to our concern that the differences in positive margin and re-excision rates between the ESL and WL groups were not statistically significant, the applicant asserted that the lack of statistical significance for re-excisions was driven solely by the sample size of the study. The applicant further noted that the retrospective cohort-matched design prioritized patient matching over sample size and the study was not prospectively powered for re-excision rates as the authors had no *a priori* knowledge that this would be an outcome of interest. The applicant claimed that, in hindsight, reasonably achievable increases in sample size would have made statistical conclusions possible. Specifically, the applicant claimed that with a sample size of 150 (rather than 97) in each group, and assuming identical re-excision rates, the difference between the ESL and WL groups becomes statistically significant (p=0.049, Fisher's exact test). The applicant further noted that ESL results were from the initial cases performed with ESL at the study center and included a learning curve, whereas the control wire localization cases were performed at a time where the learning curve had been overcome and surgeons had decades of experience with thousands of wire localization cases. In addition, the applicant asserted that the Elucent system is being used predominantly for treatment of breast cancer, and that the early results demonstrate lower positive margin rates and removal of less normal tissue resulting in lower rates of re-excision by >50%.

The applicant also noted other clinical impacts of the Navigators and SmartClip™ in supporting its claim of substantial clinical improvement. The applicant claimed that the electromagnetic navigation allows for more precise and accurate tissue localization, resulting in 34.5% less normal functioning tissue being removed at the time of surgery with ESL compared to WL. According to the applicant, this results in less deformity and simpler oncoplastic reconstructions and may decrease complications and post-procedure pain. The applicant noted

that the amount of excess (i.e., unnecessary) tissue removed was statistically significant between the WL and ESL groups in the study abstract it referenced, and that even with less tissue removed, the re-excision rate decreased for the ESL group. According to the applicant, the removal of less normal functioning non-neoplastic tissue during surgery when using the Navigator compared to WL will cause less tissue deformity, pain, and suffering and, in and of itself, is evidence of substantial clinical improvement under § 419.66(c)(2) – specifically, that the removal of less normal functioning tissue substantially improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

In response to our concern that the applicant had not provided conclusive evidence that use of the SmartClip™ reduces surgical site infection rates, the applicant explained that this study was not specifically powered to address surgical site infections, but stated that when compared to wires, there are several surgical principles that should contribute to lower SSI rates in adequately powered studies. The applicant noted that the protrusion of the wire from the patient is an infection risk because the wire is placed prior to surgery (often hours) in a separate physical location from the operating room (often radiology) and the patient is then transported to the operating room with a semi-sterile dressing. The applicant added that the wire is a further infection risk due to the added tissue trauma associated with removal of larger volumes of tissue to minimize positive margins and future additional procedures.

In response to our concern that the applicant had not provided conclusive evidence that use of the SmartClip™ reduces risk of tissue marker migration, the applicant claimed that there is currently no standard to determine tissue marker migration other than the histopathological results. The applicant stated that migration of the marker clip would result in an increase in

positive margins and re-excisions as well as an increase in the volume of tissue excised due to uncertainty as to the exact position of the target, but that neither of these findings was seen in the study. The applicant noted that the lower re-excision rates and lower positive margins seen in the ESL group are evidence of lack of tissue marker migration, in addition to the smaller specimens and excess tissue excised.

Finally, the applicant asserted that breast cancer is the second leading cause of cancer mortality in women, and that the current standard localization technique (hook-wire) is both insufficient and has not changed for many decades, despite high positive margin rates. The applicant noted that in contrast to this, during this same time period, larger investments in advanced technologies have been made to decrease positive margin rates and increase quality of life in male-predominant tumors such as prostate cancer. Thus, the applicant asserted that technology-driven improvements in patient outcomes are particularly important in breast cancer.

Response: We appreciate the applicant's responses to our questions as well as the other comments we received about the SmartClip™. However, we maintain the concerns we articulated in the proposed rule. The provided published studies did not demonstrate a statistically significant difference in positive margin and re-excision rates between the ESL and WL technologies or provide evidence that SmartClip™ reduces surgical site infection rates or risk of tissue marker migration. Although the applicant noted that the amount of excess tissue removed was statistically significant between the WL and ESL groups in the study abstract it referenced, we do not agree that this result, in and of itself, is evidence of substantial clinical improvement under § 419.66(c)(2) – that is, we do not believe that this result, in itself, is evidence that the technology substantially improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part. We continue to believe that

additional information and evidence is necessary from larger, multi-center published studies (including studies involving non-breast cancer related procedures) that provide comparative outcomes between the SmartClip™ and existing technologies. Because of these concerns, we do not believe that the SmartClip™ represents a substantial clinical improvement relative to currently existing technologies. After consideration of the public comments we received, and our review of the device pass-through application, we are not approving the SmartClip™ for transitional pass-through payment status in CY 2023 because the device does not meet the newness or substantial clinical improvement criterion.

We note that we received comments from the applicant with regard to the cost criteria for this device, but because we have determined that the device does not meet the newness or substantial clinical improvement criteria, and therefore, is not eligible for approval for transitional pass-through payment status for CY 2023, we are not summarizing comments received or making a determination on those criteria in this final rule.

(4) Evoke® Spinal Cord Stimulation (SCS) System

Saluda Medical Inc. submitted an application for a new device category for transitional pass-through payment status for the Evoke® Spinal Cord Stimulation (SCS) System for CY 2023. The applicant described the Evoke® SCS System as a rechargeable, upgradeable, implantable spinal cord stimulation system that provides closed-loop stimulation controlled by measured evoked compound action potentials (ECAPs). According to the applicant, the Evoke® SCS System is used in the treatment of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. Per the applicant, the Evoke® SCS System's rechargeable battery is indicated for use up to 10 years.

The applicant explained that SCS consists of applying an electrical stimulus to the spinal cord which causes the activated fibers (e.g., Aβ-fibers) to generate action potentials. Aβ-fibers are the low-threshold sensory fibers in the dorsal column that contribute to inhibition of pain signals in the dorsal horn. The action potentials summed together form the ECAP. Therefore, the applicant asserted that ECAPs are a direct measure of spinal cord fiber activation that generates pain inhibition for an individual.

According to the applicant, the Evoke® SCS System is comprised of 5 implanted and 12 external components. The applicant identified the following five implanted components of the Evoke® SCS System: (1) Closed Loop Stimulator (CLS): a rechargeable, 25- channel implantable pulse generator (IPG or stimulator) which generates an electrical stimulus and measures and records the nerve fibers' response to stimulus (i.e., ECAPs). Although named ''Closed Loop Stimulator,'' the applicant indicated that this stimulator delivers both open-loop and closed-loop stimulation modes; (2) Percutaneous Leads: Electrical current is delivered to the spinal cord via the electrodes on leads that are introduced into the epidural space through an epidural needle and connected to the stimulator. Per the applicant, ECAPs are measured using two non-stimulating contacts of the leads; (3) Lead Extension: Used to provide additional length if needed to connect the implanted lead to the CLS or external closed-loop stimulator (eCLS); (4) Suture Anchors and Active Anchors: Used to anchor the lead to the supraspinous ligament or deep fascia; and (5) CLS Port Plug: Used to block unused ports in the CLS header. Additionally, the applicant stated there are 12 external components of the Evoke® SCS System (e.g., surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers).

According to the applicant, the Evoke® SCS System is the first and only SCS system that provides closed-loop stimulation. In closed-loop stimulation, the system automatically measures

the impact of the prior stimulation signal on the nerve and adjusts the next stimulation signal accordingly to maintain the prescribed physiologic response. Per the applicant, this closed feedback loop provides consistency in the stimulation received by the nerve as opposed to the stimulation emitted from the device.

The applicant stated that the Evoke® SCS System measures ECAPs and adjusts the next stimulation accordingly as follows: (1) the Evoke® SCS System measures ECAPs following every stimulation pulse from two electrodes not involved in stimulation; (2) the recorded ECAP signal is sampled by the stimulator and provides a measurement of the ECAP amplitude; and (3) the Evoke® SCS System utilizes the ECAPs in a feedback mechanism to adjust the next stimulation pulse, thereby delivering closed-loop stimulation. The feedback mechanism minimizes the difference between the measured ECAP amplitude and the ECAP amplitude target by automatically adjusting the stimulation current for every stimulus. In doing so, the applicant asserted it maintains spinal cord activation near the target level. According to the applicant, this addresses the challenge all currently available SCS systems face regarding the ever-changing distance between the electrode and spinal cord that results in variable spinal cord activation, and thus, less effective therapy. Per the applicant, although there have been numerous technological advances in SCS therapy over the years, every other SCS system on the market provides open-loop stimulation, where parameters are set by the physician and the patient can only modulate those parameters within defined limits based upon how they feel. However, physiological functions such as breathing, heartbeat and posture changes alter the distance between the spinal cord target fibers and SCS electrodes. Therefore, the applicant asserted that the number of nerve fibers activated by open-loop stimulation continually changes, resulting in inconsistent therapy delivery (i.e., under- or over-stimulation) and that ECAP-controlled closed-loop therapy

produces a significantly higher degree of spinal cord activation that is maintained within the therapeutic window which drives superior outcomes. The applicant asserted that a consistent neural response at the prescribed level may only be achieved with a closed-loop system that continually adjusts on every stimulation pulse.

With respect to the newness criterion at § 419.66(b)(1), on February 28, 2022, the Evoke® SCS System received PMA approval from FDA as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Evoke® SCS System on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We invited public comment on whether the Evoke® SCS System meets the newness criterion.

Comment: The applicant reasserted that the Evoke® SCS System meets the newness criterion at § 419.66(b)(1) as the application was submitted within 3 years of FDA approval.

Response: We appreciate the commenter's input and agree that because we received the application for the Evoke® SCS System on March 1, 2022, which was within 3 years of the FDA premarketing approval on February 28, 2022, the Evoke® SCS System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Evoke® SCS System is integral to the service of treating and managing chronic intractable pain of the trunk and/or limbs using spinal cord stimulation. The applicant noted that some components of the system (described previously) are implanted in a patient and are in contact with human tissue. The applicant indicated that all components of the system are used for

one patient only. We noted that the external components of the Evoke® SCS System (referenced previously) are not implanted in a patient and do not come in contact with human tissue as required by § 419.66(b)(3). The applicant did not indicate whether the Evoke® SCS System meets the device eligibility requirements of § 419.66(b)(4) in regard to whether it is an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, or whether it is a supply or material furnished incident to a service. We noted that some of the external components (e.g., surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) noted previously may be considered capital as specified under § 419.66(b)(4). We invited public comment on whether the Evoke® SCS System meets the eligibility criteria at § 419.66(b).

Comment: The applicant stated the generator and charger components of the Evoke® SCS System meet the eligibility criteria at § 419.66(b)(3) and 419.66(b)(4), as the new device category would only apply to these two components. The applicant stated that the Evoke generator is an integral part of the implant procedure of spinal neurostimulator pulse generator (CPT code 63685). The applicant explained that the charger is a rechargeable battery embedded in the implantable device, and all that apply to the implant also apply to the charger. The applicant stated that the generator and charger components meet the criterion at § 419.66(b)(3) since they are used for one patient only, come in contact with human tissue, and are surgically inserted. The applicant stated that the generator and charger components meet the criterion at § 419.66(b)(4) since they are not the type of item for which depreciation and financing expenses are recovered or they are materials or supplies furnished incident to a service.

Response: Based on the information we have received and our review of the application, we agree with the applicant that the applicable components of the device are used for one patient

only, come in contact with human tissue, and are surgically implanted or inserted. We also agree with the applicant that the applicable components meet the device eligibility requirements of § 419.66(b)(4) because they are not equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and they are not a supply or material furnished incident to a service. Based on this assessment we have determined that the Evoke® SCS System meets the eligibility criteria at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criteria for establishing a device category, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that none of the existing categories appropriately describe the Evoke® SCS System. The applicant provided a list of current and prior device categories for pass-through payments for other spinal cord stimulation systems (described in Table 55 below) and explained why each category does not describe the Evoke SCS System. In summary, the applicant asserted that the existing codes do not adequately describe the Evoke SCS System because the existing codes apply to devices that: provide stimulation to organs other than the spinal cord (e.g., heart, transvenous sensing and stimulation, baroreceptors in the carotid artery), only provide open-loop stimulation, and are non-rechargeable. According to the applicant, the Evoke SCS System is a rechargeable, closed-loop neurostimulator that provides stimulation to spinal nerves. Upon review, it did not appear that there are any existing pass-through payment categories that might apply to the Evoke® SCS System. We invited public comment on whether Evoke® SCS System meets the device category criterion.

Comment: The applicant and many other commenters agreed with CMS's assessment that there are no existing pass-through payment categories that describe the Evoke® SCS System.

A competitor asserted that the Evoke® SCS System is described by an existing category. The commenter stated that, in considering existing codes, CMS noted that Evoke is not described by "C1820 - Generator, neurostimulator (implantable), with rechargeable battery and charging system" or by "C1822 - Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system" because neither code describes a closed-loop neurostimulator. However, the commenter noted that CMS acknowledges in the proposed rule that Saluda Medical, Inc., the manufacturer of Evoke "indicated that this stimulator delivers both open-loop and closed-loop stimulation modes." The commenter stated that the aforementioned codes are not explicitly for open-loop neurostimulators and have long been used for technology similar to close-loop stimulation such as Medtronic's AdaptiveStim™. The commenter stated that AdaptiveStim™, first commercially introduced by Medtronic in 2011, is also a closed-loop SCS device which incorporates an internal accelerometer in the generator to monitor patient movements and postural fluctuations and adjusts device settings such as output amplitude, thus closing the loop. The commenter stated that, while both the accelerometer technology and ECAP sensing technology purport to provide the same benefit, i.e., reduced uncomfortable paresthesias, there are no comparative clinical trials to determine if one technology is superior to the other. The commenter stated that, even if CMS asserts that codes C1820 and C1822 are only for open-loop neurostimulators as suggested in the proposed rule, the codes still apply to Evoke because the product – according to the manufacturer – also delivers open-loop stimulation mode. The commenter also stated that as the Evoke system can deliver both open-loop and closed-loop

stimulation modes, there is nothing to prevent implanting the system and programming initially as a closed-loop system, and post implantation and billing, adjust the system to an-open looped system. The commenter explained that the existing closed-loop AdaptiveStim™ system has been accurately described since its commercial introduction by C1820 and therefore, Evoke entirely meets the description of the existing code, C1820, and thus would not satisfy the newness criteria § 419.66(c)(1) for transitional pass-through payment status.

Response: We appreciate the commenters' input. It is our understanding that a closed-loop system measures and uses the system's output to adjust subsequent output. Because the Evoke® SCS System measures and uses the evoked compound action potentials to instantaneously adjust subsequent stimulation output on every stimulation pulse, we believe it is uniquely a true closed-loop system. After consideration of the public comments we received, we continue to believe that there is not an existing pass-through payment category that describes the Evoke® SCS System, and therefore, the Evoke® SCS System meets the device category eligibility criterion at § 419.66(c)(1).

TABLE 55:POTENTIAL EXISTING/PREVIOUS DEVICE CATEGORIES

HCPCS Code	Device Category	Why Category Does Not Include Evoke® SCS System
C1824	Generator, cardiac contractility modulation (implantable)	This category describes a generator that provides cardiac contractility modulation to the right ventricle in the heart. The Evoke SCS System does not provide stimulation to the heart. Therefore, this category does not describe the Evoke SCS System.
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	This category describes neurostimulators that are rechargeable and provide high frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide

		closed-loop stimulation. As the Evoke SCS System is a closed-loop neurostimulator, this category does not appropriately describe this technology.
C1767	Generator, neurostimulator (implantable), non-rechargeable	This category describes neurostimulators that are non-rechargeable and provide non-high-frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a rechargeable, closed-loop neurostimulator, this category does not appropriately describe this technology.
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	This category describes neurostimulators that are rechargeable and provide non-high-frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a closed-loop neurostimulator, this category does not appropriately describe this technology.
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	This category describes neurostimulators that provide transvenous sensing and stimulation. The Evoke SCS System delivers stimulation to spinal nerves (via closed loop stimulation) and does not provide transvenous sensing and stimulation. Therefore, this category does not describe the Evoke SCS System.
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	This category describes a generator that provides stimulation to baroreceptors in the carotid artery. The Evoke SCS System does not stimulate baroreceptors in the carotid artery and therefore this category does not describe this technology

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury

or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant asserted that the Evoke® SCS System represents a substantial clinical improvement over existing technology because its use of closed-loop stimulation provides greater improvements in key clinical outcomes over the open-loop stimulation that is currently used in existing technologies. Specifically, the applicant stated that the closed-loop stimulation of the Evoke® SCS System provides: (1) a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to Open-Loop SCS at 3 and 12 months; (2) greater percentage change in back pain measured by Visual Analog Scale at 3 and 12 months; (3) greater incidence of 50 percent reduction in back pain at 3 and 12 months; (4) greater incidence of 50 percent reduction in leg pain at 12 months; (5) greater incidence of 80 percent reduction in overall back and leg pain at 12 months; (6) consistently greater visual improvement in remaining secondary endpoint measures at 3 and 12 months; (7) a balanced safety profile between treatment groups; (8) a greater percentage of time in the therapeutic window for closed-loop patients compared to open-loop patients; (9) maintenance of clinical improvements in pain response and pain reduction at 24 months post-implantation; and (10) the results for the pivotal trial treatment group have been replicated in another multi-center trial with 12-month follow-up. With respect to this criterion, the applicant submitted three articles that supported these ten claims regarding the impact of the Evoke® SCS System on the management of chronic intractable pain of the trunk and/or limbs, including

unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

The first article provided by the applicant in support of claims 1–8 was for the Evoke pivotal clinical study, a prospective, multicenter, double-blind, randomized controlled trial designed to compare the use of ECAP-controlled, closed-loop stimulation to open-loop stimulation for the treatment of back and leg pain.[61] The trial was done at 13 specialist clinics, academic centers, and hospitals in the USA. Patients with chronic, intractable pain of the back and legs (Visual Analog Scale [VAS] pain score ≥60 mm; Oswestry Disability Index [ODI] score 41–80) who were refractory to conservative therapy, on stable pain medications, had no previous experience with spinal cord stimulation, and were appropriate candidates for a spinal cord stimulation trial were screened. Eligible patients were randomly assigned (1:1) to receive ECAP-controlled closed-loop spinal cord stimulation (investigational group) or fixed-output, open-loop spinal cord stimulation (control group). A total of 134 subjects (67 subjects in each treatment group) were randomized. Patients, investigators, and site staff were masked to the treatment assignment. The primary outcome was the proportion of patients with a reduction of 50 percent or more in overall back and leg pain with no increase in pain medications. Noninferiority (d=10 percent) followed by superiority were tested in the intention-to-treat population at 3 months (primary analysis) and 12 months (additional prespecified analysis) after the permanent implant. This study is registered with *ClinicalTrials.gov*, NCT02924129.

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[61] Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020 Feb;19(2):123–134. Epub 2019 Dec 20.

The applicant stated that standard primary and secondary endpoints for spinal cord stimulation studies were employed. For the primary study endpoint, the study authors defined a responder as having at least 50 percent improvement in pain relative to baseline. The applicant explained that this level of improvement was found to represent a substantial improvement per the IMMPACT recommendations.[62] The study authors stated that the secondary outcomes assessed the percentage change from baseline in leg pain VAS and back pain VAS, prevalence of high responders (≥80 percent reduction) for overall back and leg pain, and prevalence of responders (≥50 percent reduction) for back pain VAS, all at 3 months and 12 months. A host of additional efficacy measures including quality of life, pain medication use, and functional outcomes were also employed as per the IMMPACT recommendations.[63] An independent, blinded Clinical Events Committee (CEC) reviewed and adjudicated all adverse events occurring in the study. The authors reported that, between February 21, 2017 and February 20, 2018, 134 patients were enrolled and randomly assigned (67 to each treatment group), and that there were no between-group differences in the diagnoses, previous treatments, or other baseline demographics or characteristics.[64] The intention-to-treat analysis comprised 125 patients at 3 months (62 in the closed-loop group and 63 in the open-loop group) and 118 patients at 12 months (59 in the closed-loop group and 59 in the open-loop group).

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[62] Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. 2008 Feb;9(2):105–21. Epub 2007 Dec 11.

[63] Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. 2005 Jan;113(1– 2):9–19.

[64] Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020 Feb;19(2):123–134. Epub 2019 Dec 20.

Regarding the applicant's first claim that the closed-loop stimulation of the Evoke® SCS System provides a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to open-loop stimulation at 3 and 12 months, the applicant cited findings from this study that a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications was achieved in a greater proportion of patients in the closed-loop group than in the open-loop group at 3 months (82.3 percent vs 60.3 percent; difference 21.9 percent; p=0.0052) and at 12 months (83.1 percent vs 61.0 percent; difference 22.0 percent; p=0.0060). Non-inferiority was met at 3 months (p<0.0001) and 12 months (p<0.0001), as was superiority (3 months, p=0·0052; 12 months, p=0.0060).

Regarding the applicant's second claim that the closed-loop stimulation of the Evoke® SCS System provides a greater percentage change in back pain measured by Visual Analog Scale at 3 and 12 months, the applicant cited Evoke pivotal clinical study findings that at 3 months, 72.1 percent (sd=29.4 percent) of patients in the closed-loop group reported improvements in back pain compared to 57.5 percent in the open-loop group (superiority p=0.015). At 12 months, 69.4 percent (sd=30.6 percent) of patients in the closed-loop group reported improvements in back pain compared versus 54 percent (sd=39.5 percent) in the open-loop group (superiority p=0.020).

Regarding the applicant's third claim that the closed-loop stimulation of the Evoke® SCS System provides a greater incidence of 50 percent reduction in back pain at 3 and 12 months, the applicant cited Evoke pivotal clinical study findings that at 3 months, 81 percent of patients in the closed-loop group reported a 50% or greater reduction in back pain compared to 57 percent in the open-loop group (superiority p=0.0033). Per the study, at 12 months, 80 percent of patients

in the closed-loop group achieved this outcome compared to 58 percent in the open-loop group (superiority p=0.0079).

Regarding the applicant's fourth claim that the closed-loop stimulation of the Evoke® SCS System provides a greater incidence of 50 percent reduction in leg pain at 12 months, the applicant cited Evoke pivotal clinical study findings that at 12 months, this outcome was met by a statistically significantly greater proportion of patients in the closed-loop group (83 percent) than in the open-loop group (61 percent) (superiority p=0.0060).

Regarding the applicant's fifth claim that the closed-loop stimulation of the Evoke® SCS System provides a greater incidence of 80 percent reduction in overall back and leg pain at 12 months, the applicant cited findings from the Evoke pivotal clinical study that at 12 months, this outcome was met by a statistically significantly greater proportion of patients in the closed-loop group (56 percent) than in the open-loop group (37 percent) (superiority p=0.039).
Regarding the applicant's sixth claim that the closed-loop stimulation of the Evoke® SCS System provides consistently greater visual improvement in remaining secondary endpoint measures at 3 and 12 months, the applicant noted the Evoke pivotal clinical study authors observations that significant and clinically important improvements in both treatment groups in all other patient-reported outcomes at 3 and 12 months, including Oswestry Disability Index (ODI), Profile of Mood states Total Mood Disturbance (POMS– TMD), Pittsburgh Sleep Quality Index (PSQI), EQ–5D–5L Index Score, and Short Form Health Survey (SF–12) Physical Component Summary (PCS) and Mental Component Summary (MCS).[65] The authors noted that, in general, the improvement was greater in the closed-loop group than in the open-loop group at both 3 and 12 months, with significant differences seen in POMS–TMD scores (p=0.0037 at 3

[65] Ibid.

months; p=0.0003 at 12 months) and SF–12 MCS scores (p=0.0005 at 3 months) and (p=0.0004 at 12 months).

Regarding the applicant's seventh claim that closed-loop patients spent a greater percentage of time in the therapeutic window compared to open-loop patients, the applicant cited Evoke pivotal clinical study findings that at 3 months, the time in therapeutic window averaged 91.1 percent in the closed-loop group compared to 59.5 percent in the open-loop group (superiority p<0.0001). At 12 months, the time in therapeutic window averaged 95.2 percent in the closed-loop group versus 47.9 percent in the open-loop group (superiority p<0.0001).

Regarding the applicant's eighth claim that the closed-loop stimulation of the Evoke® SCS System provides a balanced safety profile between treatment groups, the applicant cited findings from the Evoke pivotal clinical study that the type, nature, and severity of adverse events were similar between treatment groups. The authors reported that, among the findings, 34 study-related adverse events occurred in 24 patients (23 adverse events in the closed-loop group in 13 patients [19 percent] [95 percent CI 10.8–30.9], and 11 adverse events in the open-loop group in 11 patients [16 percent] [95 percent CI 8.5– 27.5]). The authors stated that the most frequently reported study-related adverse events in both treatment groups were lead migration (nine [7 percent] patients), implantable pulse generator pocket pain (five [4 percent]), and muscle spasm or cramp (three [2 percent]).

The second article provided by the applicant reported the results from the Evoke pivotal clinical study at 24 months follow-up.[66] The applicant submitted this article in support of its

[66] Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, McJunkin T, Carlson J, Kim CK, Yang MI, Stauss T, Pilitsis J, Poree L; Evoke Study Group, Brounstein D, Gilbert S, Gmel GE, Gorman R, Gould I, Hanson E, Karantonis DM, Khurram A, Leitner A, Mugan D, Obradovic M, Ouyang Z, Parker J, Single P, Soliday N. Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain: A Secondary Analysis of the Evoke Randomized Clinical Trial. JAMA Neurol. 2022 Jan 8: e214998. doi: 10.1001/ jamaneurol.2021.4998. Epub ahead of print. PMID: 34998276; PMCID: PMC8742908.

claim that the Evoke® SCS System maintained statistical superiority in pain response and pain reduction at 24 months. The authors reported that 50 closed-loop patients and 42 open-loop patients completed 24-month follow-up. The authors noted that the double-blind was maintained for the full study duration. The authors reported that, at 24 months, a significantly greater proportion of closed-loop patients (79.1 percent) were responders (≥50 percent reduction in overall back and leg pain) than open-loop patients (53.7 percent) (p=0.001). Similarly, the authors reported that there was a significantly greater proportion of high responders, (≥80 percent reduction in overall pain) in the closed-loop group (46.3 percent) compared to the open-loop (29.9 percent) (p=0.047). The authors report that reduction in overall back and leg pain was significantly greater for closed-loop patients (mean score=26.4; point decrease=55.6) than open-loop patients (mean score=38.3; point decrease=43.9) (mean score difference= –11.9, p=0.02).

The third article provided by the applicant reported the results from the Avalon study, a prospective, multicenter, single-arm study of the Evoke® SCS System.[67] While not a standalone claim of substantial clinical improvement, the applicant submitted this article in support of its other SCI claims to demonstrate that the relevant findings from the Evoke pivotal trial had been replicated in another multi-center trial with 12-month follow up. The authors of the third article stated that the purpose of the Avalon study was to determine whether maintaining stable SC activation has a beneficial outcome on pain relief by demonstrating the safety and performance of the new closed-loop Evoke® SCS System. The protocol was publicly registered at Australian New Zealand Clinical Trials Registry. Patients were consented at five clinical sites in Australia from August 2015 to April 2017 for the Avalon study.[68] A total of 70 patients underwent a trial

[67] Russo M, Brooker C, Cousins MJ, Taylor N, Boesel T, Sullivan R, Holford L, Hanson E, Gmel GE, Shariati NH, Poree L, Parker J. Sustained Long- Term Outcomes with Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study. Neurosurgery. 2020 Feb 5. [Epub ahead of print]
[68] Ibid.

procedure. Of these, 68 (97.1 percent) completed the end-of-trial assessments and were evaluable. Of the 68 patients, 56 (82.4 percent) with assessment data had a reduction of 40 percent or more from baseline in their overall VAS rating; of those, 48 patients elected to proceed with a permanent implant. Two additional patients with a segmental VAS reduction of 40 percent or more proceeded with a permanent implant as per the protocol inclusion criterion. Fifty subjects were implanted (71.4 percent of those trialed).

The authors of the Avalon study article stated that baseline assessments in this study included ratings of pain on the Visual Analog Scale (100-mm VAS), impact of pain (Brief Pain Inventory [BPI]), function (Oswestry Disability Index [ODI]), sleep (Pittsburgh Sleep Quality Index [PSQI]), quality of life (EuroQol instrument [EQ–5D–5L]), and medication usage. Adverse events were assessed throughout the study. Along with raw scores and percent change from baseline, VAS data were also analyzed as responders (≥50 percent pain relief) and high responders (≥80 percent pain relief). According to the article, the outcomes data were analyzed using paired t-tests with an alpha of 0.05 and results were presented for the permanently implanted patients only.

The authors reported favorable results for pain relief outcomes.[69] At 12 months, 76.9 percent of patients were back pain responders (≥50 percent pain reduction), with 56.4 percent being classified as high responders (≥80 percent pain reduction). The proportion of patients who were leg pain responders at 12 months was 79.3 percent (≥50 percent pain reduction), and 58.6 percent of patients were high responders (≥80 percent pain reduction). The proportion of patients who were overall pain responders at 12 months was 81.4 percent (≥50 percent pain reduction), and 53.5 percent of patients were high responders (≥80 percent pain reduction).

[69] Ibid.

Based upon the evidence presented by the applicant, we noted the following concerns regarding whether the Evoke® SCS System met the substantial clinical improvement criterion. First, we noted that none of the sources provided by the applicant compared the Evoke® SCS System to other currently available technologies, such as other open-loop spinal cord stimulation products. However, in the Evoke pivotal clinical study, all patients were implanted with the Evoke® SCS System, with the difference between study groups being that the implanted devices in the treatment group were set to closed-loop stimulation as opposed to open-loop stimulation. While the study is testing outcomes between different aspects of the Evoke® SCS System itself, additional information comparing the Evoke® SCS System to existing spinal cord stimulators would help inform our assessment of substantial clinical improvement. While the applicant asserted that the Evoke® SCS System is the only available closed-loop SCS, we invited public comment on whether there are other existing technologies which may be appropriate comparators. Second, we have concern regarding the patient sample size cited in the studies. Furthermore, the applicant cites the Avalon study in Australia to support its claim that the pivotal clinical study's results were replicated internationally. We requested additional details about how these two studies' results would be generalizable to the U.S. population. We invited public comments on whether the Evoke® SCS System meets the substantial clinical improvement criterion.

Comment: The applicant acknowledged that the device utilized as the control group in the Evoke® study was not commercially available at the time of the study. However, the applicant stated that the Evoke® System Summary of Safety and Effectiveness Data (SSED, P190002) published by FDA includes information highlighting that the control group can be considered representative of SCS devices that were commercially available at the time. As such,

the applicant asserts that the published clinical results of Evoke® closed-loop SCS versus the choice of control indicate that the substantial clinical improvement (SCI) criterion has been met. The applicant explained that, as stated in FDA SSED, the Evoke® System open-loop stimulation mode delivers therapy that is equivalent to other commercially available open-loop SCS systems in terms of intended use, and with respect to their biological and technical characteristics. To support these claims, the applicant provided a comparison of effectiveness outcomes between Evoke® open-loop SCS and other FDA-approved commercial open-loop systems.

Many commenters expressed the opinion that the Evoke® SCS System open-loop stimulation mode is largely equivalent to other commercially available SCS systems, consistent with the FDA's pre-market approval for Evoke®, and therefore served as an effective comparator between the Evoke® SCS System closed-loop stimulation mode and traditional open-loop stimulation.

Many commenters noted that the use of the same Evoke® device in both the experimental and control arms had multiple benefits supporting the rigor and validity of the Randomized Clinical Trial (RCT). First, it made it possible to ensure proper double-blinding in the study. Second, using the Evoke® system in both arms of the clinical trial was a way to control for confounding factors associated with differences between different systems, and only study the differences in clinical effects between the open- loop and closed- loop aspects. Third, because the Evoke® SCS System could measure the neural response in both groups by quantifying the ECAPs, using the Evoke® SCS System in both groups allowed for a more direct comparison of spinal cord activation.

Many commenters noted that the use of the Evoke® SCS System in both study groups was to the study participants' ultimate benefit since they were implanted with a device that could

be switched to a closed-loop setting that can better manage their pain after the long-term study is completed.

Response: We appreciate the applicant's and other commenters' responses to our questions regarding the Evoke® SCS System. Based on commenters' inputs, we agree that the Evoke® SCS System open-loop stimulation mode is largely equivalent to other commercially available SCS systems and thus served as an appropriate comparator for closed-loop versus open-loop spinal cord stimulation. We believe this RCT comparison served to demonstrate the substantial clinical improvement provided by the closed-loop system, differentiating it from open-loop systems typically described by existing device categories, thus supporting the creation of a new device category.

Comment: A competitor agreed with our concern regarding the use of the Evoke® device in both arms of the RCT, stating that there are no comparative data regarding the relative clinical benefit of the Evoke® closed loop system. In contrast, the commenter noted that the RCT for the Senza SCS system compared that system's 10 kHz high-frequency, open-loop stimulation to a completely different commercially available device programmed to use low-frequency, open-loop stimulation.

Response: We appreciate the commenter's input, however, we do not believe that the Senza SCS system RCT is equivalent to the situation of the Evoke® SCS System RCT, and thus does not provide a sufficient counterfactual.

Comment: The applicant stated that the Evoke study was a prospective, multicenter, randomized, double-blind study statistically powered to test the efficacy of the Evoke® SCS System to treat patients with chronic, intractable pain of the trunk and/or limbs. The applicant explained that this study design was developed to be generalizable, preserve objectivity, and

minimize bias. The sample size calculation and expected treatment effect were based on prior open-loop SCS studies by North et al. (2005)[70], Kumar et al. (2007)[71], and Kapural et al. (2015)[72], as well as the preliminary results of Evoke® closed-loop SCS from the Avalon study. The applicant explained that the study design and sample size calculation for the Evoke study were reviewed and approved by FDA to test non-inferiority and superiority of Evoke® closed-loop SCS compared to open-loop SCS.

The applicant explained that the Evoke® study randomized 134 subjects across 13 investigation sites and that no one site enrolled more than 18% of study subjects and no interaction was found in post hoc testing between study sites and treatments in the assessment of the primary study endpoint (p-value = 0.673). Additionally, the applicant explained that the randomization effectively generated directly comparable treatment groups. There were no statistically significant differences in the comparisons of the baseline characteristics between groups (p-value > 0.05). The applicant asserted that, therefore, both the multi-center and randomization requirements of this trial were effectively fulfilled, which enhances both the internal and external validity of the statistical conclusions drawn from this study.

The applicant stated that patient populations and use of the device (including clinical practice and techniques) are similar between Australia and the U.S.; and therefore, the results from the Australian Avalon study are generalizable to the U.S. population. The applicant stated that the baseline characteristics of the patients in the Avalon Australian study population were

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[70] North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery. 2005;56(1):98–106; discussion 106-7.
[71] Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome: Pain. 2007 Nov;132(1):179–88.
[72] Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, et al. Novel 10-khz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT randomized controlled trial. Anesthesiology. 2015 Oct;123(4):851–60.

very similar to those of the Evoke U.S. study population. The applicant also explained that the national medical societies from these geographies are in agreement regarding the conditions in which to recommend SCS as a treatment option for chronic pain. The clinical study protocols for both the Evoke and Avalon studies were designed in accordance with these recommendations. The applicant further explained that the US and Australian instructions for use (IFU) used in each of these studies followed similar procedures, and that study personnel were required to have the requisite skills and sufficient experience and to complete training on the Evoke system and study procedures to participate in the studies.

Many commenters stated that they believe the Evoke® RCT was powered adequately (i.e., had sufficient sample size) to detect differences in the primary outcome between groups. Many commenters also stated that they believe the demographic characteristics of the Australian and U.S. populations and uses of the device (including clinical practice and techniques) in the two countries are substantially similar, and this should not be a concern.

Response: We appreciate the manufacturer's and other commenters' responses to our questions regarding the Evoke® SCS System. We concur with the commenters' inputs that the Evoke® RCT sample size was sufficient to detect differences in the primary outcome between study groups. Based on the commenters' inputs, we also agree that the results of the Avalon study are generalizable to the U.S. population.

Comment: A competitor stated they do not believe that the Evoke® SCS System has successfully demonstrated substantial clinical improvement in relation to existing technologies. As an example, the commenter offered a comparison between some of the results of the Evoke® RCT and that of the Senza SCS system RCT. The Senza RCT compared a control arm of open-loop low-frequency stimulation to a treatment arm of open-loop high frequency 10 kHz

stimulation. First, the commenter stated that the Evoke® RCT demonstrated a treatment effect for back pain at 3 months of 18.3%, while the Senza RCT demonstrated a treatment effect of 38.4%, more than twice that shown in the Evoke® RCT. Second, the commenter stated that while the Evoke® RCT demonstrated a statistically significant improvement in the treatment group for back pain, it did not demonstrate a statistically significant improvement in leg pain. On the other hand, the commenter stated that the Senza RCT demonstrated a statistically significant improvement in both back and leg pain.

Response: We appreciate the commenter's input. We note that the treatment effects between the Evoke® RCT and Senza RCT are not directly comparable since those studies were designed to test the differences between different mechanisms of SCS (e.g., open-loop versus closed-loop and low-frequency versus high-frequency, respectively). Further, we note that the commenter only describes treatment effect differences at 3 months, while the Evoke RCT has consistently demonstrated substantial clinical improvements over 24 months. Last, with respect to the commenter's claim that the Evoke® RCT did not demonstrate a statistically significant improvement in leg pain, we believe the Evoke® RCT demonstrated statistically significant improvements in both leg pain and overall back and leg pain combined.

Comment: Many commenters stated that they believe the Evoke® SCS System has demonstrated substantial clinical improvement. The commenters pointed out that the Evoke® RCT was the first to compare SCS between traditional open-loop and a novel closed-loop system using a highly rigorous study design, and it is one of the only double-blind SCS studies with such a substantial follow-up period (e.g., follow-ups at 12 months, 24 months, and eventually at 36 months). The commenters stated that the RCT showed substantial clinical improvement in Evoke® SCS System over the open-loop SCS in terms of the overall pain reduction and other

patient-reported outcomes. The commenters stated that the results of all the cited clinical studies demonstrate that use of closed-loop therapy provides an advantage compared to use of open-loop therapy, with a clinically meaningful reduction in pain for patients who suffer from chronic, intractable pain of the trunk and/or limbs. The commenters noted that given that currently available systems offer only open-loop therapy, the availability of the Evoke® SCS System provides an important clinical benefit over contemporary systems available in the market.

Response: We appreciate the applicant's and other commenters' responses to our questions regarding the Evoke® SCS System. After consideration of the manufacturer's response and the public comments received, we believe that commenters have addressed our concerns regarding whether the Evoke® SCS System meets the substantial clinical improvement criterion and that the Evoke® SCS System represents a substantial clinical improvement over existing technologies based on the data received from commenters.

The third criteria for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Evoke® SCS System would be reported with HCPCS code 63685. To meet the cost criteria for device pass-through payment status, a device must pass all three tests of the cost criteria for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criteria, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5465 Level 5 Neurostimulator and Related Procedures, which had a CY 2021 payment rate of

$29,444.52 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 63685 had a device offset amount of $24,209.28 at the time the application was received. According to the applicant, the estimated average cost of the Evoke® SCS system is $37,000. We note that the device cost provided by the applicant encompasses the entire Evoke® SCS. However, as previously discussed, the external components of the Evoke® SCS (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) may not meet the criteria required under § 419.66(b)(3), *i.e.,* the external components are not implantable and/or do not come in contact with human tissue. Therefore, the cost of only the eligible internal components may be less than the cost of the entire system and could affect the calculations in the following formulas.

Section 419.66(d)(1), the first cost significance requirement provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $37,000 for the Evoke® SCS System is 125.7 percent of the applicable APC payment amount for the service related to the category of devices of $29,444.52 (($37,000/ $29,444.52) x 100 = 125.7 percent). Therefore, we stated that we believe the Evoke® SCS System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $37,000

for the Evoke® SCS System is 152.8 percent of the cost of the device-related portion of the APC payment amount for the related service of $24,209.28 (($37,000/$24,209.28) ·100 = 152.8 percent). Therefore, we stated that we believe that the Evoke® SCS System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $37,000 for the Evoke® SCS System and the portion of the APC payment amount for the device of $24,209.28 is 43.4 percent of the APC payment amount for the related service of $29,444.52 ((($37,000-$24,209.28)/$29,444.52) x100 = 43.4 percent). Therefore, we stated that we believe that the Evoke® SCS System meet the third cost significance requirement.

We noted a concern regarding whether the Evoke® SCS System meets all the cost criteria. Specifically, as previously discussed, the external components of the Evoke® SCS may not meet the criteria required under § 419.66(b)(3), *i.e.,* the external components (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) are not implantable and/or do not come in contact with human tissue. Therefore, the cost of only the eligible internal components may be less than the cost of the entire system. If the cost of the internal components is sufficiently lower than that of the whole system, then that could affect the calculations for the cost requirements to the point where some of those requirements are not met.

We invited public comment on whether the Evoke® SCS System meets the device pass-through payment criteria discussed in this section, including the cost criteria for device pass-through payment status.

Comment: The applicant asserted that the Evoke® SCS System meets all the cost criteria required under § 419.66(b)(3). Specifically, the applicant stated that the internal, implantable components of the Evoke® SCS System (e.g., the generator and charger) meet the cost criteria, while the external components (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) do not meet the criteria. The applicant provided a cost breakdown of the eligible internal components as a subset of the entire system: the cost of the implanted generator and charger is $32,000, while the additional components included in the "system", i.e., leads, anchors, lead extension, surgical accessories, etc. are $5,000.

Response: We appreciate the applicant's input. As the applicant explained in response to our concerns regarding the device eligibility criteria specified at § 419.66(b), their request for a new device category would only apply to the generator and charger components of the Evoke® SCS System since those are the only components that meet the device eligibility criteria. The applicant's clarification regarding the cost breakdown of the eligible versus ineligible components indicates that cost for just the generator and charger is $32,000, while the estimated average cost of the entire Evoke® SCS system is $37,000. When we recalculate the formulas for the three cost significance requirements, we find that the eligible Evoke components still meet all three cost significance requirements and, thus, the cost criteria required under § 419.66(b)(3). After consideration of the public comments we received, and consideration of the cost criteria, we have determined that the Evoke® SCS System meets the cost criteria for device pass-through payment status.

After considering the public comments we received and our review of the device pass-through application, we have determined that the Evoke® SCS System meets the criteria for

device pass-through. Therefore, we are finalizing approval for device passthrough payment status for the Evoke® SCS System effective beginning January 1, 2023.

(5) Pathfinder® Endoscope Overtube

Neptune Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Pathfinder® Endoscope Overtube (the Pathfinder®) for CY 2023. According to the applicant, the Pathfinder® is a flexible, single use, overtube with stiffening capabilities that is used to manage endoscope looping and improve tip control of the endoscope. Per the applicant, the Pathfinder® is indicated for use with an endoscope to facilitate intubation and treatment in the gastrointestinal (GI) tract in adult patients (22 years of age and older). The applicant indicated that the flexible overtube may be connected to vacuum for rigidization. Specifically, the handle includes a vacuum line which is connected to free space within the device that is completely contained, forming the vacuumable volume. The applicant stated that the handle rotator has two positions: the first connects the vacuumable volume within the device to atmosphere (vent) to stay in the flexible position, and the second position connects the vacuumable volume to a source of vacuum to transition to the rigid condition. When transitioned to the rigid condition, the device maintains its shape at the time of rigidization, allowing the endoscope to advance or withdraw relative to the overtube with minimal disturbance to the surrounding anatomy. According to the applicant, when transitioned to the flexible condition, the device can move relative to the patient anatomy and endoscope for navigation through the GI tract.

With respect to the newness criterion at § 419.66(b)(1), on August 20, 2019, the applicant received 510(k) clearance from FDA for the Pathfinder® as a Class II device to be used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the GI tract in adult

patients (22 years of age and older). We received the application for a new device category for transitional pass-through payment status for the Pathfinder® on November 30, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether the Pathfinder® meets the newness criterion.

We did not receive public comments in regard to whether the Pathfinder® meets the eligibility criterion at § 419.66(b)(1). Because we received the Pathfinder® pass-through application on November 30, 2021, which is within 3 years of August 20, 2019, the date of initial FDA marketing authorization, we agree that the Pathfinder® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Pathfinder® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. The applicant also claimed that the Pathfinder® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We solicited public comments on whether the Pathfinder® meets the eligibility criteria at § 419.66(b).

We did not receive public comments in regard to whether the Pathfinder® meets the eligibility criteria at § 419.66(b)(3) or § 419.66(b)(4). Based on our review of the application, we agree with the applicant that the Pathfinder® meets the criterion of § 419.66(b).

The criterion for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

The applicant provided a list of all established device categories used presently or previously for pass-through payment that describe related or similar products. The applicant indicated that while there are other endoscope overtubes available, there are no known competitive devices on the market that can be toggled from being flexible to rigid instantly to prevent/manage endoscope looping. The applicant stated that the Pathfinder® is unique in its ability to do this using a proprietary technology called Dynamic Rigidization™. For each established device category, the applicant provided explanations as to why that category does not encompass the nominated device: (1) C1748 (endoscope, single-use (i.e., disposable) upper GI, imaging/illumination device (insertable)), and (2) C1749 (endoscope, retrograde imaging/illumination colonoscope device (implantable)). According to the applicant, the Pathfinder® is not an imaging/illumination device. Furthermore, the Pathfinder® can be used in upper and lower GI endoscope/colonoscope procedures to eliminate device looping. As such, the applicant does not believe that the existing codes encompass the Pathfinder®.

Upon review, it did not appear that there are any existing pass-through payment categories that might apply to the Pathfinder®. We solicited public comment on whether the Pathfinder® meets the device category criterion.

We did not receive public comments in regard to whether the Pathfinder® meets the eligibility criterion at § 419.66(c)(1) and upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Pathfinder®. Therefore, we agree with the applicant that the Pathfinder® meets the criterion of § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury

or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that the Pathfinder® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of the Pathfinder® when used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the GI tract in adult patients (22 years of age and older).

Broadly, the applicant asserted the following areas in which the Pathfinder® would provide a substantial clinical improvement: (1) minimize scope looping and complications from scope looping, (2) reduce endoscopist's workload during endoscope procedure, (3) provide endoscope tip stabilization, (4) enable endoscopic procedure in patients with altered anatomy, (5) enable crossing of anastomosis, and (6) enable antegrade and retrograde enteroscopy, in use for the prevention of endoscope looping. The applicant provided eleven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that the Pathfinder® minimizes scope looping and complications from scope looping, the applicant submitted a prospective single center study performed over 11 months by two endoscopists in the United States.[73] The study population consisted of 15 patients with a mean age of 63.2 years (range 23-88 y) and mean Body Mass Index (BMI) of

[73] Park, N., Abadir, A., Chahine, A., Eng, D., Ji, S., Nguyen, P., Bernal, E., Simoni, R. & Samarasena, J. B. (2021). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. Techniques and Innovations in Gastrointestinal Endoscopy.

28.6 kg/m2 (range 16.8 – 46.2 kg/m2). Two of the patients were placed under moderate sedation, 11 had monitored anesthesia care (MAC) and two patients underwent general anesthesia. The mean (standard deviation) Boston bowel preparation scale (BBPS) score was 6.9 (1.8), with a range of 6-9. Indications for colonoscopy included surveillance (n=9), evaluation of Crohn's disease (n=2), polyp resection (n=3), and other diagnostic purpose (n=1). To complete the colonoscopy, the endoscopist resorted to the use of the rigidizing overtube in all 15 cases due to several technical difficulties encountered. The authors noted the reasons for overtube use included a history of difficult colonoscopy due to a long, tortuous colon (n=9), inability to reach the cecum (n=3) or the ileocolonic anastomosis (n=1), inability to completely visualize the ileocecal valve (n=1), and inability to advance colonoscope due to looping and bradycardia (n=1). The authors noted that colonoscopy was successfully completed in all 15 cases using the overtube device.

The applicant provided a second article to support the claims that the Pathfinder® minimizes scope looping and complications from scope looping, provides endoscope tip stabilization, enables endoscopic procedure in patients with altered anatomy, and enables crossing of anastomosis. The article consists of an abstract from a set of case studies performed in two tertiary care endoscopy centers in the United States.[74] From May 2019 to February 2020, 29 patients were consecutively treated using the Pathfinder®. The patients were predominantly male with a median age of 66 years old. Of the 29 patients scoped, one patient received an upper endoscopy, 24 received colonoscopy, and four received enteroscopy. The types of anesthesia provided to these patients included: general anesthesia for four patients, MAC for 15 patients, moderate monitored anesthesia for nine patients, and no sedation for one patient. The indication

[74] Wei, M. T., Hwang, J. H., Watson, R. R., Park, W., & Friedland, S. (2021). Novel rigidizing overtube for colonoscope stabilization and loop prevention (with video). Gastrointestinal Endoscopy, 93(3), 740-749.

for using the Pathfinder® was incomplete colonoscopy in 12 patients, enhancing insertion depth not feasible with standard endoscopy in six patients and endoscope stabilization during endoscopic resection in 11 patients, according to the study researchers.

The applicant submitted a third article,[75] which described a 57-year-old male being evaluated for high-risk colon cancer screening due to positive Cologuard, to support the claim that the Pathfinder® minimizes scope looping and complications from scope looping. The applicant pointed out that an initial colonoscopy on the patient was incomplete due to severely redundant colon, i.e., an abnormally long colon with additional loops or twists. The patient was referred to the study's tertiary care center for a repeat attempt with advanced endoscopy. A second colonoscopy was attempted, but significant looping occurred due to the large redundant colon, resulting in another incomplete colonoscopy. Maneuvers like changing to supine position, scope torsion, abdominal pressure, use of colonic overtube and Naviaid balloon-assisted colonoscopy were all unsuccessful, according to the study researchers. The study's tertiary care center performed a virtual computerized tomography (CT) colonography, which revealed a polyp in the ascending colon and markedly redundant colon. This prompted a third colonoscopy, which again showed significant looping of the colon and the colonoscopy was incomplete, per the study researchers. After three unsuccessful conventional colonoscopies, the patient had a colonoscopy with the rigidizing Pathfinder®. According to the study, the exam was technically challenging, requiring more than two hours of procedure time, but was successfully completed.

[75] Patel, P., & Khara, H. (2021). S2537 Successful Polypectomy with Novel Rigidizing Overtube with Failed Previous Colonoscopies. Official journal of the American College of Gastroenterology| ACG, 116, S1070.

A fourth article[76] was provided by the applicant to support the claim that the Pathfinder® minimizes scope looping and complications from scope looping. This article presented a challenging case of a laterally spreading tumor at the hepatic flexure in a difficult and unstable colon, which was removed by endoscopic submucosal dissection (ESD) using a novel injectable needle-type knife and with the assistance of the dynamic rigidizing Pathfinder®. The case involved a 66-year-old man with coronary artery disease, hypertension, hyperlipidemia, and diabetes mellitus who was found on screening colonoscopy to have a 35-mm laterally spreading tumor at the hepatic flexure (Paris IIaþIs). An attempted endoscopic mucosal resection was unsuccessful because of non-lifting of the lesion during submucosal injection; therefore, the patient was referred for ESD. Given the length of the procedure and the patient's medical comorbidities, the procedure was performed under general endotracheal anesthesia. A pediatric colonoscope (PCF-H190DL, Olympus America, Center Valley, Pa, USA) with a tapered-tip distal attachment cap (ST hood, Fujifilm Medical Systems, Stamford, Conn, USA) was initially advanced to the cecum and withdrawn to the hepatic flexure. However, because of a highly redundant left colon segment, the colonoscope could not be reduced into a stable, short position for ESD despite manual abdominal counterpressure and position changes. In the looped, long position at the hepatic flexure, the endoscope was noted to be in an extremely unstable position and therefore unsafe for ESD. The dynamic rigidizing Pathfinder® overtube allowed for a stable endoscopic position in a challenging ESD at the hepatic flexure per the applicant.

[76] Coronel, M., Coronel, E., Romero, L., & Phillip, S. G. (2021). Combination of a dynamic rigidizing overtube and a novel injectable needle-type knife to facilitate colorectal endoscopic submucosal dissection. VideoGIE, 6(7), 297-300.

The applicant provided a fifth article[77] to support the claims that the Pathfinder® minimizes scope looping and complications from scope looping and enables endoscopic procedure in patients with altered anatomy. This article presents two cases demonstrating the utility of the rigidizing overtube in accomplishing altered-anatomy endoscopic retrograde cholangiopancreatography (ERCP), which consisted of the overtube reducing looping and allowing for increased distances that shorter scopes (such as a side-viewing duodenoscope) are unable to achieve. According to the authors, success varies with intubation and cannulation in ERCP for patients with surgically altered anatomy. The authors concluded that this is particularly important in managing gastric loops and tight angulation at surgical anastomoses, including jejunojejunostomy anastomosis.

A sixth article[78] the applicant provided in support of its claim that the Pathfinder® minimizes scope looping and complications from scope looping was a single site case study of a 64-year-old man with a history of C5 spinal cord injury due to a diving accident who presented for screening colonoscopy. A pediatric colonoscope was used initially, but given significant looping, the colonoscope could only reach the transverse colon. The colonoscope was withdrawn, and the Pathfinder® overtube was used. The applicant pointed out that with assistance from the overtube, the colonoscope reached the cecum easily in eight minutes. A 1-cm sessile polyp was found in the ascending colon and was removed by cold snare. An additional 3 polyps measuring less than one centimeter were identified and removed by cold snare, and the procedure was terminated. Three of the polyps (including the 1-cm polyp) were determined to be tubular adenoma. The fourth polyp was identified as a hyperplastic polyp.

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[77] Wei, M. T., Friedland, S., Watson, R. R., & Hwang, J. H. (2020). Use of a rigidizing overtube for altered-anatomy ERCP. VideoGIE, 5(12), 664-666.
[78] Wei, M. T., Hwang, J. H., Watson, R., & Friedland, S. (2020). Use of a rigidizing overtube to complete an incomplete colonoscopy. VideoGIE, 5(11), 583-585.

A seventh article[79] provided in support of the same claim described a 72-year-old male who presented for surveillance colonoscopy. The colonoscope was successfully advanced to the ascending colon, however, it could not be advanced further due to loop formation. Every time the scope was advanced through the loop the patient became bradycardic to a heart rate in the 40s, presumably from a vasovagal reflex. Repeated attempts at advancing the colonoscope were unsuccessful due to looping and bradycardia despite abdominal counterpressure and position change. The scope was removed and the rigidizing overtube device was introduced onto the scope. The scope with overtube was advanced to the ascending colon in its flexible state. Once in the ascending colon, the overtube was rigidized which allowed for easy cecal intubation and successful completion of colonoscope without any loop formation, as the applicant noted.

An eighth article[80] provided by the applicant in support of the claim of a reduction in the endoscopist's workload during the endoscope procedure was a prospective, single center study performed over 6 months. Difficult colonoscopy subjects were categorized based on looping that prevented reaching the cecum despite position change and abdominal counter pressure (LOOP group), or poor stabilization to perform therapeutic polypectomy (UNSTABLE group). Parameters assessed included successful/failed salvage of the procedure, and the in-procedure National Aeronautics and Space Administration (NASA) Task Load Index (TLX)[81] before and after use of the rigidizing overtube. The TLX raw and weighted scores were compared for each type of demand (mental, physical, effort, temporal, performance, and frustration). Over the study

[79] Abadir, A., Chehade, N. E. H., Park, N., Eng, D., & Samarasena, J. (2020). S1876 Use of a Novel Dynamic Rigidizing Overtube in Difficult Colonoscopy Due to Looping. Official journal of the American College of Gastroenterology| ACG, 115, S971.
[80] Abadir, A., Park, N., Eng, D. J., Chehade, N. E. H., & Samarasena, J. (2020, October). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. American Journal of Gastroenterology (Vol. 115, pp. S83-S83). Two Commerce Square, 2001 Market St., Philadelphia, PA 19103 USA: Lippincott Williams & Wilkins.
[81] TLX @ NASA Ames - Home

period, there were 14 difficult colonoscopy procedures: eight in the LOOP group and six in the UNSTABLE group. In the LOOP group, all eight cases were salvaged, and cecum was reached after the Pathfinder® overtube was used. The TLX weighted score decreased from 81.1 to 26.0 after use (P,0.01). In the UNSTABLE group, complete polypectomy was successful in all cases using the Pathfinder® overtube. The TLX weighted score decreased from 79.7 to 40.4 after use (P,0.01). In all procedures, the TLX raw scores for each type of demand was reduced. The applicant pointed out that all six dimensions of the NASA-TLX: mental demand, physical demand, temporal demand, effort, performance, and frustration level were significantly improved after using the overtube. All score changes were statistically significant per the study researchers. The overall weighted NASA-TLX score decreased from an average of 80.30 to 30.85 after using the device as the applicant identified. In this case series, the study showed that the novel rigidizing overtube decreases burden on the endoscopist by reducing the workload perceived during the procedure, according to the study researchers.

In support of the claims about a reduction in the endoscopist's workload during the endoscope procedure and enabling antegrade and retrograde enteroscopy, the applicant submitted a ninth article,[82] which was a retrospective single site study over a 6-month period, in which two endoscopists performed retrograde and antegrade enteroscopies using a rigidizing overtube. Retrograde enteroscopy was performed via the anus by advancing the overtube to the cecum in its flexible state with the pediatric colonoscope, reducing the scope and overtube construct, and then rigidizing at the cecum. Following rigidization, the scope was pushed through the ileocecal valve and advanced maximally. Antegrade enteroscopy was performed by inserting the dynamic

[82] Park, N., Abadir, A., Eng, D., Chehade, N. E. H., & Samarasena, J. (2020). S0972 Enteroscopy Enabled Using a Novel Dynamic Rigidizing Overtube: An Initial Single Center Experience. Official journal of the American College of Gastroenterology| ACG, 115, S495-S496.

rigidizing overtube with use of the pediatric colonoscope via the mouth, rigidizing in the duodenum or jejunum, and then advancing maximally. A total of nine retrograde and three antegrade enteroscopies were performed. On retrograde enteroscopy, small bowel depth ranged from 15 cm to 70 cm from the ileocecal valve, with a mean of 48.9 cm. There were no complications associated with use of the dynamic rigidizing overtube, both in antegrade and retrograde evaluation. Of note, in one case, initial attempts at retrograde double-balloon enteroscopy failed due to looping and unfavorable angulation of the ileocecal valve. Multiple attempts at intubation including manual abdominal pressure and position changes were unsuccessful. The dynamic rigidizing overtube was then introduced with successful intubation and subsequent exploration of the ileum. Overall, both endoscopists reported significant ease of enteroscopy compared to traditional double-balloon methods, with lower perceived mental and physical demand, according to the study.

The applicant supplied a tenth article[83] that described a single site case study in support of its claim that the Pathfinder® offers improved endoscope tip stabilization. The study described using a Pathfinder® overtube 85-centimeters long to accommodate a pediatric colonoscope, upper endoscope, or enteroscope. The study presented two contrasting cases demonstrating the rigidizing overtube in colorectal endoscopic submucosal dissection (ESD). In the first case, a 70-year-old man was referred for ESD of a 20mm polyp in the ascending colon. Following submucosal injection, partial circumferential incision was performed. According to the authors, the case was challenging due to poor tip control in the right colon. The cut made by the knife was irregular and of higher risk, requiring more time to make the incision. The polyp was identified

[83] Wei, M. T., Hwang, J. H., & Friedland, S. (2021). S2027 Use of the Rigidizing Overtube in Assisting Endoscopic Submucosal Dissection Among Patients with Ulcerative Colitis. Official journal of the American College of Gastroenterology| ACG, 116, S880.

as a tubular adenoma with clear margins. In the second case, a 44-year-old man presented following recent diagnosis of ulcerative colitis. Prior colonoscopy demonstrated a large 3-5cm tubulovillous adenoma in the ascending colon. A cap and rigidizing overtube was used during the colonoscopy. During ESD, there was severe fibrosis in the distal portion of the lesion. The rigidizing overtube offered improved scope stability and tip control, facilitating precise dissection of the narrowed fibrotic submucosal space, per the applicant. The lesion was removed en bloc and was identified as a tubular adenoma with low grade dysplasia, with clear margins.

In support of its claim that the Pathfinder® enables endoscopic procedure in patients with altered anatomy, the applicant submitted an eleventh article[84] describing a single site case study about a 42-year-old female with a history of iatrogenic bile duct transection during cholecystectomy who underwent Roux-en-Y Hepaticojejunostomy (HJ). Her course was complicated by HJ stricture requiring double-balloon assisted enteroscopy with ERCP to place a fully covered metal stent. After three months the stent was removed, but restricturing occurred six months later and she developed left-sided intrahepatic stone disease. Double-balloon assisted enteroscopy to reach the anastomosis became more difficult. As a result, multiple antegrade procedures via endoscopic ultrasound (EUS) guided hepaticogastrostomy with lithotripsy were used to treat accessible intrahepatic stones, but several more stones remained. To facilitate further endoscopic procedures, a shortcut was made using laparoscopic revision to create a new entero-enterostomy from the proximal jejunum to the pancreaticobiliary (PB) limb. Repeat enteroscopy with a slim colonoscope failed to enter the PB limb despite multiple attempts due to difficult angulation and looping in the stomach. A rigidizing overtube placed over the colonoscope allowed the scope to advance to the HJ without looping in the stomach and

[84] Abadir, A., Park, N., Eng, D. J., Lee, D., & Samarasena, J. (2020). S2330 Altered Anatomy ERCP Using a Novel Dynamic Rigidizing Overtube. Official journal of the American College of Gastroenterology| ACG, 115, S1235.

provided improved control up the ascending PB limb. The colonoscope then deployed a stone extraction balloon to remove biliary duct stones. According to the article, this case demonstrates the use of a rigidizing overtube to prevent looping and assist with complex stone removal via ERCP in altered anatomy.

While the applicant provided articles that describe the clinical use of the Pathfinder® in challenging procedures, the majority of the articles are clinical case series which do not necessarily allow for a clear comparison with common mediation strategies.[85] Additionally, the applicant identified specific procedures for using the Pathfinder® when the physician needs to control looping or enhance endoscope tip control to successfully complete the procedure, but made no comparison to the use of other existing strategies or techniques that could be used for these procedures.[86] The applicant also has not provided studies comparing the efficacy of the Pathfinder® with other rigidization devices although the applicant has noted the existence of such devices. Furthermore, all the clinical case study series presented in the applicant's articles were based on small sample sizes. There are other devices available which can help assist the Endoscopist in procedures which are difficult to perform. We had a concern that there has not been adequate comparison to other available devices used for similar indication. We asked for public comment on whether Pathfinder shows superiority over the existing devices/methods used in cases of endoscope looping and abnormal anatomy.

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[85] For example, repeat colonoscopy with a different sedation method, different instruments and/or different physicians, double-contrast barium enema, CT colonography, overtube-assisted colonoscopy, double-balloon enteroscopy and colonoscopy, single-balloon enteroscopy, integrated inflated balloon, spiral overtubes, colon capsule endoscopy, C-scan Cap imaging system, and/or robotic colonoscopes). See Franco, D. L., Leighton, J. A., & Gurudu, S. R. (2017). Approach to Incomplete Colonoscopy: New Techniques and Technologies. *Gastroenterology & hepatology*, *13*(8), 476–483.

[86] According to the applicant, the Pathfinder® is used for the following procedures: difficult colonoscopy, endoscopic mucosal resection (EMR)/endoscopic submucosal dissection (ESD) of colon, EMR/ESD of the stomach, enteroscopy (both antegrade and retrograde), altered anatomy ERCP, and endoscopic ultrasonography in the colon.

Furthermore, with respect to the two articles[87,88] presented to support the substantial clinical improvement claim in reducing endoscopists' workload during endoscopy procedures; in both articles, the authorships were identical for the same study center and time frame, and there were only two participating endoscopists. Therefore, it may be difficult to make comparisons due to the lack of a diverse pool of endoscopists. Additionally, we note that factors such as center and clinical staff characteristics in both studies are difficult to control, and it is difficult to determine if observed differences resulted from the Pathfinder® or from confounding variables. Finally, we noted that there was potential for some level of selection bias if providers are allowed to select the manner and order in which patients are treated, and thereby potentially influence outcomes seen in these studies.

We invited public comments on whether the Pathfinder® meets the substantial clinical improvement criterion.

Response: No comments were submitted regarding whether the Pathfinder® meets the substantial clinical improvement criterion. As such, we maintain our concerns listed in the CY 2023 OPPS/ASC proposed rule. Specifically, we are concerned that the majority of the articles provided were a clinical case series which did not necessarily allow for a clear comparison with common mediation strategies. Additionally, the applicant identified specific procedures for using the Pathfinder® when the physician needs to control looping or enhance endoscope tip control to successfully complete the procedure, but made no comparison to the use of other existing strategies or techniques that could be used for these procedures. We noted that while there are

[87] Abadir, A., Park, N., Eng, D. J., Chehade, N. E. H., & Samarasena, J. (2020, October). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. American Journal of Gastroenterology (Vol. 115, pp. S83-S83). Two Commerce Square, 2001 Market St., Philadelphia, PA 19103 USA: Lippincott Williams & Wilkins.

[88] Park, N., Abadir, A., Eng, D., Chehade, N. E. H., & Samarasena, J. (2020). S0972 Enteroscopy Enabled Using a Novel Dynamic Rigidizing Overtube: An Initial Single Center Experience. Official journal of the American College of Gastroenterology| ACG, 115, S495-S496.

other devices available which can help assist the Endoscopist in procedures which are difficult to perform and the applicant mentioned the existence of such devices, the applicant did not provide studies comparing the efficacy of the Pathfinder® with other rigidization devices. Overall, we do not believe that there has not been an adequate comparison of the Pathfinder® to other available devices used for similar indication. In addition, we remain concerned that all the clinical case study series presented in the applicant's articles were based on small sample sizes. Moreover, we are concerned that in both articles presented to support the substantial clinical improvement claim in reducing endoscopists' workload during endoscopy procedures, the authorships were identical for the same study center and time frame and there were only two participating endoscopists. As such, we believe it is difficult to make comparisons due to the lack of a diverse pool of endoscopists. Furthermore, factors such as center and clinical staff characteristics in both studies were difficult to control, which makes it difficult to determine if observed differences resulted from the Pathfinder® or from confounding variables. Finally, there was potential for some level of selection bias if providers were allowed to select the manner and order in which patients were treated, and thereby potentially influence outcomes seen in these studies. Because of these reasons, we do not believe that the Pathfinder® represents a substantial clinical improvement relative to existing technology currently available.

After our review of the device pass through application, we are not approving the Pathfinder® for transitional pass-through payment status in CY 2023 because the technology does not meet the substantial clinical improvement criterion. Because we have determined that the Pathfinder® does not meet the substantial clinical improvement criterion, we are not evaluating whether the device meets the cost criterion.

(6) The Uretero1

STERIS submitted an application for a new device category for transitional pass-through payment status for the Uretero1 for CY 2023. The applicant states that the Uretero1 is a sterile, single-use, disposable digital flexible ureteroscope. According to the applicant, the Uretero1™ Ureteroscope System consists of the following components: (1) the Uretero1, a sterile, single-use flexible disposable digital flexible ureteroscope; and (2) Vision 1, a touch screen camera control unit, with a high-resolution HD imaging system.

Per the applicant, the single use ureteroscope, the Uretero1, consists of: (1) handle, to hold scope (made of polycarbonate, and has no patient contact); (2) articulation lever, an angulated distal tip (polycarbonate 10 percent glass filled, and has no patient contact); (3) handle button, a button to take pictures, video, and zoom live image (made of silicone, and has no patient contact); (4) accessory Port with port cover to prevent backflow during procedures, pass instruments (Makrolon 2458, Indirect/limited patient contact); (5) irrigation port, for fluid access (Makrolon 2458, which has indirect or limited patient contact); (6) flexible shaft (Pebax, made of polyurethane, and has patient contact); (7) shaft strain relief (Santoprene and has contact with limited mucosal membrane); (8) bending/articulation section, which bends the tip of the scope to move the camera (made of stainless-steel compression coils and pull cables and has no patient contact); (9) distal tip, (ABS, and has patient contact); (10) instrument channel (PFA and has indirect and limited patient contact); (11) illumination fiber (made of polymethyl methacrylate (PMMA)/fluorinated polymer and has no patient contact); and (12) the camera (consists of glass and has limited mucosal membrane patient contact), and connector cables and plugs, which have no patient contact.

The Uretero1™ Ureteroscope System is a software-controlled system that consists of the Vision1 (Touch Screen Camera Control Unit (CCU)) and the sterile, single-use high-resolution

flexible ureteroscope. Per the applicant, the Uretero1 is inserted to find the causes of problems in the ureters or kidney, and to visualize organs, cavities, and canals in the urinary tract by transurethral or percutaneous access routes. The applicant notes the Uretero1 can also be used with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract, such as kidney stone management (treatment of nephrolithiasis).

According to the applicant, the device is used by urologists during ureteroscopy, a minimally invasive outpatient procedure typically performed under general anesthesia. The applicant states that once the patient is prepped and anesthesia takes effect, the urologist inserts a rigid scope into the urethra to the bladder to examine the ureteral orifices. Per the applicant, a guidewire is placed through the instrument channel of the rigid scope via fluoroscopic guidance through the orifice, up to the ureter. The applicant states that the rigid scope is removed, and the access sheath is advanced over the inserted guidewire. According to the applicant, the position of the access sheath is confirmed via fluoroscopy, and the obturator is removed from the access sheath, as well as the guidewire (if desired by the surgeon). The applicant states that the flexible ureteroscope is inserted through the access sheath up into the ureters and kidneys. During a procedure, an appropriate sterile solution is passed through the instrument channel of the ureteroscope to fill the bladder to allow greater visibility. If a kidney stone is located (depending on its size), the surgeon will perform laser lithotripsy to fragment the stone into smaller pieces, then remove the fragments.

Per the applicant, the Uretero1 can be used for 4 hours (exceeding the average procedure time of 60 mins), and the device has a timer which notifies the user at three separate intervals of remaining use time: one at 60 minutes, the next at 30 minutes, and the last at 5 minutes of remaining use time. According to the applicant, when the 4 hours of usage time has elapsed, and

if the scope is still plugged in, the user will be advised via a message on the screen that a new scope should be inserted and the current ureteroscope will no longer produce a live image. The applicant states that the scope timer only counts down while the device is powered on and plugged in; if it is unplugged, the time stops.

With respect to the newness criterion at § 419.66(b)(1), on November 23, 2021, the applicant received 510(k) clearance from FDA to market the Uretero1 to visualize organs, cavities, and canals in the urinary tract via transurethral or percutaneous access routes. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Uretero1 on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether the Uretero1 meets the newness criterion.

We did not receive public comments in regard to whether the Uretero1 meets the newness criterion at § 419.66(b)(1). Because we received the Uretero1 pass-through application on March 1, 2022, which is within 3 years of November 23, 2021, the date of FDA 510(k) approval to market the Uretero1, we have concluded that the Uretero1 meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Uretero1 is integral to the service provided, is used for one patient only and comes in contact with human tissue when it is inserted to visualize organs, cavities, and canals in the urinary tract.[83] Per the applicant, the Uretero1 is reasonable and necessary to diagnose problems in the ureters and kidneys via transurethral or percutaneous access routes. The applicant claims that the Uretero1 meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are

recovered, and it is not a supply or material furnished incident to a service. We solicited public comments on whether the Uretero1 meets the eligibility criterion at § 419.66(b).

We did not receive any comments on whether the Uretero1 meets the eligibility criteria at § 419.66(b)(3) or § 419.66(b)(4). We agree with the applicant that the Uretero1 device meets the criteria of § 419.66(b)(3) and § 419.66(b)(4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that the device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes the Uretero1 as a single use, disposable, digital flexible ureteroscope that is used in urologic procedures (ureteroscopy) that diagnose and treat conditions of the urinary tract (e.g., kidney stones, blockage, polyps, abnormal growths, etc.). According to the applicant, a possible existing pass-through code is C1748 (Endoscope, single use (i.e., disposable), upper GI, imaging/illumination device (insertable)), was made effective July 1, 2020.[84] The applicant notes that while this category is for a single use device, it is only appropriate for GI imaging, and more specifically, for endoscopic retrograde cholangiopancreatography (ERCP) procedures. Therefore, the applicant asserts this category would not apply to a single use, disposable, ureteroscope for use in urological procedures. We solicited public comment on whether the Uretero1 meets the device category criterion.

We did not receive any comments on whether the Uretero1 meets the criterion for establishing new device categories specified at § 419.66(c)(1). However, we agree that there is no existing pass-through payment category that appropriately describes the Uretero1. The Uretero1 is a single use, disposable, digital flexible ureteroscope that may be used in urologic

procedures (ureteroscopy) to diagnose and treat conditions of the urinary tract. Therefore, the existing pass-through code for a single-use, disposable, endoscopic device for GI imaging does not apply. Based on this information, we have determined that the Uretero1 meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that the Uretero1 represents a substantial clinical improvement over existing technology. With respect to this criterion, the applicant submitted studies that examined the impact of the Uretero1 on various diagnostic and therapeutic procedures in the urinary tract.

According to the applicant, the Uretero1 is a single use, disposable, digital flexible ureteroscope that is used in urologic procedures (ureteroscopy) to diagnose and treat conditions of the urinary tract, such as kidney stones, blockages, polyps, and abnormal growths. Broadly, the applicant outlined the following areas for which it claimed the Uretero1 would provide a substantial clinical improvement: (1) prevention of infection transmission, (2) reduced contamination risk, (3) improved deflection performance over reusable ureteroscopes, (4) reduced hospitalization rate and use of antibiotic therapy, (5) reduced complication rate,

(6) reduced post-operative infection rate, (7) reduced procedure delay, (8) increased patient safety and education, and (9) improved patient outcome when the device is used to perform various diagnostic and therapeutic procedures and treatment in the urinary tract. The applicant provided five articles, an FDA advisory letter, and a set of manufacturer's instructions for cleaning and reprocessing flexible endoscopes specifically for the purpose of addressing the substantial clinical improvement criterion.

The applicant provided a journal pre-proof and two articles to support its claim that the Uretero1 is effective at preventing the transmission of infection. Each of these sources examine the steps required in the complex and time-consuming process to clean and sterilize flexible reusable ureteroscopes so they are fully reprocessed for use. The sources also describe the negative sequelae that follow instances of inefficient and or incomplete device reprocessing. The journal pre-proof of a literature review by Cori Ofstead et al. outlines the steps used to reprocess reusable ureteroscopes.[85] Studies summarized within this literature review described several instances of negative outcomes when ureteroscopes were processed incorrectly or inefficiently. As part of that literature review, Kumarage et al. described an outbreak of *Pseudomonas aeruginosa* later found to be due to an infected flexible reusable ureteroscope that had been used.[86] Fourteen patients of the 40 who were exposed were infected (35 percent attack rate). The root cause of the infected ureteroscopes was attributed to substandard reprocessing of the devices, including processing that was delayed overnight. Kumarage et al. also noted a separate outbreak of a gram-positive cocci which was traced to the use of five ureteroscopes after five patients presented to the ED with urinary tract infections (UTIs) due to the same gram-positive cocci after having each undergone ureteroscopy. Research into the underlying causes and

possible sources of the device contamination found that there had been breakdowns in the reprocessing steps.

Another article included in the literature review by Ofstead et al[87]. describes the risks associated with inefficient processing of reusable ureteroscopes using a time-driven activity-based costing (TDABC).[88] This article, by Isaacson et al. (2017), notes the time and costs involved in the decontamination and sterilization processes of reusable flexible ureteroscopes.[89] The authors also measured the time when reprocessing steps were performed inefficiently or were delayed as a result of repairs needed for any damaged ureteroscopes. After following ten ureteroscopes through the reprocessing steps required to fully clean them and determined, via process mapping, that the average reprocessing time was 229.0 ±74.4 minutes. According to the authors' calculations, drying the ureteroscopes was the single most time-consuming step and took 126.5±55.7 minutes, and was further dependent on the optimal location and position of the ureteroscopes. Ureteroscopes that needed repair required approximately 143 minutes, causing further delays to availability of the devices.

To further support its claim that the Uretero1 can prevent infection transmission, the applicant cited an April 1, 2021, advisory letter to providers from FDA that outlines concerns about the effectiveness of reprocessing reusable urologic endoscopes.[90] In the letter, FDA confirms it has received over 450 Medical Device Reports (MDRs) describing patient infections associated with reprocessing of reusable devices, which include ureteroscopes. FDA is still investigating these episodes but notes the importance of following manufacturer's instructions for device reprocessing. The applicant also references a report by Grandview Research which notes the market for disposable endoscopes is expected to experience compound growth at a rate of 17 percent between 2022 and 2030, largely due to the growing cross-contamination issue

associated with reusable endoscopes.[91] Per the applicant, the projected market growth of disposable cystoscopes, endoscopes, and ureteroscopes is expected to continue to rise over the forecast period due to the advancement in the design of disposable devices and related to the risk of nosocomial infections following ureteroscopy procedures.[92]

To support its second claim that the Uretero1 reduces risk of contamination, the applicant again cited the literature review by Ofstead et al.[93] Referencing the article by Lee et al., titled "Increasing potential risks of contamination from repetitive use of endoscope,"[94] Ofstead noted that wear and tear of the repeated-use devices contributes to the likelihood that infectious material will remain attached to the device even after reprocessing, as found during Lee et al.'s simulated-use study. Therefore, and per the applicant, the single use Uretero1 eliminates the risk of contamination.

The applicant's third claim with regard to the substantial clinical improvement offered by the Uretero1 is in relation to its improved deflection performance over that of reusable devices. When used in the context of describing ureteroscopes, "deflection" refers to the adjustability of the device, which enables the surgeon to see more of the urinary tract.[95] Therefore, improved deflection supports the surgeon's ability to access the kidneys and ureters and perform various diagnostic and therapeutic procedures in the urinary tract. The applicant cited a literature review by Ventimiglia et al. to support its claim.[96] Ventimiglia et al. conducted a literature review on available reusable flexible ureteroscopes and single-use flexible ureteroscopes with a focus on the related costs of each, in terms of performance, maintenance, and reprocessing. As part of its review, Ventimiglia et al. noted that the deflection capability of the Olympus URF-V and Karl Storz Flex-Xc, both single-use flexible ureteroscopes, was equivalent to the deflection capability of reusable flexible ureteroscopes. Ventimiglia et al. did not mention the Uretero1, nor its

deflection capability, in the study. Of note, Ventimiglia's literature review referenced the original study by Hennessey et al., which compared the single-use flexible devices with the reusable flexible devices, and which found the performance of the single-use device was equivalent, if not better than the reusable flexible ureteroscopes.[97] The Uretero1 device was not included as a comparison in this study either.

The applicant referred to a study by Bozzini et al.[98] to support its fourth, fifth, and sixth claims that the Uretero1 device demonstrates substantial clinical improvement over existing devices. These claims are that the Uretero1 enables, respectively: reduced hospitalization rate and antibiotic therapy, reduced complication rate, and reduced post-operative infection rate. Using a multicenter, randomized, clinical trial study format, Bozzini et al. enrolled 180 patients who had a renal stone and were scheduled to receive Retrograde Intrarenal Surgery (RIRS) into two groups: Group A (90 patients) underwent treatment with a reusable flexible ureteroscope and Group B (90 patients) (underwent treatment with a disposable flexible ureteroscope). While the outcome of the surgical procedure was not significantly different across the two groups (stone free rates of 86.6 percent for Group A and 90.0 percent for Group B, $p=0.11$), the number of hospitalization days and of antibiotic therapy were higher for Group A ($p\leq0.05$), those subjects who had been in the reusable flexible ureteroscope trial group. In addition, Group A patients experienced more complications (8.8 percent) than Group B patients (3.3 percent, and with a p=value of ≤0.05), and Group A patients had more major complications. Finally, the overall postoperative infection rate was 16.6 percent for Group A patients compared with 3.3 percent for Group B patients ($p\leq0.05$). It was noted that none of the Group B patients developed urosepsis, while three patients in Group A developed urosepsis ($p<0.05$).

The applicant referred to an article in *OR Manager* in support of its seventh and ninth claims that the Uretero1 single-use flexible ureteroscope reduces procedure delays and increases patient safety.[99] In addition to the discussion about the introduction of contamination during reprocessing of reusable flexible ureteroscopes, the article notes the high frequency of failures during procedures, resulting in the need for repair. Mathias specifically references a prospective study by Ofstead et al. (2017) conducted at two large healthcare facilities in the Midwest, in which 16 ureteroscopes were cultured and visually inspected after they had been cleaned and sterilized with hydrogen peroxide gas.[100] In this study, 100 percent of the devices were found to have substantial protein contamination, and two had visible bacteria, while others had debris, oily deposits, and residual fluid discoloration.[101] The Mathias article also describes the "high frequency of damage and repairs" for reusable flexible ureteroscopes, noting that they then need to be sent out for repairs, resulting in delayed procedures, interrupted workflow, and wasted resources. Per Ofstead, the annual cost per ureteroscope is between $4,000 and $11,000, and findings from the same study showed that the average number of uses between repairs was 19.[102] The Mathias article summarizes the steps that can be taken to reduce risks related to ureteroscope contamination and to focus on patient safety. In addition to following manufacturer's steps for reprocessing the devices, Ofstead suggests the use of single-use endoscopes and accessories which are currently available in the list of recommendations.

Finally, the applicant referenced an FDA advisory letter to health care providers published April 1, 2021, which the applicant stated was released to raise awareness around the risk of infections associated with reprocessing urological endoscopes (e.g., ureteroscopes), although there is no mention of single use ureteroscopes. The applicant pointed to another FDA letter in support of single use duodenoscopes to reduce the risk of infection. The applicant cited

these FDA letters in support of its eighth claim that the Uretero1 can be responsible for increased patient education, and patient safety.[103]

In summary, the applicant references these citations to support its assertions that the Uretero1 single-use disposable digital flexible ureteroscope presents a substantial clinical improvement over existing devices. We noted that many studies included provide details regarding the importance of following established reprocessing guidelines for reusable devices. The evidence provided in the clinical studies emphasizes the risks associated with reprocessing reusable devices. However, none of the studies the applicant included reference another disposable device as a comparator against which to evaluate and assess the Uretero1. While we find that the source articles provide background about multiple risks associated with reprocessing reusable devices, we welcomed additional evidence demonstrating a comparison of the Uretero1's performance against other similarly disposable devices. We also noted that the applicant cited an FDA news release[104] in support of single use duodenoscopes to reduce risk of infection, but this is not the device in question. Additionally, the previously referenced FDA advisory letter[105] regarding ureteroscopes does not mention single-use devices, and it is not clear how the recommendations in the letter support the applicant's claims of substantial clinical improvement related to the use of the Uretero1.

We solicited public comments on whether the Uretero1 meets the substantial clinical improvement criterion.

We did not receive any comments in regard to the second criterion for establishing a device category as specified at § 419.66(c)(2), or a response to our concern about a direct comparison to another disposable device. The applicant provided source articles that demonstrated the increased risks associated with using reusable devices, but did not provide

clinical studies that referenced another disposable device as a comparator. While we agree that it would be helpful to see comparative studies between the single-use Uretero1 device and other disposable devices, we agree that the evidence demonstrating the improved patient outcomes and reduced patient risk associated with the disposable device in comparison with reusable devices represents substantial clinical improvement.

The third criteria for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Uretero1 would be reported with the following HCPCS codes listed in Table 56.

TABLE 56: HCPCS CODES REPORTED WITH THE URETERO1

HCPCS Code	Long Descriptor	SI	APC
50575	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with endopyelotomy (includes cystoscopy, ureteroscopy, dilation of ureter and ureteral pelvic junction, incision of ureteral pelvic junction and insertion of endopyelotomy stent)	J1	5375
52344	Cystourethroscopy with ureteroscopy; with treatment of ureteral stricture (e.g., balloon dilation, laser, electrocautery, and incision)	J1	5374
52345	Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (e.g., balloon dilation, laser, electrocautery, and incision)	J1	5374
52346	Cystourethroscopy with ureteroscopy; with treatment of intra-renal stricture (e.g., balloon dilation, laser, electrocautery, and incision)	J1	5375
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic	J1	5374
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	J1	5374

52353	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)	J1	5375
52354	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion	J1	5375
52355	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor	J1	5375
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (e.g., gibbons or double-j type)	J1	5375

To meet the cost criteria for device pass-through payment status, a device must pass all three tests of the cost criteria for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criteria, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5374 - Level 4 Urology and Related Services, which had a CY 2021 payment rate of $3,076.34 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 52344 had a device offset amount of $475.29 at the time the application was received. According to the applicant, the cost of the Uretero1 is $1,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $1,500 for Uretero1 is 48.76 percent of the applicable APC payment amount for the service related to the category of devices of $3,076.34 (($1,500/$3,076.34) x 100 = 48.76 percent). Therefore, we believe the Uretero1 meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $1,500 for Uretero1 is 315.60 percent of the cost of the device-related portion of the APC payment amount for the related service of $475.29 (($1,500/$475.29) x 100 = 315.60 percent). Therefore, we believe that the Uretero1 meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $1,500 for the Uretero1 and the portion of the APC payment amount for the device of $475.29 is 33.31 percent of the APC payment amount for the related service of $3,076.34 ((($1,500-$475.29)/$ 3,076.34) x 100 = 33.31 percent). Therefore, we believe that the Uretero1 meets the third cost significance requirement.

We solicited public comment on whether the Uretero1 meets the device pass-through payment criteria discussed in this section, including the cost criteria for device pass-through payment status.

We did not receive any comments with regard to any of the cost significance requirements specified at § 419.66(d). Based on our findings from the first, second, and third cost significant tests, we believe that the Uretero1 device meets the cost significance criteria specified at § 419.66(d).

After reviewing the device pass-through application, we have determined that the Uretero1 single-use flexible disposable digital flexible ureteroscope meets the criteria for device pass-through. Therefore, we are approving the Uretero1 for transitional pass-through payment status beginning January 1, 2023.

B. Proposal to Publicly Post OPPS Device Pass-through Applications

As noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44620), applicants seeking OPPS transitional pass-through status for medical devices ("OPPS device pass-through") must submit an application to CMS containing certain information.[89] The application is currently undergoing the Paperwork Reduction Act reapproval process, which has notice and comment periods separate from the CY 2023 OPPS/ASC proposed rule. The CMS-10052 package 60-day notice was published in the **Federal Register** on April 29, 2022 (87 FR 25488). The CMS-10052 package 30-day **Federal Register** Notice was published on July 15, 2022 and was submitted to OMB on July 18, 2022 as an extension with no changes. CMS accepts OPPS device pass-through applications on an ongoing basis throughout the year, but must receive complete applications sufficiently in advance of the first calendar quarter in which OPPS device pass-through status is sought to allow time for analysis, decision-making, and systems changes. In particular, CMS must receive a completed application and all additional information by the first

[89] The application form, titled "Process and Information Required to Apply for Additional Device Categories for Transitional Pass-Through Payment Status Under the OPPS," describes the process and information required to apply for OPPS device-pass-through status for a medical device and is available on CMS's website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf. Applicants must submit such information as: proposed name or description of additional category; trade/brand names of any known devices fitting the proposed additional category; list of all established categories used presently or previously for pass-through payment that describe related or similar products, along with an explanation as to why the a category does not encompass the nominated device(s); detailed description of clinical uses of each nominated device; a complete description of the nominated devices, including, but not limited to, what it is, what it does, and how it is used; its clinical characteristics; the HCPCS codes for procedures with which it is used; substantial clinical improvement information; sales and marketing information; cost information; FDA approval information; contact information; and other information CMS may require.

business days in March, June, September, or December of a year for the earliest possible potential pass-through effective dates of July 1, October 1, January 1, or April 1, respectively, of that year. We post complete application information and the timeframes for submitting applications on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.

In the CY 2016 OPPS/ASC final rule with comment period, we adopted a policy that beginning in CY 2016, all OPPS device pass-through applications submitted through the quarterly subregulatory process would be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle, including those that were approved upon quarterly review (80 FR 70418). All applications that are approved upon quarterly review are automatically included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review have the option of having their application discussed in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration entirely. We explained that no special reconsideration process would be necessary, as no denial decision would be made except through the annual rulemaking process. Applicants are able to submit new data, such as clinical trial results published in a peer-reviewed journal, for consideration during the public comment process for the proposed rule. We explained that this process allows those applications that we are able to determine meet all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications.

In the proposed rule, CMS summarizes the information contained in the application, including the applicant's explanation of what the device does, the cost of the device, information

about device's FDA approval/clearance, and the applicant's assertions and supporting data on how the device meets the OPPS device pass-through payment criteria under § 419.66. In summarizing this information for inclusion in the proposed rule, CMS restates or paraphrases information contained in the application and attempts to avoid misrepresenting or omitting any of an applicant's claims. CMS also tries to ensure that sufficient information is provided in the proposed rule to facilitate public comments on whether the medical device meets the OPPS device pass-through criteria. Currently, however, CMS does not make the applications themselves, as submitted by the applicants, publicly available.

In the CY 2023 OPPS/ASC proposed rule, we stated that in the past, CMS has received requests from the public to access and review the OPPS device pass-through applications to further facilitate comment on whether a medical device meets the OPPS device pass-through payment criteria. We further stated in the proposed rule that, after considering this issue, we agree that review of the original source information from the applications for OPPS device pass-through status may help to inform public comment. Further, we explained that making this information publicly available may foster greater input from experts in the interested party community based on their review of the completed application forms and related materials. Accordingly, as we discuss further in this section, we stated that we believe providing additional information to the public by posting the applications and related materials online may help to further engage the public and foster greater input and insights on the various new medical devices and technologies presented annually for consideration for OPPS device pass-through payment.

We also stated in the proposed rule that we believe posting the applications online would reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by

applicants, or be perceived as misrepresenting such information, in our summaries in the rules. We further explained that it also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the device pass-through applications we receive have been increasing over time. That is, making the applications available to the public online would afford more time for CMS to process and analyze the supporting data and evidence in the applications rather than devoting significant time and resources to summarizing information from the applications in the rule.

Therefore, to increase transparency, enable increased interested party engagement, and further improve and streamline our evaluation process, we proposed to publicly post future applications for OPPS device pass-through payment online.[90] Specifically, beginning with applications submitted on or after March 2, 2023, we proposed to post online the completed OPPS device pass-through application forms and related materials (e.g., attachments, supportive materials) we receive from applicants. Additionally, we proposed to post online information acquired subsequent to the application submission (e.g., updated application information, additional clinical studies, etc.). We proposed that we would publicly post all completed application forms and related materials at the same time that the proposed rule was issued, which would afford interested parties the full public comment period to review the information provided by the applicant in its application in conjunction with the proposed rule. We did not propose to change our policy that applicants whose applications are not approved through the quarterly review process may elect to withdraw their application from consideration in the next applicable rulemaking cycle.

[90] CMS did not propose to make drug and biological pass-through applications public because the nature of the drug and biological application does not necessitate such an action.

With respect to copyrighted materials, we proposed that on the application form itself, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public. For any material included with the application that the applicant indicates is copyrighted and/or not otherwise releasable to the public, we proposed that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public, and CMS will then post that link or abstract or summary online, along with the other posted application materials. We solicited public comments on this proposal.

We noted in the CY 2023 OPPS/ASC proposed rule that at times applicants furnish information marked as proprietary or trade secret information along with their applications for OPPS device pass-through payment. We explained that, currently, the OPPS device pass-through application instructions specify that data provided in the application may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view.[91] Consistent with the current application instructions, we noted that should an applicant submit such information as part of its application, CMS will attempt, to the extent allowed by Federal Law, to keep this information protected from public view. We emphasized, however, that it is the applicant's responsibility to clearly identify data and information as such in its application.

Additionally, we noted that in the past we have received applications in which all the data and information are marked as proprietary or confidential, or certain information, for example,

[91] See Guidance and Instructions for OPPS Device Pass-Through Applications (Updated 2/1/2022), available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

information in support of a claim of substantial clinical improvement, is marked as such. In such cases, we reiterated that we generally would not be able to consider that data and information when determining whether a device meets the criteria for OPPS device pass-through payments. As we stated in the CY 2023 OPPS/ASC proposed rule, our process provides for public input, so it is important that we provide the information needed for the public to meaningfully comment on the OPPS device pass-through payment applications, including the claims applicants make about meeting the OPPS device pass-through payment criteria. We explained that our proposal would not change the current timeline or evaluation process for OPPS device pass-through payments, the criteria used to assess applications, or the deadlines for various data submissions. Additionally, we stated that we did not expect our proposal would place additional burdens on future applicants because we did not propose to change the information that must be submitted to apply for OPPS device pass-through status, including the supplemental information that could be furnished to support the application. As explained in the CY 2023 OPPS/ASC proposed rule and throughout this section, the aim of our proposed policy change is to increase accuracy, transparency, and efficiency for both CMS and interested parties, not to make the OPPS device pass-through process more onerous for applicants.

In connection with our proposal to post the OPPS device pass-through applications online, we stated that we expect we would also include less detail in the summaries of the device pass-through applications that we include in the annual OPPS proposed and final rules, given that the public would have access to the submitted applications themselves. We explained that we would, however, continue to provide sufficient information in the rules to facilitate public comments on whether a medical device meets the OPPS device pass-through payment criteria. Specifically, we stated that we do not anticipate summarizing in significant detail each OPPS

device pass-through application in the **Federal Register** as we have in the past, given that the public would have access to the applications under our proposal. We further stated that, in some instances, such as in the discussions of whether devices meet the substantial clinical improvement criterion, we expect to provide a more concise summary of the evidence or a more targeted discussion of the applicant's claims about how that criterion is met based on the evidence and supporting data (although this may vary depending on the application, the medical device, and the nature of the supporting materials provided). We explained that we expect that we would continue to generally include, at a high level, the following information in the proposed and final rules: the medical device and applicant name; a description of what the device does; the cost significance calculation; the FDA approval/clearance information; and a summary of the applicant's assertions or claims. We added that we also expect to provide more succinct summaries in the proposed and final rules regarding the applicant's assertions as to how the medical device meets the various OPPS device pass-through criteria under § 419.66. For example, we stated that we would include the applicant's assertions as to why the medical device meets the substantial clinical improvement criterion and a list of the sources of data submitted in support of those assertions, along with references to the application in support of this information. We stated that in the proposed rule, we would also continue to provide discussion of the concerns or issues we identified with respect to applications submitted, and in the final rule, we would continue to provide an explanation of our determination of whether a medical device meets the applicable OPPS device pass-through payment criteria. As noted in the CY 2023 OPPS/ASC proposed rule and this final rule, we believe the proposal to post online the completed application forms and other information described previously would afford greater

transparency during the annual rulemaking for purposes of determining whether a medical device is eligible for OPPS device pass-through payment.

We further noted in the CY 2023 OPPS/ASC proposed rule that if we adopted this proposal in the final rule, we would begin referring to publicly posted applications in the CY 2024 rulemaking cycle, depending on when they are received. We explained that this would mean there would be some OPPS device pass-through applications (those received as of December 31, 2022) that would follow the current process and be described fully in the proposed rule consistent with our historical practice, and other OPPS device pass-through applications (those received after the effective date of January 1, 2023) that would be summarized in the proposed rule with a cross-reference to the publicly posted application, consistent with our new policy. We stated that if our proposal is finalized effective January 1, 2023, we would allow applicants that submit an OPPS device pass-through application prior to December 31, 2022 to elect to have the application summarized and publicly posted in lieu of a full CMS write-up. We further stated that where applicants do not elect to have applications submitted prior to December 31, 2022 posted publicly and summarized in the proposed rule, we would discuss device pass-through applications in two different ways in the CY 2024 proposed and final rules (either with full write-ups or with summaries and cross-references to the publicly posted applications, depending on when the application was submitted). We stated that we believe our goals of increasing transparency and ensuring there are sufficient CMS resources to review the increasing numbers of applications are sufficiently important justify use of two approaches for one year if our proposal is finalized. Nonetheless, we also solicited comment on whether we should consider an alternative implementation date of March 1, 2023, which would mean that all OPPS device pass-through applications discussed in the CY 2024 OPPS proposed and final rules would follow

the current process and would appear in the rule as a full write-up. We stated that under this alternative approach, CMS would begin publicly posting all OPPS device pass-through applications and summarize and cross-reference the applications beginning in the CY 2025 proposed and final rules consistent with this policy.

We noted that for many of the same reasons, we included a similar proposal in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28355 through 28357) that, beginning with applications for FY 2024, we would publicly post online new technology add-on payment applications and certain related materials, as discussed further in that proposed rule. We explained that our goal in making these proposals under both the hospital OPPS and IPPS was not only to increase accuracy, transparency, and efficiency in the device pass-through and new technology add-on payment application review process for both CMS and interested parties, but also to further consistency, where possible, in our procedures and approach for addressing and engaging the public on new technologies in our annual rulemakings.

We sought public comment on our proposal to publicly post online the completed OPPS device pass-through application forms and supporting materials and updated application information submitted subsequent to the initial application submission for OPPS device pass-through payment, beginning January 1, 2023, or in the alternative, March 1, 2023.

Comment: We received several public comments regarding this policy proposal. Some commenters were fully supportive of the proposal. These commenters cited various reasons for their support, including that the proposal would enhance the transparency of the application evaluation process, streamline CMS' internal processes for reviewing and evaluating applications, and facilitate and foster more informed public comment and greater engagement from interested parties. A commenter specifically expressed appreciation for CMS' efforts to

keep confidential and trade secret information private, provided the applicant clearly marks the information as such. Another commenter who supported the proposal requested that CMS make clear in the final rule, if it moves forward with its proposal, that it will retain a mechanism to enable applicants to submit proprietary or trade secret information that is not posted online, consistent with CMS' current policy.

Finally, a commenter noted its appreciation for the improvements to the NTAP application posting process incorporated in the FY 2023 IPPS/LTCH PPS final rule, and further stated that it appreciated that CMS reflected these improvements in the proposed OPPS pass-through payment application posting process in the CY 2023 OPPS/ASC proposed rule. This commenter expressed its general support of the OPPS transitional pass-through payment policy, stating that it represents a significant success for the Medicare program. According to the commenter, the policy has helped reduce disincentives to the adoption of new technologies under the OPPS, and has accelerated access to those technologies for Medicare beneficiaries and encouraged investment in the development of innovative new products and therapies. This commenter further stated that it appreciates the significant effort and resources that CMS has dedicated to the management of the transitional pass-through payment program, and hopes the agency will proceed on any reasonable steps to improve the efficiency and capacity of the application and review process.

Response: We appreciate the commenters' support for our proposal and our efforts toward greater transparency, public input, and improving and streamlining the device pass-through application process, as well as the support for our device pass-through payment policy generally. Given this support, and after further consideration of the proposal and feedback from other commenters, as further discussed below, we are finalizing our proposal to post completed

OPPS device pass-through applications and related materials online, with a modified effective date. We note that under the policy we are finalizing in this rule, we will provide a mechanism for applicants to submit confidential information, including proprietary or trade secret information that will not be posted online, as discussed later in this section.

Comment: Some commenters urged CMS not to adopt the proposal, asserting that applicants may have proprietary and trade-sensitive information that, while appropriate to share with CMS for purposes of submission of a device pass-through application, may not be appropriate to share with the public or competitors. These commenters believed that the proposal may lead to a lack of rigorous information sharing between applicants and CMS, and that such transparency should be of primary concern to the agency as it reviews such applications to determine eligibility. These commenters asserted that public posting is unlikely to benefit Medicare patients, but is likely to impose additional legal and commercial burdens on innovators without benefit for the Medicare program.

Another commenter stated that while it appreciates the effort to provide more information to the public for input to inform pass-through status decisions, they strongly believed that CMS' policy proposal poses more risk than benefit to medical product innovation. First, the commenter explained that pass-through applications contain a significant amount of proprietary information and data, and that the protection of this data is paramount to the research and development process for medical devices and other innovative products, including drugs and biologics. The commenter stated that although CMS notes that it is incumbent on applicants to indicate which components are considered confidential or proprietary, the commenter believed that public posting of these applications introduces an opportunity for irreversible and unintentional disclosure that is not present under the current process. The commenter also pointed to CMS'

statement in the proposed rule (87 FR 44621) that, due to the need for public feedback, it would not be able to consider applications where the applicant deems the entirety of the submission to be proprietary or confidential for uses beyond internal agency review. The commenter claimed that determinations about the proprietary nature of information for purposes of public disclosure are beyond the scope of the CMS' authority, particularly when there is no clarity on what information CMS deems necessary for public feedback. The commenter asserted that manufacturers should retain discretion over what information is disclosed beyond the reviewing agency. The commenter further stated that the current approach that CMS uses to summarize, evaluate, and notify the public of its pass-through status determinations has proven adequate, and that CMS has used the notice and comment rulemaking process to collect public feedback on pass-through applications since 2016 without issue. The commenter added that should CMS find it necessary to provide additional information to the public, it should work coordinately with applicants to determine what is appropriate to disclose.

According to this commenter, the impact of publicly posting applications and supplemental material for pass-through status is likely to undermine the intent of transitional pass-through payment. The commenter asserted that, as demonstrated by its established success, the current process protects the interests of developers assuming the substantial risk of medical product innovation, while still allowing CMS to collect sufficient information to inform the public and solicit feedback. The commenter urged CMS to not finalize this policy and to protect the integrity of this vital means of allowing providers to adopt new medical products while lowering costs and improving health outcomes.

Response: We appreciate the commenters' feedback. As discussed in the proposed rule, under our current OPPS device pass-through application review process, we will have a

mechanism for applicants to submit confidential information, including proprietary and trade secret information, that will not be posted online. We anticipate providing a section on the application where applicants can submit confidential information separately from non-confidential information, or otherwise mark sections of the application for which we will not pose the information online. The OPPS device pass-through application existing instructions specify that the data provided in the application may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so CMS can attempt, to the extent allowed under Federal law, to protect the information from public view. Consistent with our current policy, and under the policy we are finalizing in this rule, if an applicant submits confidential information as part of its application and identifies it as such, we will attempt, to the extent allowed by Federal law, to keep this information from public view, including public posting. We anticipate providing a section on the application where applicants can submit confidential information separately from non-confidential information, or otherwise marking sections or questions in the application for which we will not post the information online. Applicants should expect that, unless otherwise noted in the application that certain information will not be posted publicly (for example, contact information), everything may be posted publicly. We emphasize that it is the applicant's responsibility to put confidential information only in the areas of the application designated for confidential information and not elsewhere in the application. However, as previously noted, applicants should consider what they include in a confidential section of the application given that we generally do not consider any information that cannot be made public when determining whether a device meets the pass-through payment criteria. We note that, unlike the New Technology Add-on Payment (NTAP) applications, we believe applicants generally have limited need to submit confidential information, including

proprietary or trade secret information as part of their OPPS device pass-through payment applications, given that a device must have FDA clearance or approval prior to the date of application. Because of this, and because the policy we are finalizing in this rule provides for protection of confidential information submitted as part of an application provided it is identified as such, we do not believe the policy would result lack of rigorous information sharing between applicants and CMS, or impose additional legal or commercial burdens on innovators, as suggested by a commenter.

Additionally, we note that in the past we have received applications in which all the data and information in the application are marked as proprietary or confidential, or where certain information provided in support of the applicant's assertions regarding eligibility for pass-through payment status, for example a claim of substantial clinical improvement, is marked as such. In such cases, we reiterate that we generally will not be able to consider that data and information when determining whether a device meets the criteria for OPPS device pass-through payments. Our process provides for public input, so it is important that we provide the information needed for the public to meaningfully comment on the OPPS device pass-through payment applications, including the applicants' claims about meeting the OPPS device pass-through payment criteria. We believe that maintaining transparency with respect to the information we consider in making our device pass-through payment determinations will lead to greater information exchange and more informed device pass-through payment decisions which help to ensure appropriate payment for and access to new and innovative medical devices and technologies, ultimately benefiting Medicare patients and the Medicare program generally.

In addition, because we will continue to allow applicants to identify information they consider confidential, including proprietary and trade secret information, so that it may be

protected from public view, including public posting, we do not believe public posting of applications introduces an opportunity for irreversible and unintentional disclosure, or undermines the interests of developers or the intent of the OPPS device pass-through payment program, as claimed by a commenter. Furthermore, we emphasize that under our current policy as well as the policy we are finalizing in this rule, CMS does not make determinations about the proprietary nature of information for purposes of public disclosure. Instead, as explained previously, applicants make these determinations by identifying which information is appropriate to disclose publicly and which information is confidential and should not be disclosed. Thus, the applicants, not CMS, retain discretion to determine what information can be publicly disclosed.

After considering the comments and for the reasons discussed, we are finalizing our proposal to publicly post OPPS device pass-through applications online, including the completed application forms and certain related materials (as described previously), and any additional updated application information submitted subsequent to the initial application submission (except information identified by the applicant as confidential), at the time the proposed rule is issued. In addition, we are finalizing, as proposed, a mechanism for applicants to submit confidential information that would not be posted online, such as in a separate section of the application, or by identifying particular questions for which the information submitted would not be publicly posted. Furthermore, we are finalizing as proposed our proposal with respect to the treatment of copyrighted information. With the exception of information included in a confidential information section of the application, and materials identified by the applicant as copyrighted and/or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly.

In the CY 2023 OPPS/ASC proposed rule, we proposed that this policy would apply to applications submitted on or after January 1, 2023; however, we also solicited comment on whether we should consider an alternative implementation date of March 1, 2023. We did not receive any comments regarding the implementation date of this policy, however, after further consideration, we are finalizing the alternative implementation date of March 1, 2023. As we explained in the proposed rule, if we were to finalize our proposal with an effective date of January 1, 2023, we would begin referring to publicly posted applications in the CY 2024 rulemaking cycle, depending on when applications are received. This would mean that some OPPS device pass-through applications (those received on or before December 31, 2022) would follow the current process and be described fully in the proposed rule consistent with our historical practice (unless they elect to have their applications publicly posted), and other OPPS device pass-through applications (those received after the effective date of January 1, 2023) would be summarized in the proposed rule with a cross-reference to the publicly posted application, consistent with our new policy. Thus, if our policy were effective January 1, 2023, device pass-through applications could be discussed in two different ways in the CY 2024 proposed and final rules. We believe that this would be confusing to applicants and interested parties. Therefore, we are finalizing the alternative implementation date of March 1, 2023. Using this alternative effective date, we will begin publicly posting all OPPS device pass-through applications summarized with a cross-reference to the publicly posted application, as previously described beginning in the CY 2025 proposed and final rules consistent with our final policy. As noted in the proposed rule, this means that all OPPS device pass-through applications discussed in the CY 2024 OPPS proposed and final rules will follow the current process and will be fully described in the proposed rule consistent with our historical practice.. We further clarify that we

will post these application materials at the time the proposed rule is issued, and that we will not post applications that are withdrawn prior to the date the proposed rule is issued.

C. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4 of this final rule with comment period. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3 of this final rule with comment period. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the

three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44622 through 44623) are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits

and no cost/full credit and partial credit devices discussed in sections IV.C.3 and IV.C.4 of the CY 2023 OPPS/ASC proposed rule (87 FR 44624 through 44625).

b. Use of the Three Criteria to Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy--which includes the three criteria listed previously--to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which

leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device

offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically

related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a

public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

As discussed in section X.E of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns regarding CY 2020 data as a result of the COVID–PHE, we adopted a policy to use CY 2019 claims data to establish CY 2022 prospective rates. While we believed CY 2019 represented the best full year of claims data for ratesetting for CY 2022, we stated that our policy of temporarily assigning a higher offset percentage if warranted by additional information would provide a more accurate device offset percentage for certain procedures. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, we adopted a policy to assign device offset percentages for such procedures based on CY 2020 data if CY 2020 claims information is available.

For CY 2023, consistent with our broader proposal to use CY 2021 claims for CY 2023 OPPS and ASC ratesetting purposes and our historical practice, we proposed to use CY 2021 claims information for determining device offset percentages and assigning device-intensive status.

Comment: Many commenters requested that we use invoice or cost data submitted by manufacturers to determine device-intensive status and the device offset percentage for a procedure. Other commenters requested that we use invoice data, or a subset of claims data, to determine device-intensive status for the procedure and that hospitals have inaccurately coded devices as surgical supplies and, therefore, the device offset percentage calculated from our

claims statistics does not reflect the true cost of the device. Specifically, commenters requested that we assign device-intensive status to the following procedures:

- HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance);
- CPT code 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency);
- CPT code 65426 (Excision or transposition of pterygium; with graft);
- CPT code 65778 (Placement of amniotic membrane on the ocular surface; without sutures).

Response: We are not accepting the commenters' recommendation to use invoices as an alternative data source for determining device-intensive status for procedures that do not have a device offset percentage that exceeds our 30 percent device-intensive threshold based on claims data available for this final rule with comment period. As discussed in section II.A.1 of this final rule with comment period, we rely on claims and cost report data for hospital outpatient department services, using the most recent available data to construct our database. Under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable and we believe our database represents the best source of device cost information available to us. We do not believe it would

be appropriate under our current policy to eliminate in whole or in part the available claims data that we have for ratesetting and determining device offset percentages.

Comment: One commenter recommended that we assign the device offset percentage of CPT code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) to 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with ct guidance, lumbar; first level) as both procedures use the same device.

Response: For the CY 2023 OPPS/ASC proposed rule and this final rule with comment period, we do not have any claims data for CPT code 0629T to determine a device offset percentage. Under our current policy, we may assign an alternative device offset percentage if we have claims data from a clinically similar procedure code that uses the same device. We agree with commenters that this policy can apply to CPT code 0629T. CPT code 0629T is clinically similar to CPT code 0627T and uses the same device as this procedure. Therefore, we are accepting the commenter's recommendation and, for CY 2023, we are assigning the device offset percentage of CPT code 0627T to CPT code 0629T and assigning CPT code 0629T device-intensive status.

Comment: One commenter requested that we verify that the device costs associated with CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)) include the cost of the pass-through device category HCPCS code C2596 (Probe, image-guided, robotic, waterjet ablation) which is expiring on January 1, 2023.

Response: We reviewed our device categories used to determine device offset percentages for this final rule with comment period and verified that HCPCS code C2596 is indeed categorized as a device. The costs associated with this device are reflected in the device offset percentage of CPT code 0421T.

Comment: One commenter stated that, while CMS changed the descriptor to HCPCS code C1889 (Implantable/insertable device, not otherwise classified), confusion continues to exist among hospitals, as evidenced by their reluctance to use HCPCS C1889 to report device costs for procedures that do not have device-intensive status. The commenter requested that CMS clarify that HCPCS code C1889 may be billed with a procedure that does not have device-intensive status.

Response: HCPCS code C1889 may be billed with a procedure that does not have device-intensive status. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58950), we finalized our revision to the HCPCS C1889 to remove the specific applicability to device-intensive procedures to clarify this point. Additionally, in our April 2022 update of the Hospital Outpatient Prospective Payment System, we revised Chapter 4, Section 61.1 of the Medicare Claims Processing Manual to clarify that hospitals should report HCPCS code C1889 for the use of devices that are not described by a specific HCPCS code. We will continue to monitor stakeholder feedback regarding the use of HCPCS code C1889 to determine if additional guidance is needed.

After consideration of the public comments we received, we are finalizing our proposal to use CY 2021 claims information for determining device offset percentages and assigning device-intensive status.

The full listing of the final CY 2023 device-intensive procedures can be found in Addendum P to the CY 2023 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this final rule with comment period can be found under supporting documentation for the CY 2023 OPPS/ASC final rule on our website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and

subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is "Implantable/insertable device, not otherwise classified".

Comment: Some commenters requested that CMS restore the device-to-procedure and procedure-to-device edits. Commenters recommended that we apply such edits to specific procedures, such as total hip arthroplasty or total knee arthroplasty procedures, and require a specific device code rather than any device code.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. Under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. While we believe our current device edits policy, which requires that a device code be reported on a claim for procedures that have significant device costs, continues to accurately capture the device costs associated with device-intensive procedures and provides the necessary flexibility to hospitals to code claims accurately, we will continue to monitor the reporting of device costs on

hospital outpatient claims to determine if any modifications to our existing policy are warranted in future rulemaking.

We did not propose any changes this policy for CY 2023. After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue our device edits policy for CY 2023.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the "FB" modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the "FC" modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new

device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the "FB" and "FC" modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the "FD" value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices

would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We did not propose any changes and we did not receive any public comments related to our policies regarding payment for no cost/full credit and partial credit devices for CY 2023.

V. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. Throughout the proposed rule, the term "biological" is used because this is the term that appears in section 1861(t) of the Act. A "biological" as used in the proposed rule includes (but is not necessarily limited to) a "biological product" or a "biologic" as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. "Current" refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs." As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be

made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2023 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to the proposed rule (which are available on the CMS website).[92]

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In the proposed rule, the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

[92] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

The pass-through application and review process for drugs and biologicals is described on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug

without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2022

There are 32 drugs and biologicals for which pass-through payment status expires on December 31, 2022 or for which the equitable adjustment to mimic continued pass-through payment will end on December 31, 2022, as listed in Table 57. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of January 1, 2019 through December 31, 2022. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755 through 63756), we also recognized the effects of the Public Health Emergency (PHE) on drugs and biologicals whose pass-through payment status expired or expires between December 31, 2021, and September 30, 2022, by adopting a one-time equitable adjustment under section 1833(t)(2)(E) of the Act to continue separate payment for the remainder of CY 2022 to mimic continued pass-through status for that year. Because pass-through payment status can expire at the end of a quarter, we finalized that the adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the drug or biological. For a detailed discussion of the equitable adjustment for drugs with expiring pass-through status in CY 2022, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755 through 63756).

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which was proposed to be $135 for CY 2023), as discussed further in section V.B.1 of the CY 2023 OPPS/ASC proposed rule (87 FR 44641 to 44643)). If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable ASP-based payment amount (which is proposed at ASP plus 6 percent for CY 2023 and subsequent years), as discussed further in section V.B.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44645).

Comment: We received many comments specific to providing additional quarters of separate payments for drugs and biologicals whose pass-through payment status will expire between December 31, 2022 and December 31, 2023.

Response: We refer readers to section IV of this CY 2023 OPPS/ASC final rule with comment period for a full discussion of the comments and CMS's final decision not to provide any additional quarters of separate payment for any drug, biological, or device category whose

pass-through payment status will expire between December 31, 2022 and December 31, 2023. Refer to Table 57 for the list of drugs and biologicals for which pass-through payment will expire or for which separate payment to mimic pass-through payment status will end on December 31, 2022. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of the CY 2023 OPPS/ASC final rule with comment period (which is available on the CMS website).

TABLE 57: DRUGS AND BIOLOGICALS FOR WHICH PASS - THROUGH PAYMENT STATUS OR SEPARATE PAYMENT TO MIMIC PASS-THROUGH PAYMENT WILL END ON DECEMBER 31, 2022

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9182	01/01/2019	12/31/2022*
J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2022*
J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2022*
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2022*
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2022*
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2022*
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	12/31/2022*

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	01/01/2020	12/31/2022
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	12/31/2022*
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	12/31/2022*
J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	12/31/2022*
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	12/31/2022*
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	12/31/2022*
J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	12/31/2022*
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	12/31/2022*
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	12/31/2022*
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	12/31/2022*
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	12/31/2022*
C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	12/31/2022*

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	12/31/2022*
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	12/31/2022*
J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	12/31/2022*
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	12/31/2022*
J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	12/31/2022*
J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	12/31/2022*
J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	12/31/2022*
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	12/31/2022*
J0691	Injection, lefamulin, 1 mg	G	9332	01/01/2020	12/31/2022
J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

4. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2023

We proposed to end pass-through payment status in CY 2023 for 43 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2020 and January 1, 2021, are listed in Table 40 of the CY 2023 OPPS/ASC proposed rule (87 FR 44632 through 44636). The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2023, are assigned status indicator "G" (Pass-Through Drugs and Biologicals) in Addenda A and B to the CY 2023 OPPS/ASC proposed rule (which are available on the CMS website).[93] The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status, are assigned status indicator "G" only for the duration of their pass-through status as shown in Table 40 of the CY 2023 OPPS/ASC proposed rule (87 FR 44632 through 44636).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2023, we proposed to continue to pay for pass-through drugs and biologicals at ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2023. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, we proposed that a $0 pass-through payment amount would be paid for pass-through

[93] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

drugs and biologicals under the CY 2023 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is also proposed at ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP plus 6 percent for CY 2023 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6 of the CY 2023 OPPS/ASC proposed rule (87 FR 44641). We proposed this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We proposed to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2023 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2023, consistent with our CY 2022 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP

methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC plus 3 percent (consistent with our proposed policy in section V.B.2.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44637)), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44641). If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. We refer readers to Table 58 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2023.

TABLE 58: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS TO EXPIRE DURING CY 2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	J1201	Injection, cetirizine	G	9361	04/01/2020	03/31/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		hydrochloride, 1 mg				
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J1738	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J3241	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J7402	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9591	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9144	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
J9317	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
J9318	J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-	G	9349	10/01/2020	09/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		pkrb, biosimilar, (Herzuma), 10 mg				
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J0699	J0699	Injection, cefiderocol, 10 mg	G	9380	01/01/2021	12/31/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
A9592	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
J1427	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1554	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9223	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	J9316	Injection, pertuzumab,	G	9390	01/01/2021	12/31/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		trastuzumab, and hyaluronidase-zzxf, per 10 mg				
J9349	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023

5. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2023

We proposed to continue pass-through payment status in CY 2023 for 49 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2021 and October 1, 2022, are listed in Table 59. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2022, are assigned status indicator "G" in Addenda A and B to the CY 2023 OPPS/ASC proposed rule (which are available on the CMS website).[94]

[94] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2023, we proposed to continue to pay for pass-through drugs and biologicals at ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2023. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in section V.B.1.c under the CY 2023 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP plus 6 percent for CY 2023 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6 of the CY 2023 OPPS/ASC proposed rule (87 FR 44641). We proposed this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We proposed to continue to update pass-through payment rates on a quarterly basis on our website during CY 2023 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2023, consistent with our CY 2022 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC plus 3 percent (consistent with our proposed policy in section V.B.2.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44645)), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44645). If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we proposed to have pass-through payment status expire after December 31, 2023, are shown in Table 59.

TABLE 59: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS TO EXPIRE AFTER CY 2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive	G	9413	07/01/2021	06/30/2024

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose				
Q5123	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024
C9081	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
C9082	J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
C9083	J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
C9084	J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
C9087	J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9021	J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
N/A	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
N/A	C9085	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
N/A	C9086	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
N/A	J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
N/A	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
N/A	C9092	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
N/A	C9093	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
N/A	C9091	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
N/A	C9090	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
N/A	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
N/A	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
C9098	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498	07/01/2022	06/30/2025
C9094	J1302	Inj, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
N/A	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443	07/01/2022	06/30/2025
C9095	J9274	Inj, tebentafusp-tebn, 1 mcg	G	9446	07/01/2022	06/30/2025
N/A	J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
C9096	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
N/A	J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
C9097	J2777	Inj, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
N/A	J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
N/A	A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
N/A	C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
N/A	A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
N/A	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025
N/A	A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025
N/A	J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
N/A	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048	10/01/2022	09/30/2025

6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

Under the regulation at 42 CFR 419.2(b)(15), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also, under the regulation at 42 CFR 419.2(b)(16), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs

and biologicals. Finally, under the regulation at 42 CFR 419.2(b)(4), anesthesia drugs are packaged in the OPPS. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy-packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to policy-packaged drugs, which include diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2023, as we did in CY 2022, we proposed to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 60.

TABLE 60: APCs TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2023

CY 2023 APC	CY 2023 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services

CY 2023 APC	CY 2023 APC Title
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We proposed to continue to post annually on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

Comment: We received a comment asking CMS to determine offsets to pass-through payments at the HCPCS level rather than the APC level, similar to the CMS policy for devices.

Response: We thank the commenter for their suggestion, which we will take into consideration for future rulemaking.

Comment: One commenter requested that CMS release a copy of the APC offset file with future OPPS/ASC proposed rules to enable the public to calculate the percentage of APC

payment associated with packaged drug costs using APC offset data for the upcoming calendar year.

Response: We thank the commenter for their suggestion, but at this time we disagree that it is necessary to release a copy of the APC offset file with the proposed OPPS/ASC proposed rule. After consideration of the comments received, we are finalizing our policy as proposed.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108-173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $130 for CY 2022 (86 FR 63635 through 63637).

Following the CY 2007 methodology, for the CY 2023 OPPS/ASC proposed rule, we use the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2023 and rounded the

resulting dollar amount ($133.73) to the nearest $5 increment, which yielded a figure of $135. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS's Office of the Actuary. Based on these calculations using the CY 2007 OPPS methodology, we proposed a packaging threshold for CY 2023 of $135.

Comment: Generally, commenters did not support the proposal to increase the drug packaging threshold to $135. One commenter encouraged CMS to consider rolling back the threshold since the increase in the threshold in their view has significantly outpaced the OPPS update in recent years.

Response: We appreciate the commenters' feedback on the drug packaging threshold level of $135, but we do not agree with the suggestion. We reiterate our methodology, which was adopted in the CY 2007 final rule with comment period (71 FR 68085 through 68086), for the CY 2023 drug packaging threshold calculation using the most current data available. We remind commenters that the OPPS drug packaging threshold is updated based on the Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription). We believe this methodology is the most appropriate as it specifically accounts for increases in drug pricing relative to the general OPPS update, which is not specific to drug pricing. The PPI for prescription drugs reflects the inflation from a national market, which is different from the market for other health care services. For CY 2023, we calculated the drug packaging threshold to be $135. After consideration of the public comments, we are finalizing our proposal without modification to set the drug packaging threshold for CY 2023 at $135.

b. Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold ("Threshold-Packaged Drugs")

To determine the proposed CY 2023 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2021 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2021 claims processed through June 30, 2021, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d of the CY 2023 OPPS/ASC proposed rule (87 FR 44643), or for the following policy-packaged items that we proposed to continue to package in CY 2023: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2023, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP plus 6 percent (which is the payment rate we proposed for separately payable drugs and biologicals) for CY 2023, as discussed in more detail in section V.B.2.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44642)) to calculate the CY 2023 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2021

(data that were used for payment purposes in the physician's office setting, effective April 1, 2022) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2023, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2021 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the CY 2023 OPPS/ASC proposed rule (which are available via the Internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2023 OPPS/ASC proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2022. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2021 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $135 and identify items with a per day cost greater than $135 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2021 HCPCS codes that were reported to the CY 2022 HCPCS codes that we display in Addendum B to the CY 2023 OPPS/ASC proposed rule (which is available on the CMS website)[95] for proposed payment in CY 2023.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only

[95] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in the CY 2023 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2021, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2022, along with updated hospital claims data from CY 2021. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for the CY 2023 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the final rule with comment period will be based on ASP data from the second quarter of CY 2022. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2022. These payment rates would then be updated in the January 2023 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2023. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2021 claims data and updated cost report information available for the CY 2023 OPPS/ASC final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the CY 2023 OPPS/ASC proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for this final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more

equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2023 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2022. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2023, consistent with our historical practice, we proposed to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2022 and that are proposed for separate payment in CY 2023, and that then have per day costs equal to or less than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would continue to receive separate payment in CY 2023.
- HCPCS codes for drugs and biologicals that were packaged in CY 2022 and that are proposed for separate payment in CY 2023, and that then have per day costs equal to or less than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would remain packaged in CY 2023.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2023 but that then have per-day costs greater than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would receive separate payment in CY 2023.

We did not receive any public comments on our proposal and, therefore, we are finalizing our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based

payment rate from all of the CY 2021 claims data and updated cost report information available for this CY 2023 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies, initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule is different from the same drug's HCPCS code's packaging status determined based on the data used for the final rule with comment period. For CY 2023, we are finalizing these two proposals without modification. Please refer to Addendum B to this final rule with comment period, which is available on the CMS website[96], for information on the packaging status of drugs, biologicals, and therapeutic radiopharmaceuticals.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as "policy-packaged" drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));

[96] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: "We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy" (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

Comment: Some commenters had general concerns regarding the risk of CMS packaging polices creating access barriers and incentives for stinting on care. Specifically, one commenter requested that we develop a policy to provide separate payment for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent postoperative issues.

Response: We thank commenters for their feedback. We continue to believe in the importance of our packaging policies as an inherent principle of OPPS and ASC payment policy.

In response to the commenter requesting that we develop a policy to provide separate payment for drugs that are administered at the time of ophthalmic surgery, a surgical procedure episode consists of both pre-operative and post-operative care in addition to the surgical procedure itself. If a drug used to address a post-operative concern, such as pain management, is billed together with a surgical procedure, we assume that the pain management drug was given as a part of the overall surgical procedure. Because the pain management drug is ancillary to the primary ophthalmic surgery procedure, it is considered a surgical supply. The pain management drug is only administered to the patient because the patient has received ophthalmic surgery, and the drug would not have been administered to the patient if the patient did not have the surgery. In the OPPS, we pay one rate for the entire surgical procedure; and payment for supplies, such as pain management drugs, is packaged into the payment rate for the surgical procedure. We note exceptions to this policy in the ASC setting are discussed in II.A.3.b. (Payment Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies under the ASC Payment System) of this final rule with comment period.

Comment: One commenter recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used for the procedures in their claim submissions. The commenter believes this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore requested that the radiolabeled product edits be reinstated.

Response: We appreciate the commenter's feedback; however, we are not reinstating the radiolabeled product edits to nuclear medicine procedures, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment to be made under the OPPS. As previously discussed in the CY 2020 OPPS/ASC final rule with comment period (85 FR 86033 through 86034), the edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Comment: Several commenters had concerns regarding the CMS policy to package diagnostic radiopharmaceuticals. These commenters believed radiopharmaceuticals are not supplies but instead are essential elements in driving the procedures themselves. Commenters believe that for newer, more innovative radiopharmaceuticals, packaging could lead to a lack of patient access to the technology after pass-through payment expires, especially if there is no clinical alternative. Commenters also discussed HR 4479/S. 2609 the "Facilitating Innovative Nuclear Diagnostics Act (FIND Act) of 2021" introduced in the U.S. House of Representatives, which would mandate that CMS make separate payment for precision diagnostic radiopharmaceuticals receiving FDA approval after 2008 that have an estimated mean per day product cost of at least $500.

Several commenters requested that diagnostic radiopharmaceuticals be paid separately in all cases, not just when the drugs have pass-through payment status. Some commenters

mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market, but it is not enough to make up for what the commenters believe is inadequate payment after pass-through status expires. Commenters opposed incorporating the cost of the drug into the associated APC and provided evidence showing procedures in which diagnostic radiopharmaceuticals are considered to be a surgical supply, which the commenter believed are often paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when the drug had pass-through payment status. Additionally, commenters proposed alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold; creating separate APC payments for diagnostic radiopharmaceuticals that cost more than $500; and using ASP, WAC, AWP, mean unit cost data, or various other payment methodologies to account for packaged radiopharmaceutical costs, including making sure diagnostic radiopharmaceuticals and their associated nuclear medicine APCs do not violate the "two-times rule." Commenters suggested not consolidating the Nuclear Medicine APCs. Other commenters suggested creating new Nuclear Medicine APCs in order to pay adequately for higher cost diagnostic radiopharmaceuticals.

Commenters were also concerned that by providing packaged payment for precision diagnostic radiopharmaceuticals in the outpatient setting, CMS is creating barriers for safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities. Commenters specified certain populations, such as those with Alzheimer's Disease, depend on the use of diagnostic radiopharmaceuticals. Commenters discussed difficulties enrolling hospitals in clinical studies to further research diagnostic radiopharmaceuticals due to CMS packaging policies. Commenters also suggested paying

separately specifically for radiopharmaceuticals that are used for Alzheimer's Disease.

Response: We thank commenters for their suggestions. Commenters have made many of these suggestions in the past, and we addressed them in previous rules, including the CY 2020 OPPS/ASC final rule (84 FR 61314 through 61315) and the CY 2021 OPPS/ASC final rule (85 FR 86034). We continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Accordingly, the payment for the radiopharmaceuticals should be reflected within the payment for the primary procedure. We note that rates are established in a manner that uses the geometric mean of reported costs to furnish the procedure based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. The costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, the costs are based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure. Additionally, we do not believe it is appropriate to create a new packaging threshold specifically for diagnostic radiopharmaceuticals as such a threshold would not align with our overall packaging policy, and commenters have submitted only limited data to support a specific threshold. With respect to the request that we create a new APC for each radiopharmaceutical product, we do not believe it is appropriate to create unique APCs for diagnostic radiopharmaceuticals. Diagnostic radiopharmaceuticals function as supplies during a diagnostic

test or procedure and, following our longstanding packaging policy, these items are packaged under the OPPS. Packaging supports our goal of making OPPS payments consistent with those of a prospective payment system, which packages costs into a single aggregate payment for a service, encounter, or episode of care. Furthermore, diagnostic radiopharmaceuticals function as supplies that enable the provision of an independent service and are not themselves the primary therapeutic modality. Therefore, we do not believe they warrant separate payment through creation of a unique APC at this time.

We welcome ongoing dialogue and engagement from stakeholders regarding suggestions for payment changes for consideration in future rulemaking.

d. Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2023.

For CY 2023, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2021 claims data and our pricing information at ASP plus 6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for the CY 2023 OPPS/ASC proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2021 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP plus 6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2023 drug packaging threshold of $135 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2023 drug packaging threshold of $135 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2023 is displayed in Table 61.

We did not receive any comments on our proposal and we are finalizing it as proposed.

TABLE 61: HCPCS CODES TO WHICH THE CY 2023 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2023 HCPCS Code	CY 2023 Long Descriptor	CY 2023 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

2. Payment for Drugs and Biologicals without Pass-Through Status that are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the "statutory default."

Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[97]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

[97] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2022.

b. CY 2023 Payment Policy

For CY 2023 and subsequent years, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We formally proposed to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6 of this CY 2023 OPPS/ASC final rule with comment period) but noted that we anticipated paying for 340B drugs at ASP plus 6 percent. We refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final

rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For CY 2020 and subsequent years, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318 and 85 FR 86039).

For CY 2023 and subsequent years, we proposed to continue to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also proposed to apply this provision to non-SCOD separately payable drugs. Because we proposed to establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our proposal to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, would apply whenever WAC-based pricing is used for a drug or biological under

1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, we formally proposed that the payment amount for these drugs (in this case, at a rate of WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy. We also refer readers to section V.B.6. of this CY 2023 OPPS/ASC final rule with comment period for a full discussion of our finalized CY 2023 payment policy for 340B drugs.

Consistent with our current policy, we proposed for CY 2023 and subsequent years that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also proposed that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to the CY 2023 OPPS/ASC proposed rule (available on the CMS website[98]), which illustrate the proposed CY 2023 payment of ASP plus 6 percent for separately payable nonpass-through drugs and biologicals and ASP plus 6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2022, or WAC, AWP, or mean unit cost from CY 2021 claims data and updated cost report information available for the CY 2023 OPPS/ASC proposed rule. In general, these published payment rates are not the same as the actual January 2023 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2023 will be determined through the standard

[98] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2022 (July 1, 2022, through September 30, 2022) will be used to set the payment rates that are released for the quarter beginning in January 2023 in December 2022. In addition, payment rates for drugs and biologicals in Addenda A and B to the CY 2023 OPPS/ASC proposed rule, for which there was no ASP information available for April 2022, are based on mean unit cost in the available CY 2021 claims data. If ASP information becomes available for payment for the quarter beginning in January 2023, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for the CY 2023 OPPS/ASC proposed rule (reflecting April 2022 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2023. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2021 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the CY 2023 OPPS/ASC proposed rule are not for January 2023 payment purposes and are only illustrative of the CY 2023 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2023 OPPS/ASC proposed rule.

Comment: We received several general comments on Medicare drug spending and drug spending under the OPPS and ASC. One commenter provided feedback on the rapidly rising costs of prescription drugs. Another commenter commented on the need to increase domestic generic drug manufacturing.

Response: While we note these comments are generally out of scope for purposes of this OPPS/ASC final rule with comment period, we thank commenters for their interest and feedback.

Comment: A few commenters supported separate payment for specific drugs, biologicals, and radiopharmaceuticals for CY 2023. Commenters also supported CMS paying for all separately payable drugs and biologicals as SCODs. Several commenters expressed their approval for our proposal to pay for separately payable drugs and biologicals at ASP plus 6 percent. The commenters generally believed this policy is consistent with statute and Congressional intent and generates more predictable payment for providers than previous payment methodologies for drugs and biologicals. A few of these commenters believed the ASP plus 6 percent payment policy ensures equivalent payment for drugs and biologicals between the outpatient hospital setting and the physician office, which, in their view, encourages Medicare beneficiaries to receive care in the most clinically appropriate setting.

Response: We appreciate the commenters' feedback and support.

Comment: One commenter requested that an add-on percentage of greater than 6 percent of ASP be paid for separately payable radiopharmaceuticals to reflect higher overhead and handling costs for these products.

Response: The add-on percentage of 6 percent is generally viewed as reflecting the overhead and handling cost of most drugs, radiopharmaceuticals, and biologicals that are separately payable in the OPPS even though the overhead and handling costs for individual products may be higher or lower than 6 percent of the ASP. We believe that the add-on percentage of 6 percent is appropriate for separately payable radiopharmaceuticals.

Comment: Several commenters requested that we maintain the status indicator assignment for HCPCS code Q2041 of "K" (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals), rather than assigning it a status

indicator of "N" (Items and Services Packaged into APC Rates) as shown in the proposed rule addenda.

Response: We agree with commenters and thank them for their comments on this discrepancy. HCPCS code Q2041 will be assigned to a status indicator of "K" for CY 2023 as shown in the addenda to this final rule with comment period on the CMS website.[99]

Comment: One commenter provided information regarding their drug Sinuva, described by HCPCS code J7402. This commenter believed their drug should be assigned to status indicator "K" upon pass-through expiration. This commenter explained that their drug does not fit into the category of drugs and biologicals that function as supplies when used in a surgical procedure.

Response: We thank this commenter for this information regarding their product. We refer readers to section V.A. of this final rule with comment period for details regarding pass-through expiration of their product. Upon pass-through expiration, we will publish updated status indicator assignments through the regular quarterly releases, which can be found on the CMS website.[100]

Comment: Commenters requested that we exclude radiopharmaceuticals from our proposed policy that during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, payments can be made for drugs using WAC pricing plus a 3 percent price add-on. The commenters believe the cost of preparing radiopharmaceuticals is higher than the cost of preparing other drugs and biologicals and a 6 percent price add-on should be required anytime that we use WAC to price a radiopharmaceutical.

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[99] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps
[100] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

Response: The WAC of a drug or biological is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. Because the WAC does not include discounts, it typically exceeds ASP, and the use of a WAC-based payment amount for the same drug results in higher dollar payments than the use of an ASP-based payment amount. Also, MedPAC in their June 2017 Report to the Congress (http:// www.medpac.gov/docs/default-source/ reports/jun17_reporttocongress_sec.pdf, pages 42 through 44) suggested that greater parity between ASP-based acquisition costs and WAC-based payments for Part B drugs could be achieved and recommended changing the 6 percent add-on for WAC-based payments to 3 percent. Given this evidence that WAC pricing tends to overestimate drug cost, we believe our current and proposed policy to pay drugs at WAC plus 3 percent for all drugs, biologicals, and radiopharmaceuticals when ASP is not available more accurately reflects the cost of new products recently entering the market than does WAC plus 6 percent.

After considering the public comments we received, we are finalizing our proposals related to payment for SCODs and other separately payable drugs and biologicals without modification.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual

threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we finalized a policy to implement separate HCPCS codes for biosimilar biological products that was based on the policy established in the CY 2018 PFS final rule. The policy we established allowed all biosimilar biological products to be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367).

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the payment for biosimilars without pass-through payment status that are acquired under the 340B Program. Accordingly, in the CY 2019 OPPS/ASC final rule (83 FR 58977), we implemented a policy that, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5

percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

For CY 2023 and subsequent years, we proposed to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also formally proposed to continue our current policy of paying for nonpass-through biosimilars acquired under the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. We refer readers to section V.B.6. of the CY 2023 OPPS/ASC proposed rule (87 FR 63644) for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

Comment: Commenters supported our proposal to continue our policy from CY 2018 to make biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Response: We appreciate the support of this established policy.

Comment: Commenters expressed general concerns regarding payment for pass-through biosimilars acquired by 340B entities and the impact on those biosimilars' competitors that are not on pass-through and are also acquired by 340B entities. Many acknowledged the proposed changes to the 340B payment under the OPPS in the proposed rule may no longer make this a concern; however, these commenters also expressed concerns regarding CMS's ability to change 340B payment rates in the future and were concerned this may not create an even playing field for biosimilars on pass-through status and their reference biological products not on pass-through when acquired through the 340B program. These commenters believe that pass-through

biosimilars have a substantial payment differential as compared to the innovator reference products and biosimilar biological products without pass-through status when purchased under the 340B program. Specifically, one commenter did not support our proposal to continue our CY 2018 policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenter believes that there should be a ‘‘level playing field’’ between biosimilars and their reference products in order to increase competition and reduce costs for beneficiaries. The commenter does not believe it is fair for biosimilars of a reference product to be receiving pass-through payment of ASP plus 6 percent of the reference product’s ASP. The commenter believes that this difference in the payment rates for biosimilars and their reference products could potentially lead to increased Medicare spending on biosimilars as providers utilize biosimilars instead of the biosimilars’ reference products because of the higher payment rates for biosimilars in these circumstances. The commenter believes use of biosimilars is inappropriately incentivized and that these products should not be eligible for pass-through status.

Response: As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977), we continue to believe that eligibility for pass-through payment status reflects the unique, complex nature of biosimilars and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals.

We note, for CY 2023, we are finalizing a policy to pay for biosimilars acquired under the 340B Program at the rate in which non 340B acquired biosimilars are paid, which is generally the biosimilar’s ASP plus 6 percent of the reference biological product’s ASP, subject to section d. (Increased Payment for Biosimilars in the Inflation Reduction Act of 2022) below. Our final

policy regarding the payment rate for drugs and biologicals that are acquired under the 340B program is described in section V.B.6 of this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar products, without modification, to continue the policy established in CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We are continuing our policy to pay for all biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our packaging policies as described through section V.B. of this final rule with comment period.

d. Increased Payment for Biosimilars in the Inflation Reduction Act of 2022

On August 16th, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 1847A(b)(8) of the Act, as amended by section 11403 of the IRA, requires a temporary increase in the add-on payment for qualifying biosimilar biological products from 6 percent to 8 percent of the ASP of the reference biological beginning October 1, 2022. This increase applies for a 5-year period as required by section 1847A(b)(8)(B). A qualifying biosimilar biological product is defined as a biosimilar with an ASP that is not more than the ASP of the reference biological. For qualifying biosimilar biological products for which payment was made using ASP as of September 30, 2022, the 5-year period begins on October 1, 2022. For qualifying biosimilar biological products for which payment is first made using ASP between October 1, 2022, through December 31, 2027, the 5-year period begins on the first day of the calendar quarter during which such payment is first made.

Because we generally base OPPS and ASC payments for biosimilar biological products on the methodology described in section 1847A(b)(8) of the Act (80 FR 70444 through 70446), payments for qualifying biosimilars, as defined at section 1847A(b)(8)(B)(iii) of the Act, will temporarily increase. Therefore, beginning October 1, 2022, payment for qualifying nonpass-through biosimilars under the OPPS and ASC payment systems generally changed from ASP plus 6 percent of the reference biological product's ASP, to ASP plus 8 percent of the reference biological product's ASP for a 5-year period. Similarly, payment for qualifying pass-through biosimilars under the OPPS and ASC payment systems generally changed from ASP plus 6 percent of the reference biological product's ASP to ASP plus 8 percent of the reference biological product's ASP for a 5-year period. For existing qualifying biosimilars for which payment was made using ASP as of September 30, 2022, the 5-year period began on October 1, 2022. For new qualifying biosimilars for which payment is first made using ASP between October 1, 2022, and December 31, 2027, the applicable 5-year period begins on the first day of the calendar quarter during which such payment is made. We note, additional details on the implementation of the IRA are forthcoming and will be communicated through a vehicle other than this CY 2023 OPPS/ASC final rule with comment period.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2023 and subsequent years, we proposed to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with

comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2023. Therefore, we proposed, for CY 2023 and subsequent years, to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521).

For CY 2023 and subsequent years, we also proposed to rely on the most recently available mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2023 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B of the CY 2023 OPPS/ASC proposed rule (which are available on the CMS website).[101]

[101] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

Comment: Commenters supported the continuation of this policy to provide a predicable payment methodology and avoid the payment swings that occurred prior to adoption of the statutory default rate for therapeutic radiopharmaceuticals.

Response: We thank commenters for their support and feedback on this policy.

Comment: One commenter suggested CMS investigate HCPCS code A9699. This commenter stated that this code was packaged and no separate APC payment was made. This commenter suggested that CMS revise the status indicator of this drug to a status indicator of "K" in order to allow this code to be separately payable as they believed not doing so may impede beneficiary access to new therapeutic radiopharmaceuticals that may be billed with this code.

Response: We thank this commenter for their recommendation to assign HCPCS code A9699 (*Radiopharmaceutical, therapeutic, not otherwise classified*) a status indicator of "K." We note that this code is assigned an OPPS status indicator of "N" for CY 2023, which is a longstanding status indicator assignment under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent. We are also finalizing our proposal to continue to rely on the most recently available mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2023 final payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2022, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (86 FR 63643). That is, for CY 2022, we provided payment for blood clotting factors under the OPPS at ASP plus 6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2022 updated furnishing fee was $0.239 per unit.

For CY 2023 and subsequent years, we proposed to pay for blood clotting factors at ASP plus 6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable

program instructions and posting on our website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

We proposed to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

Comment: One commenter supported our proposal to continue to pay for blood clotting factors at ASP plus 6 percent plus a furnishing fee for the clotting factors updated annually using the CPI. The commenter also supported our policy to pay the same clotting factor furnishing fee across different care settings.

Response: We appreciate the commenter's support for our policies.

After reviewing the public comment that we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data

For CY 2023 and subsequent years, we proposed to continue to use the same payment policy as in CY 2022 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. For a detailed discussion of the payment

policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2023 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to the CY 2023 OPPS/ASC proposed rule, which is available on the CMS website[102].

We did not receive any specific public comments regarding our proposed payment for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data; however, many commenters did support paying for separately payable drugs under the statutory default. Therefore, we are finalizing our CY 2023 proposal without modification, including our proposal to assign drug or biological products status indicator ‘‘K’’ and pay for them separately for the remainder of CY 2023 if pricing information becomes available. The CY 2023 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available on the CMS website.

6. OPPS Payment Methodology for 340B Purchased Drugs

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals under section 1833(t)(14)(A). Section 1833(t)(14)(A)(iii)(II) provides that, if hospital acquisition cost data is not available, the payment amount is the average price for the drug in a year established under section 1842(o), which cross-references section 1847A, which

[102] https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

generally sets a default rate of ASP plus 6 percent for certain drugs. The provision also provides that the average price for the drug in the year as established under section 1847A is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO[103] and MedPAC[104] that 340B hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. We direct readers to the CY 2018 OPPS/ASC final rule with comment period for a more detailed discussion of the 340B drug payment policy (82 FR 52493 to 52511).

This policy has been the subject of significant litigation, including the Supreme Court's recent decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). Originally, in December 2018, the United States District Court for the District of Columbia (the "District Court") concluded that the Secretary lacked the authority to adjust the default rate to bring it more in line with average acquisition cost unless the Secretary obtains survey data from hospitals. The agency then appealed to the United States Court of Appeals for the District of Columbia Circuit (hereinafter referred to as the "D.C. Circuit"), and on July 31, 2020, the court entered an opinion reversing the District Court's judgment. Plaintiffs then petitioned the United States Supreme Court for a writ of certiorari, which was granted on July 2, 2021.[105]

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[103] Government Accountability Office. ''Medicare Part B Drugs: "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at https://www.gao.gov/assets/gao-15-442.pdf

[104] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/

[105] https://www.supremecourt.gov/orders/courtorders/070221zor_4gc5.pdf

On June 15, 2022, the Supreme Court reversed the decision of the D.C. Circuit, holding that HHS may not vary payment rates for drugs and biologicals among *groups of hospitals* under section 1833(t)(14)(A)(iii)(II) without having conducted a survey of hospitals' acquisition costs under subparagraph (t)(14)(A)(iii)(I). While the Supreme Court's decision addressed payment rates for CYs 2018 and 2019, it has implications for CY 2023 payment rates. However, given the timing of the Supreme Court's decision, we lacked the necessary time to fully incorporate the adjustments to the proposed payment rates and budget neutrality calculations to account for that decision before issuing the CY 2023 OPPS/ASC proposed rule, as explained further below. For that reason, the payment rates, tables, and addenda in the CY 2023 OPPS/ASC proposed rule reflected a payment rate of ASP minus 22.5 percent for drugs and biologicals acquired through the 340B program for CY 2023, consistent with our prior policy. We also provided 340B alternate supporting files, which provide information regarding the payment effects to non-drug services from removing the 340B program payment policy and restoring drug payment to the default rate, generally ASP plus 6 percent, for CY 2023. We stated that we anticipated applying the default rate—generally ASP plus 6 percent—to such drugs and biologicals in the final rule for CY 2023, in light of the Supreme Court's recent decision. We noted we were still evaluating how to apply the Supreme Court's recent decision to prior calendar years 2018 through 2022.

Each year since 2018, we have continued the policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent. When we were developing the CY 2023 OPPS/ASC proposed rule, we intended to propose to continue our 340B policy based on the D.C. Circuit Court of Appeals' then-governing decision. That is, the rates that we previously developed, the tables, and the addenda that are part of the CY 2023 OPPS/ASC proposed rule built on the policy that had been in effect since 2018, which paid for drugs and

biologicals at one rate if they were acquired through the 340B program (generally ASP minus 22.5 percent), and at another rate if they were not acquired through the 340B program (generally ASP plus 6 percent).

Development of the annual OPPS proposed rule begins several months before publication. This process includes formulating proposed policies and calculating proposed rates, which then must be adjusted to maintain budget neutrality. In particular, section 1833(t)(9)(B) requires that, if the Secretary makes adjustments under subparagraph (A) of that subparagraph to the groups, the relative payment weights, or the wage or other adjustments, those adjustments for the year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures that would have been made absent those adjustments. In addition, section 1833(t)(14)(H) separately provides that "[a]dditional expenditures resulting from this paragraph . . . shall be taken into account" in establishing the conversion, weighting, and other adjustment factors for any calendar year after 2005.

When the Supreme Court's decision was issued on June 15, 2022, we had already developed the policies we intended to include in the proposed rule and calculated the payment rates, which included application of an adjustment to maintain budget neutrality. There was not sufficient time remaining in the proposed rule development process for us to change the policy and accompanying rates in response to the Supreme Court's decision. As we explained in the proposed rule, the OPPS is a calendar year payment system and to ensure OPPS payment rates and policies are effective on January 1, 2023, we must issue the final rule with comment period in early November to allow for the 60-day delayed effective date that the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)) requires for major rules. We generally attempt to issue the

annual OPPS/ASC proposed rule by early July to ensure that there is sufficient time to allow for the 60-day public comment period required by section 1871(b)(1) of the Act, followed by review of public comments and development of the final rule in time for the early November issuance date. If we had changed the policy and accompanying rates in response to the Supreme Court's decision, the proposed rule would have been substantially delayed, which would have jeopardized our ability to develop this final rule in time to meet the early November deadline required to adhere to the CRA's 60-day delayed effective date requirement. Therefore, the rates, tables, and addenda in the CY 2023 OPPS/ASC proposed rule reflect the proposal to pay for drugs differently if they were acquired through the 340B program, namely at ASP minus 22.5 percent, with the anticipated savings redistributed to all other items and services in a budget neutral manner. We noted that if interested parties or members of the public wished to comment on the propriety of maintaining differential payment for 340B-acquired drugs in the future, or other aspects of these as-published rates, we would consider such comments, subject to the constraints of the Supreme Court's recent decision.

That said, as we noted earlier, in light of the Supreme Court's decision in *American Hospital Association*, we fully anticipated reverting to our prior policy of paying the default rate, generally ASP plus 6 percent, regardless of whether a drug was acquired through the 340B program. We advised readers that a reversion to that policy would have an effect on the payment rates for other items and services due to the budget neutral nature of the OPPS system. To maintain OPPS budget neutrality under our anticipated final policy where non-pass-through separately payable OPPS drugs purchased under the 340B program are paid at ASP plus 6 percent in CY 2023, we explained that we would need to determine the change in estimated OPPS spending associated with the alternative policy. Based on separately paid line items with

the "JG" modifier in the CY 2021 claims available for OPPS rate-setting, which represent all drug lines for which the 340B program payment policy applied, we estimated the payment differential would be an increase of approximately $1.96 billion in OPPS drug payments. To ensure budget neutrality under the OPPS after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we indicated that we would apply this offset of approximately $1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279. This is a similar application of OPPS budget neutrality as was originally applied to the OPPS 340B program payment policy described in the CY 2018 OPPS final rule (82 FR 59258, 82 FR 59482 through 59484). In the CY 2018 OPPS final rule, this budget neutrality adjustment increased the conversion factor to budget neutralize the decreased spending for drugs acquired through the 340B program in CY 2018. In the CY 2018 proposed rule (87 FR 44648), we explained that we would apply that same calculation, but we would decrease the conversion factor to budget neutralize the increased spending associated with payments for drugs acquired through the 340B program that would result from increasing the rate of ASP minus 22.5 percent to ASP plus 6 percent. We noted that the amount of this adjustment would potentially change in the final rule due to updated data, potential modifications to the estimate methodology, and other factors. A table detailing the impact on hospital outpatient payment rates for all hospitals of removing the payment differential for 340B drugs and the corresponding budget neutrality adjustment for CY 2023 was included in the 340B Alternative supporting files.

b. Payment for 340B Drugs and Biologicals in CYs 2018 through 2022

For full descriptions of our OPPS payment policy for drugs and biologicals acquired under the 340B program, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649).

Our policies for 340B-acquired drugs have been the subject of ongoing litigation, the procedural history of which is generally described above. On December 27, 2018, in the case of *American Hospital Association v. Azar*, 348 F. Supp. 3d 62 (D.D.C.), the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.

On July 10, 2019, the district court entered final judgment. *See Am. Hospital Ass'n v. Azar*, No. 18-2084 (RC), 2019 WL 3037306. The agency appealed to the D.C. Circuit, and on July 31, 2020, the court entered an opinion reversing the district court's judgment in this matter. *See Am. Hospital Ass'n v. Azar*, 967 F.3d 818. In January of 2021, appellees petitioned the United States Supreme Court for a writ of certiorari. On July 2, 2021, the Supreme Court granted the petition and heard oral arguments in November 2021. And, as noted above, the Supreme Court this year reversed the decision of the D.C. Circuit.

Before the D.C. Circuit upheld our authority to pay ASP minus 22.5 percent for 340B drugs, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. After the CY 2020 OPPS/ASC proposed rule was issued, we announced in the

Federal Register (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for years going forward, and also may be used to devise a remedy for prior years if the district court's ruling was upheld on appeal. For a complete discussion of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs, we refer readers to the CY 2021 OPPS/ASC proposed rule (85 FR 48882 through 48891) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055). We proposed a net payment rate for 340B drugs of ASP minus 28.7 percent (minus 34.7 percent plus 6 percent) based on survey data, and also proposed in the alternative that the agency could continue its current policy of paying ASP minus 22.5 percent for CY 2021. On July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that our original interpretation of the statute to adjust ASP by minus 22.5 percent was reasonable.

During CY 2021 rulemaking, based on feedback from interested parties, we stated that we believed maintaining the policy of paying ASP minus 22.5 percent for 340B drugs was appropriate to maintain consistent and reliable payment for these drugs to give hospitals increased certainty as to payments for these drugs. For CY 2022, we continued this 340B policy without modification as described in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63648).

We are still evaluating how to apply the Supreme Court's decision to calendar years 2018 through 2022. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, "[a]t this stage, we need not address potential remedies." *Am. Hospital*

Ass'n, 142 S. Ct. at 1903. We solicited public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018 through 2022.

The Supreme Court remanded its decision to the D.C. Circuit, which in turn remanded it to the United States District Court for the District of Columbia. Upon the case's remand to the district court, the plaintiffs filed two motions seeking (1) to vacate the portion of the 340B reimbursement rate in the CY 2022 final OPPS rule that is still in effect for the remainder of 2022; and (2) to remedy the reduced payment amounts to 340B hospitals under the reimbursement rates in the final OPPS rules for CYs 2018–2022.

After the publication of the proposed CY 2023 OPPS rule, on September 28, 2022, the district court ruled on the first motion, vacating the 340B reimbursement rate for the remainder of 2022. The agency has since taken the necessary steps to implement that September 28, 2022 decision, which the court clarified was a final judgment.[106] The court also indicated in its decision on the first motion that it would issue a separate opinion resolving the second motion at a later time.

We received the following public comments in response to our comment solicitation on potential remedies affecting calendar years 2018 through 2022.

Comment: A majority of commenters requested that we promptly pay hospitals the additional amounts owed for 340B drug payments from 2018 to 2022 as a result of the 340B policy no longer applying. Some commenters additionally requested that we include interest in these payments. A majority of commenters also requested that we not seek recoupment of funds received (which they characterize as holding hospitals harmless) for the increased rates for non-

106 Vacating Differential Payment Rate for 340B-Acquired Drugs in 2022 Outpatient Prospective Payment System Final Rule with Comment Period. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps

drug services from 2018 through 2022, arguing that budget neutrality can be applied only prospectively and that there is no precedent for a retrospective budget neutrality adjustment. These commenters also argued that a retrospective payment adjustment would be unfair given the significant financial impact it would have on hospitals and that it would be penalizing hospitals for a policy that has been deemed unlawful by the Supreme Court. These commenters also pointed to the logistical and administrative burdens that retroactive payment adjustment would impose on hospitals and contended that hospitals have spent most of the overpaid funds during the PHE.

MedPAC and a few other commenters stated that any changes in response to the Supreme Court's decision should be made in a budget-neutral manner to ensure consistency with the OPPS statute and CMS's longstanding budget neutral policy and because, given scarce fiscal resources, it would be fiscally imprudent to increase Medicare spending by approximately $2 billion in each year that CMS applied the overturned 340B policy (CY 2018 through CY 2022) without making a corresponding budget neutrality adjustment.

Many commenters suggested that if CMS determines that it must address payments from 2018 through 2022 in a budget neutral manner, CMS should engage in a more fulsome notice-and-comment rulemaking process with opportunities for public comment regarding how it will carry out any policy changes. Several commenters suggested a budget neutral, prospective-only solution to address payments from 2018 through 2022. One commenter suggested that CMS defer adoption of a 340B-related budget neutrality adjustment for 2023 and instead issue a request for information to solicit comments on how to address the policy implications of the 340B policy reversal for all relevant years (2018 through 2022) and all impacted providers. One commenter emphasized that whatever methodology CMS adopts, it should not involve the

reprocessing of claims in order to avoid any impact on patient coinsurance. Several commenters urged CMS to ensure that the methodology used to remedy the reduced payment amounts between 2018 and 2022 does not inadvertently impact non-340B eligible providers, including Ambulatory Surgical Centers.

Several commenters requested that the 340B payment rates for CY 2022 be immediately updated to reflect ASP plus 6 percent given that the payment rate of ASP minus 22.5 percent was found to be unlawful. One commenter suggested that CMS develop and implement a simple attestation process for each year of reduced payment amounts pursuant to our policy in effect at the time. Another commenter suggested that CMS state clearly in the final rule that hospitals may forego collecting these payments from beneficiaries or insurance companies for the increased rate.

Response: We thank commenters for their many thoughtful comments and will take their input into account as we formulate an appropriate remedy to address reduced payment amounts to 340B hospitals for CYs 2018 through 2022. We agree with commenters who suggested that we should give stakeholders an opportunity to comment on a proposed remedy, but do not believe we need to delay the process by first issuing a separate request for information. We also acknowledge the motion pending before the district court with respect to this issue. In order to balance our ability to give the remedy the type of deliberation encouraged by the Medicare statute and Administrative Procedure Act, stakeholders' ability to comment, and their interest in a timely remedy, we plan to issue a separate proposed rule detailing our proposed remedy for CYs 2018 to CY 2022 in advance of the CY 2024 OPPS/ASC proposed rule. As we previously

announced, claims for 340B-acquired drugs paid after the district court's September 28, 2022 ruling are paid at the default rate (generally ASP plus 6 percent).[107]

c. CY 2023 340B Drug Payment Policy

As discussed above, given when the Supreme Court's decision in *American Hospital Association v. Becerra* was issued during our annual rulemaking process, we lacked the necessary time to account for that decision before issuing the CY 2023 OPPS/ASC proposed rule. For that reason, for CY 2023, we formally proposed to continue the policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. But again, in light of the Supreme Court's decision, we explained that we fully anticipated adopting a policy of paying ASP plus 6 percent for 340B-acquired drugs and biologicals in this final rule with comment period. This formal proposal was in accordance with the policy choices and calculations that CMS made in the months leading up to publication of the CY 2023 OPPS/ASC proposed rule before the Supreme Court issued its decision in *American Hospital Association.* We proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs and biologicals (assigned status indicator "K"), other than vaccines and drugs on pass-through status, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. We formally proposed to continue our current policy for calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent

107 *See* https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2022-10-13-mlnc#_Toc116466499

for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We also formally proposed to continue the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. We proposed that the 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Additionally, we proposed to continue to exempt rural sole community hospitals (as described under the regulations at § 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment.

Finally, we formally proposed continuing to require hospitals to use modifiers to identify 340B-acquired drugs. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and the requirements for use of modifiers ''JG'' and "TB."[108]

Again, we noted that, in light of the Supreme Court's decision in *American Hospital Association*, we fully anticipated reverting to our prior policy of paying for drugs at ASP plus 6 percent, regardless of whether they were acquired through the 340B program for CY 2023. We also explained that we fully expected that when we reverted to paying for drugs acquired through the 340B program at ASP plus 6 percent, we would budget neutralize that increase consistent with the OPPS statute and our longstanding policy by making a corresponding decrease to the conversion factor to account for the increase in the payment rates for these drugs. As set forth above, to ensure budget neutrality under the OPPS, after applying this alternative payment

108 CMS established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs:
• Modifier "JG" Drug or biological acquired with 340B drug pricing program discount, reported to trigger the payment reduction.
• Modifier "TB" Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.

methodology for drugs and biologicals purchased under the 340B Program, we estimated that we would apply an offset of approximately $1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279.

We welcomed public comments on the budget neutrality adjustment and stated that they would be carefully considered. For a more detailed discussion of the budget neutralizing effects of reverting to this prior policy of paying for all drugs (whether 340B-acquired or not) at ASP plus 6 percent we also published the 340B Alternative supporting files, which included an alternative impact table, the calculation of a 340B Alternative conversion factor, the budget neutrality factors associated with the 340B Alternative policy, and Addenda A, B, and C, all of which provide information regarding the effects of removing the 340B program payment policy for CY 2023.

We received the following public comments on our proposal for CY 2023.

Comment: The vast majority of commenters supported our intention to revert to our prior policy of paying for drugs at ASP plus 6 percent for non-pass-through separately payable drugs and biosimilar products acquired under the 340B program for CY 2023.

Response: We thank these commenters for their comments.

Comment: Some commenters opposed reverting to an ASP plus 6 percent payment rate and argued for a new drug cost survey to inform the payment rate for CY 2024. These commenters argued that the ASP plus 6 percent payment rate was excessive and that conducting a new drug cost survey would ensure that CMS is paying a rate that more closely approximates the costs incurred by 340B providers.

Response: We thank the commenters for their suggestions regarding drug cost surveys, we are under no statutory obligation to necessarily conduct a drug cost survey to inform the payment rate for any given year. According to the GAO hospitals survey in 2005, surveys be useful on occasion to validate rate-setting data CMS receives, such as ASP, but they also create a burden for hospitals and the data collector. For these reasons, GAO recommended that CMS survey hospitals only occasionally to validate hospital acquisition costs.[1] Nonetheless, we will take ~~this~~ the commenters' feedback regarding a survey of hospital drug acquisition costs into consideration for potential future rulemaking.

Comment: One commenter who supported CMS conducting a new drug cost survey, argued that reverting to the ASP plus 6 percent payment rate would be arbitrary and capricious under the Administrative Procedure Act because (1) CMS did not examine relevant data provided in the CY 2021 OPPS proposed rule, which provides evidence for finalizing 340B payment as ASP minus 28.7 percent; (2) CMS did not articulate a satisfactory explanation for the policy change to finalize payment at ASP plus 6 percent; (3) reversion to the ASP plus 6 percent payment rate is contrary to substantial evidence that 340B hospitals are vastly overpaid for drugs; and (4) reversion to the ASP plus 6 percent payment rate is otherwise an unreasonable decision.

Response: Our policy for CY 2023 is consistent with the Supreme Court's decision in *American Hospital Association.* Additionally, we are reverting to our longstanding payment methodology, which is described in detail throughout section V. (OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals). This payment methodology is consistent with section 1833(t)(14)(A)(iii)(II) of the Act and is based on many years of notice and comment rulemaking.

Comment: Many commenters opposed our proposal to continue requiring hospitals to use the "JG" and "TB" claims modifiers in CY 2023 to identify drugs acquired with the 340B discount and requested that we discontinue their use.

Response: We appreciate these commenters' concerns; however, it is important for us to maintain the 340B modifiers for CY 2023 to allow us to track the utilization of 340B acquired drugs and biologicals under the OPPS.

For CY 2023, we are maintaining the requirement for 340B hospitals to report the "JG" and "TB" modifiers for informational purposes, but they will have no effect on payment rates. The presence of modifier "JG" on a claim to indicate a drug is acquired under the 340B program will not trigger a payment reduction and will be used only for informational purposes. Claims for 340B drugs and biologicals identified with a "JG" modifier will be paid at the same statutory default rate as non-340B drugs and biologicals. For CY 2023, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals should continue to bill the modifier "TB" on claim lines for drugs acquired through the 340B Program. All other 340B providers should continue to report the modifier "JG." We believe maintaining both modifiers will reduce provider burden compared to shifting to a single modifier, as all providers can continue utilizing the modifier (either "JG" or "TB") in the same manner as they have been utilized for the past five calendar years.

For CY 2023, we are finalizing the reversion to a payment rate of, generally, ASP plus 6 percent as the default payment rate for drugs and biologicals acquired under the 340B program and will pay for these drugs and biologicals no differently than we pay for those drugs and biologicals that are not acquired under the 340B program.

Comment: A few commenters supported CMS's proposal to continue to require hospitals to use 340B billing modifiers to report separately payable drugs that were acquired under the 340B program.

Response: We thank commenters for their input and it is important for us to maintain the 340B modifiers for CY 2023 to allow us to track the utilization of 340B acquired drugs and biologicals under the OPPS. For CY 2023, rural SCHs, children's hospitals, and PPS-exempt cancer hospitals) will report the "TB" modifier when a drug is acquired under the 340B program and paid under the OPPS. For CY 2023, hospitals reporting the modifier "JG" when a drug is acquired under the 340B program will not trigger a payment reduction. Instead, the modifier "JG" is for informational purposes only and will be paid at the statutory payment rate for drugs and biologicals. Similarly, the "TB" modifier will continue to be for informational purpose only and reported by rural SCHs, children's hospitals, and PPS-exempt cancer hospitals. Providers shall continue utilizing the modifier (either "JG" or "TB") in the same manner as they have been utilized for the past five calendar years.

Comment: Many commenters opposed our intent to budget neutralize the increased payment for 340B drugs for CY 2023, arguing that the proposed negative 4.04 percent budget neutrality adjustment to the conversion factor would cancel out the 2.7 percent fee schedule increase. One of these commenters requested that we waive the 340B-related budget neutrality adjustment for 2023 and instead engage with interested parties in the CY 2024 OPPS/ASC proposed rule to identify other remedies. Several of these commenters suggested, in the event CMS deems that an adjustment to the CY 2023 conversion factor is necessary, that CMS spread the CY 2023 adjustment out over four to five years to mitigate the single-year impact on hospitals.

Response: We appreciate the commenters' concerns regarding the effect of the 340B budget neutrality adjustment for 2023. However, under sections 1833(t)(9)(B) and (t)(14)(H), adjustments for a year may not cause the estimated amount of expenditures for that year to increase or decrease from the estimated amount of expenditures that would have been made if the adjustments had not been made, and additional expenditures for drugs and biologicals in years after 2005 must be taken account in establishing the conversion weighting, and other adjustment factors. Accordingly, the increase in payments for 340B drugs must be accompanied by a corresponding budget neutrality adjustment in CY 2023. We calculated the proposed budget neutrality adjustment to conversion factor of 0.9596 using our standard methodology. However, we acknowledge there are alternative methodologies to calculate the budget neutrality factor consistent with the statute and, as discussed further below, agree with the commenters that such an alternative is more appropriate in these circumstances.

Comment: Many commenters requested that, in the place of the -4.04 percent adjustment to the CY 2023 OPPS conversion factor to maintain budget neutrality with CY 2022, we instead apply a budget neutrality adjustment that offsets the 3.19 percent increase we applied to the conversion factor in CY 2018 to account for the decreased payment for 340B drugs under our policy, which would have the effect of undoing that policy.

Response: We agree with commenters that under these specific circumstances it is appropriate to decrease payments for non-drug items and services by a percentage that would offset the percentage by which they were increased when CMS implemented the 340B policy in CY 2018. Accordingly, we are adopting this methodology based on the consideration of comments received. Our adjustment to the CY 2023 OPPS conversion factor will be 0.9691 rather than 0.9596, reflecting a budget neutrality adjustment of -3.09 percent rather than the -4.04

percent we proposed. Reducing the conversion factor by 3.09 percent in CY 2023 is the reduction that is necessary to fully offset the 3.19 percent increase to the conversion factor we implemented in CY 2018. The -3.09 percent adjustment is applied by multiplying the conversion factor by 0.9691(1/1.0319). This adjustment to the conversion factor is appropriate in these circumstances, including because it removes the effect of the 340B policy as originally adopted in CY 2018, which was recently invalidated by the Supreme Court as explained above, from the CY 2023 conversion factor and ensures it is equivalent to the conversion factor that would be in place if the 340B drug payment policy had never been implemented.

Comment: A commenter believed that the payment for non-drug services should have increased since 2018 as the 340B expenditure increased through application of an updated budget neutrality adjustment. The commenter suggested that CMS could apply a one-time budget neutrality adjustment for CY 2023 to increase non-drug payments to account for an what commenters believed were underpayments for non-drug items and services in CY 2020 through CY 2022. In addition, the commenter recommended CMS apply a net budget neutrality adjustment for pass-through payments of 1.03 percent in place of the 0.34 budget neutrality adjustment reflected in the proposed rule due to the CY 2023 payment rate for 340B drugs of ASP plus 6 percent.

Response: We thank the commenter for the recommendation but the first comment is related to the budget neutrality adjustment from prior years. We will take it under consideration as we prepare a separate proposed rule to address the remedy for CY 2018 to 2022. In regards to the passthrough payment comment, we have updated the passthrough payment estimate for CY 2023 to account for the change in 340B policy as discussed in the passthrough payment estimate section of this final rule.

Comment: Many commenters urged CMS to discard the 2020 drug survey for future ratesetting because the commenters contend it was not performed consistent with the statute. Many commenters also encouraged CMS to undertake, without delay, the survey of drug acquisition costs required by the Medicare statute and base OPPS payments for 340B hospitals on that survey starting with CY 2023.

Response: We are not conducting or taking into account the results of a drug acquisition cost survey for CY 2023. For CY 2023, we are finalizing our policy to generally pay ASP plus 6 percent for separately payable drugs and biologicals, regardless of whether they were acquired through the 340B program

Comment: One commenter requested that when determining its 340B payment policy for CY 2023, CMS consider the potentially negative impacts on rural hospitals that continue to struggle financially.

Response: We appreciate this commenter's feedback. We note that while the original intent of this policy was not to benefit rural hospitals financially, we recognize that ending this policy means that payment rates for non-drug items and services will decrease, which will lead to lower total payments for all hospitals, including non-340B hospitals or hospitals that were exempt from the 340B payment policy for which the 340B policy had a positive financial effect. We appreciate the role rural hospitals play in serving their communities and understand the financial challenges of rural hospitals. As discussed previously, since the Supreme Court invalidated the previous payment rate of ASP minus 22.5 percent for 340B acquired drugs and biologicals, we must decrease other rates to offset the increase in 340B drug payment. We believe the best interpretation of the statute is to require budget neutrality across the program.

Comment: Several commenters requested that the ASC payment system be insulated from any reductions to the OPPS conversion factor for CY 2023.

Response: We note the budget neutrality adjustment does not impact the ASC conversion factor; however, because the ASC standard ratesetting methodology adopts OPPS payment rates and the device portion (or device offset amount), the revised OPPS conversion factor will have an impact on the ASC payment system. Specifically, because the device portion for device-intensive procedures is held constant with the OPPS and is not calculated with the ASC conversion factor, the revised OPPS conversion factor will lower the device portion for device-intensive procedures, including the payment rates for device-intensive procedures under the ASC payment system. However, the decline in expenditures for device portions under the ASC payment system is fully offset through the ASC weight scalar, which increases payment for the non-device portions of all covered surgical procedures and certain covered ancillary services.

Comment: One commenter expressed concern that the interaction of the 340B payment reduction with the exemption for pass-through products has the potential to create a disparity between payment for biosimilars with pass-through status and their reference products and branded pass-through and nonpass-through products. The commenter contends that the disparity created by these combined policies could cause inappropriate financial incentives for prescribing biosimilars on pass-through status rather than nonpass-through reference products including financial incentives to prescribe that could conflict inappropriately with clinical guidelines and/or standards of care.

Response: We note that, by the time this final rule with comment period is issued, the 340B payment adjustment will no longer be in effect as we are reverting to our standard payment

methodology of paying a statutory default amount of, in general, ASP plus 6 percent regardless of whether a drug is acquired under the 340B program.

Comment: One commenter encouraged CMS and HHS to work with HRSA to improve the integrity of the 340B Drug Pricing Program, such as clarifying the definition of a "patient," placing greater guardrails on when contract pharmacies may access the Program's discounts, and revising the formula for Disproportionate Share Hospital status from one based on inpatient days to one that is based on outpatient utilization.

Response: We thank the commenter for this comment and note that this comment is outside of the scope of this final rule as we did not make any proposals involving the definition of a "patient," placing greater guardrails on when contract pharmacies may access the 340B program's discounts, or revising the formula for Disproportionate Share Hospital status for CY 2023.

After consideration of the public comments, for CY 2023 we are reverting to ASP plus 6 percent as the default payment rate for 340B-acquired drugs and biologicals and will pay for 340B-acquired drugs and biologicals no differently than we pay for drugs and biologicals that are not acquired through the 340B program. We are finalizing a budget neutrality adjustment to the CY 2023 OPPS conversion factor of 0.9691 percent rather than the 0.9596 percent adjustment we used for the alternative files in the proposed rule. This adjustment offsets the prior increase of 3.19 percent that was applied to the conversion factor when we implemented the 340B payment policy in CY 2018 in a budget neutrality manner.

Effective January 1, 2023, the "JG" modifier will be used by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes, rather than to trigger a payment adjustment. For CY

2023, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals will continue to use the "TB" modifier to identify 340B drugs for informational purposes.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2022, the payment rate for APC 5053 (Level 3 Skin Procedures) was $596.39, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,774.73, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,326.39. This information is also available in Addenda A and B of the CY 2022 final rule with comment period, as issued with the final rule correction notice (87 FR 2058) (the correction notice and corrected Addenda A and B are available on the CMS website [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices]).

We have continued the high cost/low cost categories policy since CY 2014, and we proposed to continue it for CY 2023. Under the current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years,

we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (85 FR 86059).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group, which, under current payment rates, can be a difference of over $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit

year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347); CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61328 to 61331).

b. Proposals for Packaged Skin Substitutes for CY 2023

For CY 2023, consistent with our policy since CY 2016, we proposed to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days)

exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPS/ASC through CY 2018 OPPS/ASC final rules with comment period, we analyzed CY 2019 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2023 MUC threshold is $47 per cm^2 (rounded to the nearest $1) and the proposed CY 2023 PDC threshold is $837 (rounded to the nearest $1). We clarified in the proposed rule that the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. We noted that Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2023, as we did for CY 2022, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we proposed to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group except that we proposed that any skin substitute product that was assigned to the high cost group in CY 2022 would be assigned to the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2023, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category. We proposed to assign skin substitutes with pricing

information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we proposed to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we proposed to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We proposed to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44645 through 44646) to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2023 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436).

In the CY 2023 PFS proposed rule (87 FR 46028 through 46029), there was a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies described under section 1861(s)(2) of the Act starting in CY 2024. We explained in the proposed rule that if this proposed policy is finalized, manufacturers would not report ASPs for skin substitute products, and we would no longer be able to use ASP+6 percent pricing for a graft skin substitute product to determine whether the product should be assigned to the high cost group or the low cost group. However, manufacturers would continue to report WAC and AWP pricing information for skin substitute products through pricing compendia. We explained that having WAC and AWP pricing would allow us to continue to use our alternative process to

assign graft skin substitute products to the high cost group when claims data for a product is not available.

Comment: The HOP Panel recommended and several commenters supported ending the packaging of the graft skin substitute add-on codes (CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278). The HOP Panel and the commenters requested that these codes be assigned to APCs that reflect the estimated costs of these service codes. Commenters claim that packaging the graft skin substitute add-on codes eliminates the variation in payment for wound care treatments based on the size of the wound. They assert that providers are discouraged from treating wounds between 26 and 99 cm^2 and over 100 cm^2 in the outpatient hospital setting because of the financial losses they experience to provide such care. Commenters believe that packaging graft skin substitute add-on codes disrupts the methodology of how the American Medical Association (AMA), the organization that manages CPT service codes, intended graft skin substitute procedures to be paid.

Response: We do not agree that the recommendation of the HOP Panel and the commenters is appropriate for paying for graft skin substitutes under the OPPS. The OPPS is a prospective payment system and not a fee-for-service payment system. That means that we generally attempt to make one payment for all of the services billed with the primary medical procedure, including add-on procedures such as the ones described by CPT codes 15272, 15274, 15276, and 15278, and HCPCS codes C5272, C5274, C5276, and C5278.

More specifically, we calculate the OPPS payment rate by first calculating the geometric mean cost of the procedure. This calculation includes claims for individual services that used a lower level of resources and claims for individual services that used a higher level of resources. The resulting geometric mean cost will reflect the median service cost for a given medical

procedure. Next, we group the medical procedure with other medical procedures with clinical and resource similarity in an APC and calculate the geometric mean of these related procedures to generate a base payment rate for all procedures assigned to the APC.

A prospective payment system like the OPPS is designed to pay providers the geometric mean cost of the primary service they provide, and such a system encourages efficiencies and cost-savings in the administration of health care. However, a prospective payment system is not intended to discourage providers from rendering medically necessary care to patients. For example, it is possible that a provider could experience a financial loss when they perform a service where a patient receives 85 cm^2 of a graft skin substitute product, but that same provider could see a financial gain when the next patient receives a skin graft where only 10 cm^2 of product is used. Paying separately for add-on codes in a prospective payment system defeats the goals of such a payment system. If providers are paid at cost or nearly at cost for each individual service they render, there is no incentive for them to control costs. Add-on codes should be packaged with the primary medical service to be able to establish a median payment rate that gives providers incentives to keep their costs in line with typical providers throughout the Medicare program. The need for cost efficiencies in the application of graft skin substitutes to treat wounds is no different than need for cost efficiencies in other procedures administered in the outpatient hospital setting. Therefore, we believe that add-on codes, including the add-on codes for the administration of graft skin substitutes, should remain packaged to maintain the integrity of the OPPS.

Comment: The HOP Panel recommended and several commenters supported ensuring that the payment rate for graft skin substitute procedures be the same no matter where on the body the graft skin substitute product is applied to the patient. There are four graft skin substitute

application procedures for high cost skin substitute products (CPT codes 15271, 15273, 15275, and 15277) and a similar four graft skin substitute applications for low cost skin substitute products (HCPCS codes C5272, C5274, C5276, and C5278). The reason there are four application service codes is that there are different service codes for applying graft skin substitutes to children and infants as compared to adults; and there are different service codes for applying graft skin substitutes to the trunk, arms, and legs as compared to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, fingers, and toes. Commenters claim that the cost to apply graft skin substitute products does not depend on the location of the wound because the same amount of product is used on the wound and the same clinical resources are used to treat the wound independent of the location of the wound.

Two other commenters made a similar request, asking that CPT code 15277 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1 percent of body area of infants and children) that is currently assigned to APC 5054 (Level 4 Skin Procedures) be reassigned to APC 5055 (Level 5 Skin Procedures). That would mean that the two graft skin substitute application procedures for children for high cost skin substitute products (CPT code 15273 and 15277) would be in the same APC.

Response: We appreciate commenters' concerns and note that that current codes describing the application of high and low cost graft skin substitutes for adults (CPT codes 15271 and 15275, and HCPCS codes C5272 and C5276) have been assigned to the same APC (5054). Because they are currently included in the same APC, OPPS payment for them is the same, and this payment policy is consistent with the recommendation from the HOP Panel and

other commenters. We note that the codes describing the application of high and low cost products for children and infants on the trunk, arms, and legs (CPT code 15273 or HCPCS code C5274) have been assigned to a lower-paying APC (APC 5054) than the APC assignment for the application of high and low cost graft skin substitute products for children in the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hand, feet, fingers, and toes—CPT code 15277 or HCPCS code C5277, which are assigned to APC 5055. The differences in costs that have determined APC assignments for these services for children have been supported by historical cost data. We also note that none of these service codes are in violation of the 2-times rule.

Comment: Multiple commenters requested that manufacturers continue to be able to use ASP+6 percent pricing for a graft skin substitute product to determine whether the product should be assigned to the high cost group or the low cost group when claims cost data from the OPPS for a product are not available. The commenters observed a contradiction between language in CY 2023 OPPS/ASC proposed rule and language in the CY 2023 PFS proposed rule. The commenters noted that the CY 2023 OPPS/ASC proposed rule stated that the CY 2023 PFS proposed rule would contain a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies described under section 1861(s)(2) of the Act, and that the proposal could take effect in CY 2023. These commenters further stated that the CY 2023 PFS rule stated that we were considering paying for skin substitute products furnished in the physician office setting as incident-to supplies. However, the commenters stated that the CY 2023 PFS proposed rule also stated that the earliest such a change would be proposed would be for CY 2024.

Response: The statement included in the CY 2023 OPPS/ASC proposed rule was incorrect. We did not propose to pay for skin substitutes as contractor-priced incident to supplies

in the CY 2023 PFS proposed rule. Instead, we proposed to treat skin substitutes (including synthetic skin substitutes) as incident to supplies as described under section 1861(s)(2)(A) of the Act when furnished in non-facility settings and to include the costs of those products as resource inputs in establishing practice expense RVUs for associated physician's services, effective January 1, 2024. We also refer interested parties to the CY 2023 PFS final rule for more information on this proposal and the policy that we are finalizing for skin substitutes furnished in the physician office setting. With respect to payment for skin substitutes under the OPPS, since the ASP data will be available, we can continue to use ASP+6 percent to determine if a skin substitute that does not have OPPS claims cost data should be assigned to the high cost or low cost skin substitute group. The ASP+6 percent rate would be used in the same manner as WAC+3 percent and 95 percent of AWP as proposed in the CY 2023 OPPS/ASC proposed rule.

Comment: One commenter requested that we assign powdered skin substitute products to the either the high cost skin substitute group or the low cost skin substitute group as is currently done for graft skin substitute products. The commenter asserted that "powder products have demonstrated the same ability to form a sheet scaffolding for wound healing as sheet products," and "powdered products generally consist of a micronized sheet skin substitute broken down into particulate form." The commenter also notes that there are no existing CPT codes that describe the application of powdered skin substitutes.

Response: The high cost and low cost skin substitute groups contain four CPT codes (CPT codes 15271, 15273, 15275, 15277) and four HCPCS codes (HCPCS codes C5271, C5273, C5275, and C5277) that describe the application of "skin substitute graft." We interpret the term "skin substitute graft" to mean the application of sheet skin substitute products that would be grafted in the wound area. A powder is not a graft even if the product forms a sheet scaffolding

similar to a skin substitute product. If a skin substitute product is not a sheet product, then it is not described by the skin substitute graft application codes, and the product cannot be assigned to the high cost or low cost skin substitute groups.

Comment: One commenter asked that we eliminate the high cost and low cost skin substitute groups for graft skin substitute products. Instead, the commenter requested that we no longer policy package skin substitute products in the OPPS. Instead, the commenter suggested we should pay for graft skin substitutes separate from the application procedure based on their ASP+6 percent price where available.

Response: A substantial portion of the cost of a skin substitute graft application procedure is the graft skin substitute product itself, and the cost of the skin substitute graft products is reflected in the cost of the overall procedure. Packaging the cost of graft skin substitute products into the affiliated procedures leads to cost savings and efficiencies in the use of graft skin substitute products. Providers have the opportunity to assess the value of products of varying costs. The payment rates for the application procedures for graft skin substitute products reflect the decisions of providers all across the United States between the costs and benefits of all available products and should limit the use of the highest-cost graft skin substitute products over lower-cost products unless the highest-cost products are found to be clinically superior. Packaging of graft skin substitute products helps to reduce costs for graft skin substitute procedures and allows more Medicare resources to be used for other categories of medical services.

Comment: Multiple commenters supported our proposal to continue to assign skin substitutes to the low cost or high cost group. Commenters also supported our proposal that any skin substitute product that was assigned to the high cost group in CY 2022 would be assigned to

the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold.

Response: We appreciate the commenters' support for our proposals.

Comment: One commenter supported our assignment of HCPCS code Q4127 (Talymed, per square centimeter) to the high cost skin substitute group. However, the commenter would prefer that we use ASP+6 percent, WAC+3 percent, or 95 percent of AWP to determine if the cost of the graft skin substitute product exceeds the overall MUC threshold or overall PDC threshold rather than using the MUC of the individual graft skin substitute product to compare against the overall MUC threshold or overall PDC threshold.

Response: We appreciate the support of the commenter regarding the high cost group assignment for HCPCS Code Q4127. However, we do not support the request to use ASP+6 percent, WAC+3 percent, or 95 percent of AWP over an individual graft skin substitute product's MUC to determine if a product should be assigned to the high cost or low cost skin substitute group. The MUC of a product based on OPPS claims data is a better estimate of the cost of a graft skin substitute product for Medicare as compared to the other pricing measures because the MUC is based on Medicare payment data and reports the actual costs of the graft skin substitute product for hospitals.

Comment: One commenter, the manufacturer, requested that we change the skin substitute group assignment for HCPCS code A2001 (Innovamatrix ac, per square centimeter) to reflect that the graft skin substitute product had been assigned to the high cost skin substitute group since January 1, 2022, and therefore should be assigned to the high cost skin substitute group for CY 2023.

Response: We will update Table 62 to reflect that HCPCS code A2001 will be assigned to the high cost skin substitute group for CY 2023.

Comment: One commenter, the manufacturer, requested that HCPCS codes Q4122 (Dermacell, per square centimeter) and Q4150 (Allowrap ds or dry, per square centimeter) continue to be assigned to the high-cost skin substitute group.

Response: HCPCS codes Q4122 and Q4150 were both assigned to the high cost group in CY 2022 and also were proposed to be assigned to the high-cost group for CY 2023. Any skin substitute assigned to the high cost group in CY 2022 will continue to be assigned to the high cost group in CY 2023 even if the MUC and PDC for the skin substitute product is below the overall MUC and PDC thresholds for all skin substitute products. Accordingly, we are finalizing our proposal to assign HCPCS codes Q4122 and Q4150 to the high-cost group in CY 2023.

After consideration of the public comments we received, we are finalizing our proposals without modification. Specifically, for CY 2023, we are finalizing our proposal to continue to assign skin substitutes with pass-through payment status to the high cost category. We are also finalizing our proposal to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold.

If ASP is not available, we are finalizing our policy to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we will use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available through pricing compendia to compare to the CY 2023 MUC and PDC thresholds. Table 62 includes the final CY 2023 cost category

assignment for each skin substitute product covered by these policies and by the policies implemented as a result of the retirement of HCPCS Code C1849.

c. Retirement of HCPCS Code C1849 (Skin substitute, synthetic, resorbable, by per square centimeter)

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86064 to 86067), we revised our description of skin substitutes to include synthetic products, in addition to biological products. We also established HCPCS code C1849 to facilitate payment for synthetic graft skin substitute products in the outpatient hospital setting. HCPCS code C1849 was established in response to the need to pay for graft skin substitute application services performed with synthetic graft skin substitute products in the OPPS in a manner comparable to how we pay for graft skin substitute application services performed with biological graft skin substitute products and was designed to describe any synthetic graft skin substitute product. We did not anticipate creating product-specific HCPCS codes for synthetic graft skin substitute products.

When the CY 2021 OPPS/ASC final rule with comment period was issued, we were aware of one synthetic graft skin substitute product described by HCPCS code C1849. The manufacturer of that product provided WAC pricing data that showed the cost of the product was above the MUC threshold for graft skin substitute products and therefore, we assigned HCPCS code C1849 to the high cost skin substitute group based on our alternative methodology to assign products with WAC or AWP pricing that exceeds the MUC threshold to the high cost skin substitute group (85 FR 86066). We noted that, as more synthetic graft skin substitute products are identified as being described by HCPCS code C1849, we would use their pricing data to calculate an average price for the products described by HCPCS code C1849 to determine

whether HCPCS code C1849 should be assigned to the high cost or low cost skin substitute group.

In the CY 2022 OPPS/ASC final rule with comment period, we stated that we had identified multiple synthetic skin substitute products that could be described by HCPCS code C1849. The average of the WAC pricing data for these products exceeded the MUC threshold (86 FR 63563). Therefore, we assigned HCPCS code C1849 to the high cost skin substitute group in CY 2022 (86 FR 63652).

While we created a single synthetic skin substitute HCPCS code for use under the OPPS beginning in CY 2021, in CY 2022 for the physician office setting we established product-specific HCPCS codes for several graft skin substitute products that were described as synthetic skin substitute products (86 FR 65119 through 65123). Because we anticipated that any graft skin substitute product assigned to the HCPCS A2XXX code series would be a synthetic product that also would be described by HCPCS code C1849 under the OPPS, we decided that graft skin substitute products assigned to the HCPCS A2XXX series would not be payable under the OPPS. Although we would pay for these products when identified by codes in the HCPCS A2XXX series in the physician office setting, it was not necessary to also make these codes payable under the OPPS because we had established HCPCS code C1849 to report the use of synthetic graft skin substitute products with graft skin substitute procedures for payment under the OPPS.

In the CY 2023 OPPS/ASC proposed rule, we noted that starting in January 2022, all new skin substitute products with an FDA 510(k) clearance received product-specific A-codes in the HCPCS A2XXX series (87 FR 44655). We also noted that FDA 510(k)-cleared skin substitute products include both biological products that are not human cell, tissue, or cellular or tissue-

based products (HCT/Ps) as well as synthetic products. The use of product-specific A-codes to identify all FDA 510(k) skin substitute products meant that several of the graft skin substitute products assigned product-specific codes in the A2XXX series starting January 1, 2022, were biological graft skin substitutes with an FDA 510(k) clearance. While graft synthetic skin substitute products are described by HCPCS code C1849, FDA 510(k)-cleared biological products are not. Nonetheless, for OPPS purposes, all graft skin substitute products with product-specific A-codes were assigned status indicator A under the OPPS (Not paid under the OPPS. Paid by [Medicare Administrative Contractors] under a fee schedule or payment system other than the OPPS). Starting in January 2022, skin substitute products with an FDA 510(k) clearance were no longer being assigned product-specific Q-codes.

Because some of the codes in the HCPCS A2XXX series identify biological skin substitute products that need to be payable under the OPPS because they are not described by HCPCS code C1849, we made all HCPCS A2XXX series codes payable under the OPPS earlier this year. In the "April 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS) – Change Request 12666" (https://www.cms.gov/files/document/r11305cp.pdf), effective April 1, 2022, we changed the status indicator of all skin substitute products described in the HCPCS A2XXX series to "N" (Paid under OPPS; payment is packaged into payment for other services). This change allowed packaged payment under the OPPS for these products when furnished with skin substitute application procedures in the hospital outpatient department setting. We also assigned unclassified skin substitute products described by HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) status indicator "N" in this Change Request and provided that payment for products identified with this code is packaged under the OPPS. HCPCS code A4100 is used to describe skin substitute products with FDA

510(k) clearance that do not have a product-specific HCPCS code. Skin substitute products with product-specific codes in the HCPCS A2XXX series or that are described by HCPCS code A4100 are subject to the same policies as other graft skin substitute products as described by section V.B.7.b of the CY 2022 OPPS/ASC final rule with comment (86 FR 63650 through 63658).

Because we now make payment under the OPPS for product-specific HCPCS A-codes for skin substitute products and for other unclassified FDA 510(k)-cleared products identified by HCPCS code A4100, we explained in the CY 2023 OPPS/ASC proposed rule that we believe HCPCS code C1849 is no longer necessary to bill for these products when they are used in the hospital outpatient department with graft skin substitute application procedures. In addition to being unnecessary, we were also concerned that the continued existence of HCPCS code C1849 may lead to confusion among providers regarding which HCPCS code to report on a claim if it is not retired, as there are currently two codes that can be reported in the hospital outpatient department setting that describe the same product: HCPCS code C1849 or the code in the HCPCS A2XXX series. For these reasons, we believed it was important to retire HCPCS code C1849.

Nonetheless, we did not want to simply retire this code without making accompanying proposals to ensure that synthetic graft skin substitute products that either currently have a product-specific HCPCS code or may receive a product-specific HCPCS code in the future and are currently assigned to the high cost skin substitute group continued to be assigned to the high cost skin substitute group after the retirement of HCPCS code C1849. Most synthetic graft skin substitute products have less than two years of claims data and would not have cost data for us to review to determine if the products could be assigned to the high cost group. If the product

manufacturers did not send WAC pricing data to us, the products would have to be assigned to the low cost group because of a lack of cost information. Submitting WAC pricing to have a skin substitute assigned to the high cost group is voluntary for manufacturers. Establishing a policy to continue to assign synthetic graft skin substitute products that are currently described by HCPCS code C1849 or would be described by HCPCS code C1849 to the high cost skin substitute group would allow manufacturers and providers to better forecast payment for synthetic graft skin substitute products, and protect them from unanticipated payment reductions. This proposal is also consistent with our proposed policy in section V.B.7.b in the CY 2023 OPPS/ASC proposed rule (87 FR 44650 through 44651) that any skin substitute product that was assigned to the high cost group in CY 2022 would be continue to be assigned to the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold, which has been our standard practice since CY 2018. Both of these proposals promote price stability for both manufacturers and providers and eliminate the risk that a skin substitute product that is currently assigned to the high cost skin substitute group would be reassigned to the low cost skin substitute group.

In summary, for CY 2023, we proposed to delete HCPCS code C1849 (Skin substitute, synthetic, resorbable, by per square centimeter). We also proposed that any graft skin substitute product that is currently assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 or is assigned a product-specific code in the HCPCS A2XXX series in the future and is appropriately described by HCPCS code C1849 would be assigned to the high cost skin substitute group. We wanted to ensure these skin substitute products continue to remain in the high cost skin substitute group throughout CY 2023 and do not risk reassignment to the low cost group during the transition from using HCPCS code

C1849 to product-specific A-codes even if cost and pricing data are not available for these products. We believed this policy would promote payment stability for providers and other stakeholders when using synthetic graft skin substitute products consistent with our long-standing policy that keeps graft skin substitute products in the high cost group for the subsequent year once a product is assigned to the high cost group for a given year.

We also proposed that HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) would be assigned to the low cost skin substitute group, which was consistent with our existing payment policy that unclassified graft skin substitute products be assigned to the low cost skin substitute group. We welcomed comments on these proposals.

Comment: Multiple commenters supported our proposal to delete HCPCS code C1849 and our proposal that any graft skin substitute product that is currently assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 or is assigned a product-specific code in the HCPCS A2XXX series in the future and is appropriately described by HCPCS code C1849 be assigned to the high cost skin substitute group.

Response: We appreciate the commenters' support for our proposals.

Comment: Two commenters supported our proposal to assign HCPCS code A4100 to the low cost skin substitute group.

Response: We appreciate the commenters' support for our proposal.

Comment: Multiple commenters noted that when we proposed to delete HCPCS code C1849 and assign any current or future product-specific code in the HCPCS A2XXX series that is described by HCPCS code C1849 to the high cost group that we did not propose any additional A-codes to be assigned to the high cost skin substitute group beyond the A-codes that

were identified as being assigned to the high cost group as of April 1, 2022. These commenters requested that we identify the A-codes that would be described by HCPCS code C1849 and assign those codes to the high cost group. These commenters also suggested products that they believe are synthetic graft skin substitute products that are described by HCPCS code C1849. Other commenters requested that newer graft skin substitute products that were given codes in the HCPCS A2XXX series after the OPPS proposed rule is released be assigned to the high cost group.

Response: We agree with the commenters that we need to state which graft skin substitute products that are assigned to the HCPCS A2XXX series will be in the high cost group starting January 1, 2023, based on the code descriptor for HCPCS code C1849 (Skin substitute, synthetic, resorbable, by per square centimeter). As explained in the CY 2023 PFS proposed rule (87 FR 46028 through 46029), the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements. Having products with both biological and synthetic elements leads to difficulty defining which of the products assigned to the A2XXX series would be considered "synthetic" and described by HCPCS code C1849. Therefore, we have decided to assign all graft skin substitute products with a HCPCS A2XXX series code to the high cost skin substitute group starting January 1, 2023.

After consideration of the public comments we received, we are finalizing our proposals with modifications. We are finalizing our proposal to delete HCPCS code C1849. We are also finalizing our proposal that any graft skin substitute product that is currently assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 or is assigned a product-specific code in the HCPCS A2XXX series in the future and is

appropriately described by HCPCS code C1849 be assigned to the high cost skin substitute group. In addition, any graft skin substitute product that is assigned a code in the HCPCS A2XXX series in the future will be assigned to the high cost skin substitute group. We want to ensure synthetic graft skin substitute products continue to remain in the high cost skin substitute group throughout CY 2023 and do not risk reassignment to the low cost group during the transition from using HCPCS code C1849 to product-specific A-codes even if cost and pricing data are not available for these products.

We are also finalizing our proposal that HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) be assigned to the low cost skin substitute group, which is consistent with our existing payment policy that unclassified graft skin substitute products be assigned to the low cost skin substitute group. Table 62 includes the final CY 2023 cost category assignment for each skin substitute product covered by these policies.

TABLE 62: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2023

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	CY 2023 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High
A2005	Microlyte matrix, per sq cm	Low	High
A2006	Novosorb synpath per sq cm	Low	High
A2007	Restrata, per sq cm	High	High
A2008	Theragenesis, per sq cm	Low	High
A2009	Symphony, per sq cm	Low	High
A2010	Apis, per square centimeter	Low	High
A2011	Supra sdrm, per sq cm	Low	High
A2012	Suprathel, per sq cm	Low	High
A2013	Innovamatrix fs, per sq cm	Low	High
A2015	Phoenix wnd mtrx, per sq cm	Low	High
A2016	Permeaderm b, per sq cm	Low	High
A2017	Permeaderm glove, each	Low	High
A2018	Permeaderm c, per sq cm	Low	High
A4100	Skin sub fda clrd as dev nos	Low	Low

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	CY 2023 High/Low Cost Assignment
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High*
Q4110	Primatrix	High	High
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	High
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High*
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	CY 2023 High/Low Cost Assignment
Q4157	Revitalon 1 square cm	High	High
Q4158	Kerecis omega3, per sq cm	High	High
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	High	High*
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	High
Q4173	Palingen or palingen xplus	High	High*
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	High	High*
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	High	High
Q4190	Artacent ac 1 sq cm	High	High*
Q4191	Restorigin 1 sq cm	Low	High
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	High	High*
Q4200	Skin te 1 sq cm	High	High
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High*

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	CY 2023 High/Low Cost Assignment
Q4209	Surgraft per sq cm	High	High*
Q4210	Axolotl graf dualgraf sq cm	Low	High
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	High
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	High	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	Low	Low
Q4225	Amniobind, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	High	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	High	High*
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	Low	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	High
Q4249	Amniply, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	High
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	High	High
Q4259	Celera per sq cm	Low	Low
Q4260	Signature apatch, per sq cm	Low	Low
Q4261	Tag, per square centimeter	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2023, but are assigned to the high cost group because they were assigned to the high cost group in CY 2022.

d. Key Objectives/Roadmap for Consistent Treatment of Skin Substitutes

We outlined our HCPCS Level II coding and payment policy objectives in the CY 2023 OPPS/ASC proposed rule as we believed it would be beneficial for interested parties to understand, as we work to create a consistent approach for treatment of the suite of products we have referred to as skin substitutes. We have a number of objectives related to refining Medicare policies in this area, including: 1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; 2) ensuring that appropriate HCPCS codes describe skin substitute products; 3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so we can incorporate payment methodologies that are more consistent; and 4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have asked CMS to address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the physician office setting; however, interested parties have also indicated that further alignment of our policies across the physician office and hospital outpatient department settings would reduce confusion.

In past years, interested parties have suggested that all skin substitutes, regardless of the inclusion of human, animal, or synthetic material in the product, should be treated as drugs and biological products. Furthermore, they believe all skin substitute products should receive product-specific "Q" codes and receive separate payment under the ASP+6 methodology. They have expressed confusion regarding our assignment of HCPCS Level II "A" codes to the 9 skin substitute products in accordance with the policy finalized in the CY 2022 PFS final rule, which

are codes we typically assign to identify ambulance services and medical supplies, instead of "Q" codes, which we typically assign to identify drugs and biologicals. They have indicated that the use of "A" HCPCS codes has caused confusion, not only for interested parties, but also for the A/B MACs, who the interested parties assert have inconsistently processed submitted claims, in part because they are assigned HCPCS "A" codes that are treated as supplies. which are subject to contractor pricing under the PFS. Additionally, interested parties have expressed concern that physicians and other practitioners are hesitant to use the products associated with "A" codes because they are unsure what they will be paid when using those products. When considering potential changes to policies involving skin substitutes, we believe it would be appropriate to take a phased approach over the next 1 to 5 years, which would allow CMS sufficient time to consider input from interested parties on coding and policy changes primarily through our rulemaking process, with the goal of ensuring access to medically necessary care involving the use of these products.

We welcomed comment on our policy objectives for creating a consistent approach for treatment of the suite of products we have referred to as skin substitutes. Additionally, we welcomed feedback on the phased approach and associated timeline. To achieve our objective of creating a consistent approach for paying for skin substitutes across the physician office and hospital outpatient department settings, we included similar proposed changes in the CY 2023 PFS proposed rule, which were issued near the time the CY 2023 OPPS/ASC proposed rule was issued.

Comment: A few commenters expressed support for CMS's efforts to create a consistent payment approach for skin substitutes across physician office and hospital outpatient department settings. One commenter agreed with the multi-year timeline and appreciated CMS recognizing

the need to ensure that changes in skin substitute policies do not adversely impact beneficiary access and encouraged CMS to promote transparency as reforms are contemplated and allow stakeholders to review and comment on detailed proposals prior to adoption.

Response: We appreciate the commenters' support of our key objectives and roadmap.

e. Changing the Terminology of Skin Substitutes

In the CY 2023 OPPS/ASC proposed rule (87 FR 44657), we stated that as we work to clarify our policies for these products, we believe that the existing terminology of "skin substitutes" is an overly broad misnomer. In the CY 2021 OPPS/ASC final rule with comment period, we revised our description of skin substitutes to refer to a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers (85 FR 86065). We noted that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that within the hospital outpatient department, these items cannot be assigned to either the high cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278. (85 FR 86066).

While this definition has been updated to provide clarity in that synthetic products typically regulated as devices by the FDA are considered to be skin substitutes, there is still confusion with the usage of the term skin substitutes because, as noted above in the definition, these skin substitute products are technically not a substitute for skin, but rather, a wound covering. We have used the term "skin substitutes" to describe the suite of products that are currently referred to as skin substitutes. Additionally, the term "skin substitutes" is used within the Current Procedural Terminology (CPT®) code series 15271-8 as maintained by American

Medical Association. Also, skin substitute products are generally regulated by the FDA as medical devices under section 510(k) of the Federal Food, Drug and Cosmetic (FD&C) Act and implementing regulations per 21 CFR part 807, or as HCT/Ps solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. The FDA approves new drugs through the New Drug Application (NDA), and approves biologic products through the Biologics License Application (BLA).

We believe that improving how we reference these products by using a more accurate and meaningful term will help address confusion among interested parties about how we describe these products, and further, how we pay for them. We proposed to replace the term "skin substitutes" with the term "wound care management" or "wound care management products." We explained that we believe these new terms more accurately describe the suite of products that are currently referred to as skin substitutes while providing enough specificity to not include bandages or standard dressings, which, as noted above, are not considered skin substitutes. We noted that we understand that the proposed terms contain "care management" which could be construed to implicate the care management series of AMA CPT codes (e.g., 99424-99427, 99437, 99439, 99487, 99489, 99490-99491) that are commonly used by healthcare professionals. We also explained that we understand that the use of "management" in the proposed terms might be construed by some to implicate AMA CPT Evaluation or Assessment and Management (E/M) codes. We clarified that the proposed terms "wound care management" and "wound care management products" would not implicate the care management series of AMA CPT codes (e.g., 99424-99427, 99437, 99439, 99487, 99489, 99490-99491), or our own G-codes that describe care management services. Nor would our proposed terms relate to the AMA CPT E/M codes. Unlike "care management" or "evaluation and management" codes and services, the

proposed terms would describe a category of items or products, not a type of services. Lastly, we noted that we also considered alternate terms such as wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds but believe the proposed terms are more technically accurate and descriptive for how these products are used than the alternatives considered.

We solicited comment on the proposal to change the terminology we use for the suite of products referred to as "skin substitutes" to instead use the term "wound care management" or "wound care management products" and on the alternative terms we considered, including wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds. We noted that we were particularly interested in how these products are referenced in current CPT coding and would appreciate feedback from the CPT Editorial Panel and other interested parties on how to address the challenges we discuss above. We also requested comment on other possible terms that could be used to more meaningfully and accurately describe the suite of products currently referred to as skin substitutes.

Comment: One commenter supported the change in terminology to wound care management or wound care management products.

Several commenters disagreed with the proposed terminology change. Some commenters suggested we should retain the term skin substitute. A few commenters suggested that CMS work directly with the CPT Editorial Panel and medical specialty societies to determine the optimal approach to updating skin substitutes terminology.

Another commenter did not agree that a terminology change is necessary, but if CMS determined that it was, they suggested the term "wound care products." The commenter stated

that inclusion of the word management in any description could be inappropriately construed to imply evaluation assessment and management services and would be confusing. Another commenter expressed support for efforts to more accurately define skin substitutes, but did not agree with the proposed terminology.

A few commenters suggested alternatives including: Cellular and/or Synthetic Grafts for Surgical Wound Management; Bioengineered, Cellular or Tissue-Based Products. A few commenters supported use of one of our alternative recommended terms, Cellular and/or tissue-based products (CTPs) for skin wounds, and stated that it was consistent with the American Society for Standards and Materials (ASTM) definition of skin substitutes, and is nomenclature used by wound care clinicians.

Response: We appreciate the feedback from commenters, and we are not finalizing a change in terminology at this time. We will take these comments into account, as well as other feedback from interested parties as we consider our approach to addressing inconsistencies in our policies for skin substitutes in future rulemaking. We also refer readers to the CY 2023 PFS final rule for additional discussion regarding changing the terminology and the roadmap for consistent treatment of skin substitutes.

8. Radioisotopes Derived from Non-Highly Enriched Uranium (non-HEU) Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, has been produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors, and has been promoting the conversion of all medical radioisotope production to non-HEU sources.

Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce new costs into the payment system that were not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the industry's conversion to alternative methods of producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipated the conversion of Tc-99m production from non-HEU sources would be completed at the end of 2019.[109] However, the Secretary of Energy issued a certification effective January 2, 2020, stating that there continued to be an insufficient global supply of molybdenum-99 (Mo-99), which is the source of Tc-99m, produced without the use of HEU, available to satisfy the domestic U.S. market (85 FR 3362). The January 2, 2020, certification was to remain in effect for up to two years.

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109 National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: https://doi.org/10.17226/23563.

The Secretary of Energy issued a new certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification stated that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. The Department of Energy also expects that the last HEU reactor that produces Mo-99 for medical providers in the United States will finish its conversion to a non-HEU reactor by December 31, 2022. In CY 2019, we stated that we would reassess the non-HEU incentive payment policy once conversion to non-HEU sources is closer to completion or has been completed (83 FR 58979). There is now a sufficient supply of non-HEU-sourced Mo-99 in the United States, and by CY 2023, there will be no available supply of HEU-sourced Mo-99 in the United States. Therefore, we believe that the conversion to non-HEU sources of Tc-99m has reached a point where a reassessment of the policy is necessary.

In the OPPS, diagnostic radiopharmaceuticals are packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost amount of the radiopharmaceutical. The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally is from two years prior to the payment year.

That means that the likely claims data used to set payment rates for CY 2023 (CY 2021 claims data) and CY 2024 (CY 2022 claims data) would likely contain claims for diagnostic radiopharmaceuticals that would reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, providers using radiopharmaceuticals that only contain non-HEU-sourced Tc-99m

might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believe that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m. Starting in CY 2025, the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) will only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, which means the data will reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that will be used by providers in CY 2025. As a result, there will no longer be a need for the additional $10 add-on payment for CY 2025 or future years.

For CY 2023 and CY 2024, we proposed to continue the additional $10 payment to ensure providers receive sufficient payment for diagnostic radiopharmaceuticals containing Tc-99m until such time as the full cost of non-HEU-sourced Tc-99m is reflected in the Medicare claims data. We also proposed that the additional $10 payment will end after December 31, 2024, since beginning with CY 2025, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m. We received the following comments on our proposals.

Comment: Two commenters opposed ending the additional $10 payment after December 31, 2024. The commenters supported continuing the payment either permanently or until a majority of radiopharmaceutical claims for Tc-99m reported HCPCS code Q9969, which would clearly show that the radiopharmaceutical is sourced with non-HEU material. These commenters were concerned that the claims data for radiopharmaceuticals does not fully report the costs of radiopharmaceuticals manufactured using non-HEU sourced materials. These commenters believe that will be the case even after all claims report radiopharmaceuticals manufactured from

non-HEU-sourced materials starting in CY 2025. One of the commenters suggested adding a new claim edit to require providers to identify whether the Tc-99m radiopharmaceutical product they use is sourced from non-HEU or HEU reactors. These same commenters also requested that the $10 additional payment be increased to an amount that reflects what the payment would have been if it was adjusted annually by the hospital market basket since it was implemented in 2013. The commenters also requested that the copayment amount for HCPCS code Q9969 be eliminated because they are concerned that the administrative burden of handling the beneficiary copayment is discouraging providers from reporting the $10 additional payment.

Response: The certification by the Secretary of Energy regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022, stated that that the last HEU reactor that produces Mo-99 for medical providers in the United States will finish its conversion to a non-HEU reactor by December 31, 2022. That means radiopharmaceuticals starting in 2023 will no longer be sourced from HEU sources. CMS will be able to use claims generated in 2023 for rulemaking in the OPPS in CY 2025. As stated in the CY 2022 OPPS final rule, the purpose of the $10 additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources (86 FR 63560). Once the transition is complete and payment rates reported for Tc-99m radiopharmaceuticals no longer include costs from HEU-sourced Tc-99m, there is no longer a need for the additional payment. This will be the case starting in CY 2025, at which time, the additional payment can cease.

We also disagree with the request to waive the copayment for HCPCS code Q9969 as we do not believe the administrative burden associated with collecting copayments is significant enough to justify such an action. Providers regularly collect copayments for services paid under the OPPS, and we do not believe that collecting a copayment for the additional $10 payment is a

significant additional burden for providers. Likewise, we do not agree with the suggestion to require a claim edit to identify a radiopharmaceutical as non-HEU or HEU sourced. We believe such a requirement would likely increase the administrative burden on providers unnecessarily. HCPCS code Q9969 is being reported on less than 15 percent of eligible claims, and it is unlikely that the use of HCPCS code Q9969 would ever exceed 50 percent of the eligible claims even if all Tc-99m radiopharmaceuticals are produced from non-HEU sources. Therefore, we are not adopting this recommendation.

Comment: One commenter supported our proposed policy to continue the $10 additional payment for CY 2023 and CY 2024 to ensure providers receive sufficient payment for diagnostic radiopharmaceuticals containing Tc-99m until such time as the full cost of non-HEU-sourced Tc-99m is reflected in the Medicare claims data. The commenter also requested that we evaluate and ensure costs reported in Medicare claims fully capture the cost of non-HEU-sourced Tc-99m before deciding to end the additional payment for non-HEU sourced Tc-99m payment starting in CY 2025.

Response: We appreciate the support of the commenter for our proposed policy and plan to review our policy prior to CY 2025 ensure that the anticipated end of using HEU-sourced material to generate Tc-99m radiopharmaceuticals has occurred by December 31, 2022, and claims data, starting in CY 2025, will only report Tc-99m radiopharmaceuticals manufactured from non-HEU sources.

Comment: One commenter supported the portion of our proposal that would continue the $10 additional payment for non-HEU sourced Tc-99m radiopharmaceuticals through December 31, 2024.

Response: We appreciate the support of the commenter.

After consideration of the public comments we received, we are finalizing without modification our proposal to continue the additional $10 payment for CYs 2023 and 2024 to ensure providers receive sufficient payment for diagnostic radiopharmaceuticals containing Tc-99m until such time as the full cost of non-HEU-sourced Tc-99m is reflected in the Medicare claims data. We also are finalizing without modification our proposal that the additional $10 payment will end after December 31, 2024, as beginning with CY 2025, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m.

C. Requirement in the Physician Fee Schedule CY 2023 Proposed and Final Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Section III.A. of the CY 2023 PFS proposed rule includes proposals to implement section 90004 of the Infrastructure Act, including a proposal that hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system. Specifically, the CY 2023 PFS proposed rule proposed that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund

amount described in section 1847A(h)(3) of the Act. The CY 2023 PFS proposed rule also proposed to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

As explained in the OPPS/ASC proposed rule (87 FR 44717), because the CY 2023 PFS proposed rule proposed to codify certain billing requirements for HOPDs and ASCs, we explained in the proposed rule that we wanted to ensure interested parties were aware of them and knew to refer to that rule for a full description of the proposed policy. Interested parties were asked to submit comments on this and any other proposals to implement Section 90004 of the Infrastructure Act in response to the CY 2023 PFS proposed rule. We stated public comments on these proposals will be addressed in the CY 2023 PFS final rule. We note that this same notice appeared in section XIII.D.3 of the CY 2023 OPPS/ASC proposed rule (87 FR 44658).

We thank commenters for their feedback on this proposal. As indicated in the OPPS/ASC proposed rule (87 FR 44717), public comments on the policies discussed above will be addressed in the CY 2023 PFS proposed rule. For final details on this policy, we refer readers to the CY 2023 PFS final rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. We note that this same notice appears in section XIII.D.3 of this CY 2023 OPPS/ASC final rule with comment period.

D. Inflation Reduction Act – Section 11101 regarding Beneficiary Co-insurance

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 11101 of the Inflation Reduction Act requires a drug manufacturer to pay a rebate if the ASP of their drug product rises at a rate that is faster than the rate of inflation.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) by adding a new paragraph (9) and subparagraph (F), respectively, that specify coinsurance under the ASC and OPPS payment systems. Section 1833(i)(9) requires that under the ASC payment system beneficiary coinsurance for a Part B rebatable drug that is not packaged be calculated using the inflation-adjusted amount when that amount is less than the otherwise applicable payment amount for the drug furnished on or after April 1, 2023. Section 1833(t)(8)(F) requires that under the OPPS payment system beneficiary copayment for a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or packaged into the payment for a procedure) is to be calculated using the inflation-adjusted amount when that amount is less than ASP plus 6 percent beginning April 1, 2023. Sections 1833(i)(9) and 1833(t)(8)(F) reference sections 1847A(i)(5) for the computation of the beneficiary coinsurance and 1833(a)(1)(EE) for the computation of the payment to the ASC or provider and state that the computations would be done in the same manner as described in such provisions. The computation of the coinsurance is described in section 1847A(i); specifically, in computing the amount of any coinsurance applicable under Part B to an individual to whom such Part B rebatable drug is furnished, the computation of such coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount determined under section 1847A(i)(3)(C) for such part B rebatable drug. The calculation of the payment to the provider or ASC is described in section 1833(a)(1)(EE), and the provider or ASC would be paid the difference between the beneficiary coinsurance of the inflation-adjusted amount and ASP plus 6 percent. We wish to make readers aware of this statutory change that begins April 1, 2023. Additionally, we refer readers to the full text of the IRA. [110] Additional details on the implementation of section 11101 of the IRA are

110 H.R. 5376 available online at: https://www.congress.gov/bill/117th-congress/house-bill/5376/text

forthcoming and will be communicated through a vehicle other than the CY 2023 OPPS/ASC regulation.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2023 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2023. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the

applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2022 or beginning in CY 2023. The sum of the proposed CY 2023 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2023 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2023, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a

competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our proposed estimate of drug and biological pass-through payment for CY 2023 for this group of items was $622.6 million, as discussed below, because we proposed that most non pass-through separately payable drugs and biologicals would be paid under the CY 2023 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which we formally proposed would be paid at ASP minus 22.5 percent, and because we proposed to pay for CY 2023 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A of the CY 2023 OPPS/ASC proposed rule (87 FR 44625). However, in light of the Supreme Court's recent decision, we explained that we fully anticipated applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in which case we explained that our estimate of drug and biological pass-through payment for CY 2023 for this group of items was $40 million.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package all non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of the CY 2023 OPPS/ASC proposed rule (87 FR 44643 through 44644). We proposed that all of these policy-packaged drugs and

biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2023, less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2023 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6 of the CY 2023 OPPS/ASC proposed rule (87 FR 44641), we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2023. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2022

or beginning in CY 2023. The sum of the CY 2023 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2023 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending for CY 2023

For CY 2023, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2023, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2022 (86 FR 63659). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023, there are 14 active categories for CY 2023. The active categories are described by HCPCS codes C1052, C1062, C1734, C1748, C1761, C1823, C1824, C1825, C1831, C1832, C1833, C1839, C1982 and C2596. Based on the information from the device manufacturers, we estimate that HCPCS code C1052 will cost $162,000 in pass-through expenditures in CY 2023, HCPCS C1062 will cost $1.9 million in pass-through expenditures in CY 2023, HCPCS code C1734 will cost $2.2 million in pass-through expenditures in CY 2023, HCPCS code C1748 will cost $2.2 million in pass-through expenditures in CY 2023, HCPCS code C1761 will cost $9.9 million in pass-through expenditures in CY 2023, HCPCS code C1823 will cost $1.5 million in pass-through expenditures in CY 2023, HCPCS code C1824 will cost $1.5 million in pass-through expenditures in CY 2023, HCPCS code C1825 will cost $749,000 in pass-through expenditures in CY 2023, HCPCS code C1831 will cost $29,900 in pass-through expenditures in CY 2023, HCPCS code C1832 will cost $18.4 million in pass-through expenditures in CY 2023,

HCPCS code C1833 will cost $5.1 million in pass-through expenditures in CY 2023, HCPCS code C1839 will cost $138,000 in pass-through expenditures in CY 2023, HCPCS code C1982 will cost $1.2 million in pass-through expenditures in CY 2023, and HCPCS code C2596 will cost $2.8 million in pass-through expenditures in CY 2023. Therefore, we proposed an estimate for the first group of devices of $48 million.

Comment: We received a comment from the manufacturer of AVITA Medical's RECELL® System (RECELL) on the proposed estimate of pass-through spending for CY 2023. The commenter stated that under section VI. B, Proposed Estimate of Pass-through Spending for CY 2023, CMS lists the estimated transitional pass-through (TPT) expenditures for the 14 active TPT HCPCS codes in CY 2023. This list includes an estimate of $18.4 million in TPT expenditures for HCPCS code C1832. The CY 2023 OPPS/ASC proposed rule indicates that the TPT expenditure estimates are based on information from device manufacturers. However, the manufacturer stated that the TPT application for RECELL System estimated approximately 800 total devices annually with 10-15 percent of cases involving Medicare beneficiaries, for a total of 80-120 devices under Medicare. With the stated list price of $7,500, the manufacturer's estimate of total annual TPT expenditures for C1832 of under $1 million (120 devices * $7,500.00 = $900,000).

Response: We appreciate the comment. We agree with the commenter, and have updated this final rule with comment period to note that the HCPCS code C1832 will cost $900,000 in pass-through expenditures in CY 2023.

Comment: A number of commenters stated that CMS provided conflicting information in the proposed rule for Table 30: Devices with Pass-Through Status (or Adjusted Separate Payment) Expiring at the End of the Fourth Quarter of 2022, in 2023, or in 2024 where the

expiration dates for devices with pass-through status expiring at the end of the fourth quarter of 2022 are also included in the proposed estimate of pass-through spending for CY 2023 as part of the first group of devices.

Response: We appreciate the commenters' input. When we estimated pass-through spending for CY 2023 for the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023 (87 FR 44660), we inadvertently included estimated device pass-through spending for device categories that are expiring in CY 2022. For the CY 2023 final rule, we have removed six (6) HCPCS codes with CY 2022 expiration dates from the final estimate of pass-through payment for CY 2023. These codes for which pass-through status expires in CY 2022 are: C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), C1824 (Generator, cardiac contractility modulation (implantable)), C1982 (Catheter, pressure-generating, one-way valve, intermittently occlusive), C1839 (Iris prosthesis), C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)), and C2596 (Probe, image-guided, robotic, waterjet ablation).In addition, we inadvertently included C1831 as part of the first group of devices consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023, where we estimated HCPCS code C1831 will cost $29,900 in pass-through expenditures in CY 2023 (87 FR 44660). Instead, C1831 should have been included as part of the estimated proposed CY 2023 pass-through spending for device categories in the second group: device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2023 and additional device categories that we estimated could be approved for pass-

through status after the development of the proposed rule and before January 1, 2023. Consistent with the final approval for device pass-through payment status of C1831 (Personalized, anterior and lateral interbody cage (implantable)), as described in section IV.2.b.1 of this final rule with comment period, we have added C1831 to Table 52 in this final rule with comment period. We inadvertently did not include C1831 in Table 30 in the proposed rule. C1831 received preliminary approval as part of the October 1, 2021 quarterly review process and had pass-through payment status in CY 2022. Therefore, the device code should have been included in Table 30 in the proposed rule. Table 52 has been updated to reflect the inclusion of C1831.

As such, for the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023, there are 7 active categories for CY 2023. The active categories are described by HCPCS codes C1052, C1062, C1748, C1761, C1825, C1832, and C1833. Based on the information from the device manufacturers, we estimate that HCPCS code C1052 will cost $162,000 in pass-through expenditures in CY 2023, HCPCS C1062 will cost $1.9 million in pass-through expenditures in CY 2023, HCPCS code C1748 will cost $2.2 million in pass-through expenditures in CY 2023, HCPCS code C1761 will cost $9.9 million in pass-through expenditures in CY 2023, HCPCS code C1825 will cost $749,000 in pass-through expenditures in CY 2023, HCPCS code C1832 will cost $900,000 in pass-through expenditures in CY 2023, and HCPCS code C1833 will cost $5.1 million in pass-through expenditures in CY 2023. Therefore, we have finalized an estimate for the first group of devices of $21 million.

In estimating our proposed CY 2023 pass-through spending for device categories in the second group, we included: device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2023; additional

device categories that we estimated could be approved for pass-through status after the development of the CY 2023 OPPS/ASC proposed rule (87 FR 44660) and before January 1, 2023; and contingent projections for new device categories established in the second through fourth quarters of CY 2023. For CY 2023, we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the proposed estimate of CY 2023 pass-through spending for this second group of device categories is $101.4 million.

We did not receive any public comments on this proposal. As stated earlier in this final rule with comment period, we are approving four devices for pass-through payment status in the CY 2023 rulemaking cycle: Uretero1™ Ureteroscope System, Evoke® SCS System, Vivistim® Paired VNS™ System, and aprevo™ Transforaminal IBF. The manufacturers of these systems provided utilization and cost data that indicate the amount of spending for the devices would be approximately $37.5 million for Uretero1™ Ureteroscope System, $7.4 million for Evoke® SCS System, $9 million for Vivistim® Paired VNS™ System, and $7.2 million for aprevo™ Transforaminal IBF. Therefore, we are finalizing an estimate of $61.1 million for this second group of devices for CY 2023.

To estimate proposed CY 2023 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2023, we proposed to use the CY 2021 Medicare hospital outpatient claims data regarding their utilization, information provided in their pass-through applications, other historical hospital claims data,

pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2023 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will continue to have pass-through payment status in CY 2023, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, which we formally proposed to pay at ASP minus 22.5 percent. Therefore, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount was $592.7 million for this group of drugs. However, in light of the Supreme Court's decision, we explained that we fully anticipated applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in which case, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount was $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we proposed to include in the CY 2023 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with

the drug receiving pass-through payment, which we estimate for CY 2023 for the first group of policy-packaged drugs to be $19.9 million.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated the CY 2023 spending estimate for this first group of drugs and biologicals as approximately $33.5 million. Because we are finalizing a payment rate of ASP+6 percent for separately payable drugs regardless of whether they are acquired under the 340B program, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is, therefore, $0.

To estimate proposed CY 2023 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the CY 2023 OPPS/ASC proposed rule (87 FR 44660 through 44661) were newly eligible or recently became eligible for pass-through payment in CY 2023, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the CY 2023 OPPS/ASC proposed rule (87 FR 44660 through 44661) and before January 1, 2023, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2023), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per-unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2023 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2023 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We did not receive any public comments on our proposal. Since the release of the CY 2023 OPPS/ASC proposed rule, we have identified eight additional policy-packaged drugs in addition to the four policy-packaged drugs that had pass-through status when the proposed rule was released. Our original proposed estimate of $10 million of additional pass-through payments for the second group of drugs and biologicals anticipated the approval of some, but not all, of the additional policy-packaged drugs and biologicals with pass-through status. Therefore, for this final rule with comment period, we are revising our estimate of pass-through spending for the second group of drugs and biologicals to be $20 million.

We estimated for the CY 2023 OPPS/ASC proposed rule (87 FR 44661) that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately $772.0 million (approximately $149.4 million for device categories and approximately $622.6 million for drugs and biologicals) which represents 0.90 percent of total projected OPPS payments for CY 2023 (approximately $86.2 billion). In light of the Supreme Court's recent decision, we explained that we fully anticipated applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule with comment period for CY 2023, in which case we estimated for the CY 2023 OPPS/ASC proposed rule (87 FR 44641) that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately $179.3 million (approximately $149.4 million for device categories and approximately $29.9 million for drugs and biologicals). This alternative would have represented only 0.21 percent of

total projected OPPS payments for CY 2023. Therefore, we estimated that pass-through spending in CY 2023 would not amount to 2.0 percent of total projected OPPS CY 2023 program spending.

We estimate for this final rule with comment period that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately $135.5 million (approximately $82 million for device categories and approximately $53.5 million for drugs and biologicals), which represents only 0.16 percent of total projected OPPS payments for CY 2023 (approximately $86.5 billion). Therefore, we estimate that pass-through spending in CY 2023 will not amount to 2.0 percent of total projected OPPS CY 2023 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2023, we proposed to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue our payment policy for critical care services for CY 2023. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

In the CY 2023 OPPS/ASC proposed rule (87 FR 44502), we solicited public comments on any changes to these codes that we should consider for future rulemaking cycles. We

continued to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

Comment: We received a comment suggesting that CMS develop a national standard for Emergency Department (ED) visit guidelines for all ED levels.

Response: We thank the commenters for their suggestion. As we noted in CY 2008 OPPS/ASC final rule with comment period (72 FR 66579), we understand the interest in promulgating national guidelines, but we continue to believe that it is unlikely that one set of straightforward national guidelines could apply to the reporting of all ED visits. We may revisit this topic in the future as necessary.

After consideration of the public comments, we are finalizing our proposal to continue our current ED outpatient visits and critical care payment policies.

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-excepted off-campus provider-based departments (PBDs) continues to apply for CY 2022 and subsequent years. More specifically, we are continuing to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments. The PFS-equivalent rate for CY 2023 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2023.

Additionally, for CY 2023 we proposed that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier "PO" on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, would be exempt from the clinic visit payment policy that applies a

Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this proposal we refer readers to section X. of the CY 2023 OPPS/ASC proposed rule (87 FR 44502). For CY 2023, we will be finalizing our proposal to exempt rural SCHs from the clinic visit payment policy. For a full discussion of this policy, we refer readers to section X. of this final rule with comment period.

Comment: We received several comments on our overall clinic visit payment policy. Many commenters continued to express the belief that this policy undermines congressional intent and exceeds the agency's legal authority. As they have in previous years, commenters argued that the policy is based on flawed assumptions and urged CMS to eliminate this policy altogether.

Response: We continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.[111] As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In most cases, the difference in payment is leading to unnecessary increases in the volume of

[111] Available at: https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.

covered outpatient department services, and we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. We continue to believe that our method will address the concerns as described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005).

Additionally, we note that this policy was previously litigated. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. The appellees petitioned the United States Supreme Court for a writ of certiorari. On June 29, 2021, the Supreme Court denied the petition.

Comment: Many commenters characterized the reductions to hospital payments for clinic visits as excessive and harmful, especially during the COVID-19 PHE. One commenter noted that "Continuing to impose a 60% cut on clinic visit services in 2023, on top of the dire financial impacts on U.S. hospitals and health systems due to COVID-19, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries."

Response: We share commenter's concerns about the financial difficulties brought on by the COVID-19 PHE. We have taken a variety of actions to support hospitals so they can more effectively respond during the COVID-19 PHE, including waiving the provider-based rules and permitting on-campus and excepted off-campus provider-based departments to temporarily relocate and continue to be paid under the OPPS if they submit a temporary extraordinary relocation exception request to their Regional Office. We have continued to monitor the volume

control clinic visit policy and will make adjustments as appropriate. For CY 2023, we are finalizing our proposal to exempt rural SCHs from the clinic visit payment policy. For a full discussion of this exemption, we refer readers to section X of this final rule with comment period.

Comment: We received comments supporting CMS' efforts to continue implementing its method to control for unnecessary increases in the volume of outpatient services. One commenter asked that CMS continue to consider ways to expand and strengthen the current site-neutral payment policies. They noted that there may be other provider-based department settings where it makes sense to apply site-neutral payment policies, such as on-campus PBDs, ambulatory surgery centers, and emergency departments.

Response: We appreciate the commenters' support and we will continue to monitor this policy and take commenters' suggestions into consideration for potential future rulemaking.

After consideration of the public comments, we are finalizing our proposal to continue the volume control method under which we utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus PBDs.

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a

physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for

hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the

Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID-19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling,

and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID-19 PHE.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the

Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

B. PHP APC Update for CY 2023

1. PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2023 only, we proposed to calculate the CMHC and hospital-based PHP geometric mean per diem costs in accordance with our existing methodology, except that while we proposed to use the latest available CY 2021 claims data, we proposed to continue to use the cost data that was available for the CY 2021 rulemaking, which is the same cost data used for the CY 2022 rulemaking (86 FR 63665 through 63666). This proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682). Following this proposed methodology, we proposed to use the geometric mean per diem cost of $131.71 for CMHCs as the basis for developing the CY 2023 CMHC APC per diem rate, and to use the geometric mean per diem cost of $264.06 as the basis for developing the CY 2023 hospital-based APC per diem rate. In addition, we proposed not to include data from certain nonstandard cost center lines in the OPPS ratesetting database construction for CY 2023; however, we solicited public comment about these data for use in future ratesetting. Lastly, in accordance with our longstanding policy, we proposed to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)).

We are finalizing the proposals in this CY 2023 OPPS/ASC final rule as proposed, but with a modification. For only CY 2023, and not subsequent years, we are applying an equitable adjustment, under the authority of section 1833(t)(2)(E) of the Act, to finalize $142.70 as the CY

2023 CMHC PHP APC payment rate, which is the same payment rate in effect for the CY 2022 CMHC PHP APC. Using the most recent updated claims and the cost report data that was available for the CY 2021 rulemaking as proposed, the final hospital-based PHP geometric mean per diem cost is $275.83. We discuss our rationale and the public comments received in the following sections.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2023, we followed the PHP ratesetting methodology described in section VIII.B.2 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687) and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666). As discussed in section VIII.B.1 of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. As discussed in section VIII.B.1.a of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666 through 63668), the costs for CMHC service days are calculated using cost report information from HCRIS.

As mentioned in the CY 2023 OPPS/ASC proposed rule (87 FR 44662 through 4663), we proposed a change from our longstanding practice similar to what we finalized last year in light

of the effects of the COVID-19 PHE. We discuss this proposal and our rationale in greater detail in the following paragraphs.

First, we considered whether the latest available CY 2021 claims would be appropriate to use for CY 2023 ratesetting. Ordinarily, the best available claims data is the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2023 OPPS/ASC proposed rule ratesetting, the best available claims data would typically be the 2021 calendar year outpatient claims data processed through December 31, 2021. As discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we noted significant decreases in the number of PHP days for both hospital-based PHPs and CMHCs. For the CY 2023 OPPS/ASC proposed rule (87 FR 44662 through 44664), we noted that we continue to observe a decrease in the number of hospital-based PHP days in our trimmed CY 2021 claims dataset, which has approximately 18 percent fewer days than the CY 2020 dataset. Likewise, for CMHCs, we noted that we continue to observe this decrease in our trimmed CY 2021 claims dataset, which has approximately 32 percent fewer CMHC PHP days than the CY 2020 dataset did. Given the continued effects of COVID-19 observed on the Medicare claims and cost report data, coupled with the expectation for future variants, we stated that we believe it is reasonable to assume that there will continue to be some limited influence of COVID-19 PHE effects on the data we use for ratesetting.

Despite the continued effects of COVID-19 that we noted in the PHP data, we also noted that even though hospital operations do not appear to have returned to the same levels as in 2019, the Medicare outpatient service volumes appear to be returning to more normal pre-pandemic levels. As discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), based on our review of the CY 2021 outpatient claims available for ratesetting,

we observed that the non-PHP outpatient service volumes are generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims, however, we stated that we recognize that future COVID-19 variants may have potentially varying effects and that we believe it is reasonable to assume that there will continue to be some effects of COVID-19 PHE on the outpatient claims that we use for ratesetting. As a result, we explained that we believe the more recently available CY 2021 claims data would better represent the volume and mix of claims for the CY 2023 OPPS. Accordingly, we stated that we believe it is appropriate to use CY 2021 data for purposes of CY 2023 OPPS ratesetting. Consistent with the proposal discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44681 through 44683), we proposed to use the latest available CY 2021 claims for CY 2023 PHP ratesetting.

We also reviewed the cost report data from the December 2021 HCRIS data set, which we would ordinarily have used for this CY 2023 OPPS/ASC proposed ratesetting. As discussed in greater detail in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44681 through 44683), we explained that we believe cost report data that overlap with CY 2020 are too influenced by the COVID-19 PHE for purposes of calculating the CY 2023 PHP payment rates. In the case of PHP, we observed a negative impact of the cost report data from the December 2021 HCRIS data set on the calculated geometric mean per diem cost for CMHCs. Specifically, we observed that the CMHC geometric mean per diem costs calculated using the latest available cost report data from the December 2021 HCRIS data set would have been $127.38, which would have been a decrease from the cost floor of $136.14 used to calculate the CY 2022 CMHC APC 5853 payment rate (86 FR 63668). Therefore, we stated that we believe it is appropriate to continue to use the same set of cost reports that we used in developing the CY 2021 OPPS, to

mitigate the impact of that 2020-based data. We noted that we would continue to review the updated cost report data as they are available.

Based on the results of this analysis, we proposed to use the cost information from prior to the COVID-19 PHE – in other words, cost information that was available for the CY 2021 OPPS/ASC rulemaking, which is the same as that used last year for the CY 2022 OPPS/ASC rulemaking (86 FR 63665 through 63669). Specifically, we would use cost report data from the June 2020 HCRIS data set, which only includes cost report data through CY 2019.

Therefore, consistent with what we proposed to do for other APCs under the OPPS as discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44683), we proposed to use the latest available CY 2021 claims, but use the cost information from prior to the COVID-19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs.

Comment: We received one comment which expressed support of our proposal to use the CY 2021 claims and the cost information from prior to the COVID-19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs.

Response: We thank the commenter for their support of our proposal for CY 2023. We intend to continue monitoring the claims and cost report information for PHP providers during the ongoing COVID-19 PHE, and to consider which data are the best available for rulemaking in the future.

Comment: We received 11 comments from providers, hospital associations, and national organizations expressing concerns about the proposed decrease in PHP per diem rates. Several commenters noted that the proposed CY 2023 PHP payment rates were below the calculated

geometric mean per diem costs, and erroneously concluded that CMS had applied a different methodology to calculate PHP payment rates than in prior years. Commenters expressed that the proposed rates would not be sufficient to ensure the sustainability of the PHP program and could impact access to PHP services. Many of the commenters requested that CMS refrain from going forward with the proposed rate cuts for PHP services in CY 2023 and requested that CMS reconsider the proposed methodology for CY 2023 and its impact on the immediate future of PHP services. A few commenters suggested CMS explore alternate ways to protect against rate reductions, such as freezing the APC weights for PHP services at their CY 2022 levels or establishing a PHP base rate that is updated annually by an inflation factor.

Response: We understand the concerns that commenters raised the regarding the proposed decreases in the PHP rates. Contrary to what some commenters suggested, the methodology we applied in calculating the proposed PHP payment rates is consistent with the methodology we have applied in prior years. We proposed to calculate the PHP payment rates based on our longstanding methodology, in accordance with the statutorily required relative payment weight calculations under the OPPS. Under the longstanding OPPS ratesetting methodology, CMS establishes APC payment rates by annually reviewing and revising the relative payment weights for APCs in accordance with sections 1833(t)(2) and 1833(t)(9) of the Act, as further described in section II.A.4 of this final rule with comment period. We further note that the OPPS is subject to budget neutral adjustments to the weight scaler as described in section II.A.4. and is also subject to the OPPS conversion factor described in II.B. of this final rule with comment period. As a result of those OPPS budget neutrality adjustments, the proposed and final APC payment rates may be higher or lower than their estimated APC geometric mean costs.

Regarding commenters' suggestion to establish a fixed PHP base rate that is updated annually by an inflation factor, we do not believe such a methodology would be consistent the statutory requirements under sections 1833(t)(2) and 1833(t)(9) of the Act. However, we share commenters' concerns that the CMHC PHP payment rate be sufficient to protect access to CMHC PHP services in CY 2023. As we discussed in the CY 2023 OPPS/ASC proposed rule, we believed the most appropriate methodology to use for setting PHP rates was our longstanding methodology. After considering the potential impact to PHP geometric mean per diem costs, we proposed to use the latest available CY 2021 claims, but we proposed to use the same set of cost reports that we used in developing the CY 2021 OPPS to mitigate the impact of that 2020-based data. We believed that this proposed methodology would appropriately mitigate the effects of the COVID-19 PHE on the cost report data while accounting for the overall trend in Medicare outpatient service volumes, which we have noted appear to be returning to more normal pre-pandemic levels. After considering the comments we received, we agree with commenters requesting that CMS not finalize the proposed rate cuts for CMHC PHP services in CY 2023. As we have stated in previous rules, our goal is to support ongoing access to PHPs in CMHCs and, in furtherance of that goal, we have historically established mitigation policies in situations when we believe fluctuations in PHP payments do not accurately reflect a commensurate decrease in the cost of providing those services, particularly because costs generally increase over time. We have also implemented mitigation policies to stabilize CMHC PHP geometric mean per diem costs and thereby established PHP APC payment rates that would otherwise change significantly from one year to the next; these have been especially important to supporting the stability of the program given the small number of CMHC PHP providers.

More specifically, even though the final CY 2023 CMHC PHP geometric mean cost of $135.68 is nearly the same as the final CY 2022 geometric mean cost floor of $136.14, the calculated payment rates for the 2 years are substantially different, with the CY 2022 final payment rate being $142.70 and the proposed and final calculated payment rates for CY 2023 being $130.54 and $131.94, respectively. In addition, the final CY 2023 CMHC PHP geometric mean per diem cost is $135.68, which is higher than the calculated CY 2023 CMHC PHP APC payment rate of $131.94. However, the application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. We believe this decrease in the calculated CY 2023 PHP APC payment rate for CMHC providers is likely not an accurate reflection of the cost of providing PHP services this year, since geometric mean costs for those services have remained relatively constant from CY 2022 to CY 2023. We are therefore concerned that the CY 2023 calculated payment rate for the CMHC PHP APC would not pay appropriately for those services and may result in access issues to PHP services in CMHCs. We believe providers would not expect their calculated final CY 2023 CMHC PHP APC payment rate to be significantly lower than the CY 2022 CMHC PHP APC payment rate under the existing payment methodology. In addition, as noted above, minimizing significant fluctuations in CMHC PHP payments is important to stabilizing the PHP program. Given the unique circumstances of CMHCs, which are only considered a Medicare provider of services for PHP, we are concerned that the decrease in the CMHC APC payment rate for CY 2023 that would occur if we were to finalize the final calculated rate would not protect access for Medicare beneficiaries to PHP services in CMHCs, and we have considered in this final rule an approach to mitigate the proposed decrease in the

CMHC PHP APC payment rate. Therefore, in the interest of accurately paying for CMHC PHP services, under the unique circumstances of budget neutralizing all other OPPS policy changes this year, and in keeping with our longstanding goal of protecting continued access to PHP services provided by CMHCs by ensuring that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community, we are using the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services. This equitable adjustment will apply for only CY 2023 and not subsequent years.

Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. As such, we are making an adjustment under this authority to the final CY 2023 CMHC PHP APC payment rate to more equitably and appropriately pay for CMHC PHP services. For this final rule, while we are using the latest available CY 2021 claims and the cost information from prior to the COVID-19 PHE, as proposed, we are finalizing that the CY 2023 payment rate for the CMHC APC is the same payment rate as for CY 2022, that is, $142.70, because we believe CMHC providers would expect to manage their programs to align with the CY 2022 CMHC APC payment of $142.70. We note that we are applying this adjustment for CY 2023 only and not for subsequent years.

Additionally, as mentioned above and discussed in greater detail in section II.A.1.c of the CY 2023 OPPS/ASC proposed rule (87 FR 44510 through 44511), we have identified that we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We have found that hospitals are routinely reporting a number of nonstandard cost centers in this way. One such cost center is

cost center 03550, which is used to report Psychiatric/Psychological Services.[112] Based on the program logic to process HCRIS data used for OPPS ratesetting, we obtain the cost center number based on the line and subscript number on which the cost center is reported. Our internal analysis of hospital cost report information found that providers are routinely reporting this cost center on cost report lines other than 35.50 (that is, line 35 subscript 50), and therefore, this nonstandard cost center and others reported this way have not been included in the OPPS ratesetting database construction. Our internal analysis shows that including this additional data could potentially decrease the geometric mean cost of APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. Additionally, we are concerned about the significant changes in APC geometric mean costs that our analysis indicates would occur if we were to include such lines. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. Therefore, consistent with the proposal at II.A.1.c of the CY 2023 OPPS/ASC proposed rule (87 FR 44510 through 44511) for other OPPS services, we proposed to not include data from nonstandard cost centers reported on lines that do not correspond to the cost center number in our PHP ratesetting for CY 2023. We solicited comment on whether there exist any specific concerns with regards to the accuracy of

[112] Chapter 40 of the Provider Reimbursement Manual (PRM), Part 2, available on the CMS website at https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Paper-Based-Manuals.

the data from these nonstandard cost center lines that we would need to consider before including them in future OPPS ratesetting.

We did not receive any public comments on whether there exist any specific concerns with regards to the accuracy of the data from nonstandard cost center lines that we would need to consider and are finalizing as proposed to not include data from nonstandard cost centers reported on lines that do not correspond to the cost center number in our PHP ratesetting for CY 2023.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this final rule with comment period, we used HCRIS as the source for the CMHC cost information as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666) and prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465). However, as discussed above, we proposed to use CY 2021 claims data and the cost information from prior to the COVID-19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2023 CMHC PHP APC per diem cost.

Prior to calculating the final geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 28 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2023 ratesetting, two CMHCs had a

geometric mean cost per day above the trim's upper limit of $470.86, and one CMHC had a geometric mean cost per day below the trim's lower limit of $39.72. Therefore, we are excluding data for ratesetting from these three CMHCs.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2023 final rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also exclude providers without any days containing 3 or more units of PHP-allowable services. One provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their State location (80 FR 70463). For the CY 2023 OPPS/ASC final rule ratesetting, there was one CMHC with a CCR greater than one, and seven CMHCs with missing CCR information. Therefore, we are defaulting the CCRs for these eight CMHCs for ratesetting to the applicable statewide hospital CCR for each CMHC based on its urban/rural designation and its State location.

In summary, the application of these data preparation steps resulted in an adjusted CCR during our ratesetting process for eight CMHCs having either a CCR greater than one or having no CCR. We are also excluding one CMHC because it had no days containing three or more services, and three CMHCs for failing the ±2 standard deviation trim resulting in the inclusion of

24 CMHCs. There were 483 CMHC claims removed during data preparation steps due to the ±2 standard deviation trim or because they either had no PHP-allowable codes or had zero payment days, leaving 3,732 CMHC claims in our CY 2023 final ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691), using the CMHC CCRs calculated based on the cost information from HCRIS as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666), to calculate the CMHC APC geometric mean per diem cost.[113] The calculated CY 2023 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC APC 5853) is $135.68, an increase from $129.93 calculated last year for CY 2022 ratesetting (86 FR 63667).

Comment: We received several comments expressing concern about the proposed CY 2023 CMHC geometric mean per diem cost, which was $131.71. Specifically, commenters noted the proposed CY 2023 geometric per diem cost is a reduction from the CY 2021 geometric per diem cost, which was used as a floor for ratesetting in the CY 2022 OPPS/ASC final rule with comment period. One national association noted that the decrease in the proposed CY 2023

[113] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR (or statewide CCR, where the overall CCR was greater than 1 or was missing) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

PHP rates, coupled with inflation across the country and labor costs for CMHCs, results in a gap between payments and costs for providing partial hospitalization services, making it difficult for these programs to continue operating. Some commenters recommended that CMS apply a cost floor for CY 2023 equal to the CMHC geometric mean per diem cost calculated for CY 2021.

Response: We appreciate the concerns that commenters raised and recognize the importance of ensuring that PHP payment rates accurately reflect the financial costs to providers of providing PHP services to their communities. Under our longstanding methodology, the proposed and final calculated geometric mean per diem costs are based on the actual provider-reported claims and cost data and, therefore, we believe they accurately represent the cost of providing PHP services.

As we noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44663), overall Medicare outpatient service volumes appear to be returning to more normal pre-pandemic levels. As discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that the non-PHP outpatient service volumes are generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims. However, we recognize that future COVID-19 variants may have potentially varying effects and that we believe it is reasonable to assume that there will continue to be some effects of COVID-19 PHE on the outpatient claims that we use for ratesetting. As a result, we explained that we believe the more recently available CY 2021 claims data would better represent the volume and mix of claims for the CY 2023 OPPS. Accordingly, we stated that we believe it is appropriate to use CY 2021 data for purposes of CY 2023 OPPS ratesetting. In order to mitigate the effects of the COVID-19 PHE on the CMHC geometric mean per diem cost calculation, we proposed to

continue to use the cost data that was available for the CY 2021 rulemaking, which is the same cost data used for the CY 2022 rulemaking (86 FR 63665 through 63666).

However, as we noted above, while the CY 2023 CMHC PHP geometric mean per diem cost accurately represents the cost of providing PHP services, we share commenters' concerns that the calculated final CY 2023 CMHC PHP APC payment rate of $131.94 is unexpectedly below the final CY 2023 CMHC PHP geometric mean per diem costs of $135.68 and may not support ongoing access to PHPs in CMHCs in CY 2023.

As we have stated in previous rules, our goal is to support ongoing access to PHPs in CMHCs and, in furtherance of that goal, we have historically established mitigation policies where we believe fluctuations in PHP payments do not accurately reflect a commensurate decrease in the cost of providing those services, particularly because costs generally increase over time. We have also implemented mitigation policies to stabilize CMHC PHP geometric mean per diem costs that would otherwise change significantly from one year to the next; these have been especially important in supporting the stability of the program given the small number of CMHC PHP providers.

More specifically, as noted above, even though the final CY 2023 CMHC PHP geometric mean cost of $135.68 is nearly the same as the final CY 2022 geometric mean cost floor of $136.14, the calculated payment rates for the two years are substantially different, with the CY 2022 final payment rate being $142.70 and the proposed and final calculated payment rates for CY 2023 being $130.54 and $131.94, respectively. In addition, the final CY 2023 CMHC PHP geometric mean per diem costs is $135.68, which is higher than the calculated CY 2023 CMHC PHP APC payment rate of $131.94. However, the application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique

to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. We believe this decrease in the calculated CY 2023 PHP APC payment rate for CMHC providers is likely not an accurate reflection of the cost of providing PHP services this year, since geometric mean costs for those services have remained relatively constant from CY 2022 to CY 2023. We are therefore concerned that the CY 2023 calculated payment rate for the CMHC PHP APC would not pay appropriately for those services and may result in access issues to PHP services in CMHCs. We believe providers would not expect their calculated final CY 2023 CMHC APC rate to be significantly lower than their calculated CY 2023 CMHC APC calculated costs using the existing methodology. We believe CMHC providers would expect to manage their programs to align with the CY 2022 CMHC APC payment of $142.70. As such, we are making an adjustment to the final CY 2023 CMHC APC payment to more equitably and appropriately pay for PHP services in CMHCs. This adjustment will apply for only CY 2023 and not subsequent years.

Section 1833(t)(2)(E) of the Act states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. Using the authority set forth in section 1833(t)(2)(E) of the Act, we are making an adjustment to the final CY 2023 CMHC APC payment rate to more equitably and appropriately pay for CMHC PHP services. This equitable adjustment will apply for CY 2023 and not for subsequent years.

After consideration of the public comments we received, under the authority set forth in section 1833(t)(2)(E) of the Act, we are making an equitable adjustment to finalize $142.70 as the CY 2023 CMHC PHP APC payment rate. We reiterate that we are applying this adjustment for only CY 2023 and not for subsequent years.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For the CY 2023 OPPS/ASC final rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. However, as discussed above, we proposed to use CY 2021 claims data and the cost information from prior to the COVID-19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2023 hospital-based PHP APC per diem cost. The CY 2021 PHP claims included data for 425 hospital-based PHP providers for our calculations in this CY 2023 OPPS/ASC final rule.

Consistent with our policies, as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. For the CY 2023 OPPS/ASC final rule ratesetting, no hospital-based PHP providers had a CCR greater than 5. Therefore, no hospital-based provider was excluded as a result of this trim. In addition, six hospital-based PHPs were removed for having no days with PHP payment. One hospital-based PHP was removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html)[114].

Overall, we removed eight hospital-based PHP providers (6 with no PHP payment) + (1 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 326 (334 total – 8 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the CY 2023 geometric mean per diem cost for hospital-based PHP APC 5863 by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[115] The calculated CY 2023 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $275.83, which is an increase from $253.02 calculated last year for CY 2022 ratesetting (86 FR 63668).

Comment: We received several comments expressing concern about the proposed CY 2023 hospital-based geometric mean per diem cost, which was $264.06. Specifically,

[114] Click on the link labeled "CY 2023 OPPS/ASC Notice of Final Rulemaking", which can be found under the heading "Hospital Outpatient Prospective Payment System Rulemaking" and open the claims accounting document link at the bottom of the page, which is labeled "2023 NFRM OPPS Claims Accounting (PDF)".

[115] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

commenters noted that payment updates are failing to keep pace with the growth in costs to deliver care, which will impact access to PHP services and medically necessary treatment. Several commenters noted that inflation across the country and rising labor costs are affecting hospital-based PHP providers. Several commenters noted that the CY 2023 hospital-based PHP cost per day was higher than the cost per day calculated for CY 2022, but one national association expressed concern that the proposed CY 2023 hospital-based PHP payment rate was calculated without using a cost floor, as it had been calculated in prior years.

Response: We appreciate the concerns that commenters raised and recognize the importance of ensuring that PHP payment rates accurately reflect the financial costs to providers of providing PHP services to their communities. Under our longstanding methodology, the proposed and final calculated geometric mean per diem costs are based on the actual provider-reported claims and cost data and, therefore, we believe they accurately represent the cost of providing PHP services.

With respect to the commenters' suggestions about continuing the use of cost floors, we did not propose to apply this methodology for CY 2023 and we are not finalizing such a methodology in this final rule. As we noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44663), overall Medicare outpatient service volumes appear to be returning to more normal pre-pandemic levels. As discussed in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that the non-PHP outpatient service volumes are generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims. However, we recognize that future COVID-19 variants may have potentially varying effects and that we believe it is reasonable to assume that there will continue to be some

effects of COVID-19 PHE on the outpatient claims that we use for ratesetting. As a result, we explained that we believe the more recently available CY 2021 claims data would better represent the volume and mix of claims for the CY 2023 OPPS. Accordingly, we stated that we believe it is appropriate to use CY 2021 data for purposes of CY 2023 OPPS ratesetting. In order to mitigate the effects of the COVID-19 PHE on the hospital-based PHP geometric mean per diem cost calculation, we proposed to continue to use the cost data that was available for the CY 2021 rulemaking, which is the same cost data used for the CY 2022 rulemaking (86 FR 63665 through 63666).

We further note that a cost floor would effectively have no impact on the CY 2023 hospital-based PHP geometric mean per diem cost calculation because both the proposed and final CY 2023 hospital-based geometric mean per costs are higher than those calculated in either CY 2021 or CY 2022. As discussed earlier in this final rule with comment period, we note that the proposed and final PHP payment rates are calculated in accordance with the statutorily required relative payment weight calculations under the OPPS. Accordingly, the CY 2023 hospital-based PHP payment rate calculation depends not only on the geometric mean per diem cost for PHP services, but also on the budget neutral adjustments to the weight scaler as described in section II.A.4. of this final rule and on the OPPS conversion factor described in II.B. of this final rule. As a result of those OPPS budget neutrality adjustments, the proposed and final APC payment rates may be higher or lower than their estimated APC geometric mean costs.

After consideration of the public comments we received, we are finalizing our proposal to calculate the costs per day using CY 2021 claims data with cost report data through CY 2019 (prior to the PHE), which is consistent with the approach recommended for the broader CY 2023

OPPS rate-setting. The calculated CY 2023 geometric mean per diem cost for all hospital-based PHPs for providing three or more services per day (APC 5863) is $275.83.

The final CY 2023 PHP geometric mean per diem costs are shown in Table 63 and are used to derive the final CY 2023 PHP APC per diem rates for CMHCs (subject to the equitable adjustment discussed earlier in this section of this final rule) and hospital-based PHPs. The final CY 2023 PHP APC per diem rates are included in Addendum A to this final rule with comment period (which is available on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html).

TABLE 63: CY 2023 PHP APC Geometric Mean Per Diem Costs

CY 2023 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$135.68
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$275.83

C. Outpatient Non-PHP Mental Health Services Furnished Remotely to Partial Hospitalization Patients after the COVID-19 PHE

1. Background

As discussed in the April 30, 2020 interim final rule with comment entitled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85 FR 27562 through 27566), effective as of March 1, 2020, and for the duration of the COVID-19 PHE, hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation and provider-based rules to the extent

not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID-19 PHE. In that same interim final rule (85 FR 27564), we also stated that although these services can be furnished remotely, all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still require an order by a physician, must be supervised by a physician, must be certified by a physician, and must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. We also stated that in accordance with the longstanding requirements that are detailed in the Medicare Benefit Policy Manual, Pub 100–02, chapter 6, section 70.3, documentation in the medical record of the reason for the visit and the substance of the visit is required.

As we discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44665), we received four comments in response to the April 30, 2020 interim final rule with comment regarding the interim final policy for PHP. Detailed summaries and responses to these comments are found in section XXII.B.4 of this CY 2023 OPPS/ASC final rule. In that section of this final rule, we are confirming as final the interim policy set forth in the April 30, 2020 interim final rule with comment.

In the CY 2022 OPPS/ASC proposed rule (86 FR 42187), CMS solicited comments on whether there were changes commenters believed we should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes. We acknowledged that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care

through the use of that technology, and that we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes.

Although we did not solicit comments on extending the use of remote technology to provide partial hospitalization services to beneficiaries in their homes after the end of the COVID-19 PHE, we received several comments in response to the CY 2022 OPPS/ASC proposed rule expressing support for the flexibilities allowing PHP services to be furnished to beneficiaries in their homes via telecommunication technology during the COVID–19 PHE and encouraging CMS to maintain these flexibilities beyond the PHE or consider making these temporary policies permanent (86 FR 63750). Commenters expressed that these flexibilities, especially those allowing the use of audio-only telecommunication technology, increase access to vital mental health services amidst a persistent shortage of health care professionals and allow much greater and timelier access to mental health services, especially in rural areas and for vulnerable populations, while also helping drive reductions in the rates at which patients missed appointments. Commenters also shared research and analysis supporting the effectiveness of providing PHP services using telecommunication technology. One academic health center discussed outcomes analysis it conducted of its PHP services and noted that its analysis did not show a decrement in clinical care for patients who received only virtual PHP services. A national association of behavioral healthcare systems shared research showing that the main differences between patients who participated in PHPs via telecommunication technology and those who attended in-person was that those who participated via telecommunication technology had greater lengths of stay and were more likely to stay in treatment until completed[116]. In response to these comments and others that we received pertaining to the comment solicitation, we noted

[116] https://www.psychiatrist.com/jcp/covid-19/telehealth-treatment-patients-intensive-acute-care-psychiatric-setting-during-covid-19/

that we would consider them for future rulemaking and that CMS would continue to explore how hospital payment for virtual services could support access to care in underserved and/or rural areas. However, we note that section 1861(ff)(3)(A) of the Act, which defines partial hospitalization services, specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting.

2. Outpatient Non-PHP Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes after the COVID-19 PHE

As discussed in section X.A.5 of the CY 2023 OPPS/ASC proposed rule (87 FR 44676 through 66479), we proposed payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital. While we did not propose to recognize these proposed OPPS remote services as PHP services, we clarified that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital if that proposal is finalized.

Additionally, we reminded readers that section 1835(a)(2)(F) of the Act requires that in the absence of partial hospitalization services, the individual would require inpatient psychiatric care; that is, partial hospitalization services are in lieu of inpatient hospitalization. This requirement is codified in the PHP regulations at § 424.24(e)(1)(i), which requires that the PHP patient certification state that the individual would require inpatient psychiatric care if the partial hospitalization services were not provided. Furthermore, in accordance with § 410.43(c)(7), all

PHP is intended for patients who have the cognitive and emotional ability to participate in the active treatment process and should be able to tolerate the intensity of the partial hospitalization program.

In addition, we reiterated that the physician certification and plan of care requirements at § 424.24(e)(1) and (2) require that each PHP patient must be under an individualized written plan of treatment that is periodically reviewed by a physician in consultation with appropriate staff participating in the program. This plan of treatment must set forth the physician's diagnosis; the type, amount, duration, and frequency of the services; and the treatment goals under the plan. As discussed in the CY 2009 OPPS/ASC final rule (73 FR 68695), and § 410.43(c), partial hospitalization programs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in a patient's plan of care. We expect that PHP patients are receiving the amount and type of services identified in the plan of care for generally all weeks under the program stated in the plan of care rather than in the actual hours of therapeutic services a patient receives.

In accordance with these requirements, we stated that if the proposal at section X.A.5 of the CY 2023 OPPS/ASC proposed rule were finalized, we would expect that a physician would update the patient's PHP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP patient receives non-PHP remote mental health services from a hospital outpatient department. We also noted that the medical documentation should continue to support the patient's eligibility for participation in a PHP.

Lastly, we noted that section 1866(e)(2) of the Act includes CMHCs as a Medicare provider of services, but only with respect to the furnishing of partial hospitalization services.

As noted earlier in this section, we did not propose to recognize the proposed OPPS remote services as PHP services; therefore, CMHCs are not permitted to bill Medicare for any remote mental health services furnished by clinical staff of the CMHC in an individual's home. However, we stated that a PHP patient who typically receives PHP services at a CMHC could receive non-PHP remote mental health services from a hospital outpatient department if the proposal at section X.A.5 of the CY 2023 OPPS/ASC proposed rule were finalized, or from a physician or other type of practitioner who is authorized to furnish and bill for Medicare telehealth services. As discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44666 through 44667), we requested information on the need for remote mental health services by CMHC patients, as well as potential pathways CMS could consider to address this need within the current statutory framework.

Comment: We received 17 comments in support of making remote behavioral health services available to patients in PHPs. Commenters noted that these services have not only been vital to ensure access to mental health care during the COVID-19 PHE, but have also demonstrated the general need for remote outpatient mental health services, especially for rural communities. Specifically, commenters stated that small rural hospitals have leveraged virtual care to meet the surging demand of behavioral health needs in the communities they serve, which has improved continuity of care and removed barriers to access mental health care in these isolated and underserved communities. Two commenters noted that remote services for PHP patients have been of great value in improving access to behavioral health by removing transportation, geographical, and adverse weather barriers that would otherwise prohibit patients from receiving services. In addition, they indicated remote services for PHP patients improve access for patients with challenging diagnoses, including trauma, agoraphobia, and anxiety, as

well as provide access to medically complex patients who have difficulty leaving their home for outpatient services.

Three commenters encouraged CMS to closely monitor the use of non-PHP remote mental health codes for patients receiving PHP services. These commenters also noted that under the proposed clarification, remote behavioral health services would not be recognized as PHP services, and they encouraged CMS to carefully monitor whether clinicians are under the impression that these remote services may count toward the required care for PHP patients. These commenters further encouraged CMS to provide more specific instructions related to the documentation requirement to update the patient's PHP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP patient receives non-PHP remote mental health services from a hospital outpatient department.

Response: We thank commenters for their support. As some commenters noted, we did not propose to recognize remote mental health services as PHP services. In response to the concerns that commenters raised, we are clarifying that non-PHP remote mental health services furnished to a beneficiary in a PHP will not be counted as PHP services in the determination of payment for a PHP day. When these services are furnished to a beneficiary by a hospital, they will be paid at the established APC payment amount as discussed in section X.A.5 of this final rule. We also note that our longstanding OPPS policy limits the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services.

We agree with commenters that remote non-PHP mental health services can help address barriers related to transportation, adverse weather, or other unforeseen circumstances. We clarified in the CY 2023 OPPS/ASC proposed rule that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital, including the proposed non-PHP remote mental health services.

Although we will not recognize remote mental health services as PHP services, we acknowledge that there will be circumstances when a patient under a PHP plan of care may need to temporarily receive remote mental health services. We are clarifying that remote mental health services that are included in a PHP patient's plan of care will not limit a patient's eligibility for continued participation in a PHP if all other program requirements are met. That is, for a patient who needs at least 20 hours per week of PHP services, we will consider remote mental health services that are included in the patient's plan of care to be consistent with the regulation at § 410.43(c)(1), which states that PHPs are intended for patients that require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. As discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44666 through 44667) and earlier in this final rule, we expect that PHP patients are receiving the amount and type of services identified in the plan of care for generally all weeks under the program stated in the plan of care rather than in the actual hours of therapeutic services a patient receives. Therefore, if a PHP patient receives non-PHP mental health services remote services, we expect that the plan of care will reflect such services, and we would not consider the inclusion of such services in the plan of care to limit the patient's eligibility for continued participation in a PHP to the extent that other patient eligibility requirements are met. In accordance with § 410.43(c)(7), PHP is intended for

patients who have the cognitive and emotional ability to participate in the active treatment process and should be able to tolerate the intensity of the partial hospitalization program. For patients under a PHP plan of care that receive remote services, the medical documentation should continue to support the patient's eligibility for participation in a PHP. Regarding comments about access for medically complex patients and those with challenging diagnoses, we further note that the Medicare home health benefit may be available to meet the needs of the kinds of patients that commenters identified, provided all eligibility requirements are met. The home health beneficiary eligibility requirements at § 409.42 specify, among other requirements, that the beneficiary be confined to the home; under the care of a physician or allowed practitioner; be receiving services under a plan of care established and periodically reviewed by a physician or allowed practitioner; need skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy. For more information on the home health benefit, we refer readers to the Medicare Benefit Policy Manual, Pub 100–02, chapter 7.

Comment: One commenter requested CMS clarify that facility fees for providing PHP services via telehealth will continue to be covered after the end of the COVID-19 PHE.

Response: As we discussed earlier in this final rule, we did not propose to recognize remote mental health services as PHP services. As discussed in section XXII.B.4 of this final rule with comment period, we are confirming as final that the flexibilities allowing PHP services to be furnished remotely will apply only for the duration of the COVID-19 PHE. Accordingly, facilities will not be permitted to bill for PHP when services are provided remotely. However, hospital outpatient departments will be permitted to bill for remote mental health services on an

individual basis and paid at the established APC payment amount as discussed in section X.A.5 of this final rule with comment period.

In addition, as discussed in section XXII.B.5 of this final rule with comment period, we are finalizing that when a patient is receiving a professional service via telehealth in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. We are also finalizing the applicability of section 603 of the BBA 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion locations). Once the PHE for COVID-19 ends, these flexibilities will end as well.

After consideration of the public comments we received, we are finalizing the clarification that PHP patients can continue to receive the full range of hospital outpatient services, including the new HCPCS codes that describe mental health services furnished to beneficiaries in their homes by clinical staff of the hospital. We are also finalizing the clarification that for PHP patients, the plan of care should be updated to reflect that remote services are being provided.

3. Request for Information Regarding Remote PHP Services Furnished by Hospital Outpatient Departments and CMHCs during the COVID-19 PHE

In the CY 2023 OPPS/ASC proposed rule, we stated our interest in better understanding the use of remote mental health services for PHP patients during the COVID-19 PHE and the potential need for such services in the future among PHP patients who receive care from CMHCs and HOPDs. Specifically, we requested public comments on the following questions:

- How have CMHCs and HOPDs used the flexibilities allowing the provision of remote PHP services and incorporated remote PHP services into their operations during the COVID-19 PHE?
- What are the needs and circumstances in which remote PHP services have most often been used? What situations and patient populations have these flexibilities best served? How have these needs, circumstances, and patient populations differed between HOPDs and CMHCs?
- What, if any, barriers would there be to access to remote mental health services for PHP patients of a CMHC? What if any possible pathways do commenters believe might exist to minimize these barriers, while taking into consideration section 1861(ff)(3)(A) of the Act?

We stated that while we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. We asked that comments identify the question commenters are responding to, and include as much data as possible that supports their responses.

We received 27 comments in response to the CY 2023 OPPS/ASC proposed rule pertaining to the questions raised in the request for information regarding remote PHP services furnished by hospital outpatient departments and CMHCs during the COVID-19 PHE. Commenters included members of national associations who overall responded that the flexibilities of remote mental health services for PHP patients during the COVID-19 PHE have allowed providers of PHP services to maintain continuity of care for patients and expand their programs to individuals otherwise outside of the provider's service area. Commenters explained remote PHP services have most often been used when patients are in quarantine due to contracting COVID-19, when patients do not have transportation to attend in-person services, and to reach individuals living in an area without accessible PHP services.

We thank commenters for their detailed responses to this request for information. We will take these comments into consideration to potentially inform future policy development.

D. Outlier Policy for CMHCs

For 2023, we proposed to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar- threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G.1 of the CY 2023 OPPS/ASC proposed rule (87 FR 44533) for our general policies for hospital outpatient outlier payments.

We did not receive any public comments on our proposal and are finalizing as proposed.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- Step 1: We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

(0.01 x Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.

- Step 2: We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3 of the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs

exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.D.3 of the CY 2023 OPPS/ASC proposed rule (87 FR 44668), to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.D.5 of the CY 2023 OPPS/ASC proposed rule (87 FR 44668), so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs - Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A x 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 x Provider's Total Estimated Per Diem Payments), then cap adjusted- B = (0.08 x Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- Step 3: We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1: (Estimated CMHC Outlier Payments / Total OPPS Outlier Payments).

We proposed to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2023. Therefore, based on our CY 2023 payment estimates, CMHCs are projected to receive 0.01 percent of total hospital outpatient payments in CY 2023, excluding outlier payments. We proposed to designate approximately

less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

We did not receive any public comments on our proposal and are finalizing as proposed.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 x (CMHC Cost – (3.4 x APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083). For CY 2023, we proposed to continue to pay for partial

hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2023, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost - (3.4 × APC 5853 rate))].

We did not receive any public comments on our proposal and are finalizing as proposed.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We proposed to continue these policies for partial hospitalization services provided through PHPs for CY 2023. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS

Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing Internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf).

We did not receive any public comments on our proposal and are finalizing as proposed.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. In the CY 2023 OPPS/ASC proposed rule, we did not propose any changes to this policy.

We did not receive any public comments on our proposal and are finalizing as proposed.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed--dollar threshold in

addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508). We proposed to continue this policy for CY 2023.

We did not receive any public comments on our proposal and are finalizing as proposed.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described

above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual

cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be furnished in most outpatient departments.

3. The procedure is related to codes that we have already removed from the IPO list.

4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.

5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC covered procedures list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal

from the IPO list and was safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians thoroughly reviewed all information submitted within the context of the established criteria and if, following this review, we determined that there was sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assigned the service to an APC and included it as a payable procedure under the OPPS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and review the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services

that are typically provided only in an inpatient setting and that, therefore, will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088) we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the CY 2022 OPPS/ASC final rule with comment period, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list using the above five criteria, we returned most services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We also amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition. We also finalized our proposal to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23 (86 FR 63678).

B. Changes to the Inpatient Only (IPO) List

Using the five criteria listed above, in the CY 2023 OPPS/ASC proposed rule, for CY 2023, we identified 10 services described by the following codes that we proposed to remove from the IPO list for CY 2023: CPT code 16036 (Escharotomy; each additional incision (list separately in addition to code for primary procedure)); CPT code 22632 (Arthrodesis, posterior

interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)); CPT code 21141 (Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft); CPT code 21142 (Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft); CPT code 21143 (Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft); CPT code 21194 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)); CPT code 21196 (Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation); CPT code 21347 (Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches); CPT code 21366 (Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)); and CPT code 21422 (Open treatment of palatal or maxillary fracture (lefort i type)). The services that we proposed to remove from the IPO list for CY 2023 and subsequent years, including the CPT codes, long descriptors, and the proposed CY 2023 payment indicators and APC assignments were displayed in Table 46 (87 FR 44672).

As noted above, we proposed to remove the service described by CPT code 16036 from the IPO list for CY 2023. After reviewing the clinical characteristics of the service described by CPT code 16036, we believed that this procedure met criteria 2 and 3 in our regulation text at §419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient departments and the service or procedure is related to codes that CMS has already removed from the IPO list. CPT code 16036 is an add-on code that is

typically billed with the primary procedure described by CPT code 16035 (Escharotomy; initial incision), which was removed from the IPO list in CY 2007 OPPS/ASC final rule with comment period (71 FR 68156). For CY 2023, we proposed to assign CPT code 16036 to status indicator "N". We solicited public comment on our conclusion that the service described by CPT code 16036 meets criteria 2 and 3 as well as our proposal to assign this service to status indicator ''N'' for CY 2023.

Additionally, we proposed to remove the service described by CPT code 22632 from the IPO list for CY 2023. CPT code 22632 is an add-on code that is typically billed with the primary procedure described by CPT code 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar), which was removed from the IPO list in CY 2021 (86 FR 63708). CPT code 22632 was previously removed from the IPO list in CY 2021 as part of the first stage of the elimination of the IPO list, but was then returned to the list for CY 2022 when the elimination of the IPO list was halted. After further in-depth clinical review of this procedure, we believed CPT code 22632 met criteria 2 and 3 in our regulation text at §419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient departments and it is related to CPT code 22630, which CMS has already removed from the IPO list. For CY 2023, we proposed to assign CPT code 22632 to status indicator "N". We solicited public comment on our conclusion that the service described by CPT code 22632 meets criteria 2 and 3 as well as our proposal to assign this service to status indicator ''N'' for CY 2023.

As stated above, we also proposed to remove the following maxillofacial procedures from the IPO list: CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422. These services were previously removed from the IPO list in CY 2021 as part of the first phase

of the elimination of the IPO list and were added back to the IPO list when the elimination of the IPO list was halted for CY 2022. After further in-depth review of the clinical characteristics of these procedures, the claims data, and additional evidence provided by interested parties, we stated that we believe these services meet criteria 1, 2, and 3 in the regulation text at §419.23(b)(1), (2), and (3) because most outpatient departments are equipped to provide the procedures; the simplest procedures described by the codes may be performed in most outpatient departments; and the procedures are related to codes that CMS has already removed from the IPO list, and we proposed to remove them from the IPO list for CY 2023. We proposed to assign these eight services to APC 5165 - Level 5 ENT Procedures and status indictor "J1". We solicited public comment on our conclusion that the services described by CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422 met criteria 1, 2, and 3 and our proposal to assign these services to APC 5165 - Level 5 ENT Procedures and status indicator ''J1''.

We proposed to add eight services described by codes that were newly created by the AMA CPT Editorial Panel for CY 2023 to the IPO list. The codes for these services, which will be effective on January 1, 2023, are CPT codes 15778, 22860, 49596, 49616, 49617, 49618, 49621, and 49622. We note that these codes were referred to by the placeholder codes 157X1, 228XX, 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14 respectively in the CY 2023 OPPS/ASC proposed rule. After clinical review of these services, we found that they require a hospital inpatient admission or stay and we proposed to assign these services to status indicator "C" for CY 2023. The CPT codes, long descriptors, and the proposed CY 2023 payment indicators were displayed in Table 65.

Comment: We received several public comments in support of our proposal to remove CPT codes 16036, 21141, 21142, 21143, 21194, 21196, 21347, 21366, 21422, and 22632 from

the IPO list and for the proposed status indicator and APC assignments for these codes for CY 2023. We also received several comments in support of adding CPT codes 15778, 22860, 49596, 49616, 49617, 49618, 49621, and 49622 to the IPO list for CY 2023. Multiple commenters urged CMS to continue its current process of evaluating individual services against the five longstanding criteria to determine if the services are appropriate to remove from the IPO list. A few commenters also noted that they believed the current policy allows for the flexibility for physicians and their patients to choose the appropriate care and increases access to safe and affordable care, along with reducing potential harm to Medicare beneficiaries.

Three commenters specifically expressed support for removing CPT codes 16036 and 22632 because they are add-on codes that are performed with primary procedures that have previously been removed from the IPO list. One commenter who supported our proposal to remove CPT code 22632 from the IPO list requested that we not assign the code to status indicator "N", and instead provide separate payment for the code because the commenters believe it is a device intensive procedure and not providing separate payment would be problematic for providers.

Response: We thank commenters for their support.

We note that CPT code 22632 is an add-on code and will always be performed with a primary procedure. Because of this, we believe that assigning CPT code 22632 to status indicator "N" is the appropriate assignment and we are finalizing our proposal to reassign CPT 22632 to status indicator "N" for CY 2023.

Comment: We received one comment that encouraged CMS to reconsider removing the proposed services from IPO list. The commenter stated that the proposed services cannot be safely performed in an outpatient setting because they require the care and services available in

the inpatient setting. The commenter believed that removing the proposed services would cause these services to be performed at lower levels of care than appropriate for the patients.

We also received one comment that opposed removing CPT code 16036 from the IPO list and recommended keeping the service on the list. The commenter stated that this service was typically provided in the operating room or emergency department if required, but is not widely performed in the hospital outpatient department setting and would not be performed in an ASC. They noted that for 2020, 84 percent of Medicare claims for this service had inpatient hospital status while 8 percent of claims for this service were outpatient, which they believed represented the patients who received emergency treatment and then were sent to an outpatient burn center after stabilization. The commenter also expressed concern that claims submitted for both CPT code 16036 and its primary procedure of CPT code 16035 were being miscoded as being performed in a non-facility setting, which could give the false impression that these services can safely be performed in an outpatient or non-facility setting and should therefore be removed from the IPO list.

Response: We thank commenters for their feedback. In regard to the stakeholder's concerns about removing CPT code 16036, after further review, we agree with the stakeholder that this service would typically be performed in the inpatient setting. For this reason, we are not finalizing our proposal to remove CPT code 16036 from the IPO list and instead will continue to assign CPT code 16036 to a status indicator assignment of "C".

We disagree that CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, 21422, and 22632 cannot be safely furnished in the outpatient setting. As noted above, our clinical review found that these procedures were appropriate to remove from the IPO list. In regards to the stakeholders' concern that Medicare beneficiaries would receive these services at lower

levels of care, we note that, as stated above, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting. The comments we received were generally in support of removing these services, with commenters noting that they believed the services could be appropriately furnished in the outpatient setting. We did not receive any additional supportive evidence or arguments that further explained why these procedures could not be performed in the hospital outpatient department setting. Given these reasons, we are finalizing our proposal to reassign CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422 and to status indicator "J1" and APC 5165. We are also finalizing our proposal to reassign CPT code 22632 to status indicator "N".

Comment: We received three comments requesting that CMS remove CPT code 47550 (Biliary endoscopy, intraoperative (choledochoscopy) (List separately in addition to code for primary procedure)) from the IPO list and reassign it to status indicator "N". The commenters stated that this add-on code is only reported as secondary to a primary procedure and allows for direct visualization and identification of abnormalities of tortuous anatomy and aids in the facilitation of the primary procedure, including diagnostic brushing/washing, biopsy, stone removal, strictures, and stenting within the biliary tract. The commenters noted that this service is associated and performed with several primary procedures that are not on the IPO list, including those described by CPT codes 47553 through 47541. Additionally, the commenters cited multiple studies that supported that this service can be performed safely in the outpatient setting. The commenters added that while the literature showed that the outpatient setting was not appropriate for all patients for this service, it needs to be an accessible site of service option. Additionally, the commenters noted that Medicare claims data show that this service has been

billed by physicians in the outpatient setting, with 21.5% of physician claims being performed in the outpatient setting in CY 2020. The commenters argued that removing CPT code 47550 from the IPO list would increase access for Medicare beneficiaries and allow providers to determine the most appropriate site of service. Furthermore, this issue was presented at the 2022 HOP Panel, with the Panel recommending that CPT code 47550 be removed from the IPO list.

Response: We thank commenters for their feedback. After further in-depth review of the evidence provided, we agree with the commenters that this service meets criteria 3 in our regulation text at §419.23(b)(3) because the service or procedure is related to codes that CMS has already removed from the IPO list and can be appropriately removed from the IPO list. We are reassigning CPT code 47550 to status indicator "N" for CY 2023.

Comment: One commenter requested that CMS also remove CPT codes 21188, 21255, 21343, 21344, 21348, 21423, and 21436 from the IPO list, stating that these procedures can be performed outside of the inpatient setting similarly to proposed CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422. The long descriptors for the requested codes are listed in Table 64 below.

TABLE 64: MAXILLOFACIAL PROCEDURES REQUESTED FOR REMOVAL FROM THE INPATIENT ONLY (IPO) LIST FOR CY 2023

CY 2023 CPT Code	CY 2023 Long Descriptor
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)
21343	Open treatment of depressed frontal sinus fracture

CY 2023 CPT Code	CY 2023 Long Descriptor
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)

Response: We thank the commenter for their feedback. After further review of the recommended codes, we agree with the stakeholder that the service described by CPT code 21255 can be appropriately removed from the IPO list and meets criteria 2 and 3 in our regulation text at §419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient departments and the service or procedure is related to codes that CMS has already removed from the IPO list. We are reassigning CPT code 21255 to status indicator "J1" and APC 5165 - Level 5 ENT Procedures, and continuing to assign CPT codes 21188, 21343, 21344, 21348, 21423, and 21436 to status indicator "C" for CY 2023.

Comment: We received two comments requesting that CMS reconsider reversing the elimination of the IPO list that was finalized in the CY 2021 OPPS/ASC final rule with comment period. These commenters stated that they supported the elimination of the IPO list to allow for greater site-of-service flexibility. One commenter believed that physicians are in the best position to determine whether a procedure can be performed appropriately in the hospital outpatient setting or whether inpatient care is necessary. They continued to state that they believe

that physician judgment, along with licensure and accreditation requirements, provide appropriate safeguards. Additionally, one commenter noted that innovations in medicine would lead to a less distinct difference between the need for inpatient care and the appropriateness of outpatient care.

Response: We thank the commenters for their feedback. We are not considering eliminating the IPO list at this time. As stated in the CY 2022 OPPS/ASC final rule with comment period, we believe the IPO list is a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting and remains a necessary safeguard. In that final rule, we explained that we recognized that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, that is, the typical Medicare beneficiary. Furthermore, we explained that while we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above. For further discussion on our decision to halt the elimination of the IPO list, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63671 through 63711)

Comment: We received two comments urging CMS to develop guidance on which patients are appropriate candidates for receiving services in the inpatient setting versus the outpatient setting. Commenters specified that they would like guidance on which patients would be reasonable candidates for same-day discharge. The commenters state that they believe this would mitigate denials from payers and that establishing guidance would not limit clinician

decision-making as they would still able to provide supporting clinical documentation to justify inpatient stays for patients that may otherwise be candidates for outpatient surgery.

Response: We thank the commenters for their feedback. In the CY 2022 OPPS/ASC final rule with comment period, we noted the balance between several factors on this important issue, namely, the prohibition on CMS interfering with the practice of medicine in Section 1801 of the Social Security Act, the need to provide clear information about CMS billing and payment rules that ensure hospitals, physicians, and other stakeholders can understand and operate within them, and that the specific decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary(86 FR 63675).

We also noted that the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC– QIOs) are contracted by CMS to review a sample of Medicare fee-for-service (FFS) short-stay inpatient claims (claims with hospital stays lasting less than 2 midnights after formal inpatient admission) for compliance with the 2-midnight rule. In the CY 2022 OPPS/ ASC final rule with comment period (86 FR 63736 through 63740), we reinstated a two-year period of exemption from certain BFCC-QIO medical review activities for procedures newly removed from the IPO list where the length of stay after inpatient admission is less than 2 midnights. During the exemption period, BFCC–QIOs may conduct medical reviews for education purposes but will not deny claims or make referrals to RACs for noncompliance with the 2-midnight rule for procedures that are removed from the IPO list within the first 2 years of their removal. This exemption period is intended to allow providers time to become more familiar with the application of the 2-midnight rule to procedures newly removed from the IPO

list, and allows the BFCC–QIOs the opportunity to provide education regarding application of that payment policy to such procedures. We also noted that we plan to use our experience gained through BFCC–QIO reviews to engage stakeholders to determine if developing additional materials for services that are newly removed from the IPO list would be helpful. We reiterate that any such materials will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting. For further discussion on this issue, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63674 through 63675).

In summary, after consideration of the public comments we received, we are finalizing our proposal to remove CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422 from the IPO list and reassign them to status indicator "J1" and APC 5165 beginning in CY 2023. We are also finalizing our proposal to remove CPT code 22632 from the IPO list and reassign the service to status indicator "N". We are not finalizing our proposal to remove CPT code 16036 from the IPO list and will continue to assign CPT code 16036 to status indicator "C". Finally, we are removing CPT code 47550 and reassigning it to status indicator "N" and removing CPT code 21255 and reassigning it to status indicator "J1" and APC 5165 - Level 5 ENT Procedures. Table 65 below contains the changes to the IPO list for CY 2023. The complete list of codes describing services that are proposed to be designated as inpatient only services beginning in CY 2023 is also included as Addendum E to this final rule with comment period, which is available via the internet on the CMS website.

TABLE 65: CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2023

CY 2023 CPT Code	CY 2023 Long Descriptor	Action	CY 2023 OPPS Final Status Indicator	CY 2023 OPPS Final APC Assignment
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	Remove from the IPO list	N	N/A
47550	(Biliary endoscopy, intraoperative (choledochoscopy) (List separately in addition to code for primary procedure))	Remove from the IPO list	N	N/A
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft	Remove from the IPO list	J1	5165
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	Remove from the IPO list	J1	5165
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	Remove from the IPO list	J1	5165
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	Remove from the IPO list	J1	5165
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	Remove from the IPO list	J1	5165
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	Remove from the IPO list	J1	5165
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	Remove from the IPO list	J1	5165

CY 2023 CPT Code	CY 2023 Long Descriptor	Action	CY 2023 OPPS Final Status Indicator	CY 2023 OPPS Final APC Assignment
21366	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	Remove from the IPO list	J1	5165
21422	Open treatment of palatal or maxillary fracture (lefort i type);	Remove from the IPO list	J1	5165
15778	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	Add to the IPO list	C	N/A
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	Add to the IPO list	C	N/A
49596	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	Add to the IPO list	C	N/A
49616	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	Add to the IPO list	C	N/A
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral,	Add to the IPO list	C	N/A

CY 2023 CPT Code	CY 2023 Long Descriptor	Action	CY 2023 OPPS Final Status Indicator	CY 2023 OPPS Final APC Assignment
	umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible			
49618	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, Cincarcerated or strangulated	Add to the IPO list	C	N/A
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible	Add to the IPO list	C	N/A
49622	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated	Add to the IPO list	C	N/A

X. Nonrecurring Policy Changes

A. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

1. Payment for Mental Health Services Furnished as Medicare Telehealth Services or by Rural Health Clinics and Federally Qualified Health Centers

Under the Physician Fee Schedule (PFS), Medicare makes payment to professionals and other suppliers for physicians' services, including certain diagnostic tests and preventive services. Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of Medicare telehealth services, all of which must ordinarily be furnished in person, when they are instead furnished using interactive, real-time telecommunications technology. Sections 1834(m)(4)(D) and (E) of the Act specify the types of health care professionals who can furnish and be paid for Medicare telehealth services (referred to as distant site physicians and practitioners). Section 1834(m)(4)(C) also generally limits the types of settings and geographic locations where a beneficiary can receive telehealth services (referred to as originating sites) to medical care settings in rural areas.

Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipated that health care practitioners would develop new approaches to providing care using various forms of technology when they are not physically present with the patient. We established several flexibilities to accommodate these changes in the delivery of care. For Medicare telehealth services, using waiver authority under section 1135(b)(8) of the Act in response to the PHE for the COVID–19 pandemic, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of

practitioners who may furnish telehealth services, for the duration of the PHE. We also used waiver authority to allow certain telehealth services to be furnished via audio-only telecommunications technology during the PHE.

Division CC, section 123 of the Consolidated Appropriations Act, 2021 (CAA, 2021), modified the circumstances under which payment is made under the PFS for mental health services furnished via telehealth technology following the PHE. Specifically, section 123 removed the geographic originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. These amendments were implemented in the CY 2022 PFS final rule (86 FR 65055 through 65059). In the CY 2022 PFS final rule we also implemented a similar policy for mental health visits furnished by staff of RHCs and FQHCs (86 FR 65207 through 65211).

2. Hospital Payment for Mental Health Services Furnished Remotely During the PHE for COVID-19

For services that are not paid under the PFS, there is no statutory provision similar to section 1834(m) that addresses payment for services furnished by hospitals or other institutional providers to beneficiaries who are not physically located in the hospital or facility. CMS does pay, however, for certain covered OPD services that do not require the beneficiary's physical presence in the hospital. In CY 2015, CMS began paying for CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute

exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored), which describes non-face-to-face care management services furnished by clinical staff under the direction of a physician or other qualified health professional over the course of a calendar month to a beneficiary who is not physically in the hospital (see Addendum B at: www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-FC). In CY 2019, the OPPS began making payment for certain remote monitoring services, which similarly involve a beneficiary who is not physically in the hospital but who is using a monitoring device that transmits data to hospital staff (see Addendum B at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC).

In many cases, hospitals provide hospital outpatient mental and behavioral health services (collectively hereafter, mental health services) that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, and other counseling services. For some of these types of professionals (for example, certain mental health counselors such as marriage and family therapists or licensed professional counselors), the Medicare statute does not have a benefit category that would allow them to bill independently for their services. These services can, in many cases, be covered when furnished by providers such as hospitals and paid under the OPPS.

As we explained in the interim final rule with comment period published on May 8, 2020, in the **Federal Register** titled ‘‘Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the

Skilled Nursing Facility Quality Reporting Program'' (the May 8th COVID–19 IFC) (85 FR 27550, 27563), outpatient mental health services, education, and training services require communication and interaction between the patient and the clinical staff providing the service. We stated that facility staff can effectively furnish these services using telecommunications technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We further explained that blanket waivers in effect during the COVID–19 PHE allow the hospital to consider the beneficiary's home, and any other temporary expansion location operated by the hospital during the PHE, to be a provider-based department (PBD) of the hospital, so long as the hospital can ensure the location meets all the conditions of participation to the extent they are not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognized the ability of the hospital's clinical staff to continue to deliver these services even when the beneficiary is not physically located in the hospital. Therefore, in the May 8th COVID–19 IFC (85 FR 27564), we made clear that when a hospital's clinical staff are furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We referred to this policy as Hospitals without Walls (HWW). We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service. We note that this policy is being finalized elsewhere in this final rule with comment period.

3. Comment Solicitation in the CY 2022 OPPS/ASC Proposed Rule

In the CY 2022 OPPS/ASC proposed rule (86 FR 63748 through 63750) we sought comment on the extent to which hospitals have been relying on the HWW policy to bill for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital. We stated that, given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through use of that technology, we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes.

We sought comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE. We sought comment on whether, during the PHE, hospitals have experienced a similar increase in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology. We also sought comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communications technology to provide mental health services to beneficiaries in their homes.

In response to our comment solicitation, we received approximately 60 comments that were predominantly in support of continuing OPPS payment for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital through the use of communications technology as a permanent policy post-PHE. These comments stated that the expansion of virtual

care broadly during the PHE has been instrumental in maintaining and expanding access to mental health services during the PHE.

4. Current Crisis in Mental Health and Substance Use Disorder

During the COVID-19 pandemic, the number of adults reporting adverse behavioral health conditions has increased sharply, with higher rates of depression, substance use, and self-reported suicidal thoughts observed in racial and ethnic minority groups.[117] According to CDC data "[d]uring August 19, 2020–February 1, 2021, the percentage of adults with symptoms of an anxiety or a depressive disorder during the past 7 days increased significantly (from 36.4% to 41.5%), as did the percentage reporting that they needed but did not receive mental health counseling or therapy during the past 4 weeks (from 9.2% to 11.7%)".[118]

In addition to the mental health crisis exacerbated by the COVID-19 pandemic, the United States is currently in the midst of an ongoing opioid PHE, which was first declared on October 26, 2017, by former Acting Secretary Eric D. Hargan, and most recently renewed by Secretary Xavier Becerra on April 4, 2022**,** and is facing an overdose crisis as a result of rising polysubstance use, such as the co-use of opioids and psychostimulants (for example, methamphetamine, cocaine). Recent CDC estimates of overdose deaths now exceed 107,000 for the 12-month period ending in December 2021[119], with overdose death rates surging among Black and Latino Americans.[120] While overdose deaths were already increasing in the months preceding the COVID-19 pandemic, the latest numbers suggest an acceleration of overdose deaths during the pandemic. Recent increases in overdose deaths have reached historic highs in

[117] https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm
[118] https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm
[119] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[120] Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. Drug Science, Policy and Law. doi:10.1177/2050324520940428.

this country.[121] According to information provided to CMS by interested parties, these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, as well as treatment disruptions, social isolation, and other hardships imposed by the COVID-19 pandemic; but they also reflect the longstanding inadequacy of our healthcare infrastructure when it comes to preventing and treating substance use disorders (SUD) (for example, alcohol, cannabis, stimulants and opioid SUDs). Even before the COVID-19 pandemic began, in 2019, more than 21 million Americans aged 12 or over needed treatment for a SUD in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.[122]

According to the Commonwealth Fund, the provision of behavioral health services via communications technology has a robust evidence base; and numerous studies have demonstrated its effectiveness across a range of modalities and mental health diagnoses (for example, depression, SUD). Clinicians furnishing tele-psychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (for example, immobilizing depression, anxiety, agoraphobia, and/or time consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy and therefore decrease stigma-related barriers to treatment. This flexibility could potentially bring care to many more patients in need, as well as enhance ease of scheduling,

[121] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[122] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

decrease rate of no-shows, increase understanding of family and home dynamics, and protect patients and practitioners with underlying health conditions.[123]

5. CY 2023 OPPS Payment for Mental Health Services Furnished Remotely by Hospital Staff

a. Designation of Mental Health Services Furnished to Beneficiaries in Their Homes as Covered OPD Services

During the PHE for COVID-19, many beneficiaries may be receiving mental health services in their homes from a clinical staff member of a hospital or CAH using communications technology under the flexibilities we adopted to permit hospitals to furnish these services. After the PHE ends, absent changes to our regulations, the beneficiary would need to physically travel to the hospital to continue receiving these outpatient hospital services from hospital clinical staff. We are concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided remotely by hospital staff and, during the PHE, have become accustomed to receiving these services in their homes. We are also concerned about potential disruptions to continuity of care in instances where beneficiaries' inability to continue receiving these mental health services in their homes would lead to loss of access to a specific practitioner with whom they have established clinical relationships. We believe that, given the current mental health crisis, the consequences of loss of access could potentially be severe. We also note that beneficiaries' ability to receive mental health services in their homes may help expand access to care for beneficiaries who prefer additional privacy for the treatment of their condition. We also believe that, given the changes in payment policy for mental health services via telehealth by physicians and practitioners under the PFS and mental health visits furnished by staff of RHCs and FQHCs, using interactive, real-

[123] https://www.commonwealthfund.org/blog/ 2020/using-telehealth-meet-mental-health-needsduring-covid-19-crisis

time telecommunications technology, it is important to maintain consistent payment policies across settings of care so as not to create payment incentives to furnish these services in a specific setting.

Therefore, we proposed to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services that are among the "covered OPD services" designated by the Secretary as described in section 1833(t)(1)(B)(i) of the Act and for which payment is made under the OPPS. To effectuate payment for these services, we proposed to create OPPS-specific coding to describe these services. The proposed code descriptors specified that the beneficiary must be in their home and that there is no associated professional service billed under the PFS. We noted that, consistent with the conditions of participation for hospitals at 42 CFR 482.11(c), all hospital staff performing these services must be licensed to furnish these services consistent with all applicable State laws regarding scope of practice. We also proposed that the hospital clinical staff be physically located in the hospital when furnishing services remotely using communications technology for purposes of satisfying the requirements at 42 CFR 410.27(a)(1)(iii) and § 410.27(a)(1)(iv)(A), which refer to covered therapeutic outpatient hospital services incident to a physician's or nonphysician practitioner's service as being "in" a hospital outpatient department. We solicited comment on whether requiring the hospital clinical staff to be located in the hospital when furnishing the mental health service remotely to the beneficiary in their home would be overly burdensome or disruptive to existing models of care delivery developed during the PHE, and whether we should revise the

regulatory text in the provisions cited above to remove references to the practitioner being "in" the hospital outpatient department. Please see Table 66 for the final codes and their descriptors.

TABLE 66: C-CODE NUMBERS AND LONG DESCRIPTORS

HCPCS Code	Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

When beneficiaries are in their homes and not physically within the hospital, we do not believe that the hospital is accruing all the costs associated with an in-person service and as such the full OPPS rate may not accurately reflect these costs. We believe that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resembles the PFS payment amount for similar services when performed in a facility, which reflects the time and intensity of the professional work associated with performing the mental health service but does not reflect certain practice expense costs, such as clinical labor, equipment, or supplies.

Therefore, we proposed to assign placeholder HCPCS codes CXX78 and CXX79 to APCs based on the PFS facility payment rates for CPT codes 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face;

initial 30 minutes), respectively. We explained that we believe that the APC series that is most clinically appropriate would be the Health and Behavior Services APC series. For CY 2022, CPT code 96159 has a PFS facility payment rate of around $20 while CPT code 96158 has a PFS facility payment rate of around $60. We noted that if we use these PFS payment rates to approximate the costs associated with furnishing C7900 and C7901, these codes should be placed in APC 5821 (Level 1 Health and Behavior Services) and APC 5822 (Level 2 Health and Behavior Services), respectively. As C7902 is an add-on code, payment would be packaged; and the code would not be assigned to an APC. See Table 67 for the final SI and APC assignments and payment rates for HCPCS codes C9700-C7902 (placeholder HCPCS codes CXX78-CXX80 in the proposed rule).

TABLE 67: FINAL CY 2023 SI, APC ASSIGNMENT AND GEOMETRIC MEAN COST FOR HCPCS CODE C7900-C7902

HCPCS Code	Short Descriptor	Proposed SI	Proposed Proxy Service	PFS Facility Rate	Proposed APC	APC GMC
C7900	HOPD mntl hlt, 15-29 min	S	96159	$19.52	5821	$30.48
C7901	HOPD mntl hlt, 30-60 min	S	95158	$56.56	5822	$77.67
C7902	HOPD mntl hlt, ea addl	N	N/A	N/A	N/A	N/A

We solicited comment on the designation of mental health services furnished remotely to beneficiaries in their homes as covered OPD services payable under the OPPS, and on these proposed codes, their proposed descriptors, the proposed HCPCS codes and PFS facility rates as proxies for hospital costs, and the proposed APC assignments for the proposed codes. We stated that we recognize that, while mental health services have been paid under the OPPS when

furnished by hospital staff in person to beneficiaries physically located in the hospital, the ability to provide these services remotely via communications technology when the beneficiary is at home is a new model of care delivery and that we could benefit from additional information to assist us to appropriately code and pay for these services. We invited additional information from commenters on all aspects of this proposal. We stated that we will also monitor uptake of these services for any potential fraud and/or abuse. Finally, we noted this proposal would also allow these services to be billed by CAHs, even though CAHs are not paid under the OPPS.

Comment: Many commenters supported our proposal to designate mental health services furnished by hospital staff to beneficiaries in their homes through communication technology as covered OPD services. Commenters stated that this policy would permit beneficiaries to maintain access to mental health services furnished through PHE-specific flexibilities and that it has the potential to even expand access, particularly in areas where there is a shortage of in-person mental health care. A few commenters requested that CMS allow other services, such as services provided for the treatment of immunocompromised patients, to be furnished by hospital staff to beneficiaries in their homes through the use of telecommunications technology for other types of services beyond those described by the proposed HCPCS codes.

Response: We thank commenters for their support for this proposal. We will consider any expansions to this policy for future rulemaking.

Comment: Some commenters supported the creation of Medicare-specific HCPCS codes to describe these services, while others stated that the use of C-codes was confusing because existing CPT codes described similar services and did not represent the whole range of mental health services and staff that furnish them in a HOPD. Some commenters recommended that

CMS use existing CPT codes and create a modifier to identify when the service is furnished remotely to a beneficiary in their home.

Response: We thank commenters for their support. While we understand that there may be some challenges surrounding when it would be appropriate to bill a Medicare-specific C-code where there are existing CPT codes that describe a similar service, however we believe that creating new codes rather than relying on existing CPT codes will reduce confusion because the CPT codes could also be billed by the hospital to account for the costs hospitals incurred when there is an associated professional service.. Furthermore, creation of Medicare-specific coding will allow CMS to monitor these services and make refinements to the coding to more accurately reflect clinical practice.

Comment: A few commenters supported the proposed payment rates, while many others stated that the proposed rates did not accurately capture all of the costs to the hospital of providing these services. These commenters stated that, even if the beneficiary is not physically in the hospital, the hospital would still be accruing costs associate with staffing and technology and that using the facility payment rate under the PFS is inappropriate and would not account for the additional costs to the hospital of providing these services. Some commenters supported the use of the facility payment rate under the PFS to inform the APC-assignment of these services but recommended that CMS compare them to CPT codes 90832 (Psychotherapy, 30 minutes with patient) through 90838 (Psychotherapy, 60 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)), as the commenters believe these codes better reflect the work and costs associated with care, which are consistent across physician office and hospital settings.

Response: We continue to believe that the resources associated with hospital staff furnishing mental health services to beneficiaries in their homes through telecommunications technology is better accounted for through the facility payment rate under the PFS, and that using this payment rate to inform the APC assignment is a reasonable methodology until such time as we have claims data for these services. We acknowledge that there are likely costs to the hospital other than the time of the hospital staff providing the service, including the amount of infrastructure needed to provide the service; however, we believe these costs are likely minimal given that the beneficiary is in their home and not in the hospital.

Regarding the alternative codes commenters suggested we use to make appropriate APC assignments for the proposed C codes, we note that we do not believe the OPPS rates for these services serve as an appropriate crosswalk for the new mental health codes because these psychotherapy codes are for services performed at the hospital, not remotely.

Comment: Most commenters recommended that CMS revise the requirements at 42 CFR 410.27(a)(1)(iii) and § 410.27(a)(1)(iv)(A), which refer to covered therapeutic outpatient hospital services incident to a physician's or nonphysician practitioner's service as being “in” a hospital outpatient department to remove references to the services being “in” the hospital. These commenters stated that this would allow for maximum flexibility for practitioners and could increase access to mental health services. One commenter requested clarification as to whether the supervising physician would have to be physically located at the hospital to meet general supervision requirements.

Response: We appreciate the additional information provided by commenters. We agree that not requiring the staff providing the mental health service to the beneficiary in their home to be physically in the hospital would likely maximize flexibility, particularly in areas where there

is a shortage of healthcare practitioners. Therefore, we are finalizing an amendment to 42 CFR 410.27(a)(1)(iii) to add the phrase "except for mental health services furnished to beneficiaries in their homes through the use of communication technology" and § 410.27(a)(1)(iv)(A) to add the phrase "or through the use of communication technology for mental health services." The physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

Comment: A few commenters requested that CMS clarify that when these services are furnished by hospitals that are owned or operated by the Indian Health Service, Indian Tribes, or Tribal Organizations, they are also covered, but will be paid at the applicable OMB rate that is established and published annually by the Indian Health Service rather than under the OPPS, in accordance with 42 CFR. § 419.20(b) and CMS's longstanding practice.

Response: IHS facilities may be paid at the applicable all inclusive payment rate established and published annually by the Indian Health Service rather than under the OPPS, in accordance with 42 CFR. § 419.20(b) when billing for these services.

After consideration of the public comments we received, we are finalizing as proposed to assign HCPCS codes C7900 and C7901 to APCs based on the PFS facility payment rates for CPT codes 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes), respectively. We are finalizing our proposal with modification to clarify at 42 CFR 410.27(a)(1)(iii) and § 410.27(a)(1)(iv)(A) that

mental health services provided to beneficiaries in their homes through communication technology are exempt from the requirement that therapeutic hospital or CAH services must be furnished in a hospital or CAH or in a department of the hospital or CAH.

b. Periodic In-Person Visits

Section 123(a) of the CAA, 2021 also added a new subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a Medicare telehealth service furnished in the patient's home for purposes of diagnosis, evaluation, or treatment of a mental health disorder unless the physician or practitioner furnishes an item or service in person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. In the CY 2022 PFS final rule, we finalized that, after the first mental health telehealth service in the patient's home, there must be an in-person, non-telehealth service within 12 months of each mental health telehealth service—but also finalized a policy to allow for limited exceptions to the requirement. Specifically, if the patient and practitioner agree that the benefits of an in-person, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service, and the basis for that decision is documented in the patient's medical record, the in-person visit requirement will not apply for that 12-month period (86 FR 65059). We finalized identical in-person visit requirements for mental health visits furnished through communications technology for RHCs and FQHCs.

In the interest of maintaining similar requirements between mental health visits furnished by RHCs and FQHCs via communications technology, mental health telehealth services under the PFS, and mental health services furnished remotely under the OPPS, we proposed to require

that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also proposed the same exceptions policy as was finalized in the CY 2022 PFS final rule, specifically, that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it. Exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. Hospitals must also document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies.

Section 304(a) of Division P, Title III, Subtitle A of the Consolidated Appropriations Act, 2022 (Pub. L. 117-103, March 15, 2022) amended section 1834(m)(7)(B)(i) of the Act to delay the requirement that there be an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and at subsequent intervals as determined by the Secretary, until the 152nd day after the emergency period described in section 1135(g)(1)(B)

(the PHE for COVID-19) ends. In addition, Section 304 of the Consolidated Appropriations Act, 2022 (CAA, 2022), delayed until 152 days after the end of the PHE similar in-person visit requirements for remotely furnished mental health visits furnished by RHCs and FQHCs. In the interest of continuity across payment systems so as to not create incentives to furnish mental health services in a given setting due to a differential application of additional requirements, and to avoid any burden associated with immediate implementation of the proposed in-person visit requirements, we proposed that the in-person visit requirements would not apply until the 152nd day after the PHE for COVID-19 ends.

Comment: A few commenters supported requirements for in-person visits; however, most opposed the proposal, particularly to require an in-person visit within 6 months prior to the first telehealth service. Commenters stated that CMS should defer to the clinical judgement of the treating practitioner, who is in the best position to understand the individual needs of their patients. Commenters appreciated that CMS proposed to allow exceptions to the subsequent 12-month visit requirement if the patient and practitioner agree that the benefits of an in-person, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service, and the basis for that decision is documented in the patient's medical record.

Response: In section II.D.1.e of the CY 2023 PFS final rule entitled "Implementation of Telehealth Provisions of the Consolidation Appropriations Acts, 2021 and 2022", CMS clarifies that for purposes of the requirement that an in-person visit required within 6 months prior to the initial mental health telehealth services, this requirement does not apply to beneficiaries who began receiving mental health telehealth services in their homes during the PHE or during the 151-day period after the end of the PHE. The requirement for an in-person visit within 6 months

of the initial telehealth mental health services takes effect only for telehealth mental health services beginning after the 152nd day after the end of the PHE. For reasons stated in the proposed rule, we believe it is important to maintain similar standards for mental health services furnished to beneficiaries in their homes through the use of telecommunications systems paid under OPPS. Therefore, we are making the same clarification; however, for patients newly receiving mental health services furnished remotely post-PHE, we continue to believe that the initial in-person visit within 6 months prior to the first remote mental health service is crucial to ensure the safety and clinical appropriateness of the following remote mental health services. We also reiterate that for both patients who began receiving mental health services in their homes during the PHE and those who began treatment post-PHE, we expect that these beneficiaries will receive an in-person, non-telehealth service every subsequent 12 months and that exceptions to this requirement will be documented in the patient's medical record.

After consideration of the public comments we received, we are finalizing as proposed, and clarifying that beneficiaries who began receiving mental health telehealth services in their homes during the PHE or the 151-day period after the end of the PHE before the in-person visit requirements take effect do not need to have an in-person, non-telehealth service within 6 months prior to receiving mental health service in their homes. Instead, the requirement to receive an in-person visit within 12 months of each remote mental health telehealth service would apply.

c. Audio-only Communication Technology

Section 1834(m) of the Act outlines the requirements for PFS payment for Medicare telehealth services that are furnished via a "telecommunications system," and specifies that, only for purposes of Medicare telehealth services furnished through a Federal telemedicine

demonstration program conducted in Alaska or Hawaii, the term ''telecommunications system'' includes asynchronous, store-and-forward technologies. We further defined the term, "telecommunications system," in the regulation at § 410.78(a)(3) to mean an interactive telecommunications system, which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communications between the patient and distant site physician or practitioner.

During the PHE for COVID–19, we used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology. Therefore, for certain services furnished during the PHE for COVID–19, we make payment for these telehealth services when they are furnished using audio-only communications technology. In the CY 2022 PFS final rule, we stated that, given the generalized shortage of mental health care professionals[124] and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, we believed beneficiaries may have come to rely upon the use of audio-only communications technology in order to receive mental health services, and that a sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to care (86 FR 65059). Due to these concerns, we modified the definition of interactive telecommunications system in § 410.78(a)(3) for services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home to include two-way, real-time audio-only communications technology in instances where the physician or practitioner

[124] https://bhw.hrsa.gov/data-research/review-health-workforceresearch

furnishing the telehealth service is technically capable to use telecommunications technology that includes audio and video, but the beneficiary is not capable of, or did not consent to, use two-way, audio/video technology. We stated that we believed that this requirement would ensure that mental health services furnished via telehealth are only conducted using audio-only communications technology in instances where the use of audio-only technology is facilitating access to care that would be unlikely to occur otherwise, given the patient's technological limitations, abilities, or preferences (86 FR 65062). We also made a conforming change for purposes of furnishing mental health visits through telecommunications technology for RHCs and FQHCs. We limited payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communications technology in instances where the beneficiary is not capable of, or does not wish to use, two-way, audio/video technology.

In order to maximize accessibility for mental health services, particularly for beneficiaries in areas with limited access to broadband infrastructure, and in the interest of policy continuity across payment systems so as to not create incentives to furnish mental health services in a given setting due to a differential application of additional requirements, we proposed a similar policy for mental health services furnished remotely by hospital clinical staff to beneficiaries in their homes through communications technology. Specifically, we proposed that hospital clinical staff must have the capability to furnish two-way, audio/video services but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences.

Comment: Commenters were very supportive of CMS's proposal to allow for audio-only communication technology in instances where the beneficiary did not have access to, or did not wish to use, two-way, audio/video communication technology. A few commenters disagreed with CMS's proposal to require the practitioner to have the capacity to furnish services via two-way, audio/video, stating that this may be problematic for practitioners in rural areas or areas without access to reliable broadband.

Response: As we stated in the CY 2022 PFS final rule, because services furnished via communication technology are generally analogous to and must include the elements of the in-person service, it is generally appropriate to continue to require the use of two-way, real-time audio/video communications technology to furnish the services (86 FR 65061-65062). Therefore, we are maintaining the requirement that hospital staff must have the technical capability to use an interactive telecommunications system that includes two-way, real-time, interactive audio and video communications at the time that an audio-only mental health service is furnished.

After consideration of the public comments we received, we are finalizing our proposal regarding use of audio-only communications technology as proposed.

B. Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance Use Disorder (SUD) Treatment Furnished by Intensive Outpatient Programs (IOPs)

There are a range of services described by existing coding under the PFS and OPPS that can be billed for treatment of mental health conditions, including SUD, such as individual, group, and family psychotherapy. Over the past several years, in collaboration with interested parties and the public, we have provided additional coding and payment mechanisms for mental health care services paid under the PFS and OPPS. For example, in the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled

episode of care for the treatment of Opioid Use Disorder (OUD) (HCPCS codes G2086-G2088). In the CY 2021 PFS final rule, we finalized expanding the bundled payments described by HCPCS codes G2086–G2088 to be inclusive of all SUDs (85 FR 84642 through 84643). These services are also paid under the OPPS.

Additionally, in the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing bundled payments for episodes of care for the treatment of OUD furnished by Opioid Treatment Programs (OTPs). Medicare also covers services furnished by inpatient psychiatric facilities and partial hospitalization programs (PHP). PHP services can be furnished by a hospital outpatient department or a Medicare-certified Community Mental Health Center (CMHC). PHPs are structured to provide intensive psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in §1861(ff) of the Social Security Act (the Act). According to the Medicare Benefit Policy Manual, Chapter 6, Section 70.3, the treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program and is at a level more intense than outpatient day treatment or psychosocial rehabilitation. PHPs work best as part of a community continuum of mental health services, which range from the most restrictive inpatient hospital setting to less restrictive outpatient care and support.

We understand that, in some cases, people who do not require a level of care for mental health needs that meets the standards for PHP services nonetheless require intensive services on an outpatient basis. For example, according to SAMHSA's *Advisory on Clinical Issues in Intensive Outpatient Treatment for Substance Use Disorders*, IOP programs for substance use disorders (SUDs) offer services to clients seeking primary treatment; step-down care from

inpatient, residential, and withdrawal management settings; or step-up treatment from individual or group outpatient treatment. IOP treatment includes a prearranged schedule of core services (e.g., individual counseling, group therapy, family psychoeducation, and case management) for a minimum of nine hours per week for adults or six hours per week for adolescents. SAMSHA further states that the 2019 National Survey of Substance Abuse Treatment Services reports that 46 percent of SUD treatment facilities offer IOP treatment.[125]

We solicited comment on whether these services are described by existing CPT codes paid under the OPPS, or whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs, for Medicare beneficiaries. We welcomed additional, detailed information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, the range of practitioner types that typically furnish those services, and any other relevant information, especially to the extent it would inform our ability to ensure that Medicare beneficiaries have access to this care.

Comment: Commenters were generally supportive of CMS providing payment for IOP services. Some commenters stated that existing HCPCS coding was adequate to describe IOP services, while other commenters stated that it was necessary for the OPPS to create Medicare-specific coding to describe these services.

Response: We thank commenters for the information provided and will consider their input for future rulemaking.

C. Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

[125] https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep20-02-01-021.pdf

In the interim final rule with comment period titled ‘‘Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency’’ published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in § 400.200, the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation (PR), cardiac rehabilitation (CR), and intensive cardiac rehabilitation (ICR) services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2022 PFS final rule, CMS added CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac

rehabilitation; with or without continuous ecg monitoring; without exercise, per session) to the Medicare Telehealth Services List on a Category 3 basis (86 FR 65055). These services will not be able to be furnished as Medicare telehealth services to beneficiaries in their homes after the PHE ends because of the statutory restrictions at section 1834(m)(4)(C)(ii) of the Act on eligible originating sites. However, the inclusion of these codes on the Medicare Telehealth Services List will enable payment for these services when furnished in full using two-way, audio/video communications technology when the beneficiary is in a medical setting that can serve as a telehealth originating site and meet the geographic requirements specified in section 1834(m)(4)(C). These services will remain on the Medicare Telehealth Services List through the end of CY 2023.

In order to effectuate a similar policy under the OPPS, where PR, CR and ICR rehabilitation services currently may be furnished during the PHE to beneficiaries in hospitals under direct supervision of a physician where the supervising practitioner is immediately available to be present via two-way, audio/video communications technology, we solicited comment on whether we should continue to allow direct physician supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology through the end of CY 2023. We also solicited comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

Comment: We received many comments describing the value of rehabilitation services furnished to beneficiaries in their homes. Commenters requested that CMS maintain both the Hospitals Without Walls flexibility to make beneficiaries' homes provider-based departments of the hospital, and the definition of direct supervision to include the presence of the supervising

practitioner through two-way, audio/video communication technology. Commenters requested that these changes be made permanent or, at the very least, maintained through the end of CY 2023.

Response: We thank commenters for the additional information. We do not have the flexibility to continue HWW beyond the conclusion of the PHE as it was accomplished through PHE-specific waivers that will expire when the PHE ends. This means that, following the expiration of the PHE, pulmonary, cardiac, and intensive cardiac rehabilitation services will no longer be able to be provided in a beneficiary's home. However, we note that the CPT codes describing cardiac, pulmonary, and intensive cardiac rehabilitation services were added to the Medicare telehealth services list in the CY 2022 PFS Final Rule. This will allow beneficiaries who live in rural areas to continue to receive these services through telehealth at medical facilities from 152 days after the conclusion of the PHE until the end of 2023 and beneficiaries in non-rural areas and at home to receive these services via telehealth for 151 days post-PHE. In the interest of maintaining a similar policy under the OPPS, we are finalizing extending the revised definition of direct supervision to include the presence of the supervising practitioner through two-way, audio/video when the beneficiary is physically located in the hospital until December 31, 2023.

D. Use of Claims Data for CY 2023 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A of the CY 2023 OPPS/ASC proposed rule (87 FR 44504), section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPPS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative

payment weights, and the wage and other adjustments described in paragraph (2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

When updating the OPPS payment rates and system for each rulemaking cycle, we primarily use two sources of information: the outpatient Medicare claims data and Healthcare Cost Report Information System (HCRIS) cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and set appropriate payment rates. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2023 OPPS/ASC proposed rule ratesetting, the best available claims data would typically be the CY 2021 calendar year outpatient claims data processed through December 31, 2021. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. The best available cost report data used in developing the OPPS relative weights would ordinarily be from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking. For example, under ordinary circumstances, for CY 2023 OPPS ratesetting, that would be cost report data from HCRIS extracted in December 2021, which would contain many cost reports ending in FY 2020 and 2021 based on each hospital's cost reporting period.

As discussed in the CY 2022 OPPS final rule with comment period, the standard hospital data we would have otherwise used for purposes of CY 2022 ratesetting included significant effects from the COVID–19 PHE, which led to a number of concerns with using this data for

CY 2022 ratesetting (86 FR 63751 through 63754). In section X.E. of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), we noted a number of changes in the CY 2020 OPPS claims data we would ordinarily use for ratesetting, likely as a result of the PHE. These changes included overall aggregate decreases in claims volume (particularly those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID-19 specimen collection and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the effects we observed from COVID–19 PHE-related factors in our claims and cost report data, as well as the increasing number of Medicare beneficiaries vaccinated against COVID–19, which we believed might make the CY 2022 outpatient experience closer to CY 2019 rather than CY 2020, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, were a better approximation of expected CY 2022 hospital outpatient services. Therefore, in the CY 2022 OPPS/ASC final rule with comment period, we established a policy of using CY 2019 claims data and cost reports prior to the PHE in ratesetting for the CY 2022 OPPS with certain limited exceptions, such as where CY 2019 data were not available (86 FR 63753 through 63754).

Given the effects the virus that causes COVID-19 has had on Medicare claims and cost report data the last 2 years, coupled with the expectation for future variants, we believe that it is reasonable to assume that there will continue to be some limited influence of COVID-19 PHE effects on the data we use for ratesetting. We reviewed the CY 2021 claims data available for CY 2023 OPPS proposed rule ratesetting, similar to the review we conducted for CY 2022 OPPS

ratesetting, to determine the degree to which the effects of the COVID-19 PHE had continued or subsided in our claims data as well as what claims and cost report data would be appropriate for CY 2023 OPPS ratesetting. In general, we continued to see limited effects of the PHE, with service volumes generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims. At the aggregate level, there continued to be a decrease in the overall volume of outpatient hospital claims during the PHE, with approximately 10 percent fewer claims usable for ratesetting purposes when compared to the CY 2019 outpatient claims volume. This number compares to the 20 percent reduction that we observed last year in the CY 2020 claims. Similarly, this moderate return to more normal volumes extended across claims volume and applies to a majority of the clinical APCs in the OPPS, suggesting that, while clinical and billing patterns had not quite returned to their pre-PHE levels, they were beginning to do so.

Similar to what we observed in CY 2022 OPPS ratesetting, we continued to see broad changes as a result of the PHE, including in the APCs for hospital emergency department and clinic visits. Among those APCs, the decrease in volume was approximately 20 percent, some of which may be related to changing practice patterns during the PHE. For example, we saw a significant increase in the use of the HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims during the first year of the PHE, with approximately 35,000 services billed in the CY 2019 OPPS claims and 2.1 million services billed in the CY 2020 OPPS claims. However, in the CY 2021 OPPS claims available for proposed rule ratesetting, we saw a slight decline in volume to about 1.6 million services and noted that we would expect slightly

more claims in the final rule data. Our view was that a large part of the volume increase in CY 2020 was the result of site of service changes due to the PHE.

In other cases, we saw claims data changes associated with specific services that were furnished more frequently during the PHE. For example, we identified two notable changes in the claims data for APC 5731 (Level 1 Minor Procedures) and APC 5801 (Ventilation Initiation and Management). In the CY 2020 claims data reviewed last year, we noted a significant increase in the services provided under APC 5801, from 10,340 units provided in CY 2019 claims to 12,802 units in the CY 2020 claims. However, in the CY 2021 claims available for NPRM ratesetting, there were only approximately 8,596 units of service provided through this APC, an amount even lower than the service volume we observed in CY 2019 claims.

In the case of APC 5731, HCPCS code C9803 was made effective for services furnished on or after March 1, 2020, through the interim final rule with comment period titled ‘‘Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program’’ (85 FR 27602 through 27605) to describe COVID–19 specimen collection. In the CY 2021 claims data available for ratesetting for the CY 2023 OPPS/ASC proposed rule (87 FR 44681), there were approximately 1,367,531 single claims available for ratesetting purposes for HCPCS code C9803, which, if this code were included in ratesetting, would make up 93 percent of the claims used to set the payment rate for APC 5731 (Leve1 1 Minor Procedures APC). Under current policy, HCPCS code C9803 is a temporary code that was created to support increased testing solely during the COVID-19 PHE. Given that this is a temporary code only in use for the duration of the PHE, that the PHE could conclude before CY 2023, and that the large volume of services for this code in the CY 2021 claims data would

dictate the payment rate for APC 5731 if we included this code in ratesetting, we did not believe including the claims data for this code in establishing CY 2023 payment rates would be appropriate. Our CY 2022 final policies on data used in ratesetting were established due to our expectation that the CY 2022 outpatient experience would be more similar to the CY 2019 claims rather than CY 2020 claims. Our proposed rule review of the data for CY 2023 OPPS ratesetting also was based on how well the claims and cost report data may relate to the CY 2023 outpatient experience. It is with similar considerations in mind and our belief that the volume and costs associated with HCPCS code C9803 will not be reflective of the CY 2023 outpatient experience that we believe it is appropriate to exclude claims that would typically be used to model the cost of HCPCS code C9803 from ratesetting.

Based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that many of the outpatient service volumes had partially returned to their pre-PHE levels. While the effects of the COVID-19 PHE remain at both the aggregate and service levels for certain services, as discussed earlier in this section and in section I.F of the FY 2023 IPPS proposed rule (87 FR 28123 through 28125), we recognized that future COVID-19 variants may have potentially varying effects. Therefore, we explained that we believe it is reasonable to assume that there would continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPPS ratesetting, similar to the CY 2021 claims data. As a result, we proposed to use the CY 2021 claims for CY 2023 OPPS ratesetting.

We proposed to use cost report data for the CY 2023 OPPS/ASC proposed rule (87 FR 44681) from the same set of cost reports we originally used in the CY 2021 OPPS/ASC final rule for ratesetting, which in most cases included cost reporting periods beginning in CY 2018. We ordinarily would have used the most updated available cost reports available in HCRIS

in determining the proposed CY 2023 OPPS/APC relative weights (as discussed in greater detail in section II.E of the CY 2023 OPPS/ASC proposed rule (87 FR 44681 through 44682)). As previously discussed, if we were to proceed with the standard ratesetting process of using updated cost reports, we would have used approximately 1,000 cost reports with the fiscal year ending in CY 2020, based on each hospital's cost reporting period. Under our historical process of updating cost report data, for the CY 2023 OPPS, the majority of the cost reports in our data would have cost reporting periods that overlap parts of CY 2020. Noting that we observed significant impact at the service level when incorporating these cost reports into ratesetting and the effects on billing/clinical patterns, similar to what we observed in the CY 2020 claims when reviewing them for the CY 2022 OPPS/ASC rulemaking cycle, we believe that it was appropriate to continue to use the same set of cost reports that we used in developing CY 2022 OPPS ratesetting, so as to mitigate the impact of that 2020-based data. We noted that we would continue to review the updated cost report data as they are available.

We also note that, similar to the proposed IPPS outlier policy described in section II.A.4 of the addendum to the FY 2023 IPPS proposed rule (87 FR 28868), we proposed to return to our historical process of using CCRs when determining the fixed-dollar amount threshold, and to adopt the charge and CCR inflation factors developed for the FY 2023 IPPS. For more detail regarding the proposed CY 2023 OPPS outlier policy, see section II.G of the CY 2023 OPPS/ASC proposed rule (87 FR 44681).

As a result of our expectation that the CY 2021 claims that we would typically use would be appropriate for establishing the CY 2023 OPPS, we proposed to use the CY 2021 claims for the CY 2023 OPPS/ASC ratesetting process. However, we proposed to use the cost reports from the June 2020 cost report extract, which contain only pre-PHE data, to remove the effect of the

PHE cost report data on estimated service cost. In addition, we proposed to exclude from ratesetting claims that would be used to model the estimated cost of HCPCS code C9803 in the CY 2023 OPPS/ASC proposed rule (87 FR 44681).

We also considered the alternative of continuing with our standard process of using the most updated claims and cost report data available. While the CY 2021 claims used in ratesetting would be the same as under our proposal, under this alternative our cost reports would also be updated for the most recent extract we typically would use: cost report data extracted from HCRIS in December 2021, which in most cases included cost reporting periods beginning in CY 2018. To facilitate comment on the alternative proposal for CY 2023, we made available the cost statistics and addenda utilizing the CY 2021 claims and updated cost report data we would ordinarily have provided in conjunction with the CY 2023 OPPS/ASC proposed rule. We provided all relevant files that would have changes calculated under this alternative approach including: the OPPS Impact File, cost statistics files, and addenda. The files specific to this alternative configuration were identified by the word "Alternative" in the filenames, similar to our approach in the CY 2022 OPPS/ASC proposed and final rules. We noted that the primary change as a result of the alternative proposed methodology would be in the scaled weights, which were displayed in the addenda. We refer the reader to the CMS website for the CY 2023 OPPS/ASC proposed rule for more information on where these supplemental files are located.

Comment: Many commenters supported our proposed policy to use CY 2021 claims data and the June 2020 cost report extract in CY 2023 OPPS ratesetting, believing that it was based on reasonable assumptions that recognize the unusual nature of CY 2020 claims and cost reports. These commenters generally also opposed the alternative methodology in which we would revert to our typical cost report data update.

Response: We appreciate the commenters' support for our proposal.

Comment: Three commenters believed that we should use more updated data in CY 2023 ratesetting, with one noting the option of using the December 2020 HCRIS extract, one requesting that we use our typical update process, and another recommending an update that would use Q3 2022 data. Another commenter agreed with our proposal to set CY 2023 OPPS rates using 2021 claims and the June 2020 HCRIS extract but believed that a growth estimate/cost inflation adjuster should be applied.

Response: We have concerns about using each of the types of updated data commenters suggested, whether that data is from the cost report extract or claims. While more updated cost report data is available, it has more overlap between the cost reporting periods and the PHE, meaning that using those estimated cost to charge ratios, particularly those with cost reporting periods in 2020, may reflect changes that may not persist in CY 2023 or accurately approximate the CY 2023 outpatient experience. In addition, the June 2020 HCRIS extract is one that we have used in prior cycles and maintains stability in the cost estimation process. While we are using updated CY 2021 claims data, we recognize that there are PHE-related cost report issues, because cost report data usually lag the claims data by a year. Because of similar concerns as those we expressed in the CY 2022 OPPS/ASC final rule (86 FR 63751 through 63754) about the impact of the PHE on our cost report data and as a result, our ratesetting process, we proposed to use the June 2020 HCRIS extract. We note that the commenter's request to use more recent cost report data was associated with a specific service and its estimated costs under that alternative. However, we must consider the effect of use of a particular cost report extract on the relative weights and estimated geometric mean costs for all services, not just certain ones. For these reasons, we continue to believe that the June 2020 HCRIS extract is appropriate for

calculating the CCRs used in CY 2023 OPPS ratesetting because this set of cost report CCRs maintains consistency with cost report data we have previously used in ratesetting and mitigates some of the volatility and effects of the PHE on our data process, as we noted in the CY 2022 OPPS/ASC final rule (86 FR 63751 through 63754) and CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682).

With regard to using more updated claims data, we note that there are two issues. First, we base the ratesetting on a full calendar year of claims because the OPPS operates on a calendar year basis. Using more than a single calendar year of claims would potentially distort the volume of how services are represented as a portion of that calendar year. Second, if we were to solely establish rates based on available CY 2022 claims we would have a substantially smaller set of claims available on which to estimate service cost. Therefore, we do not believe it is appropriate to use more updated data beyond what we have historically used, which are claims data from two years prior to the prospective year for which we are setting OPPS rates.

While we appreciate the request to return to the typical claims and cost report update process for ratesetting, there are issues with using that data because the data may reflect cost volatility and practice patterns specific to the PHE as noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682). As more claims and cost report data become available over time, we will continue to review them and their appropriateness for use in OPPS ratesetting.

We do not agree with the suggestion that we should apply a growth estimate or cost inflation factor. As explained in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754) and in the CY 2023 OPPS proposed rule (87 FR 44680 through 44682), we recognize that there are effects of the PHE on our claims and cost report data. We have tried to utilize a reasonable approach in addressing them through the policies we use for

ratesetting. If we were to apply a growth estimate or cost inflation factor consistently across all available cost data for all services, it would not have any impact because the OPPS relative weights would remain the same. If we were to apply a cost inflation factor only to specific services, it would potentially distort the accuracy of the relative weights. Therefore, we do not believe it is appropriate to apply an additional cost inflation factor to the cost reports we use for CY 2023 OPPS ratesetting.

We recognize that there are effects on the claims and cost report data as a result of the PHE and have applied an approach that accounts for what were some of the more significant effects of them on our data. We do not believe that it is appropriate to include those cost report data, which create significant cost volatility in our CY 2023 OPPS ratesetting process.

Comment: A commenter requested that CMS continue the use of HCPCS code C9803 after the end of the PHE, due to concerns around the degree to which hospitals would make the service available if OPPS payment is not available for it. The commenter also suggested that some portion of claims, based on projections relative to CY 2020 levels of the service, be used for ratesetting purposes.

Response: While we recognize the concern regarding the availability of the service after the PHE, the temporary nature of the code and its specific association with the duration of the PHE suggests that it is unlikely to be necessary for a separate specimen collection payment after the conclusion of the PHE. HCPCS code C9803 was created specifically to support collection of COVID-19 testing specimens by hospitals during the COVID-19 PHE. Once the PHE ends, we believe it will appropriate to pay for the collection of COVID-19 specimens as part of the COVID-19 testing payment, which is consistent with how payment for other laboratory tests is structured. As discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44681) the volume of

claims of this code in APC 5731 (Level 1 Minor Procedures) are such that they would dictate the payment rate. Given that separate payment for this code is only to be made during the PHE, we do not believe including the claims data for this code in establishing CY 2023 payment rates would be appropriate. As a result, we continue to believe that it is appropriate to exclude these claims from CY 2023 OPPS ratesetting.

Comment: A commenter agreed that including the C9803 data in CY 2023 OPPS ratesetting was not appropriate. That commenter noted that, contrary to the proposal to exclude C9803 from CY 2023 OPPS ratesetting, that data was included in ratesetting for APC 5731 (Level 1 Minor Procedures). The commenter's recommendation was that CMS either exclude the data from C9803 from ratesetting to ensure an accurate payment rate or consider establishing a second APC from the codes in the APC, based on distinguishing the two separate APCs based on differences in geometric mean cost between the services in the APC.

Response: We appreciate the commenter's support for our proposal and note that while we proposed to remove the data from CY 2023 OPPS ratesetting, we inadvertently included the cost and volume data for C9803 in establishing the proposed CY 2023 OPPS payment rate for the APC to which it was assigned. HCPCS code C9803 is a temporary code that was created to support increased testing solely during the COVID–19 PHE. Because it is a temporary code that will no longer be utilized after the PHE ends, we believe that it is appropriate to remove the claims for the service from ratesetting for this APC. In this final rule, we will remove the claims that would be used to model payment for C9803 from ratesetting.

After consideration of the public comments we received, we are finalizing our proposed policies to use CY 2021 claims and the June 2020 HCRIS extract in establishing the CY 2023

OPPS rates, as well as to exclude the claims and cost data associated with HCPCSC code C9803 from ratesetting for APC 5731.

E. Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients

1. Background

The regulation at 42 CFR 410.32 provides the conditions of Medicare Part B payment for diagnostic tests. Section 410.32(b) provides the supervision requirements for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests paid under the PFS. Prior to 2020, the regulation allowed only physicians as defined under Medicare law to supervise the performance of these diagnostic tests.

In the interim final rule with comment period published on May 8, 2020, in the Federal Register titled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (the May 8th COVID-19 IFC) (85 FR 27550, 27555 through 27556, 27620), we revised § 410.32(b)(1) to allow, for the duration of the PHE, certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) to supervise the performance of diagnostic tests to the extent they were authorized to do so under their scope of practice and applicable State law.

In the CY 2021 PFS final rule (85 FR 84590 through 84492, 85026), we further revised § 410.32(b)(1) to make the revisions made by the May 8th COVID-19 IFC permanent and to add certified registered nurse anesthetists to the list of nonphysician practitioners permitted to provide supervision of diagnostic tests to the extent authorized to do so under their scope of practice and applicable State law.

As we explained in those final rules, the basis for making these revisions was to both ensure that an adequate number of health care professionals were available to support critical COVID-19-related and other diagnostic testing needs and provide needed medical care during the PHE and to implement policy consistent with section 5(a) of the President's Executive Order 13890 on "Protecting and Improving Medicare for Our Nation's Seniors" (84 FR 53573, October 8, 2019, E.O. 13890), which directed the Secretary to identify and modify Medicare regulations that contained more restrictive supervision requirements than existing scope of practice laws, or that limited healthcare professionals from practicing at the top of their license. We refer readers to the May 8th COVID-19 IFC (85 FR 27555 through 27556, 27620) and CY 2021 PFS final rule (85 FR 84590 through 84492, 85026) for a more detailed discussion of the reasoning behind our revisions to § 410.32.

Section 410.32(b)(1), titled "Basic rule," states that ". . .all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife." Section 410.32(b)(2) provides a list of services that are excepted from the basic rule in § 410.32(b)(1). Section 410.32(b)(3) defines the levels of supervision referenced in § 410.32(b)(1): general supervision (§ 410.32(b)(3)(i)); direct supervision (§ 410.32(b)(3)(ii)); and personal supervision (§ 410.32(b)(3)(iii)). Within these three definitions, only the definition for direct supervision indicates that a "supervising practitioner" other than a physician can provide the required supervision. The definitions for general and personal supervision continue to refer only to a

physician providing the required level of supervision. Although the definitions of general and personal supervision do not specify that a "supervising practitioner" could furnish these levels of supervision, the above-described revisions to the "basic rule" governing supervision of diagnostic tests at § 410.32(b)(1) allow certain nonphysician practitioners to provide general and personal supervision to the extent they are authorized to do so under their scope of practice and applicable State law.

Section 410.28 provides conditions of payment for diagnostic services under Medicare Part B provided to outpatients by, or under arrangements by, hospitals and CAHs, including specific supervision requirements under § 410.28(e) for diagnostic tests in those settings. Section 410.28(e) relies upon the definitions of general, direct (for nonhospital locations) and personal supervision at § 410.32(b)(3)(i) through (iii) by cross-referencing those definitions. As noted above, the term "supervising practitioner" is absent from those definitions, although the "basic rule" at § 410.32(b)(1) allows certain nonphysician practitioners to provide general and personal supervision to the extent they are authorized to do so under their scope of practice and applicable State law. However, § 410.32(b) is explicitly limited to "all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule," and § 410.28(e) does not contain any such "basic rule" to clarify that nonphysician practitioners can provide general and personal supervision.

2. Proposed Revisions to 42 CFR 410.28 and § 410.27

For purposes of clarity and consistency, we proposed to revise § 410.28(e) to clarify that the same nonphysician practitioners that can provide general and personal supervision of diagnostic testing services payable under the PFS under § 410.32(b) can provide supervision of diagnostic testing services furnished to outpatients by hospitals or CAHs. Specifically, we

proposed to revise our existing supervision requirements at § 410.28(e) to clarify that nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists and certified nurse midwives may provide general, direct, and personal supervision of outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable State law.

Another revision that we proposed to § 410.28(e) was to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year in which the PHE ends. The purpose of this proposal was to ensure consistency between the hospital and CAH regulations at § 410.27 and § 410.28 with the physicians' office regulations at § 410.32. Although the proposed rule contained the proposed revisions to the regulatory text of § 410.28(e), regrettably, the above explanation of the reason for the proposed revisions was inadvertently omitted from the preamble of the proposed rule.

We also proposed to replace the cross-references at § 410.28(e) to the definitions of general, direct (for outpatient services provided at a nonhospital location), and personal supervision at § 410.32(b)(3)(i) through (iii) with the text of those definitions as newly designated paragraphs (1), (2)(i), (2)(ii), (2)(iii), and (3) so that they are now contained within § 410.28.

Similarly, since § 410.27, which provides the supervision requirements for therapeutic outpatient hospital and CAH services, also relies on the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii), we proposed to replace the cross-references at § 410.27(a)(1)(iv)(A) and (B) with the text of those definitions so that they are now contained within § 410.27. Additionally, for clarity we proposed to designate the existing definition of

direct supervision and the proposed definition of personal supervision at § 410.27(a)(1)(iv)(B) as § 410.27(a)(1)(iv)(B)(1) and (2), respectively. Finally, since § 410.27(a)(1)(iv)(B) and (D) contain duplicate definitions for direct supervision, we proposed to remove § 410.27(a)(1)(iv)(D) in its entirety and add its language regarding pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services and the virtual presence of a physician through audio/video real-time communications technology during the PHE to the newly designated § 410.27(a)(1)(iv)(B)(1).

We received the following comments in response to our proposal:

Comment: The majority of commenters supported our proposal, citing clarity, consistency, increased patient access to care and allowing nonphysician practitioners to practice at the top of their licenses and clinical training.

Response: We thank commenters for their support for our proposal.

Comment: Two commenters supported the proposal but objected to the continued use of the term "nonphysician practitioner." One commenter suggested that we replace "nonphysician practitioner" with each practitioner's professional title (i.e., "nurse practitioner," "physician assistant," etc.) or, collectively, "advance practice providers" and update all related regulations, guidance and information collection instruments accordingly. The second commenter similarly suggested that we expressly list "physician assistant," "nurse practitioner," and other professionals in the place of "nonphysician practitioner" and accordingly revise all related guidance documents.

Response: We appreciate these comments and agree with the importance of employing the appropriate designations for these practitioners. We note that § 410.27(g) and § 410.28(e) specifically list the professional titles that are included in the term "nonphysician practitioner"

for the purpose of each regulation. It is therefore unnecessary and would be impractical to replace all instances of "nonphysician practitioner" throughout each regulation with a list of each practitioner's professional titles. With respect to replacing "nonphysician practitioner" with "advance practice providers," we understand the importance of using the most relevant and up to date terminology to describe these practitioners. However, as acknowledged by the commenters, "nonphysician practitioner" is used in multiple regulations, guidance and other documents and any change in terminology would need to be considered in light of ensuring consistency across these authorities. We will take this suggestion into consideration for future rulemaking.

Comment: One commenter supported the proposal and requested, for improved clarity and to eliminate inefficiencies or delays in care caused by a misinterpretation of supervision policy, that we revise the definitions for general and personal supervision at § 410.32(b)(2)(i) and § 410.32(b)(2)(iii) to include the "or other supervising practitioner" language contained in the definition for direct supervision at § 410.32(b)(2)(iii). Another commenter suggested that we revise the definitions for general and personal supervision at § 410.32(b)(2)(i) and § 410.32(b)(2)(iii) to specifically reference "physician assistant."

Response: We appreciate the commenters' suggestions but disagree that adding "or other supervising practitioner" or individual professional titles to the definitions for general and personal supervision at § 410.32(b)(2)(i) and § 410.32(b)(2)(iii) would improve clarity or eliminate inefficiencies or delays in care caused by a misinterpretation of supervision policy. As acknowledged by the commenter, the "basic rule" governing supervision of diagnostic tests at § 410.32(b)(1) provides the authority for nonphysician practitioners to provide all three levels of supervision for the purposes of diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests. Since regulations other than § 410.32 rely upon the supervision definitions at §

410.32(b)(2)(i) and § 410.32(b)(2)(iii) and those regulations may or may not allow nonphysician practitioners to provide general or personal supervision, it would be inappropriate to add "or other supervising practitioner" to § 410.32(b)(2)(i) and § 410.32(b)(2)(iii) and doing so would likely result in further misinterpretations of supervision policy.

Comment: Two commenters opposed the proposed change, arguing that nonphysician practitioner skill sets are not interchangeable with those of fully educated and trained physicians and that physicians' more extensive and rigorous educational and training requirements make them uniquely qualified to supervise diagnostic tests. The first commenter maintains that physicians must supervise diagnostic tests to ensure patient safety and the accuracy of test results due to the complexity of certain diagnostic tests and studies demonstrating that nonphysician practitioners order more diagnostic tests, including tests subjecting patients to harmful radiation, than physicians. This commenter also refers to a study that concluded that allowing nurse practitioners and physician assistants to function with independent patient panels under physician supervision in the primary care setting resulted in higher costs, higher utilization of services and lower quality of care as compared to panels of patients with a primary care physician. The second commenter references surveys indicating that patients prefer physicians to lead their health care team and that more patients trust a physician to deliver their medical care in an emergency as compared to a nurse, nurse practitioner or physician assistant. Finally, both commenters argue that expanding the scope of practice of nurse practitioners will not increase patient access to care because the actual practice locations of nurse practitioners reveal that they tend to work in the same large urban areas as physicians.

Response: We acknowledge that physician skill sets are not fully interchangeable with the skill sets of nonphysician practitioners and that the education and training requirements of

physicians differ from nonphysician practitioners. However, we do not agree that the skill sets, education and training of physicians render them solely qualified to supervise diagnostic services. With respect to the commenter's concerns about nonphysician practitioners' abilities to safely and accurately perform diagnostic tests, we note that the proposed regulation explicitly limits nonphysician supervision to that which is permitted under the nonphysician practitioner's scope of practice and state law. Furthermore, nothing in the proposed regulation prohibits or limits physicians from continuing to supervise any and all diagnostic tests. Providers and physicians are free to use their own judgment to determine whether supervision by nonphysician practitioners is appropriate on a systemic, categorical or case-by-case basis.

As to the studies and surveys cited by commenters related to the functioning of nonphysician practitioners with independent patient panels in the primary care setting and patient preferences regarding who leads their care team and provides their emergency care, it is not clear what the relevancy of these are to allowing nonphysician practitioners to supervise diagnostic tests.

Finally, we do not agree with commenters' claim that the practice locations of nurse practitioners demonstrate that patient access to care will not increase by allowing nonphysician practitioners to supervise diagnostic tests. We do not find the evidence submitted by the commenters sufficient to support the commenters' conclusion that most nurse practitioners tend to live in the same urban areas as physicians. Further, even if this evidence was sufficient, it only includes nurse practitioners; it fails to account for those rural areas in which nurse practitioners do reside, where it could be expected that allowing nonphysician practitioners to supervise diagnostic tests would increase patient access to care; and it fails to account for

medically underserved urban areas where it could also be expected that allowing nonphysician practitioners to supervise diagnostic tests would increase patient access to care.

Comment: One commenter supported making the terminology used for supervision definitions consistent but cautioned CMS against what the commenter characterized as "rolling back" supervision guidelines. This commenter argued that the continued proposals and regulatory changes allowing nonphysician practitioners to supervise services of various complexities undermines the expertise of physicians and the value of their work. The commenter also expressed concern that many providers conflate physician supervision with physician work, creating scenarios for abuse and inadequate support for clinical staff. Finally, the commenter requested that CMS consult with interested parties and clinical staff from various specialties capable of speaking to the impact these continued changes have had on services provided to beneficiaries.

Response: We do not agree that allowing certain nonphysician practitioners to supervise diagnostic tests will undermine the expertise of physicians or the value of their work. As discussed above, NPPs may only supervise diagnostic tests to the extent they are permitted to do so under their scope of practice and state law and nothing prohibits physicians from continuing to supervise any and all diagnostic tests. We appreciate the commenter's suggestion that CMS consult with interested parties and clinical staff capable of speaking to the impact of allowing certain nonphysician practitioners to supervise diagnostic tests, and we will consider doing so in the future.

After consideration of the public comments we received, we are finalizing, as proposed, our revisions to replace cross-references at § 410.27(a)(1)(iv)(A) and (B) and § 410.28(e) to the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii) with the text of those

definitions and to revise § 410.28(e) to (1) extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year in which the PHE ends, and (2) clarify that certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law.

F. Coding and Payment for Category B Investigational Device Exemption Clinical Devices and Studies

1. Medicare Coverage of Items and Services in FDA-Approved Investigational Device Exemption Clinical Studies

Section 1862(m) of the Act (as added by section 731(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) allows for Medicare payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study. Under the general rulemaking authority under section 1871 of the Act, CMS finalized changes to the IDE regulations (42 CFR 405 Subpart B), effective January 1, 2015 (78 FR 74809). CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies.

2. Background on Medicare Payment for FDA-Approved IDE Studies

Medicare may make payment for routine care items and services furnished in an FDA-approved Category A (Experimental) study if CMS determines that the Medicare coverage IDE study criteria in 42 CFR 405.212 are met. However, Medicare does not make payment for the

Category A device, which is excluded from coverage by 1862(a) of the Act. A Category A (Experimental) device refers to a device for which ‘‘absolute risk’’ of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective. As described in § 405.211(b), with regard to a Category B (Nonexperimental/investigational) IDE study, Medicare may make payment for the Category B device and the routine care items and services in the study if CMS determines that the Medicare coverage IDE study criteria in § 405.212 are met. A Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type (§ 405.201(b)).

3. Coding and Payment for Category B IDE Devices and Studies

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61223 through 61224), we created a temporary HCPCS code to describe the V-Wave Interatrial Shunt Procedure, including the cost of the device, for the experimental group and the control group of the study after hearing concerns from interested parties that current coding for the V-Wave procedure would compromise the scientific validity of the study. Specifically, for that randomized, double-blinded control Category B IDE study, all participants received a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also received the V-Wave interatrial shunt procedure while participants assigned to the control group only received right heart catheterization. We stated that

the developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the Category B IDE device--the interatrial shunt--because an additional procedure code would be included on the claims for participants receiving the interatrial shunt. Therefore, we created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved IDE study) to describe the service, including the cost of the device, and we assigned the service to New Technology APC 1589 (New Technology--Level 38 ($10,001- $15,000)).

In addition to the previously described procedure and the creation of HCPCS code C9758, CMS has created similar codes and used similar payment methodologies for other similar IDE studies. For example, the following HCPCS codes were also created and described blinded procedures, including the cost of the device, in which both the active treatment and placebo groups are described by the same HCPCS code: HCPCS code C9782 (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an

approved Investigational Device Exemption (IDE) study), and HCPCS code C9783 (Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study).

For CY 2023, we proposed to make a single blended payment and establish a new HCPCS code or revise an existing HCPCS code for devices and services in Category B IDE studies when the Medicare coverage IDE study criteria at § 405.212 are met and where CMS determines that a new or revised code and/or payment rate is necessary to preserve the scientific validity of such a study. We intended that this proposal would preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned. For example, it is expected that, in a typical study, those receiving the placebo may have a lesser Medicare payment due to absence of the Category B device, and, therefore, the payment amount may unblind the study and compromise its scientific validity. As has occurred previously, we anticipated interested parties would engage with us and notify us, for instance, if they have concerns that an existing HCPCS code may compromise the scientific validity of a Category B IDE study. Therefore, we proposed to create a new HCPCS code or revise an existing HCPCS code to describe a Category B IDE device and study, which would include both the treatment and control arms and related device(s), as well as routine care items and services as specified under § 405.201, if we determine it is necessary to do so to preserve the scientific validity of the study; we would assign the new or revised code a blended payment rate. The single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational

device is used compared to placebo. For example, in a study for which CMS determines the Medicare coverage IDE study criteria in § 405.212 are met and where there is a 1:1 assignment of the device to placebo (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the placebo in a 1:1 ratio. Furthermore, costs for routine care items and services in the study, as specified under § 405.201, would be included in the single blended payment.

Section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other information and factors. Consistent with this requirement, we proposed this policy to ensure we pay appropriately under the OPPS for Category B IDE devices and studies in a manner that preserves the studies' scientific validity. This proposal is similar to our standard practice of setting payment rates based on the frequency of resources used. Our proposal to create new HCPCS codes or revise existing HCPCS codes to operationalize our proposal to make a single payment for the blended cost of the device depending on the frequency with which it is used in the study, together with the study costs, is consistent with our historical practice of creating new codes for OPPS and ASC programmatic needs. We noted that, in addition to our general authority to review and revise the APC groups and the relative payment weights in section 1833(t)(9)(A) of the Act, section 1833(w) of the Act is additional authority that would support our proposal. In particular, section 1833(w) of the Act authorizes the Secretary to develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to

those that would otherwise apply under section 1833, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies. For example, Medicare may make an alternative method of payment for items and services provided under clinical trials where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design. We invited comments on our proposal.

Comment: Commenters were very supportive of our proposal. Commenters expressed that, if finalized as proposed, this proposal would help preserve the scientific validity of IDE studies involving blinding procedures. One commenter requested that CMS update our guidance related to coverage of IDE clinical studies to provide additional information for manufacturers regarding implementation and operation of the new policy. This commenter noted that the proposal did not provide details regarding the process for manufacturers to engage CMS in discussions regarding the appropriateness and need in relation to specific IDE studies and other operational issues.

Response: We thank the commenters for their support. We agree with comments received that this proposal would help ensure the scientific validity of blinded category B IDE trials. Regarding manufacturer engagement with CMS, we envision that manufacturers will engage with CMS to notify us of a need for a unique code to preserve the scientific integrity of a Category B IDE trial. Billing instructions for Category B IDE device trials are provided in the Medicare Claims Processing Manual (Pub. 100-04) Chapter 68, Section 2 and will be updated to include any changes in policy.

After consideration of the public comments received, we are finalizing our Category B IDE coding and payment policy as proposed for CY 2023.

4. Coding and Payment for Category B IDE Studies Regulation Text Changes

We proposed to codify our proposed process of utilizing a single packaged payment for Category B IDE studies, including the cost of the device and routine care items and services, in the regulation text for payment to hospitals in a new § 419.47. In particular, we proposed to provide in new § 419.47(a) that CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which would include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201, when CMS determines that the Medicare coverage IDE study criteria at § 405.212 are met, and a new or revised code is necessary to preserve the scientific validity of the IDE study, such as by preventing the unblinding of the study. Additionally, in a new section, § 419.47(b), we proposed that when we create a new HCPCS code or revise an existing HCPCS code under proposed paragraph (a), we would make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under § 405.201. The payment would be based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

We did not receive any public comments on the specific regulation text changes. Because we are finalizing the coding and payment policy as proposed, we are also finalizing the corresponding regulation text changes as proposed.

G. OPPS Payment for Software as a Service

1. Background on Clinical Software and OPPS Add-on Codes Policy

Rapid advances in innovative technology are having a profound effect on every facet of health care delivery. Novel and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve

outcomes, and reduce overall costs to the program. In some cases, these innovative technologies are substituting for more invasive care and/or augmenting the practice of medicine.

New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), are becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients. While many of these technologies are new, we note that clinical software, particularly CAD, has been used to aid or augment clinical decision making for decades. These technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. We refer to these algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per-use basis, as Software as a Service (SaaS).

Starting in 2018, we began making payment for the SaaS procedure Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow. HeartFlow is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow SaaS procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, its use may eliminate the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the main

diagnostic/image procedure (i.e., the primary service). In the CY 2018 OPPS/ASC final rule, however, we determined that it was appropriate for HeartFlow to receive a separate payment because the analytics are performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan (82 FR 52422 through 52425). We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the SaaS procedure that indicated the price of the procedure was approximately $1,500. In CY 2020, we utilized our low-volume payment policy to calculate HeartFlow's arithmetic mean to assign it to New Technology APC 1511 (New Technology –Level 11 ($901-$1000)) with a payment rate of $950.00 (84 FR 61220 through 61221). We continued this APC assignment in CY 2021 and CY 2022 using our equitable adjustment authority (84 FR 85941 through 85943; 86 FR 63533 through 63535). For CY 2023, we proposed to move HeartFlow (HCPCS 0503T) from New Technology APC 1511 to APC 5724 (Level 4 Diagnostic Tests and Related Services), a clinical APC, as we believe we have enough data to make an appropriate clinical APC assignment for HeartFlow. We direct readers to section III.E of this final rule with comment period for a more detailed discussion of the proposed Heartflow clinical APC assignment.

While HeartFlow was the first SaaS procedure for which we made separate payment under the OPPS, we have since begun paying for other SaaS procedures. In CY 2021, we assigned CPT code 92229 (Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral), an artificial intelligence system to detect diabetic retinopathy known as IDx-DR to APC 5733 with the status indicator "S" (85 FR 85960 to 85961). IDx-DR uses an artificial intelligence algorithm to review images of a

patient's retina to provide a clinical decision as to whether the patient needs to be referred to an eyecare professional for diabetic retinopathy or rescreened in twelve months (negative for mild diabetic retinopathy). Also in CY 2021, we began paying for CPT code 0615T (Eye-movement analysis without spatial calibration, with interpretation and report), which involves the use of the EyeBOX system as an aid in the diagnosis of concussion. We assigned EyeBOX to APC 5734 with the status indicator "Q1," to indicate that the code is conditionally packaged when performed with another service on the same day (85 FR 85952 to 85953).

Over the past several years, the AMA has established several codes that describe SaaS procedures. HeartFlow, IDx-DR, and the EyeBox System are each described by single CPT codes. But for a procedure known by the tradename LiverMultiScan, the CPT editorial panel created two CPT codes for CY 2022, a primary code and an add-on code:

- 0648T: Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session.
- 0649T: Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure).

LiverMultiScan uses clinical software to aid the diagnosis and management of chronic liver disease through analysis using proprietary algorithms of MR images acquired from patients' providers. As described above, the coding for LiverMultiScan is bifurcated into CPT code

0648T, billable when LiverMultiScan is used to analyze already existing images, and CPT add-on code 0649T, describing the LiverMultiScan software analysis, which is adjunctive to the acquisition of the MR images. In accordance with our OPPS policy, we review all new CPT codes and, for those that are payable under the OPPS, we assign them to appropriate APCs and make status indicator assignments for them. In the CY 2022 OPPS/ASC final rule with comment period, we assigned CPT code 0648T to New Technology APC 1511 (86 FR 63542).

Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of our longstanding OPPS packaging principles, payment for add-on codes is generally packaged into the primary procedure. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74945) and in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817 through 66818), we stated that procedures described by add-on codes represent an extension or continuation of a primary procedure, which means they are ancillary, supportive, dependent, or adjunctive to a primary service. Add-on codes describe services that are always performed in addition to a primary procedure and are never reported as a stand-alone code. Because the second LiverMultiScan code – CPT code 0649T – is an add-on code, in accordance with our current OPPS policy, we packaged payment for it with the primary service with which it is furnished, rather than paying for it separately as we do for the primary LiverMultiScan code – CPT code 0648T (86 FR 63541 through 63543).

2. Recent CPT Codes for SaaS Procedures

The AMA has continued to establish new CPT codes that describe SaaS procedures using two codes: a primary code that describes the standalone clinical software service and an add-on code that describes a clinical software service that is adjunctive to and billed concurrent with a diagnostic imaging service. The standalone code is billed when no additional imaging is required

because raw images from a prior scan are available for the software to analyze, while the add-on code is billed with an imaging service when a prior imaging scan is unavailable, or the prior images are insufficient. If a patient needs a SaaS procedure and has no existing diagnostic images, the patient would undergo the diagnostic imaging (i.e., CT or MRI), and the SaaS procedure. In this scenario, the provider would report the diagnostic imaging service code and the SaaS add-on code on the same day of service. In contrast, if a patient has pre-existing diagnostic images, the provider would only need to perform the SaaS procedure and would only report the standalone SaaS code.

Please see Table 68 for recent CPT codes for SaaS procedures, including LiverMultiScan. For CY 2022, the CPT Editorial Panel also established CPT codes 0721T, 0722T, 0723T, and 0724T.

TABLE 68: SAAS PROCEDURE CPT CODES, LONG DESCRIPTORS, APC ASSIGNMENTS AND STATUS INDICATORS

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
0648T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0649T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List	NA	N

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
		separately in addition to code for primary procedure)		
0721T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	1508	S
0722T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	NA	N
0723T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0724T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NA	N

The standalone codes associated with LiverMultiScan (CPT code 0648T), Optellum LCP (CPT code 0721T), and QMRCP (CPT code 0723T) are paid separately under the OPPS and assigned to specific APCs as described in Table 68. However, according to our existing packaging policy, we would package payment for the add-on codes, specifically, CPT codes 0649T, 0722T, and 0724T, into the associated diagnostic imaging service.

3. CY 2023 SaaS Add-on Codes

From 2021 to 2022, we reviewed and approved New Technology applications for the LiverMultiScan, Optellum, and QMRCP SaaS procedures. LiverMultiScan was assigned to a New Technology APC effective January 1, 2022, and Optellum and QMRCP were assigned to New Technology APCs effective July 1, 2022. While the standalone codes for these services are assigned to New Technology APCs and are separately payable, applicants have informed us that the services described by the add-on codes, specifically, CPT codes 0649T, 0722T, and 0724T, should also be paid separately because the technologies are new and associated with significant costs.

Although the CPT Editorial Panel has designated these codes as add-on codes, the services described by CPT codes 0649T, 0722T, and 0724T are not consistent with our definition of add-on services. In many instances, the costs associated with the add-on codes exceed the costs of the imaging service with which they would be billed, and we believe these add-on codes describe separate and distinct services that should be paid separately, rather than as services that are ancillary, supportive, dependent, or adjunctive to a primary service into which their payment is packaged. Therefore, for CY 2023, we proposed not to recognize the select CPT add-on codes that describe SaaS procedures under the OPPS and instead establish HCPCS codes, specifically, C-codes, to describe the add-on codes as standalone services that would be billed with the

associated imaging service. We explained that we believe the payment for the proposed C-codes describing the SaaS procedures with add-on CPT codes, when billed concurrent with the acquisition of the images, should be equal to the payment for the SaaS procedures when the services are furnished without imaging and described by the standalone CPT code because the SaaS procedure is the same regardless of whether it is furnished with or without the imaging service. Therefore, we proposed the C-codes be assigned to identical APCs and have the same status indicator assignments as their standalone codes.

For the LiverMultiScan service, we proposed not to recognize CPT code 0649T under the OPPS and instead proposed to establish C97X1 to describe the analysis of the quantitative magnetic resonance images that must be billed alongside the relevant CPT code describing the acquisition of the images. Below is the proposed long descriptor for the service:

- C97X1: Quantitative magnetic resonance analysis of tissue composition (e.g., fat, iron, water content), includes multiparametric data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure).

For the Optellum LCP service, we proposed not to recognize CPT code 0722T and instead proposed to establish placeholder HCPCS code C97X2 to describe the use of Optellum LCP that must be billed alongside a concurrent CT scan. Below is the proposed long descriptor for the service:

- C97X2: Quantitative computed tomography (CT) tissue characterization, includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with concurrent CT examination of any structure contained in the acquired diagnostic imaging dataset.

For the QMRCP service, we proposed not to recognize CPT code 0724T and instead proposed to establish placeholder HCPCS code C97X3 to describe the use of QMRCP that must be billed alongside a concurrent CT scan. Below is the proposed long descriptor for the service:

- C97X3: Quantitative magnetic resonance cholangiopancreatography (QMRCP) includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure).

The proposed payment rates for placeholder HCPCS codes C97X1, C97X2, and C97X3, as well as the standalone CPT codes that describe the same SaaS procedures, can be found in Addendum B to the CY 2023 OPPS/ASC proposed rule, which is available via the CMS website.

We received the following comments in response to our proposal:

Comment: Some commenters, including MedPAC, opposed separate payment for expensive services that do not necessarily provide a substantial clinical improvement. MedPAC stated that paying separately undermines the integrity of PPS payment bundles and can limit the competitive forces that generate price reductions among like services, lead to overuse (to the extent clinically possible), and shift financial pressure from providers to Medicare. A commenter encouraged CMS to seek ways to increase packaging and the extent to which services can be bundled with related services based on encounters or episodes of care. Another commenter requested further stakeholder engagement and asked CMS to refrain from finalizing a SaaS payment policy until all policy considerations and concerns have been fully vetted.

Response: We note that we only provide payment for SaaS technologies that have been approved by the FDA and that have received a CPT code from the AMA. We agree with the commenter that we should seek ways to increase packaged services, to the extent possible,

because we believe packaging encourages efficiency and is an essential component of a prospective payment system. However, the services described by CPT add-on codes 0649T, 0722T, and 0724T are not consistent with our definition of add-on services for the purposes of our packaging policy. In many instances, the costs associated with the add-on codes exceed the costs of the imaging service with which they would be billed; and we believe these add-on codes describe separate and distinct services that should be paid separately, rather than as services that are ancillary, supportive, dependent, or adjunctive to a primary service into which their payment is packaged. We believe equitable payment for SaaS procedures represented by add-on codes can be achieved by setting their payment rates commensurate with the SaaS procedures represented by standalone codes.

Comment: Commenters supported CMS's proposal to recognize the SaaS procedures described by CPT add-on codes as separate and distinct services. These commenters stated that these AI technologies are not consistent with the established definition for an add-on service and that they are separate and distinct services that should be paid for separately, rather than being packaged into a primary service payment. They stated that payment for SaaS procedures, when billed concurrently with the acquisition of the images, should be commensurate with the payment for the identical SaaS procedures when the services are furnished without imaging and described by the standalone CPT codes.

Response: We agree with the commenters that the SaaS add-on codes describe separate and distinct services that should be paid for separately, rather than as services that are ancillary, supportive, dependent, or adjunctive to a primary service into which their payment would be packaged. We agree with the commenters we should pay separately for SaaS procedures

furnished without an associated imaging service code at the same amount that we pay when SaaS procedures are furnished with an associated imaging service code.

Comment: Some commenters supported our proposal to pay separately for SaaS procedures under the OPPS by creating HCPCS C-codes to replace the CPT add-on codes and assigning the HCPCS C-codes to the same APCs and status indicators as the standalone codes. The commenters stated that creating HCPCS codes is a consistent approach to pay separately for the same AI services represented by standalone codes and provides a mechanism to capture cost data for AI technology services. The commenters also noted that the creation of HCPCS codes may be necessary to facilitate appropriate facility billing and payment. Additionally, the commenters believed creating HCPCS C-codes in lieu of the CPT add-on codes would be an appropriate method to ensure consistent payment across payment systems.

Other commenters recommended that we provide for separate payment under the OPPS for SaaS procedures described by CPT add-on codes by creating HCPCS codes G-codes to replace the CPT add-on codes, rather than HCPCS C-codes. These commenters stated that if CMS creates new codes despite the significant confusion that different codes may create for providers in billing Medicare versus non-Medicare payers, CMS should use HCPCS G-codes instead of HCPCS C-codes because HCPCS G-codes are more recognized by non-Medicare payers.

Other commenters supported our proposal to pay separately for SaaS procedures described by CPT add-on codes but opposed our proposal to create HCPCS C-codes for payment under the OPPS, rather than paying for the CPT codes already in use. These commenters expressed concerns that creating HCPCS C-codes for SaaS procedures for which there are already CPT add-on codes would be inefficient, duplicative, and confusing for providers and

commercial payers. Commenters argued that because commercial payers do not recognize HCPCS C-codes, the existence of different codes for Medicare and non-Medicare payers for the same services would likely create significant confusion.

A commenter stated that the designation of a code as an add-on code simply describes the relationship between two codes where the add-on code should be performed and reported with another code and noted that the concept of packaging is a concept specific to the OPPS. Another commenter argued that CMS can choose to pay separately under the OPPS for CPT add-on. The commenter acknowledged that 42 CFR 419.2(b)(18) requires packaging of certain services described by add-on codes, but contended that CMS is not required to package all services described by add-on codes but rather, that CMS has discretion to identify "certain services." Therefore, the commenter believed CMS could choose not to identify SaaS add-on codes as among the "certain services" described by add-on codes for which payment is packaged under the regulation at 42 CFR 419.2(b)(18).

Response: We agree with the commenters that creating HCPCS C- or G-codes for OPPS payment for SaaS procedures for which there are already CPT add-on codes is not an ideal or the only way to ensure separate payment under the OPPS. Furthermore, we agree with the commenters that the concept of packaging is specific to the OPPS and that AMA CPT's designation of certain codes as add-on codes is to signify a relationship between services that are performed together, not to dictate the way payment is made for add-on codes. For these reasons, we agree with commenters that we should pay separately for SaaS CPT add-on codes, rather than creating new HCPCS codes for these services.

Our policy in 42 CFR 419.2(b)(18) to package the costs of certain services described by add-on codes with payment for related procedures is services is consistent with the principle of a

prospective payment system of promoting efficiency. However, where add-on codes do not identify separately paid services under the OPPS that are associated with another procedure or service, as is the case with SaaS add-on codes, we believe it is appropriate to except them from our packaging policy. We acknowledge that there are circumstances in which exceptions are needed in order to provide equitable payment for some services, such as drug administration add-on codes, which are currently paid separately under OPPS. We believe it is appropriate to except certain SaaS add-on codes from our general policy of packaging add-on services. We believe payment for the SaaS procedures assigned CPT add-on codes, when billed concurrent with the acquisition of the images, should be made separately at an amount equal to the amount of payment for the SaaS procedure when the service is furnished without imaging and described by the standalone CPT code. We believe this final policy is appropriate because the SaaS procedure is the same and requires the same resources regardless of whether it is furnished with or without the imaging service. Therefore, we believe it is appropriate to assign SaaS CPT add-on codes to identical APCs and status indicator assignments as their standalone codes.

After consideration of the public comments we received, we are finalizing our proposal with modification. Specifically, we are recognizing SaaS CPT add-on codes and paying separately for them. We are not establishing HCPCS codes, specifically, C-codes, to describe the add-on codes as standalone services that would be billed with the associated imaging service. Based on public comments, we believe establishing a duplicative set of codes in place of CPT add-on codes is unnecessary and would be burdensome for hospitals. For CY 2023, we are adopting a policy that SaaS add-on codes are not among the "certain services described by add-on codes" for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18). The SaaS CPT add-on codes will be assigned to identical

APCs and have the same status indicator assignments as their standalone codes. For CY 2023, please see Table 69 for a list of recognized SaaS CPT codes and their APC and status indicator assignments.

TABLE 69: SAAS PROCEDURE CPT CODES, LONG DESCRIPTORS, APC ASSIGNMENTS AND STATUS INDICATORS

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
0648T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0649T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	1511	S
0721T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	1508	S
0722T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset	1508	S

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
		(List separately in addition to code for primary procedure)		
0723T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0724T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	1511	S

4. Comment Solicitation on Payment Policy for SaaS Procedures

Consistent with our OPPS payment policies, we review new CPT codes and determine whether the items or services described by the codes are appropriate for payment under the OPPS. For codes that are appropriate for payment, we propose the appropriate payment indicator, known as the status indicator (SI) under the OPPS, and APC assignment, according to our OPPS policies. We note the new SaaS procedures have been assigned Category III CPT codes by the AMA. Because we generally do not have hospital claims data for new codes, the

payment indicator and APC assignments are determined based on several factors, which include but are not limited to:

- Review of resource costs and clinical similarity of the service to existing procedures;
- Input from our medical advisors; and
- Other information available to us (75 FR 71909).

Although we have begun paying separately for SaaS procedures under the OPPS relatively recently, with the HeartFlow procedure being the first separately payable SaaS procedure in CY 2018, we recognize that certain clinical decision support software, including machine learning or "AI," has been available for many years. In the past ten years, clinical decision support software has been commonly used alongside electronic medical records by medical practitioners. Nonetheless, the number of FDA approved or cleared "machine learning" or "AI" clinical software programs has rapidly increased in the past few years. We note that the FDA has approved many SaaS procedures for similar functions: there are at least six software products that purport to detect findings in Computed Tomography studies of the chest.[126] Additionally, we note some clinical software developers are now using alternative licensing that charges per use rather than using the traditional annual subscription or bulk use subscription. Empirical research has shown that pay-per-use may lead to overuse of "AI" technology.[127] As a result of these variables and potentially others, there is significant price variation within the SaaS procedure space.

We recognize that, as described in the introduction to this section, SaaS procedures are a heterogenous group of services, which presents challenges when it comes to adopting payment

[126] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices
[127] https://www.nature.com/articles/s41746-022-00609-6.pdf

policy for SaaS procedures as a whole. Due to the novel and evolving nature of these technologies, it has been challenging to compare some SaaS procedures to existing medical services for purposes of determining clinical and resource similarity.

We therefore solicited public comment on a payment approach that would broadly apply to SaaS procedures, including:

- How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS;
- How to identify costs associated with these kinds of services;
- How these services might be available and paid for in other settings (physician offices, for example); and
- How we should consider payment strategies for these services across settings of care.

We also solicited comment on the specific payment approach we might use for these services under the OPPS as SaaS-type technology becomes more widespread across healthcare, which is not limited to imaging services. For example, we could consider packaging payment for the diagnostic image and the SaaS procedure under new HCPCS codes, (i.e., G-codes), to efficiently and cost effectively pay for SaaS procedures. These G-codes could broadly describe the diagnostic image service and any SaaS procedure performed. Under this approach, the OPPS would not recognize either the standalone or the add-on codes describing SaaS procedures. Instead, all associated imaging and the SaaS procedure would be described by a single HCPCS code, which could be assigned to a relevant clinical APC. An example of this would be hypothetical code GXXX1 (Computed tomography, thorax, diagnostic; with or without contrast material and with concurrent or subsequent computed analysis of the original image for further interpretation and report using a standardized computing instrument.), which describes both

diagnostic imaging and any associated SaaS procedure for the thorax region of the body and could be assigned to APC 5573 (Level 3 Imaging with Contrast).

Alternatively, we could expand composite APCs, which provide a single payment for groups of services that are performed together, including the diagnostic imaging and SaaS procedure, during a single clinical encounter to result in the provision of a complete service.

A third approach could utilize HCPCS codes (i.e., G- or C- codes) to describe both the diagnostic imaging and the SaaS procedure, and then assign the code that describes the combined services to New Technology APCs that would pay for both services.

We welcomed input from interested parties on these payment approaches and any additional payment approaches that would enhance our ability to provide equitable payment for SaaS procedures while protecting the Medicare trust fund.

Finally, we are aware that bias in software algorithms has the potential to disparately affect the health of certain populations.[128] Therefore, in addition to our comment solicitation on payment approaches, we solicited comments on how we could encourage software developers and other vendors to prevent and mitigate bias in their algorithms and predictive modeling. We also solicited comment on how we can accurately evaluate and ensure that the necessary steps have been taken to prevent and mitigate bias in software algorithms to the extent possible.

We received the following public comments in response to our comment solicitation:

Comment: Several commenters stated that SaaS technology represents a heterogenous group of technologies and that CMS's characterization of SaaS technology is overly inclusive. One commenter identified a need among interested parties in the CPT Editorial Panel process for consistent terminology to better understand how AI medical services fit into the CPT code set.

[128] https://www.science.org/doi/10.1126/science.aax2342

Another commenter suggested that CMS adopt more clear and consistent definitions for AI-enhanced medical devices that incorporate the terms defined in the AMA AI taxonomy to ensure consistent definitions across agencies and interested parties. Another commenter expressed concern that our proposed payment approach did not account for independent SaaS procedures without an associated diagnostic imaging procedure. Some commenters suggested that CMS follow a framework established by the AMA and Digital Medicine Payment Advisory Group (DMPAG). Another commenter suggested that CMS consider SaaS as encompassing services furnished using software regulated by the FDA as Software as a Medical Device (SaMD).

Some commenters argued that CMS should not establish a single policy that would apply to all SaaS-type technology but instead separately evaluate each new technology to determine the appropriate HCPCS coding, including whether or not a potential CPT code can be used to support payment for the separate and distinct service under the OPPS.

Another commenter stated that CMS should be discerning in its classification of SaaS procedures so as not to include technologies that are designed to assist the clinician in decision making.

Response: We thank commenters for their valuable information and will consider it for future rulemaking.

Comment: Some commenters provided input on payment approaches suggested in the CY 2023 OPPS/ASC proposed rule with comment period. Several commenters did not support the creation of broad G-codes that could describe the diagnostic image and the SaaS procedure, citing operational concerns. Some commenters also did not support expansion of composite APCs to provide a single payment for groups of services that are performed together during a single clinical encounter because they believe CMS does not appreciate the wide array and

diversity of AI-based services for this option. They stated that CMS should not assume that the cost and resources are similar for all SaaS procedures for a given imaging modality and should not limit payment for SaaS to technologies used with imaging modalities.

Some commenters expressed interest in using HCPCS codes (i.e., G- or C- codes) to describe both the diagnostic imaging and the associated SaaS procedure, and then assigning the code that describes the combined services to a New Technology APC that would pay for both services. However, these commenters also expressed concerns about the creation of a new combined code and CMS not recognizing either the standalone SaaS code or the add-on code. They also expressed concerns about disruption and undervaluation that could result from combining imaging and SaaS procedures into a single code.

Response: We thank commenters for their valuable feedback on SaaS payment approaches and we will consider their input in future rulemaking.

Comment: Some commenters suggested close communication and collaboration between CMS and the FDA to ensure appropriate standardization of transparency and bias prevention as the regulatory structure around software-based products evolves. Another commenter stated the FDA, not CMS, should evaluate an AI product's potential for introducing inappropriate bias into clinical decision making, especially bias which could influence outcomes for minoritized groups, and that such evaluation should be incorporated into the requirements for AI developers seeking authorization to market.

Another commenter recommend that software developers use principles of transparency, reproducibility, and explainability, in addition to bias-control strategies, when developing products. The commenter stated that developers should also test algorithms in various populations with differential characteristics in terms of age, gender, race, sexual orientation,

gender identity, and other demographic factors. The commenter also suggested that developers document and display the principles, techniques, methods, and populations they used in the evaluation and validation of their product.

Response: We thank commenters for their valuable feedback on how to evaluate and mitigate bias in software algorithms.

H. Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators

In the FY 2023 IPPS/LTCH PPS proposed rule, we requested public comments on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators (87 FR 28622 through 28625). Given the importance of NIOSH-approved surgical N95 respirators in protecting hospital personnel and beneficiaries from the SARS-CoV-2 virus and future respiratory pandemic illnesses, we indicated we were considering whether it might be appropriate to provide payment adjustments to hospitals to recognize the additional resource costs they incur to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. We stated that NIOSH-approved surgical N95 respirators, which faced severe shortage at the onset of the COVID-19 pandemic, are essential for the protection of patients and hospital personnel that interface with patients. We indicated that procurement of NIOSH-approved surgical N95 respirators that are wholly domestically made, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals.

We said we were interested in feedback and comments on the appropriateness of payment adjustments that would account for these additional resource costs. We stated that we believe

such payment adjustments could help achieve a strategic policy goal, namely, sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We stated we were considering such payment adjustments for 2023 and potentially subsequent years.

As described in more detail in the sections that follow, and for the reasons discussed there, in the CY 2023 OPPS/ASC proposed rule (87 FR 44689 through 44696), we proposed to make a payment adjustment under the OPPS and IPPS for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023.

2. General Background and Overview of Proposal

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, President Biden issued Executive Order (E.O.) 13987, titled "Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security" on January 20, 2021 (86 FR 7019). This order launched a whole-of-government approach to combat the coronavirus disease 2019 (COVID-19) and prepare for future biological and pandemic threats. This response has continued over the past year. In March 2022, President Biden released the National COVID-19 Preparedness Plan that builds on the progress of the prior 13 months and lays out a roadmap to fight COVID-19 in the future.[129] Both the ongoing threat of COVID-19 and the potential for future pandemics necessitate significant investments in pandemic preparedness.

Availability of personal protective equipment (PPE) in the health care sector is a critical component of this preparedness, and one that displayed significant weakness in the beginning of

[129] White House, National COVID-19 Preparedness Plan, March 2022; https://www.whitehouse.gov/wpcontent/uploads/2022/03/NAT-COVID-19-PREPAREDNESS-PLAN.pdf

the COVID-19 pandemic. In spring of 2020, supply chains for PPE faced severe disruption due to lockdowns that limited production, and unprecedented demand spikes across multiple industries. Supply of surgical N95 respirators—a specific type of filtering facepiece respirator used in clinical settings—was one type of PPE that was strained in hospitals. So-called "just-in-time" supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough surgical N95 respirators to protect health care workers. Prices for surgical N95s soared, from an estimated $0.25–$0.40 range[130] to $5.75[131] or even $12.00 in some cases.[132] Unable to obtain surgical N95s regulated by NIOSH, hospitals had to turn to KN95s—a Chinese standard of respirator— and other non-NIOSH-approved disposable respirators that were authorized under Emergency Use Authorization (EUA). Concerns were raised during the COVID-19 pandemic regarding counterfeit respirators. NIOSH evaluates and approves surgical N95s to meet efficacy standards for air filtration and protection from fluid hazards present during medical procedures. KN95 respirators, on the other hand, are not regulated by NIOSH. KN95s have faced particular counterfeit and quality risks—with NIOSH finding that about 60 percent of KN95 respirators that it evaluated during the COVID-19 pandemic in 2020 and 2021 did not meet the particulate filter efficiency requirements that they intended to meet.[133] Failure to meet these requirements compromises safety of health care personnel and patients.

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[130] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis

[131] Society for Healthcare Organization Procurement Professionals, COVID-19 PPD Cost Analysis, April 2020; http://cdn.cnn.com/cnn/2020/images/04/16/shopp.covid.ppd.costs.analysis_.pdf

[132] Washington Post, "U.S. sent millions of face masks to China early this year, ignoring pandemic warning signs," April 2020; https://www.washingtonpost.com/health/us-sent-millions-of-face-masks-to-china-early-this-yearignoring-pandemic-warning-signs/2020/04/18/aaccf54a-7ff5-11ea-8013-1b6da0e4a2b7_story.html

[133] U.S. Centers for Disease Control and Prevention "Types of Masks and Respirators"; https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

Over the course of the pandemic, U.S. industry responded to the shortages and dramatically increased production of N95s. Today, the majority of surgical N95s purchased by hospitals are assembled in the U.S., and prices have returned to rates closer to $0.70 per respirator.[134] However, risks remain to maintain preparedness for COVID-19 and future pandemics. It is important to maintain this level of domestic production for surgical N95s, which provide the highest level of protection from particles when worn consistently and properly, protecting both health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material—including the virus that causes COVID-19. Additionally, it is important as a long-term goal to ensure that a sufficient share of those surgical N95s are wholly made in the U.S.—that is, including raw materials and components. The COVID-19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. In a future pandemic or COVID-19-driven surge, hospitals need to be able to count on PPE manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Sustaining a level of wholly domestic production of surgical N95 respirators is integral to maintaining that assurance.

This policy goal—ensuring that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE— is emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as a deliverable of President Biden's Executive Order 14001 on "A Sustainable Public Health Supply Chain." To help achieve this goal, the U.S. Government is committing to purchase wholly domestically made PPE in line with new requirements in section 70953 of the Infrastructure

[134] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis

Investment and Jobs Act (Pub. L. 117-58). These new contract requirements stipulate that PPE purchased by covered departments must be wholly domestically made—that is, the products as well as their materials and components must be grown, reprocessed, reused, or produced in the U.S.

The Federal Government's procurement of wholly domestically made PPE will help achieve the stated policy goal. However, the U.S. Government alone cannot sustain the necessary level of production. As outlined in the previously mentioned National Strategy for a Resilient Public Health Supply Chain, the U.S. Government is only one small part of the market for PPE. Hospitals are the primary purchasers and users of medical PPE including surgical N95 respirators. Sustaining a strong domestic industrial base for PPE—in order to be prepared for future pandemics or COVID-19-driven surges and protect Americans' health during such times—therefore, requires hospitals' support.

Surgical N95 respirators are a particularly critical type of PPE needed to protect personnel and beneficiaries from the SARS–CoV–2 virus and future respiratory pandemic illnesses. However, wholly domestically made NIOSH-approved surgical N95 respirators are generally more expensive than foreign-made ones. Therefore, we stated in the FY 2023 IPPS/LTCH PPS proposed rule that we believe a payment adjustment that reflects, and offsets, the additional marginal costs that hospitals face in procuring wholly domestically made NIOSH-approved surgical N95 respirators might be appropriate. These marginal costs are due to higher prices for wholly domestically made NIOSH-approved surgical N95s, which, in turn, primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in countries such as China, where many N95 and other respirators are made. We stated that such a payment adjustment might provide sustained support over the long term to hospitals that

purchase wholly domestically made NIOSH-approved surgical N95 respirators, and could help safeguard personnel and beneficiary safety over the long term by sustaining production and availability of these respirators.

As summarized in the CY 2023 OPPS/ASC proposed rule (87 FR 44690), we received many helpful comments in response to our comment solicitation in the FY 2023 IPPS/LTCH PPS proposed rule. After considering the comments received, we proposed in the CY 2023 OPPS/ASC proposed rule (87 FR 44689 through 44696) to make a payment adjustment under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators, as defined in Section X.H.3 of the CY 2023 OPPS/ASC proposed rule (87 FR 44690 through 44691), for cost reporting periods beginning on or after January 1, 2023.

For the IPPS, we proposed to make this payment adjustment under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. For the OPPS, we proposed to make this payment adjustment under section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

Comment: We received many comments supporting the proposed payment adjustments. Several of these commenters acknowledged the challenges hospitals faced in acquiring surgical N95 respirators during the COVID-19 pandemic and the importance of investing in domestic supply chains for future emergency preparedness.

We also received several comments that were not supportive of the proposed payment adjustments, including from MedPAC, which stated that this proposal would undermine the

prospective, bundled nature of Medicare's hospital payments by paying hospitals more as their costs increase. A few commenters expressed doubt on whether the proposed payment adjustments would be effective in achieving the stated policy goal. Some commenters stated that the payment adjustment amounts were not large enough to shift hospital purchasing decisions and that much more would need to be done beyond the Medicare program to achieve the stated policy goal.

A few commenters raised concerns that the proposed payment adjustments could be susceptible to unintended consequences. One commenter stated that if manufacturers or vendors are aware that purchasers of their domestically produced surgical N95 respirators will be reimbursed, they may artificially inflate the price of their products. This commenter and others stressed that CMS should monitor utilization and cost data for any unintended consequences.

One commenter stated that a more appropriate policy would be one in which CMS provides a payment adjustment to providers who attest to purchasing surgical N95s through contracts that include terms related to on-hand inventory. This commenter stated that a significant problem during the pandemic was the inability of domestic manufacturers to ramp up production quickly enough to meet spikes in demand. The commenter believes this alternative payment adjustment would incentivize domestic manufacturers to hold more inventory on-hand in the event of another spike in demand in the future.

Response: We thank the commenters for their feedback on our proposals. While we agree with MedPAC and other commenters that payment for hospital services under the prospective payment systems should generally be made as part of the prospective, bundled payment, we believe that a payment adjustment that offsets hospitals' additional marginal costs in procuring wholly domestically made NIOSH approved surgical N95 respirators is appropriate in order to

ensure that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE. As discussed in the proposed rule and later in this final rule, as we gain more experience with this policy and the data collected, we may also consider modifications to the reasonable cost-based payment approach we are finalizing. With respect to those comments expressing doubt as to whether the proposed payment adjustments would be large enough to shift hospital purchasing decisions, we believe that by significantly lessening the cost disincentive that hospitals currently face when deciding whether to purchase domestic surgical N95 respirators over non-domestic surgical N95 respirators, the proposed payment adjustments would encourage the purchase of larger quantities of domestic surgical N95 respirators and thereby help to provide sustained support for the production and availability of these respirators over the long term. With respect to those comments expressing doubt as to whether the proposed payment adjustments would be effective in achieving this policy goal, and that more would need to be done outside of the Medicare program, we note that this policy would not be adopted in isolation. For complementary efforts related to strengthening the U.S. public health and medical supply chain and industrial base, we refer the public to the "Public Health Supply Chain and Industrial Base One-Year Report" available on the HHS website at https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.

We appreciate the comments regarding potential unintended consequences. We also thank the commenter for the suggested alternative payment adjustment approach. We will consider alternative approaches and/or modifications to address any unintended consequences for future rulemaking as we gain experience under the policy we are adopting in this final rule, as discussed further in this section.

Comment: We received many comments urging CMS to expand this policy to cover other forms of PPE and critical medical supplies beyond surgical N95 respirators. A few commenters stated that other forms of PPE suffered shortages during the pandemic similar to surgical N95 respirators and therefore investing in domestic production for these products was also important for future emergency preparedness.

Response: We thank these commenters for their broader interest in ensuring domestic production of PPE. We will consider these comments for future rulemaking if appropriate as we gain more experience with our policy.

After consideration of these comments, as well as the other comments received on our proposal that we summarize and respond to in the sections that follow, we are finalizing the proposed payment adjustments under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators.

3. Proposed Definition of Domestic NIOSH-approved Surgical N95 Respirators

In the CY 2023 OPPS/ASC proposed rule (87 FR 44690 through 44691), for purposes of this policy, we proposed to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: 1) Domestic NIOSH-approved surgical N95 respirators; and 2) Non-domestic NIOSH-approved surgical N95 respirators.

As discussed, it is critically important to ensure that a sufficient share of surgical N95s are wholly made in the U.S.—that is, including raw materials and components. In the proposed rule, we stated our belief that the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore, considered domestic for purposes of the proposed adjustments, is the Berry Amendment. The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD)

from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States.[135] Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225-7002, and State DOD cannot acquire specified "items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the United States."[136] Unless DOD grants a waiver because domestic firms do not make the product or because other exceptions in the law are met, the entire production process of an affected product, from the production of raw materials to the manufacture of all components to final assembly, must be performed in the United States.[137]

The Berry Amendment has been critical to the viability of the textile and clothing production base in the United States and has been critical to maintaining the safety and security of our armed forces, by requiring covered items to be produced in the United States.[138] In the CY 2023 OPPS/ASC proposed rule, we stated our belief that using the Berry Amendment as the basis for defining domestic NIOSH-approved surgical N95 respirators will provide similar support to U.S. surgical N95 respirator manufacturers and help ensure that quality surgical N95 respirators are available to health care personnel when needed.

Therefore, based on the Berry Amendment, we proposed to define a NIOSH-approved surgical N95 respirator as domestic if the respirator and all of its components are grown, reprocessed, reused, or produced in the United States. We proposed that for purposes of this policy all other NIOSH-approved surgical N95 respirators would be non-domestic.

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[135] https://www.trade.gov/berry-amendment
[136] https://www.trade.gov/berry-amendment-implementation
[137] https://sgp.fas.org/crs/misc/R44850.pdf
[138] https://www.trade.gov/berry-amendment

We recognize that a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under our proposed definition. Therefore, we proposed that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our proposed definition. The written statement must have been certified by one of the following: (i) the manufacturer's Chief Executive Officer (CEO); (ii) the manufacturer's Chief Operating Officer (COO); or (iii) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. The written statement, or a copy of such statement, could be obtained by the hospital directly from the manufacturer, obtained through the supplier or Group Purchasing Organization (GPO) for the hospital who obtained it from the manufacturer, or obtained by the hospital because it was included with or printed on the packaging by the manufacturer. This written statement may be required to substantiate the data included on the supplemental cost reporting form as discussed in section X.H.5 of this final rule. The recordkeeping requirements at current § 413.20 require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

Comment: One commenter supported CMS using the Berry Amendment as a basis for our proposed definition of domestic NIOSH-approved surgical N95 respirators because the Berry Amendment is a familiar standard for the manufacturing industry. The commenter believes the definition is appropriate for incentivizing the domestic manufacturing of raw materials and other componentry for N95 masks. The commenter also stated that based on their own analysis, they believe there is a sufficient number of domestic manufacturers producing surgical N95 respirators that meet the proposed definition and therefore the policy could be sustained.

We received a few comments expressing concern with our proposed definition of domestic NIOSH-approved surgical N95 respirators. One commenter was concerned that the hospital community was not familiar with the Berry Amendment. The commenter believes that hospitals are more familiar with the Federal Trade Commission (FTC) "Made in USA" designation and that CMS should consider surgical N95 respirators compliant with the FTC's Made in USA labeling rule as domestic for purposes of the proposed payment adjustment. The commenter stated that utilizing the Made in USA framework would drive greater efficiency, especially since exceptions under the Berry Amendment may evolve, making it more challenging for providers to receive written statements from manufacturers with each order.

One commenter supported the requirement that the respirators be fully assembled in the U.S. but was concerned that the proposed definition would require all raw materials and components used in assembling the respirators to also be domestic. This commenter suggested that CMS instead adopt the content threshold requirements outlined in the Federal Acquisition Regulations that implement the Buy American Act, which require 60 percent of the value of a product's components to be manufactured in the U.S. The commenter stated that adopting the 60 percent threshold in the first year of the policy would allow the domestic raw materials supply base time to ramp up the production capacity required to support greater volume of domestically produced surgical N95 respirators.

Response: We thank the commenters for their feedback on our proposed definition of domestic NIOSH-approved surgical N95 respirator for purposes of this policy. We agree with the commenter that the Berry Amendment is a familiar standard for the manufacturing industry, as also discussed in the CY 2023 OPPS/ASC proposed rule. We believe this is important since we proposed that a hospital may rely on a written statement from the manufacturer stating that

the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our proposed definition – which is based on the Berry Amendment. Moreover, using a definition of "domestic" that is based on the Berry Amendment, a contracting standard, provides a robust standard that will help ensure that a sufficient share of surgical N95 respirators are wholly made in the U.S.—that is, including raw materials and components. Therefore, we disagree that the FTC "Made in USA" designation, which is not a contracting standard, would be a more appropriate option for classifying domestic surgical N95 respirators for purposes of this policy. In response to the commenter's concern that exceptions under the Berry Amendment may evolve, we note that our proposed definition of a domestic NIOSH-approved surgical N95 respirator did not include any of the exceptions allowed under the Berry Amendment. We utilized language from the Berry Amendment, which is familiar to manufacturers, to develop a proposed definition of a domestic NIOSH-approved surgical N95 respirator that is specifically applicable to this policy. We also note, as discussed in more detail below, we are not requiring the written manufacturer statements to cover a specific order or lot of domestic respirators purchased by a hospital as long as all of the domestic respirators purchased by the hospital are covered by associated written manufacturer statements.

With respect to the comment suggesting CMS modify the proposed definition of a domestic surgical N95 respirator to include respirators in which at least 60 percent of the value of a product's components were manufactured in the U.S., we continue to believe manufacturers already have significant capacity to produce surgical N95 respirators that meet our proposed definition, as discussed in the proposed rule (87 FR 44695). Moreover, as discussed previously, we believe it is important to ensure that a sufficient share of surgical N95 respirators are wholly made in the U.S.—that is, including raw materials and components—because in a future

pandemic or COVID-19-driven surge, hospitals need to be able to count on domestic manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Therefore, we do not believe adopting this modified definition would be either necessary or maximally effective in achieving our stated policy goal of maintaining sufficient production levels of wholly domestically made surgical N95 respirators.

Comment: We received several comments expressing concern that these proposed payment adjustments would significantly increase hospitals' reporting burden. Many of these commenters urged CMS to determine a less burdensome method of attestation and reporting for these payment adjustments. Some commenters not supportive of the proposed payment adjustments stated that the proposal would increase providers' costs and administrative burden beyond any additional payment. One of these commenters suggested that CMS not finalize this policy and instead raise payment rates across the board as means to compensate hospitals for increased costs without adding administrative burden. Commenters cited the proposed requirement that hospitals differentiate on their cost report domestic respirators purchased from non-domestic respirators purchased as an example of an increase in reporting burden. Commenters also cited the need for hospitals to obtain a written statement from the manufacturer stating that the surgical N95 respirators the hospital purchased are domestic as an example of an increase in reporting burden. These commenters questioned how hospitals would be able to obtain such a written statement from the manufacturer. Some commenters expressed concern that the proposed policy would not require manufacturers to provide such statements and therefore hospitals could potentially miss payment adjustments even if they purchased domestic surgical N95 respirators. Some commenters suggested that CMS should require manufacturers to meet new labeling and reporting requirements to reduce burden. Another commenter suggested CMS

maintain a list of manufacturers whose products meet the proposed domestic definition and make this information available.

Response: As discussed in the proposed rule (87 FR 44815), we believe the burden associated with this proposal would be the time and effort necessary for the provider to locate and obtain the relevant supporting documentation to report the quantity and aggregate costs of domestic NIOSH-approved surgical N95 respirators and non-domestic NIOSH-approved surgical N95 respirators purchased by the hospital for the period. As discussed later in the Collection of Information (COI) section of this document, we estimates that the total burden associated with this policy for each hospital would be 0.50 hours per year at a cost of $25.43. We note that we will be soliciting additional comment on the information collection requirements discussed in this section. The notice will be announced in the Federal Register and advise the public on how to obtain copies of the information collection request and on how to submit public comments. As described in the section X.H.5 of this final rule, the collection of this information is required in order to calculate each hospital's payment adjustment.

In response to the suggestion that CMS instead raise payment rates across the board as means to compensate hospitals for increased costs, we do not think such an alternative policy would be effective in helping to sustain production and availability of wholly domestically made NIOSH-approved surgical N95 respirators because the additional payments would not be directly and measurably associated with the purchase of domestic NIOSH-approved surgical N95 respirators by hospitals.

As reflected in the burden estimate previously discussed, we do not agree with commenters that obtaining written statements from the manufacturer would significantly increase hospitals' reporting burden. In the proposed rule (87 FR 44691), we listed multiple ways in

which a hospital could acquire written statements from the manufacturer. We also do not currently share commenters' concerns that manufacturers may not be willing to provide these written statements or that CMS should maintain a list of such manufacturers. We believe that providing these written statements would be in the manufacturers' best interest, given hospitals comprise a significant portion of their customer base. While some commenters suggested that CMS should require manufacturers to meet new labeling and reporting requirements to reduce burden, they did not suggest a mechanism for doing so. As stated previously, once we gain experience under the policy we are adopting in this final rule, we may consider modifications in future rulemaking.

Comment: One commenter found certain aspects of the proposed attestation process unclear. This commenter questioned whether a hospital would need to obtain a separate statement for every order and connect each statement to specific lots purchased. This commenter questioned whether manufacturers would be required to use a specific form and whether a hospital would need to verify the written statement provided is appropriately certified. The commenter also questioned whether suppliers or GPOs would be required to make this information available or verify manufacturers' statements or adherence to the proposed rule's requirement.

Response: We thank the commenter for these questions. In recognition of the different purchasing practices of hospitals with respect to NIOSH-approved surgical N95 respirators, we are not requiring the written manufacturer statements to cover a specific order or lot of domestic respirators purchased by a hospital as long as all of the domestic respirators purchased by the hospital are covered by associated written manufacturer statements. As one of the simplest examples, if a hospital were to exclusively purchase respirators made by one manufacturer and

all the respirators purchased from that manufacturer were domestic, a single written statement from that manufacturer covering all of the respirators purchased by that hospital for the hospital's cost reporting period might be sufficient documentation. As one alternative to that approach, a hospital could choose to obtain a written statement for each purchase throughout the year. Again, different approaches are acceptable as long as all of the domestic NIOSH-approved surgical N95 respirators purchased by the hospital and reported on its cost report as such are covered by associated written manufacturer statements.

We are not requiring a specific format for the written statements from the manufacturers. As discussed in the proposed rule, hospitals should ensure that the written statements they receive directly or indirectly from the manufacturer for domestic NIOSH-approved surgical N95 respirators have been certified by one of the following: (i) the manufacturer's Chief Executive Officer (CEO); (ii) the manufacturer's Chief Operating Officer (COO); or (iii) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. If the written statement from the manufacturer indicates that it has been certified by one of these individuals, a hospital is not required to perform additional independent verification.

We did not propose that suppliers or GPOs be required to obtain, provide to hospitals, or verify written statements from the manufacturers. However, we believe it is in the suppliers' and GPOs' best interest to obtain and provide such written manufacturer statements to hospitals given hospitals comprise a significant portion of their customer base.

4. Payment Adjustment Amount under the IPPS and OPPS for Domestic NIOSH-approved Surgical N95 Respirators

In the CY 2023 OPPS/ASC proposed rule (87 FR 44691), we discussed our expectation that domestic NIOSH-approved surgical N95 respirators will continue to be generally more

costly than non-domestic respirators. However, we stated that it is challenging to precisely predict and quantify the future cost differences given the dynamic nature of the current marketplace and data limitations. Therefore, we proposed to initially base the payment adjustments on the IPPS and OPPS shares of the estimated difference in the reasonable costs[139] of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. We proposed that these payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. Under this proposal the biweekly interim lump-sum payments would be available for cost reporting periods beginning on or after January 1, 2023. Any provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the MAC, consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into twenty-six equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15-1 2405.2 for additional information.) The MACs would determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that will be included on the N95 supplemental cost reporting form as discussed in section X.H.5 of the CY 2023 OPPS/ASC proposed rule (87 FR 44692 through 44694). We stated that in future years, the MACs would determine the interim biweekly lump-sum payments utilizing information from the prior year's surgical N95

[139] In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9

supplemental cost reporting form, which may be adjusted based on the most current data available. This would be consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15-1 2405.2. As described in more detail in section X.H.5 of the CY 2023 OPPS/ASC proposed rule (87 FR 44692 through 44694), a hospital would separately report on its cost report the aggregate cost and total quantity of domestic NIOSH-approved surgical N95 respirators and non-domestic respirators for cost reporting periods beginning on or after January 1, 2023. This information, along with existing information already collected on the cost report as shown in section X.H.5 of the CY 2023 OPPS/ASC proposed rule (87 FR 44692 through 44694), would be used to calculate a Medicare payment for the estimated cost differential, specific to each hospital, incurred due to the purchase of domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators.

As previously discussed, for the IPPS, we proposed to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1886(d)(5)(I) of the Act. To further support the strategic policy goal of sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency, we did not propose to make the IPPS payment adjustment budget neutral under the IPPS.

As also previously discussed, for the OPPS, we proposed to make the payment adjustment for these additional resource costs under section 1833(t)(2)(E) of the Act. Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner, other adjustments (in addition to outlier and transitional pass-through payments) necessary to

ensure equitable payments, such as adjustments for certain classes of hospitals. Consistent with this authority, we proposed the OPPS payment adjustment would be budget neutral.

Comment: Several commenters expressed concern with the proposed OPPS payment adjustment being budget neutral and urged CMS to provide the OPPS payment in a non-budget neutral manner. A few commenters stated that they are opposed to the proposed OPPS payment adjustment if the adjustment is budget neutral. Several commenters stated that redistributing payments from an already underfunded system will not benefit providers or patients. A few commenters believe that implementing the OPPS payment adjustment in a budget neutral manner would not incentivize hospitals to purchase domestic N95 respirators and therefore may prevent CMS from achieving the stated policy goal. One commenter believes that applying a budget neutral adjustment could have a detrimental effect on safety net or smaller hospitals, which may be less able to absorb the higher costs of acquiring domestically produced medical supplies. Similarly, another commenter stated that there are differences in the degree that hospitals have access to domestic surgical N95 respirators due to their size and geography and therefore, the commenter is concerned that a budget neutral approach would penalize more vulnerable hospitals that are not able to procure domestic respirators at the same rate as other hospitals. Several commenters urged CMS to work with Congress to pass a law that would allow CMS to implement the OPPS payment adjustment in a non-budget neutral manner.

Response: The OPPS authority for this payment adjustment is section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. Implementing this policy in a non-budget neutral manner under the OPPS would not be consistent with the requirement in section 1833(t)(2)(E) of the Act that equitable adjustments be budget neutral. We

acknowledge the concerns that some commenters raised regarding the impact of the budget neutrality adjustment on more vulnerable hospitals but reiterate that implementing this policy without an OPPS budget neutrality adjustment would not be consistent with section 1833(t)(2)(E) of the Act. Furthermore, we note that the proposed OPPS budget neutrality adjustment is relatively small. Therefore, we do not believe the budget neutrality adjustment will broadly disincentivize hospitals from purchasing domestic surgical N95 respirators or have a meaningful impact on hospitals that do not procure domestic surgical N95 respirators at the same rate as other hospitals.

5. Calculation of the OPPS and IPPS Payment Adjustments on the Cost Report

In order to calculate the N95 payment adjustment for each eligible cost reporting period, we proposed to create a new supplemental cost reporting form that will collect from hospitals the additional information described in this section. This information would be used along with other information already collected on the hospital cost report to calculate IPPS and OPPS payment adjustment amounts. The information collection requirements for the proposed new supplemental cost reporting worksheet are discussed in section XXII.F of the CY 2023 OPPS/ASC proposed rule (87 FR 44815). The draft new supplemental cost reporting worksheet was assigned OMB control number 0938-1425[140].

In this section we describe the information we proposed to collect on the new supplemental cost reporting form and the proposed steps for determining the IPPS and OPPS payment adjustment amounts.

<u>Step 1 – Collect additional information on the new supplemental cost reporting form.</u>

[140] https://www.reginfo.gov/public/do/DownloadNOA?requestID=431065

To determine the IPPS and OPPS payment adjustments, we proposed to collect the following information on a new supplemental cost reporting form:

1) Total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital.[141]

2) Total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital.

3) Total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

4) Total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

Step 2 – Calculate a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators.

With the respirator information reported on the new supplemental cost reporting form we proposed to calculate the following statistics on the new cost report form:

1) The average cost of domestic NIOSH-approved surgical N95 respirators purchased. This would be calculated by dividing the reported total aggregate cost of the domestic NIOSH-approved surgical N95 respirators purchased by the reported total quantity of domestic NIOSH-approved surgical N95 respirators purchased. If the hospital purchased zero NIOSH-approved surgical N95 domestic respirators, this value would be set to 0.

2) The average cost of non-domestic NIOSH-approved surgical N95 respirators purchased. This would be calculated by dividing the reported total aggregate cost of the non-domestic NIOSH-approved surgical N95 respirators purchased by the reported total quantity of

[141] We note for this discussion, reference to the "hospital" refers to the "hospital and hospital healthcare complex" that completes the cost report form CMS-2552-10.

non-domestic NIOSH-approved respirators purchased. If the hospital purchased zero non-domestic NIOSH-approved surgical N95 respirators, this value would be set to 0.

3) The hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. This would be calculated by subtracting the average cost of non-domestic NIOSH-approved surgical N95 respirators purchased from the average cost of domestic NIOSH-approved surgical N95 respirators purchased. If the average cost of non-domestic NIOSH-approved surgical N95 respirators purchased is greater than the average cost of domestic NIOSH-approved surgical N95 respirators purchased, this value would be set to 0. We stated in the proposed rule that, as discussed in section X.H.8 of the proposed rule, we may consider in future rulemaking establishing a national minimum average cost for non-domestic NIOSH-approved surgical N95 respirators purchased that could be used in determining the hospital-specific unit cost differential for hospitals that only purchased domestic NIOSH-approved surgical N95 respirators or that have unusually low average costs for their non-domestic NIOSH-approved surgical N95 respirators.

Step 3 – Calculate a total cost differential for the purchase of domestic NIOSH-approved surgical N95 respirators.

The next step in the proposed payment adjustment calculation is determining the total cost differential for the purchase of domestic NIOSH-approved surgical N95 respirators. This amount represents the total additional costs the hospital incurred by purchasing domestic NIOSH-approved surgical N95 respirators over purchasing non-domestic NIOSH-approved surgical N95 respirators. We proposed to calculate this amount by multiplying the hospital-specific unit cost differential calculated in Step 2 by the total quantity of domestic NIOSH-approved surgical N95 respirators purchased reported in Step 1.

Step 4 – Determine IPPS and OPPS share of total hospital costs.

The total cost differential calculated in Step 3 is reflective of all domestic NIOSH-approved surgical N95 respirators used throughout the hospital while treating all patients. This total cost differential needs to be disaggregated to estimate the additional costs incurred by purchasing domestic NIOSH-approved surgical N95 respirators used in treating patients receiving services paid under IPPS and OPPS, specifically. To apportion the total cost differential to the IPPS and OPPS services, we proposed to use cost data already reported on the hospital cost report. We specifically proposed to use the following from the OMB No. 0938-0050, Form CMS-2552-10:

a) Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services as reported in Worksheet C Part I line 202 column 5.

b) Total Medicare Part A hospital inpatient costs as reported in Worksheet D-1 Part II, line 49, column 5.

c) Total Medicare Part B hospital outpatient costs as reported in Worksheet D Part V, line 202, column 5 + column 6 + column 7.

We proposed to calculate the IPPS percent share of the total cost differential (calculated in Step 3) as total Medicare Part A hospital inpatient costs (Step 4b) divided by total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services (Step 4a). We proposed to calculate the OPPS percent share of the total cost differential as total Medicare Part B hospital outpatient costs (Step 4c) divided by total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services (Step 4a).

Step 5 – Determine IPPS and OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.

To calculate the IPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators, we proposed to multiply the IPPS cost share (determined in Step 4) by the total cost differential for the purchase of domestic respirators (Step 3). To calculate the OPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators, we proposed to multiply the OPPS cost share (determined in Step 4) by the total cost differential for the purchase of domestic respirators (Step 3). As described previously, these calculated payment adjustments would be reconciled against interim lump-sum payments received by the hospital for this policy.

Comment: We received comments expressing concern with our proposed methodology for determining the payment adjustments. A few commenters expressed concern with CMS limiting this payment adjustment only to the estimated share of surgical N95 respirators used by the hospital when treating Medicare fee-for-service beneficiaries. One commenter was concerned that limiting this payment only to the Medicare share will not increase demand for domestically produced surgical N95 respirators enough to achieve the stated policy goal. This commenter urged CMS to expand these payment adjustments to cover the cost of domestic surgical N95 respirators used in treating all patients and if CMS does not have statutory authority to do this, that CMS work with Congress to include this flexibility in the Medicare statute. Other commenters raised equity issues and were concerned that hospitals that treat a high percentage of Medicaid patients or have low Medicare fee-for-service utilization would be disadvantaged by the use of the Medicare share.

Response: We thank the commenters for sharing these concerns regarding the use of the Medicare share in determining the amount of the payment adjustments under the proposed methodology. With respect to those comments expressing concern that limiting this payment only to the Medicare share would not increase demand for domestically produced surgical N95

respirators enough to achieve the stated policy goal, we note that this policy would not be adopted in isolation. For complementary efforts related to strengthening the U.S. public health and medical supply chain and industrial base, we refer the public to the "Public Health Supply Chain and Industrial Base One-Year Report" available on the HHS website at https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.

Comment: MedPAC, while not supportive of the proposed payment adjustments, stated that if CMS concludes in this final rule that the proposed payment adjustments are necessary, CMS should set the unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators at a national level (rather than on a hospital-by-hospital basis). MedPAC believes this would reduce the administrative burden on hospitals, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs. MedPAC expressed concern that under our proposal, hospitals could artificially inflate their reported surgical N95 respirator costs by getting discounts on other products in exchange for paying high prices on surgical N95 respirators.

Conversely, we also received a comment that expressed concern with moving to a national unit cost differential in the future. This commenter stated that utilization of surgical N95 respirators varies by hospital and is dependent on factors such as localized COVID-19 infection rates. This commenter was concerned using a national unit cost differential would lead to underpayments for hospitals that utilize a higher number of surgical N95 respirators.

Response: We appreciate the comments submitted on the proposed payment adjustment methodology. With respect to MedPAC's concerns about utilizing hospital-specific unit cost differentials, as discussed in the proposed rule (87 FR 44695), as we gain more experience with

the policy and the data collected, we may consider setting the unit cost differential at the national level in future rulemaking.

We believe the commenter who asserted such a change would lead to underpayments for hospitals that utilize a higher number of surgical N95 respirators may misunderstand the policy. If we were to make such a change in the future, the national unit cost differential would still be multiplied by the hospital-specific quantity of domestic surgical N95 respirators purchased. Thus, individual hospital volume of respirators would still be taken into account.

Comment: One commenter requested that CMS provide additional clarity regarding the amount of the payment adjustment per surgical N95 respirator as this information is needed to inform hospitals' purchasing decisions.

Response: It is unclear to us what additional clarification this commenter is seeking. Using the payment methodology as described previously, in conjunction with the written manufacturer statements regarding which surgical N95 respirators are domestic under CMS's definition, hospitals can estimate the approximate payment amounts under various purchasing scenarios.

To help demonstrate these calculations, in Table 70 we have provided an example for a mock hospital that purchased both domestic and non-domestic NIOSH-approved surgical N95 respirators during its cost reporting period beginning on or after January 1, 2023. The example shows the additional data the hospital would report on its supplemental cost reporting form, the cost data pulled from other hospital cost report worksheets, and the calculations performed to determine the hospital's IPPS and OPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators. Please note that the cost report below is a draft and is still subject to final OMB approval.

TABLE 70: Mock N95 Supplemental Cost Reporting Form

Line Description	Data Source	Value
Line 1: Total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	150,000
Line 2: Total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	$112,500
Line 3: Total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	150,000
Line 4: Total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital .	Entered by hospital on new form.	$82,500
Line 5: Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services	Worksheet C Part I, line 202 column 5.	$100,000,000
Line 6: Total Medicare Part A hospital inpatient costs	Worksheet D-1 Part II, line 49, column 5.	$20,000,000
Line 7: Total Medicare Part B hospital outpatient costs	Worksheet D Part V, line 202, column 5 + column 6 + column 7.	$10,000,000
Line 8: Average unit cost of domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 2 / Line 1. If line 1 is equal to 0, then set value to 0.	$0.75
Line 9: Average unit cost of non-domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 4 / Line 3. If Line 3 is equal to 0, then set value to 0.	$0.55
Line 10: Difference in average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 8 - Line 9. If value is less than 0, then set value to 0.	$0.20
Line 11: Total cost differential for purchasing domestic NIOSH-approved surgical N95 respirators.	Calculation: Line 1 * Line 10.	$30,000
Line 12: Medicare Part A hospital inpatient cost share.	Calculation: Line 6 / Line 5.	0.20
Line 13: Medicare Part B hospital outpatient cost share.	Calculation: Line 7 / Line 5.	0.10
Line 14: IPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 12.	**$6,000**

Line Description	Data Source	Value
Line 15: OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 13.	**$3,000**

6. Establishment of the OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators in a Budget Neutral Manner

As noted earlier, section 1833(t)(2)(E) of the Act provides that the Secretary shall establish adjustments necessary to ensure equitable payments in a budget neutral manner. In order to maintain OPPS budget neutrality, we proposed to develop a spending estimate associated with this proposed policy. Specifically, this spending estimate would reflect the OPPS payment adjustment that would be made in CY 2023 for the additional resource costs of domestic NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients. The data currently available to calculate this spending estimate is limited. However, we believe the proposed methodology described next to calculate this spending estimate for CY 2023 is reasonable based on the information available.

We proposed to calculate the estimated total spending associated with this policy by multiplying together estimates of the following:

1) Estimate of the total number of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023.

2) Estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators.

3) Estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023 that are domestic.

For purposes of this estimate, we believe it is reasonable to assume that one NIOSH-approved surgical N95 respirator is used per OPPS encounter. Based on the outpatient claims volume available for ratesetting in the CY 2023 OPPS proposed rule, we had approximately 103.4 million OPPS claims. Therefore, in the proposed rule, for CY 2023, we estimated that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of OPPS patients in CY 2023 is 103.4 million. Based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators was $0.20.

It is particularly challenging to estimate the percentage of domestically manufactured NIOSH-approved surgical N95 respirators that will be used in the treatment of OPPS patients in CY 2023. The OMB's Made in America Office recently conducted a data call on capacity in which several entities attested to being able to supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand. We recognize that it may take time for this capacity to be fully reflected in hospital purchases. Therefore, although this would be sufficient capacity to supply the entire hospital industry if it were to be available and focused on this segment of the marketplace in 2023, we believe it is reasonable to assume that it will take time for hospitals to adjust their purchasing patterns and therefore hospitals in aggregate may in fact be able to purchase less than half of their NIOSH-approved surgical N95 respirators as domestic in 2023. Therefore, for purposes of this OPPS budget neutrality estimate, we proposed to set the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023 that are domestic to 40 percent, or slightly less than half.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44695), we estimated that total CY 2023 OPPS payments associated with this policy will be $8.3 million (or 103.4 million claims * $0.20 * 40 percent). This represents approximately 0.01 percent of the OPPS, which we proposed to budget neutralize through an adjustment to the OPPS conversion factor.

We received no comments on the proposed methodology for determining the budget neutrality factor associated with the proposed OPPS payment adjustment.

We noted in the proposed rule that the volume of claims data available for ratesetting typically increases between the proposed and final rules, so the proposed rule spending estimate may change in the final rule. As such, based on the outpatient claims volume available for ratesetting in this CY 2023 OPPS/ASC final rule with comment period, we have approximately 109.3 million OPPS claims. Therefore, for CY 2023, we are now estimating that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of OPPS patients in CY 2023 is 109.3 million. Our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators remains $0.20 and our best estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPPS patients in CY 2023 that are domestic remains 40 percent. Therefore, we now estimate that total CY 2023 OPPS payments associated with this policy will be $8.7 million (or 109.3 million claims * $0.20 * 40 percent). This represents approximately 0.01 percent of the OPPS, which we are budget neutralizing through an adjustment to the OPPS conversion factor.

As stated in the proposed rule, we believe this methodology is the best way to approximate CY 2023 OPPS spending associated with the proposed policy. However, we recognize that this approach to estimating budget neutrality under the OPPS is based on the

limited data available. We may consider refining this approach for future years, especially once data collected on cost reports for this policy is available.

7. Regulation Amendments

For the IPPS, we proposed to codify this payment adjustment in the regulations by adding new paragraph (f) to § 412.113 to specify that, for cost reporting periods beginning on or after January 1, 2023, a payment adjustment is made to a hospital for the additional resource costs of domestic NIOSH-approved surgical N95 respirators. The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. We also proposed to make conforming changes to § 412.1(a) and § 412.2(f) to reflect the proposed payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators.

For the OPPS, we proposed to codify this payment adjustment in the regulations by adding a new paragraph (j) to § 419.43 to specify at new paragraph (j)(1) that, for cost reporting periods beginning on or after January 1, 2023, CMS makes a payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators. New paragraph (j)(2) would provide that the payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. Finally, new paragraph (j)(3) would state that CMS establishes the payment adjustment under paragraph (j)(2) in a budget neutral manner.

We did not receive any public comments on these proposed changes to the regulation text.

In summary, after consideration of the comments received on our proposed policy, we are finalizing as proposed without modification the payment adjustments under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators, including the proposed amendments to the regulation text, as previously described.

I. Exemption of Rural Sole Community Hospitals from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of the clinic visit service furnished in excepted off-campus provider-based departments (PBDs) by removing the payment differential that drives the site-of-service decision and, as a result, unnecessarily increases service volume in this care setting as compared to the physician's office setting. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and rationale for the volume control method we adopted beginning in CY 2019. Below we discuss the specific policy we finalized in the CY 2019 OPPS/ASC final rule with comment period and its full application under the OPPS beginning in CY 2020.

1. Implementation of a Method to Control Unnecessary Increases in the Volume of Certain Clinic Visit Services

For the CY 2019 OPPS, under our authority at section 1833(t)(2)(F) of the Act, we applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS-equivalent rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). The PFS-equivalent rate, however, was not immediately applied in full. Instead, we phased in the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted off-campus PBD setting over two years. For CY 2019, the payment reduction was transitioned by applying 50 percent of the total reduction in payment that would have applied if these departments (departments that bill the modifier "PO" on claim lines) were paid the PFS-equivalent rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). Consequently, these departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second and final year of the 2-year phase-in, we stated that we would apply the total reduction in payment that would be applied if these departments (departments that bill the modifier "PO" on claim lines) were paid the site-specific PFS-equivalent rate for the clinic visit service described by HCPCS code G0463. The PFS-equivalent rate for CY 2020 was 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate) for CY 2020. Under this policy, departments were paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in

CY 2020) for the clinic visit service in CY 2020. The fully phased-in policy has been in effect since CY 2020.

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), for CY 2019 and subsequent years, this policy has been implemented in a non-budget neutral manner. To effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS, we explained that we believed the method must be adopted in a non-budget neutral manner in accordance with the OPPS statute.

We note that this policy was previously litigated. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. The appellees petitioned the United States Supreme Court for a writ of certiorari. On June 29, 2021, the Supreme Court denied the petition.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those providers that are rural sole community hospitals (SCHs). Commenters to the CY 2019 OPPS/ASC proposed rule expressed concern that this policy proposal would disproportionately affect safety net hospitals and rural providers (83 FR 59013). Numerous commenters representing a rural SCH and beneficiaries in the State of Washington expressed concern about the impact the proposal would have on their rural SCH.

Several commenters also requested that both urban and rural SCHs, rural referral centers (RRCs), and Medicare-dependent hospitals be exempted from this policy.

At the time we responded that we shared the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. We stated that we believed that implementing our policy with a 2-year phase-in would help to mitigate the immediate impact on rural hospitals (83 FR 59013). We noted that we might revisit this policy to consider potential exemptions in the CY 2020 OPPS rulemaking.

In CY 2020 OPPS/ASC final rule with comment period (84 FR 61367), we again discussed commenters' continued concerns about this policy's impact on rural providers and safety net health systems. While acknowledging the validity of these concerns, we emphasized our belief that a phased-in implementation would help mitigate the impact rural hospitals might otherwise face. We reiterated that we would continue to monitor trends for any access to care issues and would potentially revisit this policy in future rulemaking.

2. Proposed Exemption for Rural Sole Community Hospitals from the Method to Control Unnecessary Increases in the Volume of Clinic Visits Furnished Beginning in CY 2023

Since the volume control method was fully phased in by the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142), we have continued to assess how this policy has been implemented, as it affects both the Medicare program itself and the beneficiaries it serves. This policy was designed to address unnecessary increases in the volume of clinic visit services furnished in excepted off-campus PBDs. While we believe that the method we adopted to control this growth is appropriate, we are continuing to examine whether all excepted off-campus PBDs should be subject to the site-specific PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463. In the CY 2019 OPPS/ASC proposed rule (83 FR 37142), we

explained our position that shifts in the sites of service are unnecessary if the beneficiary can safely receive the same service in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. We described this as beneficiaries moving from (lower cost) physician offices to (higher cost) HOPDs because of the higher payment rate available in the HOPD. In these cases, we maintain that to the extent similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another as doing so results in service volume increases that we believe are unnecessary. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the physician's office setting to the hospital outpatient department for many hospital types, which unnecessarily increases hospital outpatient department volume and Medicare program and beneficiary expenditures. Nonetheless, we recognize that the volume of clinic visits furnished in off-campus PBDs of certain hospital types may primarily be driven by factors other than higher payment, such as service shifts from the inpatient hospital to outpatient hospital setting and access issues. As explained further below, we proposed to exempt excepted off-campus PBDs of rural SCHs from our volume control method policy because we believe the volume of the clinic visit service in PBDs of these hospitals is driven by factors other than the payment differential for this service. We proposed to pay the full OPPS payment rate, rather than the PFS-equivalent rate under our volume control method, when the clinic visit is furnished in these departments.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers five rural hospital payment designations in which rural or isolated

hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital[142], Sole Community Hospital (SCH)[143], or Medicare Dependent Hospital[144]—each of which has different eligibility criteria and payment methodologies. With the exception of Critical Access Hospitals, rural hospitals may also qualify as Low Volume Hospitals[145] and Rural Referral Centers (RRCs)[146], which qualify eligible hospitals for additional payments or exemptions. Not all rural or isolated hospitals receive special payment treatment under the OPPS. For instance, CAHs are not paid under the OPPS and are reimbursed at 101 percent of reasonable costs for outpatient services. PBDs of CAHs are not subject to Section 603 of the Bipartisan Budget Act of 2015.

Rural SCHs are a hospital type that has received special payment treatment under the OPPS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary by January 1, 2006 to provide for an appropriate adjustment under paragraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A), that the costs to rural

[142] 42 CFR 485.601–647
[143] 42 CFR 412.92
[144] 42 CFR 412.108
[145] 42 CFR 412.101
[146] 42 CFR 412.96

hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in Section II.E of this final rule, for CY 2023 we finalizing our proposal to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

Rural SCHs have also been excluded from our policy to adjust payment for drugs and biologicals acquired under the 340B program. When we proposed to adjust payments for 340B drugs in the CY 2018 OPPS/ASC proposed rule (82 FR 33635), we sought public comment on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals). Commenters noted that rural 340B covered entity hospitals depend on the drug discounts they receive through the 340B Program to provide access to expensive, necessary care such as labor and delivery and oncology infusions (82 FR 59365).

Commenters expressed that even with 340B discounts, rural hospitals like rural SCHs are financially threatened. They noted that rural hospitals are typically located in lower income economic areas and would not be able to absorb the proposed reduction in payment for 340B-purchased drugs. Moreover, commenters suggested that the proposal would disproportionately affect rural hospitals compared to urban hospitals and requested that CMS exempt hospitals with an RRC or SCH designation from the 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as “economic engines” for many rural communities. Taking into consideration these comments, for CY 2018 we finalized a policy to

exclude rural SCHs from our 340B drug payment policy and have continued to do so in CYs 2019 through 2022.

b. Utilization of the Clinic Visit Service in Off-Campus Provider-Based Departments of Rural SCHs

In the CY 2019 OPPS/ASC final rule with comment period in which we adopted the volume control method policy for certain clinic visits, we said that to the extent there are lower-cost sites of service available, beneficiaries and the physicians treating them should be able to choose the appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons (83 FR 37139). However, many rural providers, and rural SCHs in particular, are often the only source of care in their communities[147], which means beneficiaries and providers are not merely choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas further drives utilization to off-campus PBDs in areas where rural SCHs are located.

Rural areas often experience lower availability of health care professionals and hospitals than urban areas[148]. Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries healthy and out of the hospital because beneficiaries in rural settings face unique challenges that impact their health. Compared to their urban counterparts, rural residents generally are older and poorer.[149] Rural areas are also disproportionally affected by declining population rates and decreasing employment rates.[150] We have targeted rural SCHs with their

[147] https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf
[148] https://www.gao.gov/assets/gao-21-93.pdf
[149] https://www.gao.gov/assets/gao-21-93.pdf
[150] https://www.gao.gov/assets/gao-21-93.pdf

add-on payment and exemption from the 340B payment reductions in an effort to ensure that these providers with demonstrated additional resource costs remain open to serve the beneficiaries who rely on them for their care.

We believe that exempting rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines) would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments. Our proposal also aligns with the special payment treatment rural SCHs receive under the OPPS.

Accordingly, for CY 2023, we proposed that excepted off-campus PBDs (departments that bill the modifier "PO" on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, would be exempt from our volume control method of paying the PFS-equivalent rate for the clinic visit service, as described by HCPCS code G0463. Additionally, we solicited comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds, from our volume control method of paying the PFS-equivalent rate for the clinic visit service.

In CY 2023, for a Medicare beneficiary who receives a clinic visit service in a non-excepted off-campus PBD of a rural SCH, the standard unadjusted Medicare OPPS final payment would be approximately $121, with an approximate average copayment of $24. The final PFS-equivalent rate for a clinic visit would be approximately $48, with an approximate average copayment of $10. Under this final policy, an excepted off-campus PBD of a rural SCH

would continue to bill HCPCS code G0463 with the "PO" modifier in CY 2023, but the payment rate for services described by HCPCS code G0463 when billed with modifier "PO" would now be the full OPPS payment rate. This would cost beneficiaries an average of an additional $14 per visit.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we implemented the volume control method in a non-budget neutral manner consistent with the OPPS statute. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS, we stated that the volume control method in general would be implemented in a non-budget neutral manner. Here, we proposed to simply remove the effects of this volume control method for one type of provider (rural SCHs), which is only a subset of the providers currently affected by our policy, and thus propose this exception would not increase OPPS spending overall as compared to OPPS spending with no volume control method whatsoever. We estimate that this exemption would increase OPPS spending by approximately $71 million in CY 2023 compared to spending if we did not implement this exemption to the volume control method. The impact associated with this policy is further described in section XXVI of the CY 2023 OPPS/ASC final rule.

As detailed later in this section, after consideration of public comments, we are finalizing our proposal to exempt rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). We

will continue to take information submitted by the commenters into consideration for future analysis.

The following is a summary of the comments we received and our responses to those comments.

Comment: The majority of commenters supported our proposal to exempt rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). Commenters urged us to finalize the exemption for rural SCHs. We received numerous comments from individuals in rural Washington describing how this policy has impacted their community and how the exemption would be a significant step in the continued stabilization of rural health care delivery systems. Commenters noted that rural SCHs are typically the chief, if not sole, source of community outpatient care for rural residents and this exemption is vital to ensuring continued access to the care they need. Further, commenters agreed that exempting rural SCHs from the clinic visit policy would support the ability of these critical providers to continue to maintain access to care in their rural communities.

Response: We thank the commenters for their support. As we stated in the CY 2023 OPPS proposed rule, we believe that exempting rural SCHs from payment of the site-specific PFS-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines) would help to maintain access to care in rural areas by

ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments.

Comment: Commenters noted that, while it is necessary to distinguish between urban and rural hospitals for a number of payment and policy mechanisms, they believe the Metropolitan Statistical Areas (MSAs) CMS uses to delineate between these areas is not the most precise tool. One commenter argued that CMS should extend this exemption to urban SCHs because using MSAs to determine urban and rural areas is imprecise and unfairly disadvantages urban SCHs that may be the sole source of hospital services in their communities.

Response: We acknowledge the commenters' points about the important role that urban SCHs serve in their communities. However, we have not found that urban SCHs have the additional resource costs for covered outpatient department services that rural SCHs have, and as such are only applying the clinic visit policy exemption to rural SCHs.

Comment: Several commenters suggested extending the exemption to hospitals that provide a disproportionate share of the nation's uncompensated care, and serve high proportions of Medicaid, Medicare, and uninsured patients.

The commenters argued that PBDs of these hospitals are disproportionately impacted by site-neutral payment policies and shielding these PBDs from the impact of these policies would ensure they can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas. The commenters did acknowledge that CMS has not defined hospitals that meet these criteria and would need to do so in order to exempt associated PBDs from the clinic visit policy. They further recognized that rural SCHs are easily identified because there is an existing definition to capture the hospitals that fall into this group. They recommended that CMS first define a group of hospitals that meet

these criteria and then exclude those hospitals' excepted PBDs from the clinic visit policy to ensure continued access for marginalized communities without other reliable sources of care.

Response: As the commenter stated, CMS has not created a definition for the group of hospitals the commenter cited and would need to do so in order use this definition to exempt associated PBDs from the clinic visit policy. We will continue to monitor this issue and revisit any additional exemptions in future rulemaking as appropriate.

Comment: One commenter presented data showing that 56 percent of rural SCHs, 73 percent of urban SCHs, and 60 percent of MDHs are located in at least one type of medically underserved area as designated by the Health Resources & Services Administration. Another commenter suggested that CMS consider using an expanded exception policy to help hospitals maintain essential primary care services, particularly for beneficiaries residing in shortage areas, and to provide patients in these areas with sufficient choices of providers. They suggested that one way that CMS could establish such an exception policy would be to determine which excepted off-campus provider-based departments are in a Primary Care Health Professional Shortage Area (PC-HPSA) or treat a certain percentage of patients that reside in a PC-HPSA, and instead pay them at the full OPPS rate for the clinic visit service.

Response: We do not currently utilize MUAs or PC-HPSA designations to determine payment for covered outpatient department services under the OPPS. We believe our policy to exempt rural SCHs is consistent with our other policies that target this hospital type, which we have determined have higher resource costs for covered outpatient department services, and therefore, is an appropriate policy from an OPPS perspective.

Comment: One commenter noted that while they support this exemption, they request that CMS monitor the effects of exempting these locations from site neutral payments. They

went on to say that CMS should monitor utilization, trends in vertical consolidation among rural facilities, the types of financial relationships rural SCHs have with physicians, any shifts in services from other locations to rural SCHs, and the effect of site neutral payment exceptions on beneficiary cost sharing. Further, they requested that CMS release data to interested parties so they can also assess these impacts and that CMS reserve the right to modify this policy if the agency's findings point to any adverse, unintended consequences.

Response: We share this commenter's concern and will continue to monitor the effects of exempting rural SCHs from the clinic visit policy. We may revisit this in future rulemaking as necessary.

Comment: Many commenters suggested other provider types that may be appropriate to exempt from this policy. Many commenters felt that Medicare Dependent Hospitals (MDHs) or rural hospitals with fewer than 100 beds should also be exempt from the clinic visit policy. Commenters expressed that the same reasoning that led CMS to propose to exempt rural SCHs also applies to MDHs. One commenter noted that MDHs hospitals have a larger percentage of inpatient days or discharges for Medicare patients and that they are therefore more vulnerable to inadequate Medicare payments than other hospitals because they are less able to cross-subsidize inadequate Medicare payments with more generous payments from private payers. Commenters expressed that this greater dependence on Medicare may make certain hospitals more financially vulnerable and thus, more worthy of being exempt from the clinic visit policy.

Other commenters suggested that it would be appropriate to extend the exemption to urban SCHs. Commenters gave specific examples of instances where an SCH is designated urban by CMS, but the hospital is actually a considerable distance from the nearest urban area. Commenters expressed that there are many factors that underscore why urban SCHs and MDHs

should also receive the payment exemption, including below-average patient care margins at these types of hospitals. Commenters also argued extending this exemption to MDHs and urban SCHs would only add nominally to the cost of the proposed policy.

A few commenters suggested that Rural Referral Centers (RRCs) that provide rural populations with local access to a wide range of health care services should be exempt from the clinic visit policy. Commenters explained that RRCs localize care, minimize the need for further referrals and travel to urban areas, and provide services at costs lower than would be incurred in urban areas. Commenters also said these hospitals commonly establish satellite sites and outreach clinics to provide primary and emergency care services to surrounding underserved communities, a function that is becoming increasingly important as economic factors force many small rural hospitals to close.

Commenters also urged CMS to extend this exemption to providers deemed Medicaid Disproportionate Share (DSH) hospitals as well. They explained that communities served by DSH hospitals are similar to those served by SCHs. They felt DSH hospitals are characterized by especially large numbers of low-income, Medicaid-covered, dually eligible, and uninsured residents. They also argued exempting DSH hospitals could entice physicians to practice in these communities and enhance access to care.

Commenters also suggested that the exemption be extended to Medicare DSH hospitals. One commenter drew a parallel based on documented improvements in access after the Affordable Care Act's temporary increase in Medicaid payment rates for primary care went into effect; they believe that exempting Medicare DSH hospitals from the site-neutral policy will similarly reduce wait times for Medicare beneficiaries. Finally, commenters also suggested that Low-Volume Adjustment hospitals receive the exemption.

Response: In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561) we uniquely identified rural SCHs as providers with demonstrated additional resource costs. We found that rural SCHs have significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. Building upon that foundation, for CY 2018 we finalized a policy to exclude rural SCHs from our 340B drug payment policy and have continued to do so in CYs 2019 through 2022 (we note that we are finalizing a policy to pay for 340B drugs and biologicals under the OPPS at the same rates we pay for non-340B drugs and biologicals (generally, ASP plus 6 percent)). We believe exempting rural SCHs, which have demonstrated additional resource costs, is appropriate to ensure these hospitals can remain open to serve the beneficiaries who rely on them for their care. We share commenters' concerns about the financial difficulties associated with maintaining access to care in medically vulnerable communities. However, in each of these cases, Congress did not determine that any of these hospital types required additional payments for outpatient services.

Section 1833(t)(13)(B) authorizes an appropriate adjustment for hospitals located in rural areas where the Secretary determines, based on a study, that the costs incurred by these hospitals by APC group exceed costs incurred by hospitals in urban areas. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we summarized our study of the cost of covered outpatient department services to hospitals in rural areas and found that rural SCHs were the only rural hospital type that had higher resource costs for covered outpatient department services. Rural SCHs demonstrated significantly higher cost per unit than urban hospitals after controlling for labor input prices, service-mix complexity, volume, facility size, and type of hospital. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561) we stated that we found no significant difference in cost between all small rural hospitals with 100

or fewer beds and urban hospitals. We found that there was insufficient evidence to conclude that rural hospitals with 100 or fewer beds have higher costs than urban hospitals.

We proposed a narrow exception to our clinic visit policy largely based upon the historical treatment and documented additional resource costs of rural SCHs under the OPPS. We are only excepting rural SCHs because we continue to believe that the underlying principles of the clinic visit policy continue to justify application of the volume control method for clinic visits to the remaining hospital types, including most rural and safety-net providers. Where the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. Further, we do not believe that commenters provided sufficient reasoning or data to show that the other provider types suggested (Medicare Dependent Hospitals, Urban Sole Community Hospitals, Rural Referral Centers, Medicaid DSH, Medicare DSH, and Low-Volume Adjustment Hospitals) demonstrate the additional resource costs that rural SCHs do and should therefore also be exempted from this OPPS payment policy. We share commenters' concerns about maintaining access to care in urban and rural settings and enhancing access to care in medically vulnerable communities. We also share commenters' concerns about profit margins. However, we are must balance the concerns of providers with the concerns of beneficiaries regarding the affordability of their care. For hospitals subject to the clinic visit policy, the proposed PFS-equivalent rate for a clinic visit brings the approximate average copayment down from $26 to $10. We will continue to study access and cost to see if further exemptions to the clinic visit policy are appropriate.

After consideration of public comments we received, we are finalizing our proposal to exempt rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). We believe that exempting rural SCHs from the clinic visit policy will help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at same rate paid when the service is furnished in on-campus departments. Finalizing this policy also aligns with the special payment treatment rural SCHs receive under the OPPS. We will continue to monitor the effects of this change in Medicare payment policy.

XI. CY 2023 OPPS Payment Status and Comment Indicators

A. CY 2023 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and whether particular OPPS policies apply to the code.

For CY 2023, we proposed to revise the definition of status indicator "A" to include unclassified drugs and biologicals that are reportable under HCPCS code C9399. When HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's average wholesale price (AWP) using the Red Book or an equivalent recognized compendium, and processes the claim for payment. The payment at 95 percent of AWP is made under the OPPS. In addition, we proposed to revise the definition of

status indicator "F" by removing hepatitis B vaccines. Hepatitis B vaccines should not be subject to deductible and coinsurance similar to other preventive vaccines, but services that are currently listed under the definition of status indicator "F" are subject to deductible and coinsurance. We also proposed to revise the definition of status indicator "L" in order to add hepatitis B vaccines to the list of other preventive vaccines that are not subject to deductible and coinsurance.

We solicited public comments on the proposed definitions of the OPPS payment status indicators for 2023.

Comment: We received several comments in support of removing C9399 from packaging when the code is included on a claim with status indicator "J1" or "J2" and adding a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with C9399.

Response: We thank commenters for their support. After consideration of the public comments we received, we are finalizing without modification the revision of status indicator "A".

We did not receive any public comments related to the revision of status indicators "F" and "L". Therefore, we are finalizing our proposals to revise these status indicators without modification.

The complete list of CY 2023 payment status indicators and their definitions is displayed in Addendum D1 to the CY 2023 OPPS/ASC final rule with comment period, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.

The CY 2023 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to the CY 2023 OPPS/ASC final rule

with comment period, which are available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

B. CY 2023 Comment Indicator Definitions

In the CY 2023 OPPS/ASC proposed rule (87 FR 44699), we proposed to use four comment indicators for the CY 2023 OPPS. These comment indicators, "CH", "NC", "NI", and "NP", are in effect for CY 2022 and we proposed to continue their use in CY 2023. The proposed CY 2023 OPPS comment indicators are as follows:

- "CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- "NC"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- "NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- "NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for CY 2023 are listed in Addendum D2 to the CY 2023 OPPS/ASC final rule with comment period, which is available on the CMS

website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

We believe that the existing CY 2022 definitions of the OPPS comment indicators continue to be appropriate for CY 2023. Therefore, we proposed to use those definitions without modification for CY 2023.

We solicited public comments on our proposed definitions of the OPPS comment indicators for 2023.

We did not receive any public comments on our proposal and therefore, we are finalizing those definitions without modification for CY 2023.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2022 report.

A. OPPS Payment Rates Update

The March 2022 MedPAC "Report to the Congress: Medicare Payment Policy," recommended that Congress update Medicare OPPS payment rates by the amount specified in current law. We refer readers to the March 2022 report for a complete discussion of this

recommendation.[151] We appreciate MedPAC's recommendation and, as discussed further in Section II.B of the CY 2023 OPPS/ASC proposed rule (87 FR 44527 through 44528), we proposed to increase the OPPS payment rates by the amount specified in current law. Comments received from MedPAC for other OPPS policies are discussed in the applicable sections of this final rule with comment period.

B. ASC Conversion Factor Update

In the March 2022 MedPAC "Report to the Congress: Medicare Payment Policy," MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased prior to the effects of COVID-19 PHE in CY 2020, and ASC access to capital has been adequate.[152] As a result, MedPAC stated that payments to ASCs are adequate and recommended that, in the absence of cost report data, no payment update should be applied for CY 2023 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the productivity-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in Section XIII.H 2.b. of the CY 2023 OPPS/ASC proposed rule (87 FR 44724 through 44725), we proposed to apply a 2.7 percent productivity-adjusted

[151] Medicare Payment Advisory Committee. March 2022 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.65-66. Available at: http://www.medpac.gov.
[152] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.161-162. Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf.

hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the proposed CY 2023 ASC payment amounts. The final CY 2023 ASC conversion factor for ASCs meeting quality reporting requirements and the final hospital market basket update factor are discussed in section XIII of this final rule with comment period.

C. ASC Cost Data

In the March 2022 MedPAC "Report to the Congress: Medicare Payment Policy," MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program but should make cost reporting a condition of ASC participation in the Medicare program.[153]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we did not propose any cost reporting requirements for ASCs in the CY 2023 OPPS/ASC proposed rule, we continue to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing

[153] Medicare Payment Advisory Committee. March 2022 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.162. Available at: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf.

an ASC-specific market basket index for updating payment rates under the ASC payment system.

Comments received from MedPAC for other ASC payment system policies are discussed in the applicable sections of this final rule with comment period. The full March 2022 MedPAC Report to Congress can be downloaded from MedPAC's website at: http://www.medpac.gov.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2022 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410, 85 FR 86121 through 86179, and 86 FR 63761 through 63815 respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under §§ 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020,

are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15.

Since the implementation of the ASC prospective payment system, we have historically defined a "surgical" procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as "surgery" (CPT codes 10000 through 69999) (72 FR 42478). We also have included as "surgical" procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range.

As we noted in the August 7, 2007 ASC final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, "surgery-like" procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. In that final rule, we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through

69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL. These criteria included that a procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and that the procedure is separately paid under the OPPS.

In CY 2021, we revised the definition of covered surgical procedures to only surgical procedures specified by the Secretary that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153). However, in the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to reinstate the general standards and exclusion criteria in place prior to CY 2021 (86 FR 63779) and revised the language in the regulation text at § 416.166 accordingly.

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology

services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the AMA and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update

HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, III, MAAA, and PLA CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

● Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;

● Category III CPT codes, which describe new and emerging technologies, services, and procedures; and

● Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we referred to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in the CY 2023 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we solicited public comments in the CY 2023 OPPS/ASC proposed rule (and respond to those comments in this final rule with comment period) or whether we are soliciting public comments in this final rule with comment period.

We note that we sought public comments in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63767-63768) on the new and revised Level II HCPCS codes effective on either October 1, 2020 or January 1, 2021. These new and revised codes were flagged with comment indicator "NI" in Addenda AA and BB to the CY 2022 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2022 OPPS/ASC final rule with comment period. In the CY 2022 OPPS/ASC proposed rule (86 FR 42196), we stated that we will finalize the treatment of these codes under the ASC payment system in this CY 2023 OPPS/ASC final rule with comment period.

2. April 2022 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

For the April 2022 update, there were no new CPT codes appropriate for separate payment under the ASC payment system; however, there were several new Level II HCPCS codes. In the April 2022 ASC quarterly update (Transmittal 11303, dated March 24, 2022, CR 12679), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 51 of the CY 2023 OPPS/ASC proposed rule (87 FR 44702) displayed the new Level II HCPCS codes that were implemented April 1, 2022. We note that the proposed comment indicators (CI), payment indicators (PI), and payment rates for these April codes were listed in Addendum BB to the CY 2023 OPPS/ASC proposed rule. In addition, we note that the entire ASC addenda, which consist of the addenda listed below, are available via the Internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices:

- ASC Addendum AA: ASC Covered Surgical Procedures (Including Surgical Procedures for Which Payment is Packaged)

- ASC Addendum BB: Covered Ancillary Services Integral to Covered Surgical Procedures (Including Ancillary Services for Which Payment is Packaged)
- ASC Addendum DD1: ASC Payment Indicators (PI)
- ASC Addendum DD2: ASC Comment Indicators (CI)
- ASC Addendum EE: Surgical Procedures Excluded from Payment in ASCs
- ASC Addendum FF: ASC Device Offset Percentages

We invited public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2022 through the quarterly update CRs, and as listed in Table 71 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2022). The new codes that were effective April 1, 2022, were assigned to comment indicator "NP" in ASC Addendum BB to the CY 2023 OPPS/ASC proposed rule to indicate that the codes are assigned to interim payment indicators and comments would be accepted on their interim assignments. We proposed to finalize the payment indicators in this CY 2023 OPPS/ASC final rule with comment period. We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2022 and are finalizing the proposed ASC payment indicator assignments for these codes.

We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes. Their replacement codes are also listed in Table 71. In addition, although in prior years we included the final ASC payment indicators in the coding tables in the preamble, because we include the same information in the ASC addenda, we have not included them in Table 71. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system.

The list of ASC payment indicators and definitions used under the ASC payment system can be found in the ASC addenda. We note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) are available via the Internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.

TABLE 71: NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2022

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
A2011	A2011	Supra sdrm, per square centimeter
A2012	A2012	Suprathel, per square centimeter
A2013	A2013	Innovamatrix fs, per square centimeter
A4100	A4100	Skin substitute, fda cleared as a device, not otherwise specified
C9090	J2998	Injection, plasminogen, human-tvmh, 1 mg
C9091	J9331	Injection, sirolimus protein-bound particles, 1 mg
C9092	J3299	Injection, triamcinolone acetonide (xipere), 1 mg
C9093	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
C9781	C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed
J0219	J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0491	J0491	Injection, anifrolumab-fnia, 1 mg
J9071	J9071	Injection, cyclophosphamide, (auromedics), 5 mg
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg
J9359	J9359	Injection, loncastuximab tesirine-lpyl, 0.1 mg
Q4224	Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Q4225	Amniobind, per square centimeter
Q4256	Q4256	Mlg-complete, per square centimeter
Q4257	Q4257	Relese, per square centimeter
Q4258	Q4258	Enverse, per square centimeter

3. July 2022 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

In the July 2022 ASC quarterly update (Transmittal 11472, Change Request 12773, dated June 23, 2022), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 52 (New Level II HCPCS Codes for

Covered Surgical Procedures and Covered Ancillary Services Effective July 1, 2022) of the CY 2023 OPPS/ASC proposed rule displayed the new HCPCS codes that were effective July 1, 2022. We invited public comments on the proposed payment indicators for these Level II HCPCS codes, and indicated that the proposed comment indicators, payment indicators, and payment rates for these codes were listed in Addendum AA and Addendum BB of the proposed rule. These new codes that were effective July 1, 2022, were assigned to comment indicator "NP" in ASC Addendum AA and Addendum BB to the CY 2023 OPPS/ASC proposed rule to indicate that the codes were assigned to interim payment indicators and comments would be accepted on their interim assignments. We further stated that we proposed to finalize the payment indicators in this CY 2023 OPPS/ASC final rule with comment period. We note that several of the temporary drug HCPCS C-codes have been replaced with HCPCS J-codes and HCPCS Q-codes. Their replacement codes are also listed in Table 72. In addition, although in prior years we included the final ASC payment indicators in the coding tables in the preamble, because we include the same information in Addendum AA and Addendum BB, we have not included them in Table 72. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system.

We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes that we added to the list of covered surgical procedures and ancillary services implemented as of July 2022 and we are finalizing the proposed ASC payment indicator assignments for these codes.

We note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) are available via the Internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.

TABLE 72: NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
A9596	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9601	A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie
C9094	J1302	Injection, sutimlimab-jome, 10 mg
C9095	J9274	Injection, tebentafusp-tebn, 1 microgram
C9096	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
C9097	J2777	Inj, faricimab-svoa, 0.1 mg
C9098	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
J0739	J0739	Injection, cabotegravir, 1 mg
J1306	J1306	Injection, inclisiran, 1 mg
J1551	J1551	Injection, immune globulin (cutaquig), 100 mg
J2356	J2356	Injection, tezepelumab-ekko, 1 mg
J2779	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2998	J2998	Injection, plasminogen, human-tvmh, 1 mg
J3299	J3299	Injection, triamcinolone acetonide (xipere), 1 mg
J9331	J9331	Injection, sirolimus protein-bound particles, 1 mg
J9332	J9332	Injection, efgartigimod alfa-fcab, 2mg
Q4259	Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Q4260	Signature apatch, per square centimeter
Q4261	Q4261	Tag, per square centimeter

In addition, through the July 2022 quarterly update CR, we added three new Category III CPT codes to the list of ASC covered ancillary services, effective July 1, 2022. These codes were listed in Table 53 (New Category III CPT Codes for Covered Ancillary Services Effective July 1, 2022) of the CY 2023 OPPS/ASC proposed rule (87 FR 44704), and also listed in Table 73 of this CY 2023 OPPS/ASC final rule with comment period. We invited public comments on

the proposed payment indicators for these new Category III CPT codes, and indicated that the proposed comment indicators, payment indicators, and payment rates for these codes were listed in Addendum BB of the proposed rule. We further stated that we would finalize the payment indicators in this CY 2023 OPPS/ASC final rule with comment period.

We did not receive any comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes that we added to the list of covered ancillary services implemented in July 2022 and we are finalizing the proposed ASC payment indicator assignments for these codes. We note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) are available via the Internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.

TABLE 73: NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2023 HCPCS Code	CY 2023 Long Descriptor
0714T	0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0715T	0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
0716T	0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score

4. October 2022 HCPCS Codes for Which We Are Soliciting Public Comments in this Final Rule with Comment Period

For CY 2023, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2022, would be flagged with comment indicator "NI" in Addendum BB in the CY 2023 OPPS/ASC final rule with comment period to indicate that we have assigned the codes interim ASC payment indicators for CY 2023. We are inviting

public comments in this final rule with comment period on the interim payment indicators, which would be finalized in the CY 2024 OPPS/ASC final rule with comment period.

5. January 2023 HCPCS Codes

a. Level II HCPCS Codes for Which We Are Soliciting Public Comments in this Final Rule with Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that, unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the C and G-codes listed in Addendum O to the CY 2023 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules, however, the codes are flagged with comment indicator "NI" in ASC Addendum AA and Addendum BB to this final rule with comment period to indicate that we are assigning them an interim payment status, which is subject to public comment. Therefore, as we stated in the CY 2023 OPPS/ASC proposed rule, these Level II HCPCS codes that will be effective January 1, 2023, are included in this final rule with comment period, and will also be released to the public through in the January 2023 ASC Update CR and the CMS HCPCS website.

In addition, for CY 2023, we propose to continue our established policy of assigning comment indicator “NI” in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2023, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments in this final rule with comment period on the

payment indicator assignments, which would be finalized in the CY 2024 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Solicited Public Comments in the Proposed Rule

For the CY 2023 ASC update, we received the CPT codes that will be effective January 1, 2023, from the AMA in time to be included in the CY 2023 OPPS/ASC proposed rule. The new, revised, and deleted CPT codes can be found in Addendum AA and Addendum BB to the CY 2023 OPPS/ASC proposed rule (which is available via the Internet on the CMS website at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1772-p). We note that the new and revised CPT codes are assigned to comment indicator "NP" in ASC Addendum AA and Addendum BB of the CY 2023 OPPS/ASC proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We stated that we would accept comments and finalize the payment indicators in this CY 2023 OPPS/ASC final rule with comment period. Further, we reminded readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new CY 2023 CPT codes in Addendum O to the CY 2023 OPPS/ASC proposed rule so that the public could comment on our proposed payment indicator assignments. The 5-digit placeholder codes were listed in Addendum O to the CY 2023 OPPS/ASC proposed rule, specifically under the column labeled "CY 2023 OPPS/ASC Proposed Rule 5-Digit Placeholder Code." We also stated that we would include the final CPT code numbers in this CY 2023 OPPS/ASC final rule with comment period.

We did not receive any comments on the proposed ASC payment indicators for the new CPT codes effective January 1, 2023, so we are finalizing these codes as proposed.

Finally, in Table 74, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

TABLE 74: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	CY 2023 OPPS/ASC proposed rule	CY 2023 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2023	CY 2023 OPPS/ASC final rule with comment period	CY 2024 OPPS/ASC final rule with comment period

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as "office-based" those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule with payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered

surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2023 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2023 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d. of this final rule with comment period), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2021 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2022 of "G2" (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2", "P3", or "R2" in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

In our CY 2022 OPPS/ASC final rule with comment period (86 FR 63770), we discussed that we, historically, review the most recent claims volume and utilization data and clinical characteristics for all covered surgical procedures that were assigned a payment indicator of "G2" for CY 2021. For the CY 2022 OPPS/ASC final rule with comment period, the most recent claims volume and utilization data was CY 2020 claims. However, given our concerns with the use of CY 2020 claims data as a result of the COVID-19 PHE as further discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we adopted

a policy to not review CY 2020 claims data and did not assign permanent office-based designations to covered surgical procedures that were assigned a payment indicator of "G2" in CY 2021 (86 FR 63770 through 63771).

As discussed further in Section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), in our review of the CY 2021 outpatient claims available for ratesetting for this CY 2023 OPPS proposed rule, we observed that many outpatient service volumes have partially returned to their pre-PHE levels and it is reasonable to assume that there will continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPPS ratesetting. As a result, we proposed to use the CY 2021 claims for CY 2023 OPPS ratesetting. Similarly, in the CY 2023 OPPS/ASC proposed rule (87 FR 44705 through 44708), we proposed to resume our historical practice and review the most recent claims and utilization data, in this case data from CY 2021 claims, for determining office-based assignments under the ASC payment system.

Our review of the CY 2021 volume and utilization data of covered surgical procedures currently assigned a payment indicator of "G2" (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of 6 surgical procedures that we believed met the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believed that the services are of a level of complexity

consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2023 are listed in Table 75.

TABLE 75: PROPOSED ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2023

CY 2023 CPT/HCPCS Code	CY 2022 Long Descriptor	CY 2022 ASC Payment Indicator	Proposed CY 2023 ASC Payment Indicator*
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	G2	R2*
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	G2	P2*
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	G2	P3*
21198	Osteotomy, mandible, segmental;	G2	R2*
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral	G2	P2*
40830	Closure of laceration, vestibule of mouth; 2.5 cm or less	G2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2023 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2023 PFS proposed rule.

Comment: One commenter recommended that we do not assign an office-based payment indicator of "P3" to CPT code 36595 (Mechanical removal of pericatheter obstructive material (eg, fibrin sheath) from central venous device via separate venous access) as this procedure was assigned a non office-based payment indicator of "G2" in prior years and was assigned a payment indicator of "J8" – Device-intensive procedure; paid at adjusted rate – for CY 2022.

Response: In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75071 through 75072), we finalized our proposal to permanently designate CPT code 36595 as an

office-based procedure. As we have stated in past rulemaking (76 FR 74409 and 80 FR 70483), our current policy is for device-intensive status to supersede the assignment of the office-based designation. If the procedure no longer meets our criteria for device-intensive status we believe the permanent office-based designation should still apply. After reviewing CY 2021 claims data available for this final rule, CPT code 36595 does not meet our criteria for device-intensive status for CY 2023. Therefore, we are not accepting the commenter's recommendation and are finalizing our proposal to assign an office-based payment indicator to CPT code 36595 for CY 2023.

Comment: Some commenters did not support our proposal to assign a permanent office-based designation to CPT code 15275 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area). One commenter claimed that an insufficient ASC payment rate has contributed to a low claims volume and a site of service shift away from the ASC setting. Another commenter stated that our office-based analysis only looked at the ASC and physician office claims volume and did not account for all outpatient settings, including hospital outpatient department utilization.

Response: The commenter has inaccurately described our analysis for making office-based determinations under the ASC payment system. We propose procedures to be permanently designated as office-based based on physician claims that report the procedure across all settings of care, both inpatient and outpatient. If the office-based utilization exceeds 50% of total utilization across all settings of care and total utilization exceeds 50 claims, we propose such procedures be permanently designated as office-based. Based on our review of CY 2021 claims and utilization data for this final rule with comment period, for CPT code 15725, there were a

reported 90,211 claim lines in the physician office setting and a reported 154,108 claim lines across all settings of care. We believe this is volume is more than sufficient to make a permanent office-based designation to CPT code 15275 under our current policy.

Comment: One commenter supported our proposal to assign a permanent office-based designation to CPT code 31574 (Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral).

Response: We appreciate the commenter's support of our office-based designation for CPT code 31574.

After consideration of the comments received, we are finalizing our proposal, without modification, to permanently designate the procedures in Table 76 as office-based procedures.

TABLE 76: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2023

CY 2023 CPT/HCPCS Code	CY 2022 Long Descriptor	CY 2022 ASC Payment Indicator	Final CY 2023 ASC Payment Indicator*
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	G2	R2*
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	G2	P2*
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	G2	P3*
21198	Osteotomy, mandible, segmental;	G2	R2*
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral	G2	P2*
40830	Closure of laceration, vestibule of mouth; 2.5 cm or less	G2	P2*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2023 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2023 PFS final rule.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence of claims data, we use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

We reviewed CY 2021 volume and utilization data for 8 surgical procedures designated as temporarily office-based in the CY 2022 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically "P2," "P3" or "R2" as shown in Table 77. For all 8 surgical procedures, there were fewer than 50 claims or no claims in our data. Therefore, we proposed to continue to designate these procedures, shown in Table 77, as temporarily office-based for CY 2023. The procedures for which the proposed office-based designation for CY 2023 is temporary are indicated by an asterisk in Addendum AA to the CY 2023 OPPS/ASC proposed rule (which is available via the internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices).

TABLE 77: PROPOSED CY 2023 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2022 OPPS/ASC FINAL RULE

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator	Proposed CY 2023 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2023 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2023 PFS proposed rule.

We did not receive any public comments on our proposal to assign temporary office-based designations to the procedures listed in Table 77. However, as discussed in section XIII.C.1.d of this final rule with comment period, we are finalizing the addition of a new CPT

code 0581T (Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral) to the ASC list of covered surgical procedures. We believe this procedure is clinically similar to CPT code 19105 (Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma) which is currently assigned an office-based payment indicator of "P2" under the ASC payment system. Therefore, we are finalizing our proposal, with a modification to include CPT code 0581T, to designate the procedures shown in Table 78 as temporarily office-based for CY 2023.

TABLE 78: CY 2023 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator	Final CY 2023 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P3*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	N.A.	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator	Final CY 2023 ASC Payment Indicator*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2023 PFS final rates. For a discussion of the final PFS rates, we refer readers to the CY 2023 PFS final rule with comment period.

b. Device-Intensive ASC Covered Surgical Procedures

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2023

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;

- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

Comment: Many commenters requested that we use invoice or cost data submitted by manufacturers to determine the device portion for the ASC payment rate in lieu of the proposed default device offset percentage of 31 percent, specifically for the following procedures:

- HCPCS Code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed);
- CPT code 30469 (Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling);
- CPT code 69714 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy).

Other commenters requested that we use invoice data or a subset of claims data to determine device-intensive status for certain procedures and stated that hospitals have inaccurately coded devices as surgical supplies, therefore, the device offset percentage calculated from our claims statistics does not reflect the true cost of the device. Specifically, commenters requested that we assign device-intensive status to the following procedures:

- HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable);
- CPT code 0499T (Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed);
- CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance);
- CPT code 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent).

Response: We are not accepting the commenters' recommendations to use invoice data in lieu of claims data or a subset of our cost data to determine the device portion of the ASC payment rate. As we stated in the CY 2023 OPPS/ASC proposed rule (87 FR 44623-24), we may temporarily assign a higher offset percentage if warranted by additional information in certain rare instances. Additionally, for new procedures that do not have claims data, we may assign a device offset percentage from a predecessor code, or, from a clinically similar procedure code that uses the same device. For procedures that we proposed to assign a default device offset percentage of 31 percent due to a lack of claims data and lack of either a predecessor code or clinically similar code that uses the same device, including HCPCS code C9781, CPT codes 30469 and 69714, we believe the default device offset percentage of 31 percent encourages efficiencies under the ASC payment system and is appropriate until we have available claims.

We are also not accepting the commenters' recommendation to use invoice data from device manufacturers or a subset of claims data for determining device-intensive status for procedures that do not have a device offset percentage that exceeds our 30% device-intensive threshold based on claims data available for this final rule with comment period, including HCPCS code C9761, CPT codes 0499T, 55880, and 66174. Under our current policy, hospitals are expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable and we believe our claims database represents the most accurate source of device cost information available to us. We do not believe it would be appropriate to exclude in whole or in part the available claims data that we have for ratesetting and for determining device offset percentages.

Comment: Some commenters recommended that we refrain from wage-adjusting the device portion of device-intensive procedures by the wage index for that particular area and only

wage-adjust non device portions of the ASC payment rate. The commenters contend that wage-adjusting 50 percent of the ASC payment rate by the wage index for a particular area can reduce ASC payment rates below the cost of certain devices.

Response: We appreciate the commenters' recommendation. We did not propose such a change to our application of the ASC wage index but, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59042), such a policy would increase payment for providers with a relatively low wage index (that is, a wage index value of less than 1) and decrease it for providers with a relatively high wage index (that is, a wage index value of greater than 1). We did not make such a proposal, but we will consider the feasibility of this change and take this comment into consideration for future rulemaking.

Comment: Commenters asked for further clarification on the source of the ASC device offset amount when billing for devices that have received transitional pass-through status under the OPPS and are separately paid under the ASC payment system. Commenters contend the procedure reduction in the ASC code pair file, which reflects the device offset amount, conflicts with information found in Addendum FF.

Response: Addendum FF lists device offset percentages as well as device portions for all ASC covered surgical procedures. The device offset percentages are based on hospital outpatient cost data using the ASC standard ratesetting methodology and are a main component in determining whether or not a procedure can be assigned device-intensive status under the ASC payment system. These percentages are not the procedure reduction percentages that are found in the ASC code pair file when billing for devices that have received transitional pass-through status. In a footnote to the CY 2023 OPPS/ASC proposed rule Addendum FF as well as Addendum FF to this final rule with comment period, we have clarified this distinction. In this

final rule with comment period, we are restating that for device-intensive and non device-intensive procedures, unless otherwise specified, the device portion, which is found in Addendum FF, is the associated device offset dollar amount when billing for devices that have received transitional pass-through status under the OPPS and are separately paid under the ASC payment system. The procedure reduction percentage that is applied to the ASC payment rate which is found in the ASC code pair file can be calculated by dividing the procedure's device portion by the ASC payment rate.

Comment: One commenter requested that we consider a modification to our established policy that would allow the continuation of the default device offset of 31 percent for procedures for which there were fewer than 100 claims used to calculate the device offset percentage.

Response: We appreciate the commenter's request. We are concerned that such a policy would inaccurately assign device-intensive status to procedures that would otherwise consistently be ineligible for device-intensive assignment. While we do not believe at this time that continuing the default device offset percentage over available claims data would be an improvement to our methodology for determining device offset amounts and device-intensive status for procedures for which there were fewer than 100 claims used to calculate the device offset percentage, we will take this comment into consideration for future rulemaking.

Comment: One commenter recommended that we assign the device offset percentage of CPT code 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) to 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level) as both procedures use the same device.

Response: For the CY 2023 OPPS/ASC proposed rule and this final rule with comment period, we do not have any claims data for CPT code 0629T to determine a device offset percentage. Under our current policy, we may assign an alternative device offset percentage if we have claims data from a clinically similar procedure code that uses the same device. We agree with commenters that this policy can apply to CPT code 0629T, which is clinically similar to CPT code 0627T and uses the same device as this procedure. Therefore, we are accepting the commenter's recommendation and, for CY 2023, we are assigning the device offset percentage of CPT code 0627T to CPT code 0629T and assigning CPT code 0629T device-intensive status.

Comment: Commenters supported the proposed device offset percentages for the following procedures:

- CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more);
- HCPCS code C9764 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed); and,
- HCPCS code C9766 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed).

Response: We appreciate the commenters' support. We are finalizing our proposal to assign device-intensive status to CPT code 0671T, HCPCS code C9764, and HCPCS code C9766. For final CY 2023 device offset percentages based on available claims data for this final

rule with comment period, we refer readers to Addendum FF of this final rule with comment period.

Comment: One commenter requested that we recalculate the device offset percentages, and subsequent ASC payment rate, for procedures performed with OPPS transitional pass-through device category C1748 (Endoscope, single-use (i.e. disposable), Upper GI, imaging/illumination device (insertable)) after expiration of its transitional pass-through status on July 1, 2023 for the July 2023 quarterly update.

Response: We appreciate the commenter's recommendation. For procedures performed with transitional pass-through device categories that expire on April 1st, July 1st, or October 1st, we use the best claims data available to us to determine the procedures' applicable device offset percentages and recalculate the ASC payment rate if necessary.

Comment: One commenter requested that we not assign device-intensive status to CPT code 0428T (Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only).

Response: We agree with the commenter that CPT code 0428T does not involve significant device costs and is therefore ineligible for device-intensive status under our current policy. Therefore, for CY 2023, we are accepting the commenter's recommendation and assigning an ASC payment indicator of "G2" – Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight. – to CPT code 0428T for CY 2023.

As discussed in more detail in section XIII.D.1.c of the CY 2023 OPPS/ASC proposed rule (87 FR 44712 through 44714), we proposed to create a special payment policy under the ASC payment system whereby we would add new C codes to the ASC CPL to provide a special

payment for code combinations eligible for complexity adjustments under the OPPS. These code combinations reflect separately payable primary procedures on the ASC CPL as well as add-on procedures that are packaged with an ASC payment indicator of "N1" (Packaged service/item; no separate payment made.). Under our proposal, the C code would retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. The device offset percentage for a C code would be established by dividing the device portion of the primary procedure by the OPPS complexity-adjusted APC payment rate based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of a C code.

Based on our existing criteria as well as our proposal to add to the ASC CPL new C codes that reflect code combinations eligible for complexity adjustments under the OPPS, for CY 2023, we proposed to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology. For CY 2023, where CY 2021 claims data are available, the device-intensive payment methodology relies on the proposed device-offset percentages of each device-intensive procedure using the CY 2021 OPPS claims and cost report data available for the CY 2023 OPPS/ASC proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2023, are assigned payment indicator "J8" and are included in ASC Addendum AA and Addendum FF to the CY 2023 OPPS/ASC proposed rule (which is available via the internet on the CMS website

at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1772-p). The CPT code, the CPT code short descriptor, the proposed CY 2023 ASC payment rate are also included in Addendum AA to the CY 2023 OPPS/ASC proposed rule (which is available via the internet on the CMS website at https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1772-p). We solicited public comments on our proposal to assign device-intensive status to the new C codes that we proposed to add to the ASC CPL as well as our methodology for determining the device portion for such procedures.

Comment: Commenters were in support of our proposed device-intensive methodology for the new C codes we proposed to add to the ASC CPL and assign device-intensive status. Commenters asked that CMS publicly share data on the impact of this policy and if any adjustments are needed.

Response: We appreciate the commenters support of our proposal. We intend to share with the public the impact of our new C code policy and consider adjusting and refining this policy in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to assign device-intensive status to the new C codes that we are adding to the ASC CPL for CY 2023 if the primary procedure is assigned device-intensive status as well. We are also finalizing our proposed methodology for determining the device portion for such procedures. For CY 2023, the device-intensive payment methodology for the new device-intensive C codes that we are adding to the ASC CPL relies on the final device portions (calculated from the final device offset percentages) using the CY 2021 OPPS claims and cost report data available for this final rule with comment period. The ASC covered surgical procedures that we are finalizing to designate

as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2023, are assigned payment indicator "J8" and are included in ASC Addendum AA and Addendum FF to this CY 2023 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, the final CY 2023 ASC payment rate are also included in Addendum AA to the CY 2023 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or

with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS "FB" modifier on the line in the claim with the procedure to implant or insert the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS "FC" modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent)

of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our "FB"/"FC" modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we proposed to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years. Specifically, for CY 2022 and subsequent calendar years, we would

reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We did not receive any comments on our policies related to no/cost full credit or partial credit devices, and we are continuing our existing policies for CY 2023 and subsequent years.

d. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the Internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 and CY 2022 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805).

1. Changes to the List of ASC Covered Surgical Procedures for CY 2023

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to

the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary. For CY 2023, we conducted a review of procedures that currently are paid under the OPPS and not included on the ASC CPL. We also assessed procedures against our regulatory safety criteria at § 416.166. Based upon this review, we proposed to update the ASC CPL by adding one lymphatic procedure to the list for CY 2023, as shown in Table 79 below.

After reviewing the clinical characteristics of this procedure, as well as consulting with stakeholders and multiple clinical advisors, we determined that this procedure is separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This procedure does not result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We believe this procedure may be appropriately performed in an ASC on a typical Medicare beneficiary. Therefore, we proposed to include this procedure on the ASC CPL for CY 2023.

TABLE 79: CY 2023 SURGICAL PROCEDURES FOR THE ASC CPL

CY 2023 CPT/HCPCS Code	CY 2023 Long Descriptor
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also

believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years. We encourage stakeholders to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed on the typical Medicare beneficiary in the ASC setting.

Comment: Several specialty groups expressed broad support for expanding the ASC CPL and adding the lymph node procedure that CMS proposed to the ASC CPL for CY 2023. One hospital commenter disagreed with expanding the CPL, citing undue safety risks for patients in the ASC setting.

Response: We thank the commenters for their feedback. When adding procedures to the ASC CPL, we evaluate them against the ASC CPL criteria in order to ensure that the procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC. As medical practice continues to evolve and advance, more procedures are able to be safely offered in the ASC setting for the typical Medicare beneficiary. As we have determined that these procedures meet our existing criteria such that they can be performed safely in the ASC setting on the typical Medicare beneficiary, we disagree that they pose an undue safety risk for patients in the ASC setting.

Comment: A few stakeholders expressed disappointment that CMS only proposed to add one code for CY 2023. Multiple commenters recommended specific codes that they believed met the criteria to be added to the ASC CPL, including cardiovascular and cardiac ablation codes, thyroid-related procedures, and electroconvulsive therapy. Several orthopedic providers

requested that total shoulder arthroplasty, total ankle arthroplasty and lumbar spine fusion procedures be added to the CPL, based on claims of safe and routine performance in ASCs, low infection rates, and financial savings. We received 64 procedure recommendations in total, listed in Table 80 below. Some of these recommendations were accompanied by supporting literature or evidence, while other comments only provided anecdotal evidence and simply stated general support for these procedures to be furnished in the ASC setting.

Response: We thank commenters for their recommendations. We individually assessed each of these 64 procedures, evaluating clinical data on these procedures from multiple sites of services, reviewing the literature and experiential data provided in public comments, and examining claims volume to determine whether these procedures meet each of the regulatory criteria at 42 CFR 416.166.

Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently on the ASC CPL, we believe that four procedures (CPT codes 19307, 37193, 38531, and 43774) out of the 64 procedure recommendations we received can be safely performed for the typical beneficiary in the ASC setting and meet the general standards and exclusion criteria for the ASC CPL as set forth in 42 CFR 416.166(b) and (c), respectively. This includes CPT code 38531, which we proposed to add to the CPL in the CY 2023 OPPS/ASC proposed rule. These four codes correspond to procedures that have few to no inpatient admissions and are largely performed in outpatient settings. We agree with commenters who provided evidence stating that these procedures can be safely performed in an ASC setting. These procedures, listed in Table 81 below, are:

- CPT 19307 (Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle)

- CPT 37193 (Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed)
- CPT 38531 (Biopsy or excision of lymph node(s); open, inguinofemoral node(s))
- CPT 43774 (Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components)

Due to patient safety concerns, we believe the remaining recommended procedures should not be added to the ASC CPL. We explain our rationale for not including the 60 remaining recommended procedures below, organized by anatomical category.

- *20 vascular codes,* including arterial revascularization, coronary atherectomies, and vena cava filter insertion or removal procedures. Many of these procedures have associated inpatient admissions, where the beneficiary requires active medical monitoring and care at midnight following the procedure. Additionally, a number of these procedures would pose a significant safety risk to beneficiaries without post-operative inpatient care and because patients requiring these procedures are often higher risk at baseline. Some of the vascular codes recommended in the CPT 90000 series were also non-surgical procedures, which means they would not qualify for addition to the ASC CPL or the ancillary services list, as they are not integral to a covered surgical procedure.
- *4 gastrointestinal codes*, including paraesophageal hernia repairs, laparoscopic esophagogastric fundoplasty, laparoscopic enterolysis, appendectomy, and laparoscopic gastric restrictive procedures. While some of these procedures show increasing outpatient volume, many still have inpatient admissions and potential procedure risks, indicating that the beneficiary

would require active monitoring and care past midnight following the procedure. Additionally, these procedures can involve prolonged invasion of body cavities, and be life-threatening or emergent in nature. Additionally, several of these procedures are less commonly done in Medicare patients and more frequently performed in a younger population.

- *6 musculoskeletal codes*, including total shoulder and ankle arthroplasty procedures as well as lumbar spine fusion procedures. Although a few of these procedures have some claims volume in the outpatient setting, many of them are also complex procedures with inpatient admissions and multiple post-operative inpatient days, where infections and need for intravenous antibiotics are not uncommon events, indicating that the beneficiary would require active monitoring and care past midnight following the procedure. In addition, we acknowledge the findings of studies that commenters provided related to these procedures. However, the studies we received had significant limitations including selection bias, an absence of age groups representative of the Medicare population, and a lack of generalizability to different types of ASCs around the country.

- *4 endocrine codes,* including thyroidectomy and parathyroidectomy procedures. While these procedures have increasing outpatient volume, there are inpatient admissions associated with these procedures, indicating the beneficiary would be expected to stay past midnight following the procedure. Additionally, the intraservice time for these procedures can vary greatly, often becoming a prolonged invasion of body cavities.

- *2 nervous system codes*, including laminectomy and laminotomy procedures. These codes have associated inpatient admissions and post-operative days, indicating that the beneficiary would require active monitoring and care past midnight following the procedure.

Many of these procedures also pose a significant safety risk to the beneficiary when close post-operative neurosurgical surveillance is not frequently provided.

- *24 medicine codes,* including electroconvulsive therapy, cardioversion, echocardiography, esophageal recordings, intra-atrial and intra-ventricular recordings, comprehensive electrophysiologic evaluations. These codes are inherently non-surgical and would not qualify for the ASC CPL or the ancillary services list, as they are not integral to a covered surgical procedure.

Given these considerations, we believe that these 60 codes do not meet the proposed criteria to be included on the ASC CPL due to the following factors: inpatient admissions, multiple-day stays past midnight, safety risks to the typical beneficiary without active post-operative monitoring, involvement of major blood vessels, prolonged invasion of a body cavity, the risk of being life threatening or emergent, less common in Medicare beneficiaries, or are non-surgical.

However, as medical practice continues to evolve, we recognize that there will be additional advancements and improvements that may allow these procedures to be safely offered in the ASC setting for the typical Medicare beneficiary. We believe that there is potential for some of the procedures recommended but not added to the ASC CPL to be added in the future if there is adequate evidence that these procedures meet our criteria and can be safely performed on the typical Medicare beneficiary in the ASC setting. We encourage interested parties to continue to submit this information in future rulemaking.

Therefore, in this CY 2023 OPPS/ASC final rule with comment period, we are finalizing four procedures to be added to the ASC CPL. These procedures are listed below in Tables 80 and 81 of this CY 2023 OPPS/ASC final rule with comment period.

Comment: Commenters also offered suggestions on different approaches for CMS to consider when approaching the ASC CPL, including providing a rationale for each procedure that is added or denied, noting that CMS has previously stated they would disclose this information; standardizing CPL additions by covering all surgical procedures paid separately under the OPPS, unless the procedure meets the exclusionary criteria; offering additional guidance on the definition of the "typical Medicare beneficiary"; and allowing clinicians to decide whether their patients are eligible for care in an ASC.

Response: We thank the commenters for their suggestions and will take these suggestions into consideration for future rulemaking. CMS has provided rationales for denying codes in both CY 2022 and CY 2023. We provide rationales in code buckets, rather than for each individual code, because this format captures and conveys the various reasons we do not believe these procedures meet the ASC CPL criteria in a succinct and non-repetitive manner. We believe that all procedures that meet our ASC CPL criteria are currently on the ASC CPL and that standardizing this process by adding all eligible procedures paid separately under the OPPS would not change the list of ASC covered surgical procedures. In the CY 2022 OPPS/ASC final rule, we provided a detailed rationale for why we believe that CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, while physicians can make safety decisions for their specific beneficiaries (86 FR 63777 through 63779). We also provided additional context on the typical Medicare beneficiary, whose health status is representative of the broader Medicare population, and we believe this information is sufficient to understand the typical Medicare beneficiary terminology without additional clarification at this time.

TABLE 80: Surgical Procedures Being Added to the ASC CPL in CY 2023

CY 2023 CPT/HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	G2
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	G2
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	G2
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	G2

TABLE 81: Surgical Procedure Recommendations Received from Commenters

CY 2023 CPT/ HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	X5
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	X5
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	X5
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	X5
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	X5
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	X5

CY 2023 CPT/ HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
27702	Arthroplasty, ankle; with implant (total ankle)	X5
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	X5
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	X5
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	X5
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	X5
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	X5
44970	Laparoscopy, surgical, appendectomy	X5
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	X5
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	X5
60271	Thyroidectomy, including substernal thyroid; cervical approach	X5
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	X5
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	X5
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	X5
90870	Electroconvulsive therapy (includes necessary monitoring)	S1
92652	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report	S1
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	S1

CY 2023 CPT/ HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	S1
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	S1
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	S1
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	S1
92960	Cardioversion, elective, electrical conversion of arrhythmia; external	S1
92961	Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure)	S1
93306	Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography	S1
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report	S1
93318	Echocardiography, transesophageal (tee) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis	S1
93600	Bundle of his recording	S1
93602	Intra-atrial recording	S1
93603	Right ventricular recording	S1
93610	Intra-atrial pacing	S1
93612	Intraventricular pacing	S1
93613	Intracardiac electrophysiologic 3-dimensional mapping (list separately in addition to code for primary procedure)	N1

CY 2023 CPT/ HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
93615	Esophageal recording of atrial electrogram with or without ventricular electrogram(s);	S1
93616	Esophageal recording of atrial electrogram with or without ventricular electrogram(s); with pacing	S1
93618	Induction of arrhythmia by electrical pacing	S1
93619	Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, his bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	S1
93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, his bundle recording	S1
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (list separately in addition to code for primary procedure)	N1
93622	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left ventricular pacing and recording (list separately in addition to code for primary procedure)	N1
93623	Programmed stimulation and pacing after intravenous drug infusion (list separately in addition to code for primary procedure)	N1
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy, including induction or attempted induction of arrhythmia	S1
93642	Electrophysiologic evaluation of single or dual chamber transvenous pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	S1
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	S1
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	S1

CY 2023 CPT/ HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed	S1
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (list separately in addition to code for primary procedure)	S1
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and his bundle recording, when performed	S1
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (list separately in addition to code for primary procedure)	S1
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	X5
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	X5
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	X5
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	X5

CY 2023 CPT/ HCPCS Code	CY 2023 Long Descriptor	Final CY 2023 ASC Payment Indicator
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	X5
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	X5

Name Change and Start Date of Nominations Process

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to add a nominations process for adding surgical procedures to the ASC CPL at § 416.166(d), (86 FR 63782) which we titled "Nominations." As we have discussed in previous rulemaking, this process is simply an opportunity outside of the existing public comment period process for interested parties to submit recommendations before the proposed rule period so CMS can consider the suggestions as we develop the proposed rule. We believe this process enhances transparency and allows interested parties an additional opportunity to provide input for the ASC CPL.

However, the nominations process is not the only way for interested parties to make recommendations to CMS for adding surgical procedures to the ASC CPL. We emphasize that interested parties have been able, and may continue, to suggest surgical procedures they believe should be added to the ASC CPL during the public comment period following the proposed rule. That process remains unchanged. When interested parties submit procedure recommendations for the ASC CPL through the public comment process, CMS will consider them for the final rule with comment period. We understand, however, that the terminology we used in the CY 2022 OPPS/ASC final rule with comment period and codified at § 416.166(d) – "Nominations" – may

have led to some confusion that this process is the primary or only pathway for interested parties to suggest procedures to be added to the ASC CPL. Therefore, we proposed to change the name of the process finalized last year in the CY 2022 OPPS/ASC final rule with comment period from "Nominations" to the "Pre-Proposed Rule CPL Recommendation Process." Where the current name of the process may suggest a formality or limitation that we did not intend – one that implies the nominations process is the preferred, primary, or only means by which interested parties may submit recommendations – we believed this proposed new name would not.

In addition, we are currently working on developing the technological infrastructure and Paperwork Reduction Act (PRA) package for the recommendations process. Because we were unable to complete the infrastructure development and PRA processes (which have taken longer than we originally anticipated when we finalized the policy) in time for commenters to recommend procedures to be added to the ASC CPL prior to the CY 2023 proposed rule, we proposed to revise the start date of the recommendation process in the regulatory text. We proposed to change January 1, 2023, to January 1, 2024, so that the text at § 416.166(d) would specify that on or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year. We welcomed all procedure submissions through the public comment process, as we have in previous years.

Comment: Several commenters supported the clarification of the future pre-proposed rule recommendation process. A few commenters noted that they still preferred the term "Nominations." Some commenters stated that they prefer the proposed process as it encourages CMS transparency, and some commenters urged CMS to implement this proposal without delay.

Response: We thank the commenters for their input on this process.

After consideration of the public comments we received, we are finalizing the proposal to change the name of the process finalized last year in the CY 2022 OPPS/ASC final rule with comment period from "Nominations" to the "Pre-Proposed Rule CPL Recommendation Process" and revise the start date of the recommendation process to January 1, 2024 in the regulatory text.

2. Covered Ancillary Services

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2022, but will be packaged under the CY 2023 OPPS, we would also package the ancillary service under the ASC payment system for CY 2023 to maintain consistency with the OPPS. Comment indicator "CH" is used in Addendum BB (which is available via the Internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2023.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2023 can be found in section XIII.B of this CY 2023 OPPS/ASC final rule. All ASC covered ancillary services and their final payment indicators for CY 2023 are also included in Addendum BB to the CY 2023 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

D. Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. Final ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators “G2” and “A2”. Payment indicator “A2” was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator “A2” is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator “A2” because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators “P2”, “P3”, and “R2”) are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.1.a of this CY 2023 OPPS/ASC final rule, we update the payment amounts for office-based procedures

(payment indicators "P2", "P3", and "R2") using the most recent available MPFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.1.b of this CY 2023 OPPS/ASC final rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators "Q1" and "Q2") describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator "N1") under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is

performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal – conditionally packaged in the OPPS (status indicator "Q2") – we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2023

We proposed to update ASC payment rates for CY 2023 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b of this CY 2023 OPPS/ASC final rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we proposed that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2".

We proposed to calculate payment rates for office-based procedures (payment indicators "P2", "P3", and "R2") and device-intensive procedures (payment indicator "J8") according to our established policies and to identify device-intensive procedures using the methodology discussed in section XII.C.1.b of this CY 2023 OPPS/ASC final rule. Therefore, we proposed to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2023 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We proposed that payment

for office-based procedures would be at the lesser of the proposed CY 2023 MPFS nonfacility PE RVU-based amount or the proposed CY 2023 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2022, for CY 2023, we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

Comment: A few commenters expressed concerns about the lack of a cap on beneficiary coinsurance when a procedure is performed in the ASC setting while there is a statutory cap on beneficiary coinsurance when a procedure is performed in the HOPD setting. The commenters believe the lack of such a cap poses a financial challenge for beneficiaries, particularly with respect to transitional pass-through devices and higher-cost procedures that are device intensive, because in such cases, the coinsurance could be higher in the ASC setting than in the HOPD setting. The commenters stated their belief that ASCs are disadvantaged by the lack of a cap on coinsurance and believe this presents a beneficiary access issue. They request that CMS encourage the Congress to create a cap on coinsurance for services provided in the ASC setting.

Response: We thank the commenters for their input but note that comments related to statutory changes are out of scope for this final rule.

We did not receive any comments on the broader rate calculation methodologies for these procedures and we are finalizing our proposed policies without modification to calculate the CY 2023 payment rates for ASC covered surgical procedures according to our established rate calculation methodologies under § 416.171 and using the modified definition of device-intensive

procedures as discussed in section XIII.C.1.b. of this CY 2023 OPPS/ASC final rule with comment period. For covered office-based surgical procedures, the payment rate is the lesser of the final CY 2022 MPFS nonfacility PE RVU-based amount or the final CY 2023 ASC payment amount calculated according to the ASC standard ratesetting methodology. The final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2023. For a discussion of the PFS rates, we refer readers to the CY 2023 PFS final rule with comment period, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

c. ASC Payment for Combinations of Primary and Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section we proposed a policy to provide increased payment under the ASC payment system for combinations of certain "J1" service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

OPPS C-APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.b.1 of this CY 2023 OPPS/ASC final rule, we apply a complexity adjustment by promoting qualifying paired "J1" service code combinations or paired code combinations of "J1" services and add-on codes from the originating Comprehensive APC (C-APC) (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. A "J1" status indicator refers to a hospital outpatient service paid through a C-APC. We package payment for all add-on codes, which are codes that describe a procedure or service always

performed in addition to a primary service or procedure, into the payment for the C-APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this CY 2023 OPPS/ASC final rule, in the originating C-APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator "J1" or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of "J1" services, or combinations of a "J1" service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim to the next higher cost C-APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new C-APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the

highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the "J1" primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C-APC. We list the complexity adjustments for "J1" and add-on code combinations for CY 2022, along with all of the other final complexity adjustments, in Addendum J to the CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices).

ASC Special Payment Policy for OPPS Complexity-Adjusted C-APCs

Comprehensive APCs cannot be adopted in the ASC payment system, due to limitations of the ASC claims processing systems. Thus, we do not use the OPPS comprehensive services ratesetting methodology in the ASC payment system. Under the standard ratesetting methodology used for the ASC payment system, comprehensive "J1" claims that exist under the OPPS are treated the same as other claims that contain separately payable procedure codes. As comprehensive APCs do not exist under the ASC payment system, there is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, when multiple procedures are performed together in a single operative session, most covered surgical procedures are subject to a 50-percent reduction for the lower-paying procedure (72 FR 66830). This multiple procedure reduction gives providers additional payment when they perform

multiple procedures during the same session, while still encouraging providers to provide necessary services as efficiently as possible. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Unlike the multiple procedure discounting process used for other surgical procedures in the ASC payment system, providers do not receive any additional payment when they perform a primary service with an add-on code in the ASC payment system.

In previous rulemaking, we have received suggestions from commenters requesting that we explore ways to increase payment to ASCs when services corresponding to add-on codes are performed with procedures, as certain code combinations may represent increased procedure complexity or resource intensity when performed together. For example, in the CY 2022 OPPS/ASC final rule with comment period, one commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under the OPPS to be eligible for device-intensive status under the ASC payment system (86 FR 63775). Based on our internal data review and assessment at that time, our response to that comment noted that we did not believe any changes were warranted to our packaging policies under the ASC payment system but that we would consider it in future rulemaking.

For the CY 2023 OPPS/ASC proposed rule, we evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were eligible for complexity adjustments under the OPPS and also performed in the ASC setting. Under the ASC payment system, we identified 26 packaged procedures (payment indicator = “N1”) that combine with 42 primary procedures, which would be C-APCs (status indicator = “J1”) under the OPPS, to produce 52 different complexity adjustment code combinations. We generally estimated that ASC services were paid approximately 55 percent of

the OPPS rate for similar services in CY 2021. When we compared the OPPS complexity-adjusted payment rate of these primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, we found that the average rate of ASC payment as a percent of OPPS payment for these code combinations was 25 to 35 percent, which is significantly lower than 55 percent.

We recognize that this payment differential between the C-APC-assigned code combinations eligible for complexity adjustments under the OPPS and the same code combinations under the ASC payment system could potentially create financial disincentives for providers to offer these services in the ASC setting, which could potentially result in Medicare beneficiaries encountering difficulties accessing these combinations of services in ASC settings. As noted above, our current policy does not include additional payment for services corresponding to add-on codes, unlike our payment policy for multiple surgical procedures performed together, for which we provide additional payment under the multiple procedure reduction. However, these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPPS still represent more complex and costly versions of the service, and we believe that providers not receiving additional payment under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting which could result in barriers to beneficiary access.

In order to address this issue, we proposed a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC

complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. We proposed to add new § 416.172(h) to codify this policy.

We proposed that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPPS (as listed in OPPS Addendum J) would be eligible for this proposed payment policy in the ASC setting. Specifically, we proposed that the ASC payment system code combinations eligible for additional payment under this proposed policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. Add-on codes are assigned payment indicator "N1" (Packaged service/item; no separate payment made), as listed in the ASC addenda.

Regarding eligibility for this special payment policy, we proposed that we would assign each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under our proposal, we would add these C codes to the ASC CPL and the ancillary services list, and when ASCs bill this C code, they would receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the procedure performed. We anticipate that the C codes eligible for this proposed payment policy would change slightly each year, as the complexity adjustment assignments change under the OPPS and we expect we would add new C codes each year accordingly. We proposed new C codes to add to the ASC CPL. These C codes for CY 2023 can be found in the ASC addenda. We proposed to add new § 416.172(h)(1), titled Eligibility, to codify this policy.

We proposed the following payment methodology for this proposed policy, which we would reflect in new § 416.172(h)(2), titled Calculation of Payment. We proposed that the C codes would be subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology, meaning, they would be treated the same way as other procedure codes in the ASC setting. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the C code are performed with another separately payable covered surgical procedure in the ASC setting. We proposed to use the OPPS complexity-adjusted C-APC rate to determine the ASC payment rate for qualifying code combinations, similar to how we use OPPS APC relative weights in the standard ASC payment system ratesetting methodology. Under the ASC payment system, we use the OPPS APC relative payment weights to update the ASC relative payment weights for covered surgical procedures since ASCs do not submit cost reports. We then scale those ASC relative weights for the ASC payment system to ensure budget neutrality. To calculate the ASC payment rates for most ASC covered surgical procedures, we multiply the ASC conversion factor by the ASC relative payment weight. A more detailed discussion of this methodology is provided in the in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831).

For this proposal, we proposed to use the OPPS complexity-adjusted C-APC rate for each corresponding code combination to calculate the OPPS relative weight for each corresponding ASC payment system C code, which we believe would appropriately reflect the complexity and resource intensity of these ASC procedures being performed together. For C codes that are not assigned device-intensive status (discussed below), we would multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scalar) to determine the ASC relative

weight. We would then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each C code. In short, we would apply the standard ASC ratesetting process to the C codes. We proposed to add new § 416.172(h)(2)(i) to codify this policy.

As discussed in section XIII.C.1.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44708), certain C codes under our proposed policy may include a primary procedure that also qualifies for device-intensive status under the ASC payment system. For primary procedures assigned device-intensive status that are a component of a C code created under this proposal, we believe it would be appropriate for the C code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure had a device offset percentage of 31 percent (a proposed device offset percentage of greater than 30 percent would be needed to qualify for device-intensive status) and a device portion (or device offset amount) of $3,000, C codes that included this primary procedure would be assigned device-intensive status and a device portion of $3,000 to be held constant with the OPPS. We would apply our standard ASC payment system ratesetting methodology to the non-device portion of the OPPS complexity-adjusted APC rate of the C codes; that is, we would apply the ASC budget neutrality adjustment and ASC conversion factor. We believe assigning device-intensive status and transferring the device portion from the primary procedure's ASC payment rate to the C code's ASC payment rate calculation is consistent with our treatment of device costs and determining device-intensive status under the ASC payment system and is an appropriate methodology for determining the ASC payment rate. The non-device portion would be the difference between the device portion of the primary procedure and the OPPS complexity-adjusted APC payment rate

for the C code based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of a C code. As is the case for all device-intensive procedures, we would apply the ASC standard ratesetting methodology to the OPPS relative weights of the non-device portion for any C code eligible for payment under this proposal. That is, we would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. We proposed to add new § 416.172(h)(2)(ii) to codify this policy.

In order to include these C codes in the budget neutrality calculations for the ASC payment system, we proposed to estimate the potential utilization for these C codes. We do not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes under the ASC payment system. Therefore, we proposed to estimate CY 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, we would use the ratio of the primary procedure volume to add-on procedure volume from CY 2021 OPPS claims and apply that ratio against ASC primary procedure utilization to estimate the increased spending as a result of our proposal for budget neutrality purposes. We believe this method would provide a reasonable estimate of the utilization of these code combinations in the ASC setting, as it is based on the specific code combination utilization in the OPPS. We anticipate that we would continue this estimation process until we have sufficient claims data for the C codes that can be used to more accurately calculate code combination utilization in ASCs, likely for the CY 2025 rulemaking.

We welcomed comments on this proposal, including comments or suggestions regarding additional approaches that we should consider for this policy.

Comment: All of the commenters who responded to this policy were supportive of providing a complexity adjustment for complex procedures in the ASC setting and urged CMS to finalize the ASC special payment policy for OPPS complexity adjusted C-APCs, as proposed. Commenters noted they believed this approach would result in more appropriate payments for those ASC procedures that require greater resources than the individual primary service and align with other site neutral payment policies. They recommended CMS continue to address any ASC payments that could interfere with meaningful beneficiary access to ASC covered services.

Response: We thank the commenters for their support.

Comment: Several commenters noted that they have received feedback and questions from ASC providers asking for additional detail on the specific HCPCS code combinations that correspond to the new C-codes. These commenters requested that CMS publish an addendum file or worksheet that lists the primary and secondary procedure HCPCS code, the new C-code to which they are assigned, and the final payment rate to ensure coding compliance and ease of implementation. Commenters believe this information will also allow for easier comparison for year-to-year changes in coding combinations that qualify for this special payment policy.

Response: We thank the commenters for their input. We are providing a supplemental file to the ASC addenda that includes the requested information that be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.

Comment: Several commenters recommended that CMS annually analyze and publicly share the impact of this new policy to assess if further adjustments to the methodology are

needed. One commenter specifically noted this request in the context of retaining the device-intensive status of the primary procedure, as well as the device portion of the primary procedure rather than the device offset percentage.

Response: We thank the commenters for their feedback. We anticipate reviewing this policy annually during future rulemaking.

Comment: A few commenters noted that it is unclear why CMS proposed to create specific C-codes for these procedure combinations in the ASC payment system, unless there are claims processing limitations. They recommended CMS utilize the combination of the qualifying HCPCS codes to automatically trigger the adjusted payment level, rather than creating specific C-codes for ASC billing that may create confusion and unnecessary administrative burden.

Response: The ASC claims processing system cannot accommodate the complexity adjustment payment mechanism that we are finalizing, so we believe that the best option for implementation of this policy is to create C codes that represent the code combination.

After consideration of the public comments we received, we are finalizing the ASC special payment policy for OPPS complexity-adjusted C-APCs, as proposed. The final C codes for CY 2023 can be found in ASC addendum AA.

d. Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of the CY 2023 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology (87 FR 44712).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for the CY 2023 OPPS/ASC proposed rule, we proposed to designate 4 brachytherapy APCs and 4 clinical APCs as Low Volume APCs under the ASC payment system (87 FR 44714 through 44175). The 4 clinical APCs and 4 brachytherapy APCs shown in Table 58 of the CY 2023 OPPS/ASC proposed rule (87 FR 44715) met our criteria of having fewer than 100 single claims in the claims year (CY 2021 for the CY 2023 OPPS/ASC proposed rule) and therefore, we proposed that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. These 8 APCs were designated as Low Volume APCs in CY 2022; however, as we noted under the comprehensive ratesetting methodology section, APC 2647 (Brachytherapy, non-stranded, Gold-198), which was previously designated as a Low Volume APC for CY 2022, did not meet our claims threshold for the CY 2023 OPPS/ASC proposed rule.

We did not receive any public comments on our proposal to assign the 4 brachytherapy APCs and 4 clinical APCs as Low Volume APCs under the ASC payment system. Based on claims data available for this final rule with comment period, we are finalizing our proposal to designate the 4 brachytherapy APCs and 4 clinical APCs shown in Table 82 as Low Volume APCs under the ASC payment system, because they continue to meet our criteria of having fewer than 100 single claims in the relevant claims year (2021). The APC cost metric for these APCS are based on the greatest of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data, as proposed.

TABLE 82: COST STATISTICS FOR LOW VOLUME APCS STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2023

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	10	$167.11	$31.74	$44.35	$37.26	$44.35
2635	Brachytx, non-str, HA, P-103	28	$130.24	$34.04	$52.09	$43.30	$52.09
2636	Brachy linear, non-str, P-103	0	---*	$49.65	$53.38	$38.80	$53.38
2647	Brachytx, NS, Non-HDRIr-192	74	$144.37	$180.76	$355.64	$141.57	$355.64
5244	Level 4 Blood Product Exchanges and Related Services	0	---*	$45, 083.65	$44,786.11	$42,592.20	$45,083.65
5493	Level 3 Intraocular Procedures	10	$9,886.53	$11,754.12	$11,344.09	$10,569.27	$11,754.12
5494	Level 4 Intraocular Procedures	29	$1,782.60	$3,003.99	$3,371.64	$2,903.85	$3,371.64
5495	Level 5 Intraocular Procedures	11	$14,232.51	$17,857.96	$18,079.13	$16,117.48	$18,079.13

* For the CY 2023 OPPS/ASC proposed rule, there were no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) or APC 5244 (CPT code 38240) that were available for CY 2023 OPPS/ASC ratesetting.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N", "Q1", and "Q2") under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor "N1") under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount ("Z3"), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at

contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a “device offset” to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine

range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator "Z2" and revised the definition of payment indicator "Z2" to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator "Z3," and revised the definition of payment indicator "Z3" to include a reference to diagnostic services.

Comment: One commenter recommended that we publish guidance on how MACs are to calculate transitional pass-through payments under the ASC payment system for devices that are eligible for pass-through payment under the OPPS similar to how such guidance is provided under the OPPS. The commenter specifically recommended that CMS specify that J7 payment should be at least equal to the device cost, as reported by the ASC in box 19 or the electronic equivalent.

Response: As previously discussed, devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Transitional pass-through payments under the OPPS utilize hospital cost-to-charge ratios to

reduce the pass-through device to cost and provide the hospital an additional payment of the amount by which cost of the pass-through device exceeds the applicable device offset amount. ASCs do not submit cost reports and, as such, we are unable to replicate the OPPS transitional pass-through payment under the ASC payment system. Currently, MACs have been instructed to pay for such devices in the ASC setting based on invoice or cost. Because the calculation for transitional pass-through payments in the OPPS is different from the calculation for such payments in the ASC payment system, we believe the current guidance provided in Section 40, Chapter 14 of the Medicare Claims Processing Manual is sufficient.

b. Final Payment for Covered Ancillary Services for CY 2023

We are finalizing our proposal to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the final CY 2023 OPPS and ASC payment rates and subsequent years' payment rates. We are also finalizing our proposal to continue to set the CY 2023 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2023 and subsequent years' payment rates.

Covered ancillary services and their final payment indicators for CY 2023 are listed in Addendum BB of the CY 2023 OPPS/ASC final rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS final rates (similar to our office-based payment policy), the final payment indicators and rates set forth in the CY 2023 OPPS/ASC final rule are based on a comparison using the final PFS rates effective January 1, 2023. For a discussion of the PFS rates, we refer readers to the CY 2023 PFS final

rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

3.Requirement in the Physician Fee Schedule CY 2023 Proposed and Final Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Section III.A. of the CY 2023 Physician Fee Schedule (PFS) proposed rule includes proposals to implement section 90004 of the Infrastructure Act, including a proposal that HOPDs and ASCs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system. Specifically, we proposed in the CY 2023 PFS proposed rule that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. The CY 2023 PFS proposed rule also proposed to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

As explained in the OPPS/ASC proposed rule (87 FR 44717), because the CY 2023 PFS proposed rule proposed to codify certain billing requirements for HOPDs and ASCs, we

explained in the proposed rule that we wanted to ensure interested parties are aware of them and knew to refer to that rule for a full description of the proposed policy. Interested parties were asked to submit comments on this and any other proposals to implement Section 90004 of the Infrastructure Act in response to the CY 2023 PFS proposed rule. We stated that public comments on these proposals will be addressed in the CY 2023 PFS final rule. We note that this same notice appeared in section V.A.C. of the CY 2023 OPPS/ASC proposed rule (87 FR 44716).

We thank commenters for their feedback on this proposal. As indicated in the OPPS/ASC proposed rule (87 FR 44717), public comments on the policies discussed above will be addressed in the CY 2023 PFS proposed rule. For final details on this policy, we refer readers to the CY 2023 PFS final rule, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. We note that this same notice appears in section V.A.C. of this CY 2023 OPPS/ASC final rule with comment period.

4. Inflation Reduction Act – Section 11101 Regarding Beneficiary Co-insurance

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 11101 of the Inflation Reduction Act requires a drug manufacturer to pay a rebate if the ASP of their drug product rises at a rate that is faster than the rate of inflation. Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) by adding a new paragraph (9) and subparagraph (F), respectively, that specify coinsurance under the ASC and OPPS payment systems. Section 1833(i)(9) requires that under the ASC payment system beneficiary coinsurance for a Part B rebatable drug that is not packaged to be calculated using the inflation-adjusted amount when that amount is less than the otherwise applicable payment

amount for the drug furnished on or after April 1, 2023. Section 1833(t)(8)(F) requires that under the OPPS payment system beneficiary copayment for a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or packaged into the payment for a procedure) is to be calculated using the inflation-adjusted amount when that amount is less than ASP plus 6 percent beginning April 1, 2023. Sections 1833(i)(9) and 1833(t)(8)(F) reference sections 1847A(i)(5) for the computation of the beneficiary coinsurance and 1833(a)(1)(EE) for the computation of the payment to the ASC or provider and state that the computations would be done in the same manner as described in such provisions. The computation of the coinsurance is described in section 1847A(i); specifically, in computing the amount of any coinsurance applicable under Part B to an individual to whom such Part B rebatable drug is furnished, the computation of such coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount determined under section 1847A(i)(3)(C) for such Part B rebatable drug. The calculation of the payment to the provider or ASC is described in section 1833(a)(1)(EE), and the provider or ASC would be paid the difference between the beneficiary coinsurance of the inflation-adjusted amount and the ASP plus 6 percent. We wish to make readers aware of this statutory change that begins April 1, 2023. Additionally, we refer readers to the full text of the IRA.[154] Additional details on the implementation of section 11101 of the IRA are forthcoming and will be communicated through a vehicle other than the CY 2023 OPPS/ASC regulation.

E. ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies

[154] H.R. 5376 available online at: https://www.congress.gov/bill/117th-congress/house-bill/5376/text

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) Act (Pub. L. 115-271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C-APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the

OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy,

for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA--approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold; and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), § 416.171(b)(1), and § 416.174 as proposed. We determined that four products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy would be evaluated in future rulemaking (86 FR 63496). Table 83 lists the four drugs that met our finalized criteria established in CY 2022 and received separate payment under the ASC payment system when furnished in the ASC setting for CY 2022 as described in the CY 2022 final rule with comment period (86 FR 63496).

TABLE 83: SUMMARY OF PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2022

HCPCS Code	Long Descriptor	Final CY 2022 OPPS Status Indicator (SI)*	Final CY 2022 ASC Payment Indicator (PI)*
C9290	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	N	K2
C9089	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see the CY 2022 OPPS/ASC final rule with comment period addenda. Specifically, the ASC Addenda BB for final applicable payment rates, OPPS Addenda D1 for final SI definitions, and ASC Addenda DD1 for final PI definitions. All are available via the internet on the CMS website.

2. Eligibility Criteria Technical Clarification and Final Regulation Text Changes Regarding Pass-Through Status and Separately Payable Status

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), we finalized a policy that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, including through transitional drug pass-through status under the OPPS, are not eligible for payment under § 416.174. As we previously noted in the CY 2022 OPPS/ASC final rule with comment period, once transitional pass-through payment status expires, a drug or biological may qualify for separate payment under the ASC payment system if it meets the eligibility criteria at § 416.174 (86 FR 63489). OPPS pass-through status expires on a quarterly basis. Therefore, for products for which pass-through status has expired that qualify for separate payment under the ASC payment system as non-opioid pain management drugs and biologicals that function as surgical supplies, separate payment may begin the first day of the next calendar year quarter following pass-through expiration. For

example, a drug with expiring pass-through status on June 30, 2024, may begin to receive separate payment in the ASC setting on July 1, 2024, under this proposed policy, if it meets the other relevant criteria and such separate payment is finalized in the applicable year's OPPS/ASC rulemaking.

Although we established this policy in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), we did not reflect it in regulation text. In the CY 2023 OPPS/ASC proposed rule, we proposed to clarify our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we proposed at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we proposed that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

Comment: We received several comments from interested parties acknowledging the two technical changes outlined above. Commenters were generally supportive of this action and believed these technical changes to the regulation text were appropriate.

Response: We appreciate the support of commenters.

After consideration of the public comments we received, we are finalizing as proposed the modifications to 416.174 to reflect our current policy as follows. We are finalizing § 416.174(a)(3), which states that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we are finalizing § 416.174(a)(4), which states that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

3. Final CY 2023 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals that Function as a Surgical Supply

As noted above, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS drug packaging threshold beginning on or after January 1, 2022. For the CY 2023 OPPS/ASC proposed rule, the OPPS drug packaging threshold was proposed to be $135. As discussed in section V.B.1.a of this CY 2023 OPPS/ASC final rule with comment period, the OPPS drug packaging threshold is finalized to be $135.

The following sections include the non-opioid alternatives of which we are aware and our evaluations of whether these non-opioid alternatives meet the criteria established at § 416.174. We welcomed stakeholder comment on these evaluations.

a. Annual Eligibility Re-Evaluations of Non-Opioid Alternatives that Were Separately Paid in the ASC Setting During CY 2022

In the CY 2022 final rule with comment period, we finalized that four drugs would receive separate payment in the ASC setting for CY 2022 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg),* and HCPCS code C9089 *(Bupivacaine, collagen-matrix implant, 1 mg*).

We re-evaluated these products outlined in the previous paragraph against the criteria specified in § 416.174, including the technical clarifications we proposed to that section, to determine whether they continue to qualify for separate payment in CY 2023. Based on our evaluation, we proposed that the drugs described by HCPCS codes C9290, J1097, and C9089 continue to meet the required criteria and should receive separate payment in the ASC setting. We proposed that the drug described by HCPCS code C9088 would not receive separate payment in the ASC setting under this policy, as this drug will be separately payable during CY 2023 under OPPS transitional pass-through status. Please see section V.A, "OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals" of this CY 2023 OPPS/ASC final rule with comment period for additional details on the pass-through status of HCPCS code C9088. We welcomed comment on our evaluations below.

(a) Eligibility Evaluation for the Separate Payment of Exparel

Based on our internal review as described in the proposed rule, we believed that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), meets the criteria described at § 416.174, including the technical clarifications we proposed to that section, and we proposed to continue paying separately for it under the ASC payment system for CY 2023. Exparel was approved by FDA with a New Drug Application (NDA #022496) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on October 28, 2011.[155] Exparel's FDA-approved indication is "in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia" and "in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia".[156] No component of Exparel is opioid-based. Accordingly, we proposed that Exparel meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of the CY 2023 OPPS/ASC proposed rule (87 FR 44641 through 44643), the per-day cost of Exparel exceeds the proposed $135 per-day cost threshold. Therefore, we proposed that Exparel meets the criterion described at § 416.174(a)(2). Additionally, Exparel will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, we proposed that Exparel meets the criteria we proposed to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we believed that Exparel meets the criteria described at § 416.174 and we proposed to continue making separate payment for it as a non-opioid pain

[155] Exparel. FDA Letter. 28 October 2011. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf
[156] Exparel. FDA Package Insert. 22 March 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf

management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Comment: There was overall general support for our proposal to pay separately in the ASC setting for the four drugs proposed in the proposed rule. Specifically, commenters supported Exparel having separately payable status in the ASC setting. Commenters believed that Exparel continued to meet the criteria specified in § 416.174, including the proposed technical clarification. Commenters additionally provided clinical information supporting Exparel's use to "reduce or even replace use of postsurgical opioid pain medication." Commenters strongly advocated for Exparel to be paid separately in the HOPD setting, as well the ASC setting, citing various rationales, including patients in HOPDs being more medically complex than those in ASCs, increased access to HOPDs for certain populations compared to ASCs, and decreased utilization of Exparel in HOPDs compared to ASCs.

Response: We thank commenters for their support on our proposal to pay separately for Exparel in the ASC setting as a non-opioid pain management drug that functions as a surgical supply. We greatly appreciate the additional information provided by commenters regarding the clinical use of the drug. We refer readers to section II.3.b. of this final rule with comment period for our discussion on the comment solicitation regarding payment of non-opioid drugs and biologicals that function as surgical supplies in the HOPD setting.

After consideration of the public comments we received, we believe that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), continues to meet the criteria described at § 416.174, including the technical clarifications we proposed and are finalizing to that section. We note that our proposed rule evaluation continues to be accurate. We are finalizing that we will continue to pay separately for Exparel as a non-opioid pain

management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(b) Eligibility Evaluation for the Separate Payment of Omidria

Based on our internal review as discussed in the proposed rule, we believed that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), meets the criteria described at § 416.174(a), and we proposed to continue paying separately for it under the ASC payment system for CY 2023. Omidria was approved by FDA with a New Drug Application (NDA #205388) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on May 30, 2014.[157] Omidria's FDA-approved indication is as "an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain".[158] No component of Omidria is opioid-based. Accordingly, we proposed that Omidria meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a of the CY 2023 OPPS/ASC proposed rule (87 FR 44641 through 44643), the per-day cost of Omidria exceeds the proposed $135 per-day cost threshold. Therefore, we proposed that Omidria meets the criterion described at § 416.174(a)(2). Additionally, we believe that Omidria will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, we proposed that Omidria meets the criteria we proposed to add to the regulation text at §§ 416.174(a)(3) and (4).

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[157] Omidria. FDA Letter. 30 May 2014. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf

[158] Omidria. FDA Package Insert. December 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf

Based on the above discussion, we proposed that Omidria meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Comment: There was overall general support for our proposal to pay separately in the ASC setting for the four drugs proposed in the proposed rule. Specifically, commenters supported Omidria having separately payable status in the ASC setting. Commenters also provided updated clinical information regarding the use of Omidria and demonstrated how separate payment of Omidria in the ASC setting has supported utilization of the drug.

Response: We thank commenters for their support and for their helpful comments and data analysis regarding the use of Omidria across different settings of care.

After consideration of the public comments we received, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), continues to meet the criteria described at § 416.174, including the technical clarifications we proposed and are finalizing to that section. We note that our proposed rule evaluation continues to be accurate. We are finalizing that we will continue to pay separately for Omidria as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(c) Eligibility Evaluation for the Separate Payment of Xaracoll

Based on our internal review as discussed in the proposed rule, we believed Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174(a), and we proposed to continue paying separately for it under the ASC payment system for CY 2023. Xaracoll was approved by FDA with a New Drug Application (NDA # 209511) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on

August 28, 2020.[159] Xaracoll is "indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair".[160] No component of Xaracoll is opioid-based. Accordingly, we proposed that Xaracoll meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of the CY 2023 OPPS/ASC proposed rule (87 FR 44641 through 44643), the per-day cost of Xaracoll exceeds the proposed $135 per-day cost threshold. Therefore, we proposed that Xaracoll meets the criterion described at § 416.174(a)(2). Additionally, at this time we do not believe that Xaracoll will have transitional pass-through payment status under § 419.64 in CY 2023, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we proposed that Xaracoll meets the criteria we proposed to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we proposed that Xaracoll meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Comment: There was overall general support for our proposal to pay separately in the ASC setting for the four drugs proposed in the proposed rule. Specifically, commenters supported Xaracoll having separately payable status in the ASC setting. Commenters believed that Xaracoll continued to meet the criteria specified in § 416.174. Commenters additionally provided references to clinical literature supporting the effectiveness of Xaracoll as a pain management alternative to opioids.

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[159] Xaracoll. FDA Letter. August 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209511Orig1s000ltr.pdf

[160] Xaracoll. FDA Labeling. August 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf

Response: We thank commenters for their support on our proposal to pay separately for Xaracoll in the ASC setting as a non-opioid pain management drug that functions as a surgical supply. We greatly appreciate the additional information provided by commenters regarding the clinical use of the drug.

After consideration of the public comments we received, we believe that Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174, including the technical clarifications we proposed and are finalizing to that section. We note that our proposed rule evaluation continues to be accurate. We are finalizing that we will continue to pay separately for Xaracoll as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(d) Eligibility Evaluation for the Separate Payment of Zynrelef

Based on our internal review as described in the proposed rule, we believed that Zynrelef, described by HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg*), does not meet the criteria described at § 416.174, including the technical clarifications we proposed to that section, and we proposed not to pay separately for it under the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies for CY 2023. Zynrelef received drug pass-through payment status as of April 1, 2022. As discussed above, our policy, as finalized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), states that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, or have transitional drug pass-through status under the OPPS, would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment systems. Also discussed above, we proposed to include this requirement as a technical change in new regulation text at § 416.174(a)(3).

Zynrelef receives separate payment consistent with its drug pass-through approval, and we have proposed in section V.A of the CY 2023 OPPS/ASC proposed rule (87 FR 44641 through 44643) that its pass-through status will not expire until after CY 2023. Accordingly, we proposed that Zynrelef would not be eligible for separate payment under the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies in CY 2023.

Comment: Commenters expressed concerns with CMS no longer paying for Zynrelef under the policy at § 416.174. Specifically, commenters believed this drug should still receive separate payment as they believed the drug is beneficial for patients in managing their pain. Commenters also asked CMS to evaluate this drug for inclusion under the non-opioid pain management payment policy after the expiration of the drug's pass-through status on March 31, 2025, in order to ensure continued patient access.

Response: We thank the commenters for their feedback. However, under our current policy, which we are codifying in this final rule at 416.174, Zynrelef is not eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a supply in a surgical procedure, because it is already separately payable as a pass-through drug under § 419.64. We note for commenters that Zynrelef will still be separately paid in both the ASC and HOPD settings under its current pass-through status. Please see section V.A, "OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals" of this CY 2023 OPPS/ASC final rule with comment period for additional details on transitional drug pass-through payments.

Because Zynrelef receives separate payment consistent with its drug pass-through approval under § 419.64, and its approval will not expire until after CY 2023, we are finalizing

our proposal that Zynrelef is not eligible for separate payment under the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies in CY 2023. This is consistent with the technical changes we are finalizing to the regulation text at §§ 416.174(a)(3) and (4) and our current policy. We will evaluate this drug again when its pass-through status is set to expire, if appropriate, and if requested by interested parties.

b. Final Evaluations of Newly Eligible Non-Opioid Alternatives

In this section, we evaluate drugs or biologicals, of which we were aware as of the CY 2023 OPPS/ASC proposed rule, that we believed may be newly eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply against the criteria described at § 416.174(a). In the proposed rule, we evaluated whether Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), a drug with pass-through status expiring December 31, 2022, meets the criteria specified in § 416.174, including the technical clarifications we proposed to that section. We proposed that Dextenza receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2023. We welcomed stakeholder comment on this evaluation.

(a) Eligibility Evaluation for the Separate Payment of Dextenza

Based on our internal review as described in the proposed rule, we believed Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174; and we proposed to provide separate payment for it under the ASC payment system for CY 2023. Dextenza was approved by FDA with a New Drug Application (NDA # 208742) under section 505(c) of the Federal Food, Drug, and Cosmetic Act

on November 30, 2018.[161] Dextenza's FDA-approved indication is as "a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery" and "the treatment of ocular itching associated with allergic conjunctivitis".[162] No component of Dextenza is opioid-based. Accordingly, we stated our belief that Dextenza meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of the CY 2023 OPPS/ASC proposed rule (87 FR 44641 through 44643), the per-day cost of Dextenza exceeds the proposed $135 per-day OPPS drug packaging cost threshold, so Dextenza also meets the criterion described at § 416.174(a)(2). Additionally, Dextenza's pass-through status expires on December 31, 2022, and we did not believe that it would otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we proposed that Dextenza meets the criteria described at 416.174, including the criteria we proposed to add to the regulation text at §§ 416.174(a)(3) and (4), and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Comment: There was broad general support for the separate payment of Dextenza. Some commenters provided non-specific statements of support for separate payment, while others advocated for separate payment in the ASC specifically and urged CMS to finalize its proposal to pay for Dextenza separately in the ASC setting as a non-opioid pain management drug. These commenters also contended that Dextenza may not function as a surgical supply and should be paid separately in both the HOPD and ASC setting.

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[161]* Dextenza. FDA Letter. November 2018. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf

[162] Dextenza. FDA Labeling. October 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf

Response: We thank commenters for their responses. We believe this drug is mostly used during ophthalmic surgeries, such as cataract surgeries. The status of this drug as a surgical supply is consistent with 42 CFR 419.2(b). Historically, we have stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy (79 FR 66875). Please see section III.E.2. of this final rule with comment period for additional details on the status of HCPCS code J1096 and the CMS rationale for why we believe this drug continues to function as a surgical supply.

After consideration of the public comments, we believe Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174 including the technical clarifications we proposed and are finalizing to that section. Our proposed rule evaluation continues to be accurate. We are finalizing our proposal to pay separately for it as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023. Please see section V.A. *(OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals)* of this final rule with comment period for details on the pass-through status of J1096. Also, please see section III.E.2 of this final rule with comment period for details on the status of HCPCS code J1096 in the HOPD, as well as CPT code 68841.

3. Comment Solicitation on Payment Policies for Separate Payment for Additional Drugs and Biologicals and Other Products that Function as Supplies in Surgical Procedures for CY 2023

We solicited comment on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in § 416.174 and therefore

qualify for separate payment under the ASC payment system. We encouraged commenters to include an explanation of how the drug or biological meets the eligibility criteria in § 416.174, including the technical clarifications we proposed to that section. In this final rule with comment period, we are including a summary of comments we received and our analysis of whether these additional products suggested by commenters meet the eligibility criteria in § 416.174. We stated in the proposed rule that if we find these additional drugs or biologicals do satisfy the criteria established at § 416.174, we would finalize their separate payment status for CY 2023 in the ASC setting in this final rule with comment period.

Comment: One commenter suggested CMS expand this policy to include, Posimir, a new drug that the commenter believed meets the eligibility criteria in § 416.174. This commenter also provided additional clinical information supporting the use of Posimir as an alternative to opioids.

Response: We thank the commenter for its feedback. We agree that Posimir, described by new HCPCS code C9144 (Injection, bupivacaine (Posimir), 1 mg), meets the criteria described at § 416.174, including the technical clarifications we proposed and are finalizing to that section.

Posimir was approved by FDA with a New Drug Application (NDA # 204803) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on February 1, 2021.[163] "Posimir contains an amide local anesthetic and is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression."[164] No component of Posimir is opioid-based. Accordingly, Posimir meets the criterion described at § 416.174(a)(1).

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[163] Posimir. FDA Approval Letter. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/204803Orig1s000ltr.pdf

[164] Posimir. FDA Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204803Orig1s001lbl.pdf

Under the methodology described at V.B.1.a. of this CY 2023 OPPS/ASC final rule with comment period, the per-day cost of Posimir exceeds the finalized $135 per-day cost threshold. Therefore, Posimir meets the criterion described at § 416.174(a)(2). Additionally, as of the publication of this final rule, Posimir will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, Posimir meets the criteria we are adding to the regulation text at §§ 416.174(a)(3) and (4). If Posimir were to obtain transitional drug pass-through status under § 419.64 in CY 2023, then Posimir would no longer be eligible for separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure.

Based on the above discussion, and after consideration of the public comments we received, we believe that Posimir meets the criteria described at § 416.174 and we are finalizing separate payment for Posimir as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Table 84 below lists the five drugs that we are finalizing as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

TABLE 84: SUMMARY OF PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2023

HCPCS Code	Brand Name	Long Descriptor	CY 2023 OPPS Status Indicator (SI)*	CY 2023 ASC Payment Indicator (PI)*
C9290	Exparel	Injection, bupivacaine liposome, 1 mg	N	K2

HCPCS Code	Brand Name	Long Descriptor	CY 2023 OPPS Status Indicator (SI)*	CY 2023 ASC Payment Indicator (PI)*
J1097	Omidria	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dextenza	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Xaracoll	Bupivacaine, collagen-matrix implant, 1 mg	N	K2
C9144	Posimir	Injection, bupivacaine (posimir), 1 mg	N	K2

*Please see ASC Addenda BB for applicable payment rates, OPPS Addenda D1 for SI definitions, and ASC Addenda DD1 for PI definitions. All are available via the internet on the CMS website.

Additionally, in the proposed rule, we solicited comment on potential policy modifications and additional criteria that may help further align the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies with the intent of sections 1833(t)(22) and 1833(i)(8) of the Act. We also solicited comment on non-drug or non-biological products that should qualify for separate, or modified, payment under this authority and any data regarding any such products. Finally, we solicited comments on barriers to access to non-opioid pain management products that may exist, and how our payment policies could be modified to address these barriers. We welcomed comments and data regarding the need to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the OPPS, which is also summarized in section II.A.3 of this CY 2023 OPPS/ASC final rule with comment period.

We have summarized comments received in response to our broad comment solicitation below. As discussed in the proposed rule, we stated we would take comments into consideration for potential future changes to this policy; therefore, we are making no policy changes for CY

2023 as a result of this comment solicitation. However, we are carefully considering these comments for future policy development and encourage interested party collaboration with CMS on this policy.

Comment: A few commenters recommended that CMS create no additional criteria and found the existing criteria to be transparent and objective. These commenters thought additional criteria or criteria modifications may be burdensome.

However, several commenters discussed potential criteria modifications. Commenters recommended that CMS modify the criterion set forth in § 416.174(a)(1), which relates to FDA approval and indications. These commenters believed a specific FDA indication of pain management or as an analgesic was too restrictive and that CMS should broaden this policy to include drugs and biologicals that have pain management attributes, based on documentable clinical support or recommendations by relevant specialty societies. Some commenters recommended expanding the acceptable FDA indications, for example, to include anesthesia drugs. Other commenters requested that one drug, Dexycu, as well as drugs in similar positions, should be grandfathered into this policy for a period of two to three years in order to allow them adequate time to receive an FDA indication for pain management or analgesia. These commenters believed that a temporary grandfathering policy would provide manufacturers the time and opportunity to complete new clinical trials in order to allow their products to apply for the necessary FDA approved indications. These commenters thought this was appropriate as they believed drugs such as Dexycu were already being used as pain management alternatives to opioids, despite not yet having FDA indications for pain management or analgesia.

Additionally, several commenters recommended CMS remove the criterion set forth in § 416.174(a)(2), which requires a drug to exceed the OPPS drug packaging threshold.

Commenters stated this criterion created a perverse incentive for drug manufacturers to list their drugs at higher prices in order to qualify for this policy. Commenters thought that this criterion may result in limited access for beneficiaries to several important drugs, such as the drug Anjeso. The commenter stated that Anjeso falls below the per day cost threshold but the product has demonstrated meaningful and statistically significant reductions in post-operative opioid consumption.

Finally, some commenters suggested we add additional criteria. For example, some commenters believed CMS should require that drugs have a demonstrated statistical significance with respect to the ability to eliminate or significantly reduce post-operative opioid use in order to qualify for separate payment under this policy. Commenters also stated that statistical significance for opioid reduction should be evaluated through clinical trials with relevant data published in a peer-reviewed journal.

Response: We thank commenters for their comments on the criteria, including suggestions for changes to the criteria. We will take these comments into consideration for future rulemaking. We remind interested parties that we are not modifying our policy at § 416.174 as a result of these comments at this time.

Comment: Many commenters suggested CMS extend the policy described at § 416.174 to the HOPD setting. Generally, commenters believed these products serve a valuable clinical purpose and their use should be encouraged in all settings of care. Several commenters provided data regarding how packaging negatively impacted the utilization of their products in the HOPD setting. Some commenters conceded that it is reasonable to think that the average HOPD would be able to absorb the extra costs; however, they believe that does not mean that every HOPD would be able to do so.

Commenters also presented data showing potential access barriers affecting underserved communities. Commenters believed that the HOPD setting is more accessible to vulnerable and underserved populations relative to the ASC setting. Commenters stated that extending the policy to the HOPD setting will increase access to non-opioid pain management drugs for Black Americans, low-income Americans, and Americans living in rural areas, all of whom they believe use HOPDs more frequently than ASCs. Some commenters stated that these are the populations that are also most negatively impacted by opioids.

Response: We thank commenters for their comments urging expansion of this policy to the HOPD setting. We will take these comments into consideration for future rulemaking. We remind interested parties that we are not modifying our policy at § 416.174 or creating new policies in response to these comments at this time. Any change to or expansion of the policy described at § 416.174 would be done through notice and comment rulemaking.

Comment: We received several other suggestions for policy modifications from commenters. Some commenters recommended that CMS finalize a policy where the existing criteria will not change for several years, or finalize separate payment for particular products on a longer-term basis beyond CY 2023, or for CMS to finalize the qualification status of products after their pass-through status expires in the coming years. Commenters also suggested that CMS target its policies to directly help specific patient populations by removing all access barriers, such as packaged payment, to non-opioids for those patients who face an increased risk of long-term opioid use after addiction, such as those individuals recovering from substance use disorder, those with an active opioid use disorder, and those with a mental health condition. One commenter recommended CMS waive co-insurance for its drug, Prialt, because, in the view of

the commenter, the drug reduces opioid use, but constitutes a significant financial burden for beneficiaries.

Additionally, commenters recommended CMS apply this policy to non-drug items such as devices, including devices such as the NerveCap device and spinal stimulators, and associated procedures. Commenters also suggested CMS consider including in this policy payment for icing wraps, transcutaneous stimulators, continuous peripheral nerve blocks, topic analgesics, acupuncture, chiropractic services, osteopathic manipulation, cognitive behavioral therapy, physical therapy, ERAS protocols, multimodal protocols, acetaminophen, IV NSAIDs, systemic lidocaine, ketamine, long acting local anesthetics, gabapentinoids, "On-Q" pain relief system, polar ice devices, topical THC oil, massage, and peri-operative pain management tools such as pain blocks, as well as many other related items and services to reduce the use of opioids.

A few commenters also suggested additional criteria for these additional suggested policy extensions, including requiring devices to have peer-reviewed, published evidence demonstrating opioid reduction and effective pain management to be eligible for separate payment under this policy.

Response: We thank commenters for their recommendations for policy modifications in this space. We will take these comments into consideration for future rulemaking. We remind interested parties that we are not modifying our policy at § 416.174 or creating new policies as a result of these comment solicitations. With respect to the drug Prialt, we refer readers to our discussion in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63496).

F. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

● Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information requested in the guidance document titled "Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class" posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.

● We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

● In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests to Establish New NTIOL Classes for CY 2023

We did not receive any requests for review to establish a new NTIOL class for CY 2023 by March 1, 2022, the due date published in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63809).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2023.

The comments and our responses to the comments are set forth below.

Comment: Some commenters requested we re-evaluate our payment adjustment for a new NTIOL class. Commenters noted that our $50 payment adjustment has not been adjusted since CY 1999 and that the stagnant payment adjustment has been a barrier to intraocular lens innovation. Commenters recommended that we set the $50 payment adjustment at $86.49.

Response: We thank the commenters for their recommendations. We did not propose revising the NTIOL payment adjustment amount for CY 2023. However, we will take the commenters' recommendations into consideration in future rulemaking.

4. Announcement of CY 2023 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs.

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2024, requests for review of applications for a new class of new technology IOLs must be received by 5:00 p.m. EST, on March 1, 2023. Send requests via email to outpatientpps@cms.hhs.gov or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.

G. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008;

payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator "NI" is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NI" also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator "NP" is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator "NP" also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The "CH" comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar

year, for example if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The "CH" comment indicators that are published in this final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ''K5'' – Items, Codes, and Services for which pricing information and claims data are not available. No payment made. – to ASC Addendum DD1 (which is available via the Internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

2. Final ASC Payment and Comment Indicators for CY 2023

For CY 2023, we proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Final Category I and III CPT codes that are new and revised for CY 2023 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2023, compared to the CY 2022 descriptors, are included in ASC Addenda AA and BB to the CY 2023 OPPS/ASC final rule and labeled with comment indicator "NP" to indicate that these CPT and Level II HCPCS codes were open for comment as part of the CY 2023 OPPS/ASC proposed rule.

We did not receive any public comments on our proposal and we are finalizing their use as proposed without modification. We refer readers to Addenda DD1 and DD2 of the CY 2023 OPPS/ASC proposed rule (these addenda are available via the Internet on the CMS website) for the complete list of ASC payment and comment indicators finalized for the CY 2023 update.

H. Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term "expenditures" in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has

minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for

geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13-01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf). In the

FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13-01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15-01, which provides updates to and supersedes OMB Bulletin No. 13-01 that was issued on February 28, 2013. OMB Bulletin No. 15-01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf).

On August 15, 2017, OMB issued OMB Bulletin No. 17-01, which provided updates to and superseded OMB Bulletin No. 15-01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–03 may be obtained at https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf. A copy of OMB Bulletin No. 18–04 may be obtained at https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf).

The proposed CY 2023 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 13-01, 15-01, 17-01, 18-03, 18-04, and 20-01). We did not receive any public comments on our proposed CY 2023 ASC wage indexes. For this CY 2023 OPPS/ASC final rule with comment period, the CY 2023 ASC wage indexes fully reflect the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 13-01, 15-01, 17-01, 18-03, 18-04, and 20-01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where "contiguous" is defined as sharing a border). For example, for CY 2023, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or

rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2023 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would

increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of the CY 2023 OPPS/ASC proposed rule (87 FR 44510), we are using the CY 2021 claims data to be consistent with the OPPS claims data for the CY 2023 OPPS/ASC proposed rule (87 FR 44510). Consistent with our established policy, we proposed to scale the CY 2023 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2021, we proposed to compare the total payment using the CY 2022 ASC relative payment weights with the total payment using the CY 2023 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2022 and CY 2023. Additionally, in light of our proposal to provide a higher ASC payment rate through the use of new C codes for primary procedures when performed with add-on packaged services, CY 2023 total payments will include spending and utilization related to these new C codes. In the CY 2023 OPPS/ASC proposed rule (87 FR 44724), we estimate the additional CY 2023 spending to be $5 million.

We proposed to use the ratio of CY 2022 to CY 2023 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2023. The proposed CY 2023 ASC weight scalar was 0.8474. Consistent with historical practice, we would scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC

payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We proposed to use the CY 2021 claims data to model our budget neutrality adjustment.

Comment: Many commenters reiterated their past recommendation that we discontinue applying the ASC weight scalar to achieve budget neutrality. Commenters were concerned that the ASC weight scalar has decreased overall since the implementation of the revised ASC payment system for CY 2008 and state that relative weights have already been scaled for budget neutrality and do not require "rescaling" to achieve budget neutrality under the ASC payment system. Further, commenters requested an analysis to determine the long-term decrease in the ASC weight scalar as they contend the decrease in the ASC weight scalar has decreased ASC payment rates and driven procedures to be performed more often in the more expensive hospital outpatient setting.

Response: We disagree with commenters' assessment and are not accepting the recommendation to discontinue applying the ASC weight scalar. As we have stated in past rulemaking, (82 FR 59421), applying the ASC weight scalar, which is 0.8594 for this final rule

with comment period and an increase from the CY 2022 ASC weight scalar of 0.8544, ensures that the ASC payment system remains budget neutral. This annual budget neutrality adjustment is performed similarly to updates for the IPPS, OPPS, PFS, and other Medicare payment systems. We apply the ASC weight scalar to scaled OPPS relative weights to ensure that current Medicare payments under the ASC payment system do not increase as a result of newer data to determine the cost relativity between surgical procedures. The scaled prospective OPPS relative weights that are used to determine scaled prospective ASC relative weights have not, as commenters suggest, been adjusted to achieve budget neutrality within the ASC payment system prior to the application of the ASC weight scalar. We also note that no stakeholder presented empirical evidence that the budget neutrality adjustment under the ASC payment system has impacted beneficiary access to surgical procedures in the ASC setting.

After consideration of the public comments we received, we are finalizing our proposal to use the ratio of CY 2022 to CY 2023 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2023. The final CY 2023 ASC weight scalar is 0.8594. Consistent with historical practice, we are finalizing our proposal to scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights. Additionally, in light of the fact that we are finalizing our proposal to provide a higher ASC payment rate through the use of new C codes for primary procedures when performed with add-on packaged services, CY 2023 total payments will include spending and utilization related to these new C codes. For this final rule with comment period, we estimate the additional CY 2023 spending to be $5 million.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2023, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2021 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2023 ASC wage indexes. Specifically, holding CY 2021 ASC utilization, service-mix, and the proposed CY 2023 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2022 ASC wage indexes and the total adjusted payment using the proposed CY 2023 ASC wage indexes. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2022 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2023 ASC wage indexes and applied the resulting ratio of 1.0010 (the proposed CY 2023 ASC wage index budget neutrality adjustment) to the CY 2022 ASC conversion factor to calculate the proposed CY 2023 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban

consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intended to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2023 was projected to be 3.1 percent, as published in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 25435), based on IHS Global Inc.'s (IGI's) 2021 fourth quarter forecast with historical data through the third quarter of 2021.

Section 1886(b)(3)(B)(xi)(II) of the Act, defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2023 was projected to be 0.4 percentage point, as published in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 25435) based on IGI's 2021 fourth quarter forecast.

For CY 2023, we proposed to utilize the hospital market basket update of 3.1 percent reduced by the productivity adjustment of 0.4 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.7 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2023 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E of the CY 2023 OPPS/ASC proposed rule (87 FR 44754 through 44755) for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We proposed to utilize the hospital market basket update of 3.1 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the

0.4 percentage point productivity adjustment. Therefore, we proposed to apply a 0.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 ASC update for the final rule.

For CY 2023, we proposed to adjust the CY 2022 ASC conversion factor ($49.916) by the proposed wage index budget neutrality factor of 1.0010 in addition to the productivity-adjusted hospital market basket update of 2.7 percent discussed above, which results in a proposed CY 2023 ASC conversion factor of $51.315 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2022 ASC conversion factor ($49.916) by the proposed wage index budget neutrality factor of 1.0010 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.7 percent discussed above, which results in a proposed CY 2023 ASC conversion factor of $50.315.

We requested comments on our proposals for updating the CY 2023 ASC conversion factor.

Comment: Some commenters requested that any change as a result of the Supreme Court ruling in *American Hospital Association v Becerra* not adversely affect ASC payment rates or the ASC conversion factor.

Response: As discussed in further detail in Section V.B.6. of this final rule with comment period, the Supreme Court's decision in *American Hospital Association v. Becerra*, No. 20-1114, 2022 WL 2135490 (June 15, 2022) concluded that HHS may not vary payment rates for drugs

and biologicals among *groups of hospitals* under section 1833(t)(14)(A)(iii)(II) in the absence of having conducted a survey of hospitals' acquisition costs under subparagraph (t)(14)(A)(iii)(I). Each year since 2018, we have continued our policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent. In light of the Supreme Court's decision, for CY 2023 we are adopting a payment rate of ASP+6 percent for drugs and biologicals acquired through the 340B Program. To ensure budget neutrality under the OPPS, we are applying an adjustment to the OPPS conversion factor to offset the increase in the conversion factor that resulted from the budget neutral implementation of the payment policy for 340B drugs and biologicals in CY 2018. The budget neutrality adjustment of 0.9691 is applied to the OPPS conversion factor, for a revised OPPS conversion factor of $85.585 for CY 2023.

The Supreme Court's decision does not impact the ASC conversion factor; however, because the ASC standard ratesetting methodology utilizes OPPS payment rates and the device portion (or device offset amount), the revised OPPS conversion factor will have an impact on the ASC payment system. Specifically, because the device portion for device-intensive procedures is held constant with the OPPS and is not calculated with the ASC conversion factor, the revised OPPS conversion factor will lower the device portions and, thus, the payment rates for device-intensive procedures under the ASC payment system. However, the decline in expenditures for device portions of device-intensive procedures under the ASC payment system is offset through an increase in the ASC weight scalar, which increases non-device portions for all covered surgical procedures and certain covered ancillary services.

Comment: Many commenters supported our proposed increase to the CY 2023 ASC payment rates and several commenters requested that we amend our regulations to permanently increase ASC payment rates by the hospital market basket update. Comments from hospital

associations recommended that we end our policy of providing the hospital market basket update after CY 2023 and that CMS should work to collect ASC cost data to determine a more appropriate update factor for ASC payment rates.

Response: We appreciate the commenters support of our proposal. As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a proposal to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. We intend to update the public on our assessment of service migration and other factors in the CY 2024 OPPS/ASC proposed rule.

After consideration of the public comments we received, consistent with our proposal that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update and productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 ASC update for the CY 2023 OPPS/ASC final rule with comment period, we are incorporating more recent data to determine the final CY 2023 ASC update. Therefore, for this final rule with comment period, the hospital market basket update for CY 2023 is 4.1 percent, as published in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49056), based on IGI's 2022 second quarter forecast with historical data through the first quarter of 2022. The productivity adjustment for this final rule with comment period is 0.3 percentage point, as published in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49056) based on IGI's 2022 second quarter forecast.

For CY 2023, we are finalizing the hospital market basket update of 4.1 percent minus the productivity adjustment of 0.3 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 3.8 percent for ASCs meeting the quality reporting requirements. Therefore, we apply a 3.8 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2023 ASC payments. We are finalizing the hospital market basket update of 4.1 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.3 percentage point productivity adjustment. Therefore, we apply a 1.8 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2023, we are adjusting the CY 2022 ASC conversion factor ($49.916) by a wage index budget neutrality factor of 1.0008 in addition to the productivity-adjusted hospital market basket update of 3.8 percent, discussed above, which results in a final CY 2023 ASC conversion factor of $51.854 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are adjusting the CY 2022 ASC conversion factor ($49.916) by the wage index budget neutrality factor of 1.0008 in addition to the quality reporting productivity-adjusted hospital market 1.8 percent, discussed above, which results in a final CY 2023 ASC conversion factor of $50.855.

3. Display of the CY 2023 ASC Payment Rates

Addenda AA and BB to the CY 2023 OPPS/ASC final rule (which are available on the CMS website) display the final ASC payment rates for CY 2023 for covered surgical procedures and covered ancillary services, respectively. The final payment rates included in Addenda AA and BB to this CY 2023 OPPS/ASC final rule reflect the full ASC final payment update and not

the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the final CY 2023 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "To be Subject to Multiple Procedure Discounting" indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled "Drug Pass-Through Expiration during Calendar Year" where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled "Final CY 2023 Payment Weight" are the final relative payment weights for each of the listed services for CY 2023. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the final CY 2023 payment rate displayed in the "Final CY 2023 Payment Rate" column, each ASC payment weight in the "Final CY 2023 Payment Weight" column was multiplied by the proposed CY 2023 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The final CY 2023 ASC conversion factor uses the CY 2023 productivity-adjusted hospital market basket update factor of 3.8 percent (which is equal to the projected hospital market basket update of 4.1 percent reduced by a projected productivity adjustment of 0.3 percentage point).

In Addendum BB, there are no relative payment weights displayed in the "Final CY 2023 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "Final CY 2023 Payment" column displays the proposed CY 2023 national unadjusted ASC payment rates for all items and services. The final CY 2023 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2021.

Addendum EE to this CY 2023 OPPS/ASC final rule provides the HCPCS codes and short descriptors for surgical procedures that are finalized to be excluded from payment in ASCs for CY 2023.

Addendum FF to this CY 2023 OPPS/ASC final rule displays the OPPS payment rate (based on the standard ratesetting methodology), the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2023 for covered surgical procedures.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

We seek to promote higher quality, more efficient, and equitable healthcare for Medicare beneficiaries. Consistent with these goals, we have implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86179), we finalized updates to the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CYs 2008 through 2022 OPPS/ASC final rules for detailed discussions of the regulatory history of the Hospital OQR Program:

- The CY 2008 OPPS/ASC final rule (72 FR 66860 through 66875);
- The CY 2009 OPPS/ASC final rule (73 FR 68758 through 68779);
- The CY 2010 OPPS/ASC final rule (74 FR 60629 through 60656);
- The CY 2011 OPPS/ASC final rule (75 FR 72064 through 72110);

- The CY 2012 OPPS/ASC final rule (76 FR 74451 through 74492);
- The CY 2013 OPPS/ASC final rule (77 FR 68467 through 68492);
- The CY 2014 OPPS/ASC final rule (78 FR 75090 through 75120);
- The CY 2015 OPPS/ASC final rule (79 FR 66940 through 66966);
- The CY 2016 OPPS/ASC final rule (80 FR 70502 through 70526);
- The CY 2017 OPPS/ASC final rule (81 FR 79753 through 79797);
- The CY 2018 OPPS/ASC final rule (82 FR 59424 through 59445);
- The CY 2019 OPPS/ASC final rule (83 FR 59080 through 59110);
- The CY 2020 OPPS/ASC final rule (84 FR 61410 through 61420);
- The CY 2021 OPPS/ASC final rule (85 FR 86179 through 86187); and
- The CY 2022 OPPS/ASC final rule (86 FR 63822 through 63875).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XIV.E of the CY 2023 OPPS/ASC final rule with comment period (87 FR 44739) for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2025 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously finalized and codified at 42 CFR 419.46(h)(1) a policy to retain measures

from the previous year's measure set for subsequent years, unless removed (77 FR 68471 and 83 FR 59082). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

3. Removal of Quality Measures from the Hospital OQR Program Measure Set

a. Immediate Removal or Suspension

We previously finalized and codified at 42 CFR 419.46(i)(2) and (3) a process for removal or suspension of a Hospital OQR Program measure, based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082).[165] We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

b. Consideration Factors for Removing Measures

We previously finalized and codified at 42 CFR 419.46(i)(3) policies to use the regular rulemaking process to remove a measure for circumstances other than when CMS believes that continued use of a measure raises specific patient safety concerns (74 FR 60635 and 83 FR 59082).[166] We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

[165] We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68472 and 68473) for a discussion of our reasons for changing the term "retirement" to "removal" in the Hospital OQR Program.
[166] We initially referred to this process as "retirement" of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to "removal" during final rulemaking.

4. Modifications to Previously Adopted Measures

a. Change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination

(1) Background

The OP-31 measure was adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 and 75103). During CY 2014 OPPS/ASC rulemaking, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75103). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden by applying a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75113 through 75115). Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey, and we were unclear about the impact the use of varying surveys might have on accuracy, feasibility, or reporting burden. Therefore, we issued guidance[167] stating that we would delay the implementation of OP-31, and we subsequently finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947) the exclusion of OP-31 from the

[167] *See* Letter from Craig Bryant to Hospital OQR initiative discussions re: Outpatient Quality Reporting (OQR) Program - Delay of New Measures (Dec. 31, 2013), available at https://qualitynet.cms.gov/files/5d3792e74b6d1a256059d87d?filename=2013-40-OP.pdf; *see also* Letter from Craig Bryant to Hospital OQR initiative discussions re: Delayed Implementation of OP-31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery Measure (NQF #1536) to January 1, 2015; Data Collection Period for Two Endoscopy Measures OP-29 and OP-30 Begins (April 2, 2014), available at https://qualitynet.cms.gov/files/5d3793174b6d1a256059d8e3?filename=2014-14-OP,0.pdf.

measure set while allowing hospitals to voluntarily report measure data beginning with the CY 2015 reporting period.

(2) Considerations Concerning Previously Finalized OP-31 Measure Requirements Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2022 OPPS/ASC proposed rule (86 FR 42247), we stated that it would be appropriate to require that hospitals report on OP-31 for the CY 2023 reporting period/CY 2025 payment determination as hospitals have had the opportunity for several years to familiarize themselves with OP-31, prepare to operationalize it, and to practice reporting the measure since the CY 2015 reporting period. Many commenters expressed concern about making this measure mandatory due to the burden of reporting the measure and the impact this additional burden would have during the COVID-19 pandemic, stating that OP-31 has not been mandatory and many facilities have not been practicing reporting it (86 FR 63845). In response to these comments, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a delay in the implementation of this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination (86 FR 63845 through 63846).

As discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44727), since the publication of the CY 2022 OPPS/ASC final rule with comment period, interested parties have expressed concern about the reporting burden of this measure given the ongoing COVID-19 public health emergency (PHE). Interested parties have indicated that they are still recovering from the COVID-19 PHE and that the requirement to report OP-31 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes. Due to the continued impact of the COVID-19 PHE, such as national staffing and medical supply shortages, the 2-year delay of mandatory reporting for this measure is no longer

sufficient. Based on these factors and the feedback we received from interested parties, in the CY 2023 OPPS/ASC proposed rule, we proposed to change OP-31 from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. Under the proposal, a hospital would not be subject to a payment reduction for failing to report this measure during the voluntary reporting period; however, we strongly encourage hospitals to gain experience with the measure. We stated in the proposed rule our plan to continue to evaluate this policy moving forward. To be clear, there are no changes to reporting for CY 2023 and CY 2024, during which the measure remains voluntary.

As the OP-31 measure requires cross-setting coordination among clinicians of different specialties (that is, surgeons and ophthalmologists), we stated in the proposed rule that we believe it is appropriate to defer mandatory reporting at this time. We also stated we will consider mandatory reporting of OP-31 after the national PHE declaration officially ends and we find it appropriate to do so given COVID-19 PHE impacts on national staffing and supply shortages. We intend to consider implementation of mandatory reporting of the OP-31 measure through future rulemaking because as we noted in the CY 2015 OPPS/ASC final rule, this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive the coordination of care (79 FR 66947). We subsequently stated in the CY 2022 OPPS/ASC final rule with comment period that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a number of facilities have reported data for this measure and those that have reported these data have done so consistently (86 FR 63845).

We invited public comment on our proposal.

Comment: Many commenters expressed support for our proposal to change OP-31 from mandatory reporting to voluntary reporting beginning with the CY 2025 reporting period/CY 2027 payment determination.

Response: We thank commenters for their support.

Comment: A few commenters expressed their belief that OP-31 should be required for mandatory reporting. One commenter emphasized the need for public reporting of patient reported outcome measures to provide the public with ample quality and safety data related to outpatient procedures. Another commenter expressed that mandatory reporting for OP-31 should not be delayed further, as it has already been delayed in prior rulemaking.

Response: We thank commenters for their input and agree on the importance of including a cataract surgery patient reported outcome measure in the Hospital OQR Program. We recognize the commenters' concerns in delaying mandatory reporting of OP-31; however, due to continued impact of the COVID-19 PHE, we believe it is appropriate to delay mandatory reporting of this measure at this time. As we noted previously and in the proposed rule (87 FR 44727), we intend to monitor national staffing and supply shortages resulting from the COVID-19 PHE for improvement, and we will consider mandatory reporting of OP-31 in light of such improvements.

Comment: One commenter expressed that OP-31 should be maintained as voluntary until a digital version of the measure can be developed. The commenter explains that this strategy would support our vision to transition away from chart-abstracted measures and move toward digital measures by CY 2025.

Response: We thank the commenter for its recommendation and will take it into consideration for future rulemaking. We agree that moving from chart-abstracted measures to

digital measures is an important step in working toward interoperability, a goal which we outlined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49181).

Comment: Many commenters expressed their belief that OP-31 should never be made mandatory due to the high administrative burden of reporting this measure. A few commenters suggested we remove the measure entirely from the measure set for this reason.

Response: We thank the commenters for their feedback. However, we support the inclusion of OP-31 in the Hospital OQR Program and reiterate that the measure addresses a high impact condition not otherwise adequately assessed by the program measure set. We believe the importance of this measure as a patient reported outcome measure justifies the administrative burden of reporting the measure. The CMS National Quality Strategy includes a goal to Foster Engagement to increase engagement between individuals and their care teams to improve quality, establish trusting relationships, and bring the voices of people and caregivers to the forefront. The Meaningful Measures 2.0 goals also prioritize patient-reported measures and promoting better collection and integration of patient voices across CMS' quality programs.[168][169] Some facilities have been voluntarily reporting this measure successfully while it has not been required, thus, we believe that this indicates that the measure is not overly burdensome and that the value of the measure in regard to information it provides to consumers about quality of care justifies any potential administrative burden that would prevent facilities from reporting it. We note that while it is recommended that the facility obtain the survey results from the appropriate physician or optometrist, the surveys can be administered by the facility via phone, mail, email,

[168] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy
[169] https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization

or during clinician follow-up. We appreciate commenters' concerns and plan to retain this measure as voluntary instead of mandatory, while continuing to evaluate this policy moving forward, as we are committed to having a cataract surgery, patient-reported measure for the Hospital OQR Program.

Comment: One commenter recommended that we provide education and outreach on the survey instruments available for use with OP-31 and best practices based on the experiences of the facilities that have consistently reported the measure while it has been voluntary.

Response: We thank the commenter for these recommendations; we agree that such information would be useful. We plan on adding resource information to the Hospital OQR Program Specifications Manual and have been in contact with facilities that have consistently reported data for this measure to glean how the measure has been implemented and best practices.

Comment: One commenter expressed that instead of continuing to report OP-31, we should pursue adopting a measure related to post-operation visual function within the CMS Merit-based Incentive Payment System (MIPS) or an equivalent program that can be reported through the standard CMS platform for physician quality measures.

Response: We thank the commenters for their recommendations and will take them into consideration for future rulemaking. We note that the MIPS measures clinician-level quality reporting. We believe that assessing care through the Hospital OQR Program is essential to assess the quality of care provided at the facility level, in the outpatient setting. Quality-level reporting through the MIPS is complimentary to facility measurement within the Hospital OQR Program, not duplicative of it. Additionally, we believe that facilities are equally responsible for the quality of care provided in the outpatient departments as clinicians. Facilities have an

obligation to ensure the best quality of care is provided by the clinicians operating in their outpatient departments.

We refer readers to section 1833(t)(17) of the Act which outlines the statutory authority of the program to develop measures for care rendered in the outpatient setting.

Comment: One commenter inquired about the measure specifications for OP-31.

Response: We refer the commenter to the OP-31 measure specifications manual, which is available at: https://qualitynet.cms.gov/outpatient/specifications-manuals. After consideration of the public comments we received, we are finalizing our proposal to change OP-31 from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination.

5. Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Previously Finalized Hospital OQR Program Measure Set for the CY 2024 Payment Determination

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (85 FR 63846 through 63850) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2024 payment determination. Table 85 summarizes the previously finalized Hospital OQR Program measure set for the CY 2024 payment determination:

TABLE 85: Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival*
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention*
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

TABLE 85: Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	Measure Name
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
3636	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates

† We note that NQF endorsement for this measure was removed.
* In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824), we finalized removal of the (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3) measures beginning with the CY 2023 reporting period/CY 2025 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824) for more detail on how the OP-2 and OP-3 measures will be replaced by the STEMI-eCQM (OP-40).
**OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule (79 FR 66946 and 66947). In the CY 2022 OPPS/ASC final rule comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this final rule, we are finalizing our proposal (87 FR 44727), to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.

b. Summary of Hospital OQR Program Measure Set for the CY 2025 Payment Determination

Table 86 summarizes the Hospital OQR Program measure set including our finalized proposal in this CY 2023 OPPS/ASC final rule for the CY 2025 payment determination:

TABLE 86: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**

TABLE 86: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**
3636	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)***

† We note that NQF endorsement for this measure was removed.
* In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this final rule, we are finalizing our proposal (87 FR 44727), to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.
** In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.
*** The STEMI eCQM (OP-40) was adopted in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

c. Summary of Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

Table 87 summarizes the Hospital OQR Program measure set for the CY 2026 payment determination and subsequent years:

TABLE 87: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**

TABLE 87: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
None	OP-37e: OAS CAHPS – Recommendation of Facility**
3636	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM***

† We note that NQF endorsement for this measure was removed.
* In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this final rule, we are finalizing our proposal (87 FR 44727), to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years . .
** In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.
*** The STEMI eCQM (OP-40) was adopted in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

6. Hospital OQR Program Measures and Topics for Future Considerations

a. Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Adoption of Another Volume Indicator

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings, and since 1983, inpatient stays per capita have fallen by 31 percent.[170] In line with this trend, outpatient services increased by 0.7 percent in 2019 while inpatient services decreased by 0.9 percent.[171] Research indicates that volume in hospital outpatient departments will continue to grow, with some estimates projecting a 19 percent increase in patients between 2019 and 2029.[172]

[170] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.
[171] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.
[172] Sg2. Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. June 4, 2021. Available at: https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/.

Volume has a long history as a quality metric, however, quality measurement efforts moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes.[173] While studies suggest that larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality.[174] The Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74466 through 74468) where we adopted the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure (OP–26) beginning with the CY 2012 reporting period/CY 2014 payment determination. This structural measure of facility capacity collected surgical procedure volume data on nine[175] categories of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, Skin, and Other.[176] We adopted OP–26 based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including

[173] Jha AK. Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015.
[174] Ibid.
[175] This number has been updated from eight categories in the proposed rule to nine categorizes, as it was erroneously stated in the proposed rule (87 FR 44731).
[176] Hospital Outpatient Specifications Manuals version 9.1. Available at: https://qualitynet.cms.gov/outpatient/specifications-manuals#tab7.

decreased medical errors and mortality (76 FR 74466).[177,178,179] This may be attributable to greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74467).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59429), we removed OP–26, stating that there is a lack of evidence to support this specific measure's link to improved clinical quality. Although there is evidence of a link between patient volume and better patient outcomes, we stated that we believed that there was a lack of evidence that this link was reflected in the OP–26 measure specifically. Thus, we removed the OP–26 measure under the following measure removal criterion: performance or improvement on a measure does not result in better patient outcomes. At the time, many commenters supported the proposal to remove the OP–26 measure (82 FR 59429).

We stated in the CY 2023 OPPS/ASC proposed rule that we are considering reimplementing the OP–26 measure or another volume measure because the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures (87 FR 44730 through 44732).

Over the past few decades, innovations in the health care system have driven the migration of procedures from the inpatient setting to the outpatient setting. Forty-five percent of

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[177] Livingston, E.H.; Cao, J ''Procedure Volume as a Predictor of Surgical Outcomes''. Edward H. Livingston, Jing Cao JAMA. 2010;304(1):95–97.
[178] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. ''Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. *JAMA. 2005;294(15):1903–1908.*
[179] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B '' Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer'' *JAMA. 2000; 284 (23): 3028– 3035.*

percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of their operation due to the use of innovative techniques and technologies available in the outpatient setting. [180, 181]

Given these developments, we believe that patients may benefit from the public reporting of facility-level volume measure data that reflect the procedures performed across hospitals and provide the ability to track volume changes by facility and procedure category, and volume can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures.

OP–26 was the only measure in the Hospital OQR Program measure set that captured facility-level volume within hospitals and volume for Medicare and non-Medicare patients. As a result of its removal, the Hospital OQR Program currently does not capture outpatient surgical procedure volume in hospitals.

Furthermore, we stated in the CY 2023 OPPS/ASC proposed rule (87 FR 44731) that we are considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63902 through 63904). When considering the need for a pain management measure, we analyzed volume data to determine the proportion of ASC procedures performed for pain management using the methodology established by ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures, the

[180] Abrams KD, Balan-Cohen A, Durbha P. Growth in Outpatient Care: The role of quality and value incentives. Deloitte Insights. 2018. Available at: https://www2.deloitte.com/us/en/insights/industry/health-care/outpatient-hospital-services-medicare-incentives-value-quality.html.

[181] Chang AC, Yee J, Orringer MB, Iannettoni MD. Diagnostic thoracoscopic lung biopsy: an outpatient experience. The Annals of Thoracic Surgery. 2002;74:1942–7.

volume measure that was included in the ASCQR Program measure set (76 FR 74507 through 74509). We found that pain management procedures were the third most common procedure in CY 2019 and 2020 and concluded that a pain management measure would provide consumers with important quality of care information. Thus, a volume measure in the Hospital OQR Program's measure set would provide information to Medicare beneficiaries and other interested parties on numbers and proportions of procedures by category performed by individual facilities, including for hospital outpatient procedures related to pain management.

We noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44731) that the OP–26 measure was adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74466 through 74468) and was not reviewed or endorsed by the Measure Applications Partnership (MAP), which first began its pre-rulemaking review of quality measures across Federal programs in February 2012, after the publication of the CY 2012 OPPS/ASC final rule with comment period in November 2011.[182] Therefore, for OP–26 to be adopted in the Hospital OQR Program measure set, the measure would need to first undergo the pre-rulemaking process specified in section 1890A(a) of the Act.

(2) Solicitation of Comments on the Readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Other Volume Indicator in the Hospital OQR Program

We solicited comment on the potential inclusion of a volume measure in the Hospital OQR Program, either by re-adopting the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or adopting another volume indicator. We also solicited

[182] Measures Application Partnership. Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking Final Report. February 2012. Available at: https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.

comment on what volume data hospitals currently collect and if it is feasible to submit these data to the Hospital OQR Program, to minimize the collection and reporting burden of an alternative, new volume measure. Additionally, we solicited comment on an appropriate timeline for implementing and publicly reporting the measure data.

Specifically, we invited public comment on the following:

- The usefulness of including a volume indicator in the Hospital OQR Program measure set and publicly reporting volume data.
- Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy.
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting.
- The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

We received public comments on this topic.

Comment: A few commenters supported the reimplementation of OP–26 or another volume measure. These commenters expressed that a volume measure would provide valuable data to evaluate patient outcomes and quality of care. One commenter stated that many studies have demonstrated a relationship between superior patient outcomes and routine procedures. One commenter expressed that a volume measure would not impose a significant data collection burden for most hospitals. Another commenter specifically supported future adoption of a claims-based volume measure.

Response: We thank the commenters for supporting the reimplementation of a procedure volume measure in the Hospital OQR Program. We will take these comments into consideration as part of future notice-and-comment rulemaking.

Comment: Some commenters did not support the potential future reimplementation of OP–26 or adoption of another volume measure, expressing their belief that volume is not a clear indicator, or never is an indicator, of care quality and therefore procedure volume data would not be useful to consumers. A few commenters further stated that they believe there is a lack of evidence linking volume to quality of care and that this would make adoption of a volume measure inconsistent with the Meaningful Measures 2.0 Framework goal to "promote innovation and modernization of all aspects of quality." Several commenters expressed concern that the burden of collecting and reporting data for OP–26 outweighs its value. One commenter also opposed reimplementation of OP–26 because the measure has not been endorsed by the NQF.

Response: We thank the commenters for their feedback and acknowledge their concerns. We agree that we can determine facility volumes for procedures performed using Medicare FFS claims. However, the specifications for the OP–26 measure include reporting data for non-Medicare patients. The specifications for OP–26 are available in the Hospital Outpatient Specifications Manuals version 9.1 available at https://qualitynet.cms.gov/outpatient/specifications-manuals#tab7. As stated in the Specifications Manual, OP–26 measures the aggregate count of selected outpatient procedures in the following nine categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Skin, Respiratory, and Other. OP–26 excludes procedures performed within the emergency department (ED).

We reiterate our belief grounded in the published scientific literature that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and assist consumers in making informed decisions about where they receive care, acknowledging that many studies have shown that volume does serve as an indicator of quality of care.[183] [184] One study found that patients who had total hip arthroplasties performed at high-volume hospitals had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[185] Another study found that congestive heart failure (CHF) patients who stayed in hospitals with more experience in managing CHF received higher quality care and experienced better outcomes.[186]

The adoption of such a measure would follow our standard measure adoption process, including our consideration of relevant measures endorsed by a consensus building entity. A volume measure would not be presented to consumers alone, but would be displayed complementary with other program quality measures that are focused on clinical processes and outcomes. We will take the commenters' feedback into consideration as we consider the potential future adoption of a volume measure that is useful to consumers and appropriately assesses the quality of care provided in the outpatient setting.

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[183] Ogola, Gerald O. PhD, MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; Shafi, Shahid MD, MPH. High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. Journal of Trauma and Acute Care Surgery: September 2018 - Volume 85 - Issue 3 - p 560-565 doi: 10.1097/TA.0000000000001985

[184] Xu, B., Redfors, B., Yang, Y., Qiao, S., Wu, Y., Chen, J., Liu, H., Chen, J., Xu, L., Zhao, Y., Guan, C., Gao, R., & Généreux, P. (2016). Impact of Operator Experience and Volume on Outcomes After Left Main Coronary Artery Percutaneous Coronary Intervention. JACC. Cardiovascular interventions, 9(20), 2086–2093. https://doi.org/10.1016/j.jcin.2016.08.011

[185] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. *et al.* Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and meta-analysis. *J Orthop Surg Res* 14, 468 (2019). https://doi.org/10.1186/s13018-019-1531-0

[186] Joynt, K. E., Orav, E. J., & Jha, A. K. (2011). The association between hospital volume and processes, outcomes, and costs of care for congestive heart failure. Annals of internal medicine, 154(2), 94–102. https://doi.org/10.7326/0003-4819-154-2-201101180-00008

Comment: Several commenters suggested that CMS choose measures that would be more meaningful to patients, especially outcome-based measures of quality and safety. A few commenters recommended that CMS work with interested parties to identify measures that would better evaluate the shift in procedures to the outpatient setting and the quality of care provided. A few commenters also recommended adopting a volume measure that is limited to a specific set of procedures.

Response: We thank the commenters for their recommendations and will take them into consideration for future rulemaking.

Comment: Many commenters provided recommendations to improve volume measure reporting. Several commenters recommended that a potential volume measure should receive NQF endorsement before it is proposed for adoption. One commenter recommended that CMS track volume via claims-based data instead of requiring submission of data via a web-based tool. Another commenter recommended the adoption of an all-payer volume indicator to provide useful data about facilities that also serve non-Medicare fee-for-service (FFS) patients. One commenter stated that if a volume measure is adopted, it should be used only for confidential facility-level feedback.

A commenter recommended expanding the reporting of clinical areas beyond the existing procedure categories, while another commenter suggested that CMS consider adopting a volume indicator measure that uses procedure codes to reduce data collection and reporting burden for hospitals. One commenter suggested that a pain management measure should not be developed based on a volume measure because the healthcare system is already overburdened by the ongoing opioid epidemic and the COVID-19 PHE. One commenter encouraged CMS to develop

a volume electronic clinical quality measure (eCQM) instead of a measure that requires web-based submission through the Hospital Quality Reporting (HQR) portal.

Response: We thank the commenters for their recommendations to provide meaningful information to consumers and improve the quality of outpatient care and will take them into consideration for future rulemaking. We note that the OP–26 measure, when required for the Hospital OQR Program, included the submission of Medicare and non-Medicare volume data; conversely, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only this payer.

Comment: A commenter noted that the CY 2023 OPPS/ASC proposed rule states, "…more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of the surgery itself due to the use of innovative techniques and technologies available in the outpatient setting," while the referenced study only reviewed patients who underwent diagnostic thoracoscopic lung biopsy.

Response: We thank the commenter for this feedback. We believe that this statement still supports our point that procedures are moving from the inpatient to the outpatient setting, which has placed greater importance on tracking the volume of outpatient procedures. However, to better reflect the cited study, we acknowledge that its findings were limited to patients who undergo diagnostic thoracoscopic lung biopsy, of whom more than 70 percent of can be discharged on the day of the surgery itself due to the use of innovative techniques and technologies available in the outpatient setting.

b. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to a racial or ethnic minoritized group; being a member of a religious minority; living with a disability; being a member of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level is often associated with worse health outcomes.[187,188,189,190,191,192,193,194,195]

One approach being employed to reduce inequity across our programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. The Request for Information (RFI) included in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28479), titled "Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs" describes key considerations that we might take into account across all CMS quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address healthcare disparities and advance health equity across our programs.

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[187] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.
[188] Milkie Vu et al. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. J Womens Health (Larchmt). 2016 Jun;25(6):586-93. doi: 10.1089/jwh.2015.5517. Epub 2016 Feb 18. PMID: 26890129; PMCID: PMC5912720.
[189] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and 30-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. *British Medical Journal*, 346.
[190] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. *New England Journal of Medicine,* 371(24):2298– 2308.
[191] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. *Health Affairs*, 40(2): 307–316.
[192] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. *Rural Health Research Recap*. https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.
[193] https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.
[194] www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.
[195] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. *medRxiv*. 2020;2020.07.21. 20159327. doi:10.1101/ 2020.07.21.20159327.

We referred readers to the full RFI in the FY 2023 IPPS/LTCH PPS proposed rule for full details on these considerations as well as the FY 2023 IPPS/LTCH PPS final rule for a summary of previous comments received in response to the RFI. For comments and feedback on the application of these principles to the Hospital OQR Program, we asked commenters to respond to the CY 2023 OPPS/ASC proposed rule (87 FR 44732).

Comment: Several commenters supported CMS's overall goal of addressing health equity through quality measurement and stratification and acknowledged the importance of this work. One commenter emphasized the importance of differentiating the role of health equity in the acute care versus community settings. A commenter noted that these overarching principles presented in the RFI could also help inform future equity frameworks across CMS programs. Several commenters also highlighted their general support for the conceptual approaches, the Within-Facility Disparity Method and the Across- Facility Disparity Method for measuring disparity, known as The CMS Disparity Methods. However, one commenter noted that if CMS chooses to stratify patient experiences measures in the future, they would discourage CMS from using the Across-Facility Disparity Method for these particular measures. Similarly, several commenters recommended prioritizing the Within-Facility Disparity Method over the Across-Facility Disparity Method. A commenter suggested that when utilizing the Across-Facility Disparity Method, that essential hospitals be identified as a distinct group. One commenter noted that in addition to evaluating disparities through the Within-Facility Disparity Method and Across-Facility Disparity Method, CMS should consider absolute performance as well. A commenter provided support to expand disparities reporting to all settings.

Another commenter noted that it is important for workforce training and leadership development to be considered in efforts to improve health outcomes.

A commenter stated that building off existing programs, such as the Medicare Shared Savings Program and the Medicare Promoting Interoperability Program, could be useful in determining a health equity infrastructure, particularly in the context of involving community stakeholders as in the Accountable Health Communities Model.

Additionally, when considering potential approaches to quality measurement and stratification, a commenter expressed the importance of considering which factors are controllable by the provider in order to be as specific and targeted in measurement efforts. Similarly, another commenter emphasized that social factors outside of the providers' control should not be measured through quality measurement efforts. A few commenters stated that CMS should take a phased approach for setting goals and expectations focused on reducing healthcare disparities, particularly to accommodate how different facilities are at different stages of building and implementing a health equity framework. Another commenter expressed that collaboration among healthcare providers to address inequity can reduce provider burden as well. A few commenters noted that a holistic approach that shifts the focus on the sickness of patients to the wellness of patients is needed to effectively address healthcare disparities.

A commenter noted that they do not recommend comparing inequities across hospitals due to differing social contexts across hospitals and that this comparison can lead to incorrect conclusions in addition to not providing a facility with valuable information or incentives for improving its own performance in the health equity space.

A few commenters flagged the potential impact of measurement bias and the unintended consequences when considering approaches to health equity measurement and stratification. One commenter noted that "the implementation of a well-intentioned model" can be biased and negatively affect historically marginalized groups. Another commenter suggested that an effort

to mitigate potential unintended consequences could be to create public forums where historically marginalized groups can provide suggestions through more direct communication. This commenter emphasized the importance of stakeholder engagement and warned that not engaging stakeholders could threaten the validity of the disparity method used. A commenter also expressed that health equity frameworks should be evidence-based and ultimately focused on provider accountability.

Several comments agreed with CMS that quality measures can help inform performance across many patient populations. A commenter stated that early in the process, it is important to clearly outline the role of healthcare quality measurement as aiming to improve health care itself in addition to wider community needs. A few commenters stated that stratification contributes to the identification of disparity, but does not inherently provide resources; therefore, stratification is only one component of advancing health equity.

Response: We appreciate the feedback and suggestions provided by the commenters regarding overarching goals for measuring disparity across CMS quality programs, specifically in regard to conceptual approaches, stratification and the consideration of measurement bias. We will take commenters' feedback into consideration.

Comment: Many commenters urged CMS to prioritize use of existing measures to capitalize on existing data collection efforts and tools, large datasets, and alignment across multiple programs. Several commenters suggested that this prioritization would help mitigate some of the administrative burden of data collection on providers and suggested that the measures could be modified based on setting as appropriate. Several commenters stressed the importance of data and measure transparency to ensure both providers and patients have

adequate knowledge of disparities and efforts to address disparities. Several commenters additionally noted the potential financial burden on providers associated with data collection.

Several commenters expressed concerns about low sample sizes that could affect data collection, data completeness, and interpretability of disparity method results. One commenter suggested pooling data across multiple years to increase sample size, giving higher statistical weights to more recent data. A few other commenters similarly echoed the importance of using recent data in evaluating disparities and indicated the transient nature of some social risk factors, such as homelessness.

Several commenters offered additional suggestions about appropriate measure types to prioritize. A commenter noted the importance of considering how different measure types may be suited for different approaches to stratification. Similarly, a few commenters noted that stratification may not be suitable for all types of measures, and the measure types for which it is the most appropriate can be clarified through stakeholder input. Several commenters suggested prioritizing disparity measurement in process and access measures, and one commenter expressed that improving patient access to care is an essential goal driving health equity efforts. One commenter suggested prioritizing disparity measurement in condition-specific or in procedure-specific measures, and another commenter suggested expanding CMS's current condition- and procedure-specific measures to include evaluation of disparities for other conditions and procedures. One commenter suggested prioritizing measures of health system overuse and appropriateness of care.

Response: We appreciate the commenters' concerns about small sample sizes. We thank the commenters for their recommendations regarding prioritization of existing measures, data collection efforts, and tools and will take this feedback into consideration.

Comment: Many commenters supported using area-based indicators to stratify quality measures. Several commenters supported the use of imputed race and ethnicity data, while several other commenters conversely did not support imputed race and ethnicity data. One commenter suggested validating imputed race and ethnicity data by comparing the CMS Disparity Method results calculated using imputed data to those calculated using self-reported race and ethnicity data. Indeed, many commenters emphasized the role of self-reported patient data as the gold standard, and one commenter further noted that CMS's resources should be dedicated to collecting self-reported data rather than to data imputation.

Many commenters suggested that CMS move to standardize data definitions and data collection processes across providers, programs, and existing tools to enhance interoperability and across-hospital data consistency. Several commenters agreed that social and demographic data are not currently captured in an accessible way, and consistent, standardized data collection of social needs data is ideal. Several commenters considered data standardization to be vital to ensuring data and measure validity and reliability. One commenter expressed a concern that comprehensive screening tools may unnecessarily burden providers, but nevertheless felt that standardization across hospitals and systems would ultimately be beneficial to all providers. A few commenters expressed support for provider screening of health-related social needs as this effort contributes to the larger framework of improving health equity.

Several commenters noted that CMS should establish a timeline with data standardization and collection goals and milestones, as well as measure development and implementation. Optimizing data quality will necessitate time and new resources, such as building EHR environments to support data collection. Another commenter highlighted that data without context can contradict efforts to advance health equity through quality measurement. A

commenter stated that comprehensive and actionable data are important for driving improvement. A few commenters noted that data harmonization, aggregation and alignment are key to consider in the context of health equity measures and suggested that Electronic Health Information Exchanges (HIEs) and Regional Health Improvement Collaboratives (RHICs) can serve as useful resources.

In addition to data standardization and data harmonization, several commenters suggested that CMS incentivize use of Z-codes to capture social and demographic factors, and one commenter suggested that CMS reimburse providers for appropriately documenting Z-codes. Another commenter emphasized the importance of educating providers about the importance of collecting information regarding social drivers of health. Several commenters further suggested that CMS incentivize hospitals to collect self-reported social and demographic data from patients, and one commenter additionally suggested that payers collect these data themselves since patients may not be willing to provide social and demographic data to providers. One commenter noted that hospitals currently may collect social and demographic data to connect patients to available community resources and implementing measures may perversely incentivize providers to only perform social needs screening to collect data and not adequately follow up with patients to provide them with needed resources. Several commenters noted that data collection and disparity measurement efforts should include protections for patients. One commenter noted that CMS must ensure that patients do not face discrimination, and another commenter noted that patients' privacy must be protected.

Several commenters expressed that the current measures of social and demographic risk – dual eligibility and race and ethnicity – are imperfect measures of inequity. One commenter emphasized that because race and ethnicity are proxies of social risk on which providers are

unable to intervene, alternative direct measures of social risk should be used in measurement programs. One commenter suggested that CMS implement a standard process for validating data elements for use in future stratification efforts. Several commenters recommended convening Technical Expert Panels to provide stakeholders, including clinicians and medical coding experts, an opportunity to contribute to building valid and reliable stratification measures.

Many commenters provided suggestions for other social and demographic variables to collect. One commenter noted the importance of being able to identify disparities across multiple social and demographic risk factors. Several commenters suggested that measures capturing patient experience are important to collect. One commenter suggested capturing patients' feelings of inclusion. In addition to race and ethnicity, several commenters suggested sex, sexual orientation and gender identity, language preference, tribal membership, and disability status as important social risk factors to capture. One commenter further suggested collection of access to care, veteran status, health literacy, and religious minority status data. One commenter noted that additional important data elements to collect include employment status, education, insurance status, income level, and geographical distance from provider. One commenter suggested stratifying by urban versus rural settings.

Several commenters expressed concerns about penalizing providers for factors not in the control of the provider. One commenter questioned whether providers would be penalized in situations where patients refuse to provide social or demographic data. Another commenter expressed concern that safety-net hospitals caring for large proportions of patients with overlapping social and clinical needs would be penalized. Several commenters noted the importance of statistical risk adjustment for clinical characteristics and comorbidities, while one commenter expressed concern about adjusting quality measures for race and ethnicity. This

commenter further highlighted the difference between systemic racism versus race as a social risk factor.

Response: We thank the commenters for their support of the use of area-based indices for stratification and of imputed race and ethnicity data, but we also acknowledge the concern about using imputed race and ethnicity data instead of self-reported data. We appreciate commenters' recommendations regarding data standardization and intend to consider feedback regarding a timeline for data collection and measure development.

We will take the commenters' recommendations to collect Z-code data into consideration. We appreciate the concern that proxy measures of social and demographic risk have limitations. We thank commenters for their suggestion to convene Technical Expert Panels, and we appreciate recommendations for other social and demographic factors to collect.

We acknowledge the concern that providers should not be penalized for social and demographic risk factors outside of their control. We would like to clarify that the RFI did not directly address risk adjustment for patient social factors or demographic variables within measures, which may set different expected quality results for persons with certain social risk factors, but rather discusses approach to distinguish performance between groups to highlight underlying disparities.

Comment: Several commenters provided specific feedback on methods for identifying meaningful performance differences within disparity results. A commenter expressed the importance of determining whether a stratification approach is suitable for a specific measure type. For example, the commenter stated that they would not recommend using the Across-Facility Disparity Method for patient experience measures because it risks implying that less favorable patient experiences are typical or expected for certain subgroups. The stakeholder

suggested utilizing a benchmarking and performance threshold approach that includes the whole patient population rather than a small subgroup of patients.

A few commenters supported benchmark approaches and a commenter noted that they may become more powerful comparison tools with time.

A few commenters supported threshold approaches. On the other hand, a few commenters did not support threshold approaches; a few commenters stated that threshold approaches should follow benchmarking efforts or be used once the volume of data increases.

A few commenters did not recommend fixed intervals/rank ordering approaches due to difficulties in identifying meaningful clinical differences.

Another commenter supported peer grouping as opposed to risk adjustment for social risk factors to prevent the risk of potentially hiding disparities. Another commenter suggested the use of clinical risk grouping to categorize patients into illness burden groups for risk adjustment.

A commenter expressed that it is important for measures to be continuously tested to ensure that they can statistically show differences in care, particularly when measuring disparities "at the level of the individual clinician." Another commenter stated that data-driven improved patient outcomes (for example, avoidable hospital admissions, complications, readmissions) should be at the forefront of identifying meaningful performance differences as opposed to only focusing on process measures. A commenter suggested that variability estimates be provided along with any disparity measurement results that use a statistical approach for disparity measurement.

A few commenters stated that identifying performance differences in disparity results depends on the context of the measure, program, and setting rather than on a statistical standard

being uniformly applied across programs; a few commenters also recommended convening a Technical Expert Panel to allow stakeholder input on this topic.

A commenter suggested that if stratifying can illuminate disparities in care, then this should be a criterion for "maintaining these measures in the programs." A commenter stated that the goal of helping patients seek equitable care should remain at the forefront when considering meaningful performance differences. A commenter noted that as the methodologies are still very new, hospitals should not be compared based on their ability to reverse negative trend. This commenter further explained that steps should be taken to identify facilities that have successfully identified social needs and implemented interventions to reverse negative trends.

Response: We appreciate the feedback and suggestions provided by the commenters regarding the identification of meaningful performance differences within disparity results including threshold approaches, benchmarking, peer grouping and additional recommendations. We will take commenters' feedback into consideration in future policy development.

Comment: Several commenters provided feedback on principles for use and application of the results of disparity measurement. A commenter supported CMS's suggestion for disparity reporting decisions to be made at the program level.

Several stakeholders who commented on confidential reporting supported CMS's existing approach of an initial period of confidentially reporting stratified results before publicly reporting in order to provide facilities time to understand and improve upon their performance and to ensure sufficient data collection. A commenter noted that confidential reporting is particularly appropriate while more is learned about the impact of social determinants of health. Similarly, a commenter agreed with CMS's suggested approach of utilizing confidential reporting for new programs and measures. A few commenters expressed that when stratifying

measures by race, ethnicity, and social factors, it is important to initially confidentially report and appropriately risk adjust to ensure that providers are not being held responsible for factors outside of their control. Another commenter stated that the value of creating and confidentially reporting a health equity score would be useful to hospitals in their improvement efforts. A commenter supported CMS's recommendation of reporting stratified measure results in tandem with overall measure results, specifically through confidential reporting. One commenter suggested that a phased approach would allow EHR vendors to build and implement changes in hospital systems. A commenter stated that assuming appropriate and actionable data are collected, confidential reporting should be prioritized since raising awareness to providers about health inequity is a critical step in initiating improvements.

In terms of public reporting, a commenter supported publicly reporting stratified measure results and stated that doing so allows for useful comparisons to be made between individual facilities and state and national averages.

A few commenters were opposed to publicly reporting disparity results. One commenter stated that publicly reporting disparity measurement is not appropriate at this time. A commenter expressed that publicly reporting data that are stratified by demographic variables could further perpetuate stereotypes about the type of care provided by facilities to specific subgroups of patients. Similarly, a commenter cautioned that public reporting of stratified data presents potential for a harmful cycle where patients may not want to receive care at hospitals that care for historically marginalized communities, resulting in fewer resources for those providers and patients. A few commenters expressed potential unintended consequences of placing burden on patients to understand disparity results and that if utilizing public reporting, it is imperative that providers ensure their patients understand disparity measurement. Similarly,

several commenters expressed that efforts should be made to educate and inform patients on how to understand and interpret publicly reported disparity results.

A commenter expressed the importance for stakeholder input before public reporting, particularly in the context of newer programs and measures. A commenter emphasized a similar point that the decision to publicly report results should be widely agreed upon before implementation.

A few commenters acknowledged payment accountability as a principle for use and application of disparity measurement results. A commenter stated that a health equity score can be used for additional reimbursement to be linked with community need in order to provide more resources for specific patient populations. A few commenters made a similar point that disparity measurement data can help illuminate where additional resources are needed and this information can then inform the payment system accordingly to better meet their needs. A commenter state that it is important to carefully and slowly consider reporting options, particularly when payment is affected.

Commenters provided additional thoughts when considering principles for use and application of disparity measurement results. A commenter noted that it is important to ensure reliability of reported measure result and a commenter stated sample size should play a role in determining whether results should be publicly reported. Similarly, another commenter stated that a challenge of reporting demographic variables is using the data for meaningful healthcare improvement. A commenter noted that privacy safeguards should be implemented as part of programs' reporting processes and a commenter stated that data collected for disparity measurement should undergo a validation process.

A commenter stated that as more patient-reported data replace indirectly estimated data, those results should be reported in tandem for the purpose of comparison on an organizational basis. The commenter also suggested that allowing for a voluntary submission period would provide facilities with an opportunity to slowly begin the process of collecting and reporting equity data. Similarly, another commenter expressed that programs can ease into reporting through first reporting a smaller, well-established social risk variable while remaining transparent with overall intentions.

Response: We appreciate the feedback and suggestions provided by the commenters regarding principles for use and application of the results of disparity measurement, including commenters' feedback to implement a confidential reporting period during which hospitals will be provided their disparity method results privately and intend to consider the suggested phased approach. We will take commenters' feedback into consideration.

Comment: A few commenters emphasized the administrative burden of collecting, validating, and managing data. Similarly, a few commenters also noted that digital health technology and software upgrades would be essential to support increased data collection efforts. A commenter noted that operationalizing healthcare technology could improve the patient experience as well by not having to provide social risk and demographic information multiple times. A few commenters noted that healthcare technology requires increased funding and resources, particularly resources for historically marginalized groups and groups with increased social needs. Another commenter added that actionable and timely data can assist hospitals in make informed decisions.

A few commenters stated the importance of collaboration in advancing health equity, particularly best practices. More specifically, a commenter stated that collaboration should be

prioritized over competition through all health equity advancement efforts. Similarly, a commenter emphasized that innovation should be rewarded and those engaging in innovative work in the health equity space should share it to support other efforts. A commenter expressed that research and development can contribute to improve health equity. Another commenter recommended that CMS consider convening a workgroup to understand potential challenges to health equity efforts and to come to consensus on recommendations. This commenter further suggested that CMS's efforts support provider efforts to achieve health equity through investment, guidance, and best practice facilitation.

A commenter noted that community partnerships will need to be modified or created in order to "achieve positive outcomes on social drivers of health results." A commenter noted that additional clarification about the role of community partnerships and engagement would be beneficial. A commenter suggested that CMS sponsor a technical assistance program for providers lacking resources. A commenter stated that CMS should consider adding questions to patient experience surveys that can illuminate the healthcare experiences of historically marginalized groups while ensuring that resources are provided so that all individuals can complete the survey. One commenter suggested that CMS provide hospitals with resources for identifying key social drivers of health that may contribute to disparities.

Additionally, a few commenters noted that time is needed in order to implement these changes that would result in maximizing data collection efforts. A commenter suggested increased stakeholder engagement efforts, such as convening public forums. Another commenter stated that fair incentives for achieving value-based care objectives are important.

One commenter suggested that CMS revise the numerator of the Social Drivers of Health screening measure to include patients screened in any setting in the prior year, given that current practice recommends not screening at every admission but instead screening annually.

A commenter expressed support for reporting structural measures that that demonstrate health equity efforts integrated in hospital frameworks.

Several commenters noted that their organizations have developed health equity initiatives or projects similar to the activities described in the Health Equity RFI and offered more details about their work.

Response: We appreciate additional feedback and suggestions from commenters about additional topics such as the optimization of healthcare technology, collaboration among providers and communities and the administrative burden of data collection. We will take commenters' feedback into consideration for future rulemaking.

7. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: https://qualitynet.cms.gov/outpatient/specifications-manuals. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 and 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019, such that we will release a manual once every 12 months and release addenda as necessary.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63861), we finalized the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023

reporting period and finalized the manner to update the technical specifications for eCQMs. Technical specifications for eCQMs used in the Hospital OQR Program will be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: https://ecqi.healthit.gov/. For eCQMs, we will update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

8. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

C. Administrative Requirements

1. QualityNet Account and Security Official

We refer readers to the CYs 2011, 2012, 2014 and 2022 OPPS/ASC final rules (75 FR 72099; 76 FR 74479; 78 FR 75108 through 75109; and 86 FR 639040, respectively) for the previously finalized QualityNet security official requirements, including those for setting up a QualityNet account and the associated timelines. These procedural requirements are codified at 42 CFR 419.46(b). Hospitals will be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure

Portal). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CYs 2014, 2016, and 2019 OPPS/ASC final rules (78 FR 75108 through 75109; 80 FR 70519; and 83 FR 59103 through 59104, respectively) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these requirements at 42 CFR 419.46(b) and (c). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

Previously finalized quality measures and information collections discussed in this section were approved by OMB under control number 0938-1109 (expiration date February 28, 2025). An updated PRA package reflecting the updated information collection requirements will be submitted for approval under the same OMB control number.

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission deadlines. We codified these submission requirements at 42 CFR 419.46(d).

a. Alignment of Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year for Annual Payment Update (APU) Determinations

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 and 75111), we specified our data submission deadlines and codified our submission requirements at 42 CFR 419.46(d)(2).[196] We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 and 70520), where we shifted the quarters on which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. Prior to the adoption of this policy, the previous timeframe had extended from patient encounter quarter three of 2 years prior to the payment determination to patient encounter quarter two of the year prior to the payment determination. This timeframe provided less than two months between the time that the data were submitted for validation and the beginning of the payments that are affected by these data, creating compressed processing timelines for CMS and compressed timelines for hospitals to review their APU determination decisions. To address this issue, we changed the timeframe to begin with patient encounter quarter two of 2 years prior to the payment determination and end with patient encounter quarter one of the year prior to the payment determination.

As finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 and 70520), the patient encounter quarters for chart-abstracted measures data submitted to the Hospital OQR Program are not aligned with the January through December calendar year. Because these quarters are not aligned with the calendar year, as other CMS quality programs'

[196] The CY 2014 OPPS/ASC final rule codified this standard in § 419.46(c)(2). This provision was moved to its current location in the CY 2021 OPPS/ASC final rule with comment period.

quarters are such as the Hospital Inpatient Quality Reporting (IQR) Program[197], this misalignment has resulted in confusion among some hospitals regarding submission deadlines and data reporting quarters.

(2) Alignment of Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2023 OPPS/ASC proposed rule (87 FR 44733 through 44735), beginning with the CY 2024 reporting period/CY 2026 payment determination, we proposed to align the patient encounter quarters for chart-abstracted measures with the calendar year. All four quarters of patient encounter data for chart-abstracted measures would be based on the calendar year two years prior to the payment determination year. We proposed this change to align the patient encounter quarters for chart-abstracted measures with the calendar year schedule of the Hospital OQR Program and to further align these quarters with those of the Hospital IQR Program since some hospitals may be submitting data for both programs. The Hospital IQR Program's patient encounter quarters all occur on the calendar year 2 years prior to the payment determination year as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50221). In the proposed rule, we stated our belief that the proposed alignment would also provide more time for APU determinations by increasing the length of time between the last clinical data submission deadline and APU determinations.

As an example, the current and finalized patient encounter quarters and clinical data submission deadlines for the CY 2028 payment determination are illustrated in Tables 88 and 89, respectively.

[197] FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 and 50221).

TABLE 88: Current CY 2028 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2026 (April 1 - June 30)	11/1/2026**
Q3 2026 (July 1 – September 30)	2/1/2027**
Q4 2026 (October 1 - December 31)	5/1/2027**
Q1 2027 (January 1 - March 31)	8/1/2027**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 89: Finalized CY 2028 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2026 (January 1 - March 31)	8/1/2026**
Q2 2026 (April 1 - June 30)	11/1/2026**
Q3 2026 (July 1 – September 30)	2/1/2027**
Q4 2026 (October 1 - December 31)	5/1/2027**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.
**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

To facilitate this process, we proposed to transition to the newly proposed timeframe for the CY 2026 payment determination and subsequent years and use only three quarters of data for chart-abstracted measures in determining the CY 2025 payment determination as illustrated in the Tables 90, 91 and 92 below. However, we note that data submission deadlines would not change.

TABLE 90: CY 2024 Payment Determination* (Current state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2022**
Q3 2022 (July 1 – September 30)	2/1/2023**
Q4 2022 (October 1 - December 31)	5/1/2023**
Q1 2023 (January 1 - March 31)	8/1/2023**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 91: Finalized CY 2025 Payment Determination*(Future state—transition period)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2023 (April 1 - June 30)	11/1/2023**
Q3 2023 (July 1 – September 30)	2/1/2024**
Q4 2023 (October 1 - December 31)	5/1/2024**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 92: Finalized CY 2026 Payment Determination* (Future state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 - March 31)	8/1/2024**
Q2 2024 (April 1 - June 30)	11/1/2024**
Q3 2024 (July 1 – September 30)	2/1/2025**
Q4 2024 (October 1 - December 31)	5/1/2025**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.
**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

We solicited public comment on our proposal.

Comment: Many commenters supported our proposal to align the patient encounter quarters for chart-abstracted measures with the calendar year. Several commenters further stated that alignment would make the data submission process simpler and reduce the reporting burden for providers.

Response: We thank the commenters for their support. We agree that alignment would streamline reporting for chart-abstracted measures and reduce provider burden.

Comment: One commenter recommended that CMS consider the implications of this proposal for other measures that cross calendar years, such as the HCP Influenza Immunization measure. The commenter further stated that although the HCP Influenza Immunization measure

is only required for the Hospital IQR Program, some hospitals report it for both the Hospital IQR and Hospital OQR Programs because separating the data would cause extensive burden.

Response: We thank the commenter for its feedback and will take this recommendation into consideration for future rulemaking regarding non-chart-abstracted measures.

Comment: One commenter noted that the clinical data submission deadlines listed in Table 64 "Current CY 2028 Payment Determination" of the CY 2023 OPPS/ASC proposed rule incorrectly stated a CY 2025 date for the Q2 deadline and CY 2026 dates for the Q1,Q3, and Q4 deadlines, and should have listed a CY 2026 date for the Q2 deadline and CY 2027 dates for the Q1, Q3, and Q4 deadlines. Another commenter noted that the clinical data submission deadlines listed in Table 66 "CY 2024 Payment Determination" of the CY 2023 OPPS/ASC proposed rule incorrectly stated CY 2023 and CY 2024 dates which did not match the deadlines for this payment determination that were stated in Table 67 in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63862).

Response: We thank the commenters for their feedback and have updated the clinical submission deadlines listed in the tables in this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal to align the patient encounter quarters for chart-abstracted measures with the calendar year beginning with the CY 2024 reporting period/CY 2026 payment determination.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data are Submitted Directly to CMS

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) and the QualityNet website available at: https://qualitynet.cms.gov for a discussion of the requirements for chart-abstracted measure data submitted via the HQR

System (formerly referred to as the QualityNet Secure Portal) for the CY 2014 payment determination and subsequent years. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63863) where we finalized a 3-year reporting period for the Breast Cancer Screening Recall Rates measure (OP-39). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

4. Data Submission Requirements for the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CYs 2017, 2018, and 2022 OPPS/ASC final rules (81 FR 79792 through 79794; 82 FR 59432 and 59433; and 86 FR 63863 through 63866, respectively) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63863 through 63866), where we reaffirmed our approach to the form, manner, and timing which OAS CAHPS information will be submitted with two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents), beginning with voluntary data collection for the CY 2023 reporting period/CY

2025 payment determination and continuing for mandatory reporting for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: https://oascahps.org/. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

5. Data Submission Requirements for Measures Submitted via a Web based Tool

a. Data Submission Requirements for Measures Submitted via a CMS Web-based Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and the QualityNet website available at: https://qualitynet.cms.gov for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The information collections finalized in the aforementioned final rules with comment period were approved under OMB control number 0938-1109 (expiration date February 2, 2025). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

b. Data Submission Requirements for Measures Submitted via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Website

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. In addition, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63866), where we finalized the adoption of the COVID–19 Vaccination Coverage Among Health Care Personnel measure (OP-

38) beginning with the CY 2022 reporting period/CY 2024 payment determination. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

6. eCQM Reporting and Submission Requirements

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106 and 75107), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79785 through 79790), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59435 through 59438), and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867 through 63870) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including support for the introduction of eCQMs into the Program. Measure stewards and developers have worked to advance eCQMs that would be reported in the outpatient setting.

b. eCQM Reporting and Data Submission Requirements

In the CY 2022 OPPS/ASC final rule with comment period, we finalized the adoption of the STEMI eCQM (OP-40) and a progressive increase in the number of quarters for which hospitals must report eCQM data (86 FR 63867 and 63868). For the CY 2023 reporting period, we finalized that hospitals submit STEMI eCQM (OP-40) data during this reporting period voluntarily for any quarter (86 FR 63868). Hospitals that choose to submit data voluntarily must submit in compliance with the eCQM certification requirements in sections XV.D.6.c, XV.D.6.d, and XV.D.6.e of the CY 2022 OPPS/ASC final rule with comment period. We refer readers to

the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867 and 63868) for additional detail on the eCQM reporting and data submission requirements.

We also refer readers to Table 93 for a summary of the previously finalized quarterly data increase in eCQM reporting beginning with the CY 2023 reporting period.

TABLE 93: Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period/CY 2025 Payment Determination	Any quarter(s)	Voluntary
CY 2024 Reporting Period/CY 2026 Payment Determination	One self-selected quarter	Mandatory
CY 2025 Reporting Period/CY 2027 Payment Determination	Two self-selected quarters	Mandatory
CY 2026 Reporting Period/CY 2028 Payment Determination	Three self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination and Subsequent Years	Four quarters (one calendar year)	Mandatory

c. Electronic Quality Measure Certification Requirements for eCQM Reporting

(1) Use of Cures Update

In May 2020, the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (ONC 21st Century Cures) Act final rule (85 FR 25642 through 25961) finalized updates to the health IT certification criteria (herein after referred to as the "Cures Update"). These updates included revisions to the clinical quality measurement certification criterion at 45 CFR 170.315(c)(3) to refer to CMS Quality Reporting Data Architecture (QRDA) Implementation Guides and removal of the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25645). The ONC 21st Century Cures Act final rule provided health IT developers with up to 24 months from May 1, 2020 to make available to their customers technology certified to the updated and/or new criteria (85 FR 25670). In November 2020, ONC issued an interim final rule with comment period (85 FR 70064) which extended the compliance deadline for the clinical quality measures-report

criterion at 45 CFR 170.315(c)(3) until December 31, 2022 (85 FR 70075). These updates were finalized to reduce burden on health IT developers (85 FR 70075) and have no impact on providers' existing reporting practices for the Hospital OQR Program.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63868 and 63869), where we finalized the requirement for hospitals participating in the Hospital OQR Program to utilize certified technology updated consistent with the Cures Update for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. This period includes both the voluntary reporting period and mandatory reporting periods. We noted that this requirement is in alignment with the Hospital IQR Program, which requires use of technology updated consistent with the Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination (See 86 FR 45418). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

d. File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements.

We refer reader to the CY 2022 OPPS/ASC final rule with comment period (86 FR 42262), where we finalized, beginning with the CY 2023 reporting period/CY 2025 payment determination, that hospitals: (1) Must submit eCQM data via the QRDA Category I

(QRDA I) file format;[198] (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. We also refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for discussion on the maintenance of technical specifications including those for eCQMs. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

(2) Zero Denominator Declarations

We understand there may be situations in which a hospital does not have data to report on a particular eCQM. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869), where we finalized that if the hospital's EHR is certified to an eCQM, but the hospital does not have patients that meet the denominator criteria of that eCQM, the hospital can submit a zero in the denominator for that eCQM. Submission of a zero in the denominator for an eCQM counts as a successful submission for that eCQM for the Hospital OQR Program (86 FR 63869). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for additional detail on the zero denominator declarations policy. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

(3) Case Threshold Exemptions

We understand that in some cases, a hospital may not meet the case threshold of discharges for a particular eCQM. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869), we finalized a policy aligning the Hospital OQR Program case threshold exemption with the case threshold exemption from the Medicare Promoting Interoperability

[198] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: https://ecqi.healthit.gov/qrda.

Program (77 FR 54080) and the Hospital IQR Program (79 FR 50324). Specifically, for the Hospital OQR Program we finalized that beginning with the CY 2023 reporting period/CY 2025 payment determination, if a hospital's EHR system is certified to report an eCQM and the hospital experiences five or fewer outpatient discharges per quarter or 20 or fewer outpatient discharges per year (Medicare and non-Medicare combined), as defined by an eCQM's denominator population, that hospital could be exempt from reporting on that eCQM (86 FR 63869). We also stated that the exemption would not have to be used; a hospital could report those individual cases if it would like to. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for additional detail on the case threshold exemption policy. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

e. Submission Deadlines for eCQM Data

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870), we finalized the policy to require eCQM data submission by May 15 of the following year for the applicable CY reporting period, beginning with the CY 2023 reporting period/CY 2025 payment determination. For example, CY 2023 eCQM data would need to be reported to us by May 15, 2024. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday. We refer reads to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) for additional detail on submission deadlines for eCQM data. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

7. Population and Sampling Data Requirements for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

8. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

b. Web-Based Measures

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86184), we finalized an expansion of our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2021 reporting period/CY 2023 payment determination. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) where we finalized that hospitals have a review and corrections period for eCQM data submitted to the Hospital OQR Program. We finalized a review and corrections period for eCQM data which would run concurrently with the data submission period. We refer readers to

the QualityNet website (available at: https://qualitynet.cms.gov/outpatient/measures/eCQM) and the eCQI Resource Center (available at: https://ecqi.healthit.gov/) for more resources on eCQM reporting. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

d. OAS CAHPS Measures

Each hospital administers (via its vendor) the survey for all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (https://oascahps.org) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870). As finalized in the CY 2017 OPPS/ASC final rule with comment period, data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79793). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

9. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870 through 63873), and 42 CFR 419.46(f) for our policies regarding validation.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870), we finalized discontinuing the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2022 reporting period/CY 2024 payment determination. Hospitals must instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures. Under this policy, hospitals are required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process as directed by the CMS Data Abstraction Center (CDAC). We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts. We note that this process aligns with that for the Hospital IQR Program (See FY 2021 IPPS/LTCH PPS final rule, 85 FR 58949). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

c. Time Period for Chart-Abstracted Measure Data Validation

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule (78 FR 75117 through 75118) and codified at 42 CFR 419.46(f)(1) for the CY 2025 payment determination and subsequent years.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63871) where we finalized the revision of 42 CFR 419.46(f)(1) to change the time period given to hospitals to submit medical records to the CDAC contractor from 45 calendar days to 30 calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022

affecting the CY 2024 payment determination and for subsequent years. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

d. Targeting Criteria

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria. We finalized a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 and 68486), that for the CY 2014 payment determination and subsequent years, a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 and 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441), for the targeting criterion "the hospital has an outlier value for a measure based on the data it submits," we clarified that an "outlier value" for purposes of this criterion is defined as a measure value that appears to deviate markedly from the measure values for other hospitals. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63872), we finalized the addition of two targeting criteria: any hospital that has not been randomly selected for validation in any of the previous three years or any hospital that passed validation in the previous year and had a two-tailed confidence interval that included 75 percent. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63872) for additional information on the Hospital OQR Program's previously finalized targeting criteria.

We have codified at 42 CFR 419.46(f)(3) that we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following targeting criteria:

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An "outlier value" is a measure value that is greater than five standard deviations from the mean of the measure values for other hospitals and indicates a poor score; or
- The hospital has not been randomly selected for validation in any of the previous three years; or
- The hospital passed validation in the previous year but had a two-tailed confidence interval that included 75 percent.

(2) Addition of Targeting Criterion

In the CY 2023 OPPS/ASC proposed rule (87 FR 44737), beginning with validations affecting the CY 2023 reporting period/CY 2025 payment determination, we proposed to add a new criterion to the four established targeting criteria at § 419.46(f)(3) used to select the 50 additional hospitals. We proposed that a hospital with less than four quarters of data subject to validation due to receiving an ECE for one or more quarters and with a two-tailed confidence interval that is less than 75 percent would be targeted for validation in the subsequent validation year. We proposed this additional criterion because such a hospital would have less than four quarters of data available for validation and its validation results could be considered inconclusive for a payment determination. Hospitals that meet this criterion would be required to submit medical records to the CDAC contractor within 30 days of the date identified on the

written request as finalized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63871) and codified at § 419.46(f)(1).

It is important to clarify that, consistent with our previously finalized policy, a hospital is subject to both payment reduction and targeting for validation in the subsequent year if it either: (a) has less than four quarters of data, but does *not* have an ECE for one more or more quarters and does not meet the 75 percent threshold; or (b) has four quarters of data subject to validation and does not meet the 75 percent threshold.

Specifically, we proposed to revise 42 CFR 419.46(f)(3) to add the following criterion for targeting the additional 50 hospitals for validation:

- Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

Our proposal would allow us to appropriately address instances in which hospitals that submit fewer than four quarters of data due to receiving an ECE for one or more quarters might face payment reduction under the current validation policies.

We invited public comment on our proposal.

Comment: A few commenters supported our proposal to add an additional targeting criterion, citing fair treatment of hospitals and appropriate focus of CMS's validation efforts on hospitals.

Response: We thank the commenters for their support. After consideration of the public comments we received, we are finalizing our proposal to add a fifth criterion to the established targeting criteria at § 419.46(f)(3) used to select 50 additional hospitals for validation.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59441 through 59443) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86185) where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

9. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63873), and 42 CFR 419.46(e) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2021 OPPS/ASC final rule with comment period (85 FR 68185), and 42 CFR 419.46(g) for

our reconsideration and appeals procedures. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

E. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2023 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to

which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the Internet on the CMS website): "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", or "U". In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator "Q4" because services and procedures coded with status indicator "Q4" are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator "S" or "T". We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the "reporting ratio" to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative

payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor – 0.02)

Reporting Ratio = Reduced Conversion Factor / Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor – 0.02) / (1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this

policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2023

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2023 annual payment update factor. For this CY 2023 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $86.785, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.093. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We proposed to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", and "U" (other than New Technology APCs to which we have proposed status indicator assignments of "S" and "T"). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously

used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2023, the proposed reporting ratio was 0.9805, which, when multiplied by the proposed full conversion factor of $86.785, equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.093.

We did not receive any public comments on our proposal. For this final rule with comment period, the final reporting ratio is 0.9807, which, when multiplied by the final full conversion factor of $85.585, equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $83.934. We are finalizing our proposal to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates for hospitals that fail to meet the Hospital OQR Program requirements for CY 2023 payment.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1 of the CY 2020 OPPS/ASC final rule (84 FR 61410) for a general overview of our outpatient quality reporting programs.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CYs 2014 through 2022 OPPS/ASC final rules for an overview of the regulatory history of the ASCQR Program:

- CY 2014 OPPS/ASC final rule (78 FR 75122);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434);
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193); and
- CY 2022 OPPS/ASC final rule (86 FR 63875 through 63911).

We have codified requirements under the ASCQR Program in 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330).

B. ASCQR Program Quality Measures

Previously finalized quality measures and information collections discussed in this section were approved by OMB under control number 0938-1270 (expiration date

August 31, 2025). An updated PRA package reflecting the updated information collection requirements will be submitted for approval under the same OMB control number.

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

2. Retention and Removal of Quality Measures from the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy to retain measures from the previous year measure set for subsequent years, except when such measures are removed (76 FR 74494 and 74504; 77 FR 68494 and 68495; 78 FR 75122; and 79 FR 66967 through 66969). We did not propose any changes to this policy in the CY 2023 OPPS/ASC proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule (83 FR 59111 through 59115), we finalized and codified at 42 CFR 416.320 an updated set of factors and the process for removing measures from the ASCQR Program. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

3. Change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination

a. Background

The ASC–11 measure was adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129). During CY 2014 OPPS/ASC rulemaking, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75129). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden by applying a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75129). Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey, and we were unclear about the impact the use of varying surveys might have on accuracy, feasibility, or reporting burden. Therefore, we issued guidance stating that we would delay the implementation of ASC–11, and we subsequently finalized in the CY 2015 OPPS/ASC final rule (79 FR 66983 through 66985) the exclusion of ASC–11 from the required measure set while allowing ASCs to voluntarily report measure data beginning with the CY 2015 reporting period.

b. Considerations Concerning Previously Finalized ASC–11 Measure Requirements Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2022 OPPS/ASC proposed rule (86 FR 42272), we stated that it would be appropriate to require that ASCs report on ASC–11 for the CY 2023 reporting period/CY 2025 payment determination as ASCs have had the opportunity for several years to familiarize themselves with ASC–11, prepare to operationalize it, and to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. Many commenters expressed concern about making this measure mandatory due to the burden of reporting the measure and the impact this additional burden would have during the COVID-19 pandemic,

stating that ASC–11 has not been mandatory and many facilities have not been practicing reporting it (86 FR 63886). In response to these comments, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a delay in the implementation of this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination (86 FR 63885 through 63887).

As discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44740), we now believe it is appropriate to suspend implementation of mandatory reporting and continue voluntary reporting for the ASC–11 measure and not require reporting starting with the CY 2027 payment determination. Since the publication of the CY 2022 OPPS/ASC final rule, interested parties have expressed concern about the reporting burden of this measure given the ongoing COVID-19 public health emergency (PHE). Interested parties have indicated that facilities remain impacted by the COVID-19 PHE and that the requirement to report ASC–11 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes. Due to the continued impact of the COVID-19 PHE, such as national staffing and medical supply shortages, we believe the two-year delay of mandatory reporting for this measure is no longer sufficient. Based on these factors and the feedback we received from interested parties, in the CY 2023 OPPS/ASC proposed rule, we proposed to continue with voluntary reporting and delay mandatory reporting requirements for the ASC–11 measure until future rulemaking. Therefore, we proposed to delay mandatory reporting of the ASC–11 measure beginning with CY 2025 reporting period/CY 2027 payment determination and maintain reporting for this measure as voluntary. Under the proposal, ASCs would not be subject to a payment reduction for failing to report this measure during the voluntary reporting period; however, we strongly encourage ASCs to gain experience with the measure. We stated in the

proposed rule our plan to continue to evaluate this policy moving forward. We note, there are no changes to reporting for the CY 2023 and CY 2024, during which the measure remains voluntary.

As the ASC–11 measure requires cross-setting coordination among clinicians of different specialties (that is, surgeons and ophthalmologists), we stated in the proposed rule that we believe it is appropriate to defer mandatory reporting at this time. We also stated we will consider mandatory reporting of ASC–11 after the national PHE declaration officially ends and we find it appropriate to do so given COVID-19 PHE impacts on national staffing and supply shortages. As we noted in the CY 2015 OPPS/ASC final rule, this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive the coordination of care (79 FR 66984). We subsequently stated in the CY 2022 OPPS/ASC final rule with comment period that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a number of facilities have reported data consistently for this measure and those that have reported these data have done so consistently (86 FR 63886).

We invited public comment on this proposal.

Comment: Many commenters expressed support for our proposal to change ASC–11 from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination.

Response: We thank the commenters for their support.

Comment: One commenter recommended that ASC–11 should be maintained as voluntary until a digital version of the measure is developed. The commenter stated that this

strategy would support our vision to transition away from chart-abstracted measures and move toward digital measures by 2025.

Response: We thank the commenter for its recommendation and will consider it for future rulemaking. We agree that moving from chart-abstracted measures to digital measures is an important step in working toward interoperability, a goal which we outlined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49181).

Comment: One commenter recommended that we provide education and outreach on the survey instruments available for use with ASC–11 and best practices based on the experiences of the facilities that have consistently reported the measure while it has been voluntary.

Response: We thank the commenter for these recommendations; we agree that such information would be useful. We plan on adding resource information to the ASCQR Program Specifications Manual and have been in contact with facilities that have consistently reported data for this measure to glean how the measure has been implemented and best practices.

Comment: Some commenters stated this measure was developed, tested and previously endorsed by the National Quality Forum (NQF) as a clinician-level measure (NQF #1536) and not to measure facility performance. Some of these commenters noted that CMS regulations at 42 CFR 416.2 prohibit ASCs from offering anything beyond limited surgical services or separate but integral ancillary services immediately before, during or immediately after a surgical procedure and that the suggestion made in the ASCQR Specifications Manual that surveys be performed "during clinician follow-up" are at odds with this prohibition. These commenters further noted that ASCs have been very purposefully limited by the Federal government to providing care narrowly focused to the day of surgery, and expectations that centers will easily

be able to perform the extended follow-up for CMS quality measures is not very realistic. Some commenters stated most ASCs would find it challenging to conduct phone, mail or emails surveys of cataract surgery patients both pre-operatively and 90 days post-operatively.

Response: We agree with these commenters that the NQF #1536 measure was endorsed as a clinician-level performance measure; this alone does not preclude the measure from use in the ASCQR Program. The ASCQR Program is charged with reporting quality of care measures for care furnished in the ambulatory surgical center setting. We reiterate that facilities are equally responsible for the quality of care provided in ASCs as clinicians. Facilities have an obligation to ensure the best quality of care is provided by the clinicians they employ in their ASCs. Further, ASCs are responsible for the clinicians allowed to perform procedures upon their premises as well as aspects of the facility that contribute to care, for example. sterilization, the physical setting, and supporting staff that can contribute to quality of care.

Regarding the ASC-11 measure, the measure specifies that follow-up is to be made “within 90 days”; however, we agree that acceptable minimum timeframes for administration of the follow-up survey should be clarified. Per 42 CFR 416.52, the ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed. Additionally, when appropriate, ASCs are to make a follow-up appointment with the physician and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC of information including their physician contact information for follow-up care.

With respect to the concern that surveys being performed "during clinician follow-up” may be at odds with the prohibition on ASCs providing care beyond the narrow focus of day of surgery, we recognize that some centers may not be able to coordinate with the patient's treating

physician to obtain these survey results. However, a number of facilities have been able to collect these data and have been able to successfully report this measure during the voluntary reporting period. We believe these data are beneficial to patients and their caregivers when available, we believe it is appropriate to continue to allow voluntary reporting.

Comment: Many commenters recommended that ASC–11 never be made mandatory due to the high administrative burden of reporting this measure. A few commenters suggested CMS remove the measure from the measure set for this reason. One commenter recommended that in addition to removing ASC-11, CMS adopt the Toxic Anterior Segment Syndrome (TASS) measure instead.

Response: We thank the commenters for their recommendations. However, we believe ASC-11 remains important to assess the quality of care provided in the ASC setting because cataract surgery is one of the most commonly performed procedures in ASCs and there is currently no measure assessing the quality of care provided for this procedure for the ASCQR Program.

We believe the importance of this measure as a patient reported outcome measure justifies the administrative burden of reporting the measure. The CMS National Quality Strategy includes a goal to Foster Engagement to increase engagement between individuals and their care teams to improve quality, establish trusting relationships, and bring the voices of people and caregivers to the forefront. The Meaningful Measures 2.0 goals also prioritize patient-reported measures and promoting better collection and integration of patient voices across CMS' quality programs.

Additionally, some facilities have been voluntarily reporting this measure successfully while it has not been required, thus, we believe that this indicates that the measure is not overly

burdensome and that the value of the measure in regard to information it provides to consumers about quality of care justifies any potential administrative burden that would prevent facilities from reporting it. We note that while it is recommended that the facility obtain the survey results from the appropriate physician or optometrist, the surveys can be administered by the facility via phone, mail, email, or during clinician follow-up. We appreciate commenters' concerns and plan to retain this measure as voluntary, instead of mandatory, while continuing to evaluate this policy moving forward as we are committed to having a cataract surgery, patient-reported measure for the ASCQR Program.

After consideration of the public comments we received, we are finalizing our proposal to change ASC–11 from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination.

4. ASCQR Program Quality Measure Set

a. Summary of Previously Finalized ASCQR Program Quality Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63875 through 63893) for the previously finalized ASCQR Program measure set for the CY 2023 program year and subsequent years.

Table 94 summarizes the previously finalized ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination and the CY 2024 reporting period/CY 2026 payment determination.

TABLE 94: ASCQR Program Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.
* The ASC-11 measure is voluntarily collected, as set forth in the CY 2015 OPPS/ASC final rule (79 FR 66984 through 66985).

b. Finalized ASCQR Program Quality Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 95 summarizes the previously finalized ASCQR Program measure set for the CY 2025 reporting period/CY 2027 payment determination and as modified by the finalized proposal in this CY 2023 OPPS/ASC final rule.

TABLE 95: Finalized ASCQR Program Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11*	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy

ASC #	NQF #	Measure Name
ASC-15a	None	The Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) - About Facilities and Staff
ASC-15b	None	OAS CAHPS - Communication About Procedure
ASC-15c	None	OAS CAHPS - Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS - Overall Rating of Facility
ASC-15e	None	OAS CAHPS - Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.
* The ASC-11 measure was previously finalized as mandatory for the CY 2025 program year as set forth in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63885 through 63887) and is being finalized as voluntary in this final rule.

5. ASCQR Program Measures and Topics for Future Consideration

a. Request for Comment: A Potential Future Specialty Centered Approach for the ASCQR Program

An overarching ASCQR Program goal is to have an up to date, comprehensive set of quality measures for widespread use to promote informed decision-making regarding clinical care and quality improvement efforts in the ASC setting. We recognize the clinician and clinician-group centered, specialized nature of care delivered in ASCs. We, therefore, sought comment on a potential future direction of quality reporting under the ASCQR Program that would allow quality-related data for ASCs to be reported on a customizable measure set that more accurately reflects the care delivered in this setting and accounts for the services provided by individual facilities. ASC services for Medicare beneficiaries are concentrated in a limited number of procedures. Because of this, there could be a set of measures related to different specialties, for example, ophthalmology, from which ASCs could choose a specified number, but individualized combination of measures. Another option could include the creation of specific specialized tracks which would standardize quality measures within a specialty area. Such a reporting structure could benefit ASCs by allowing them to focus on practice-specific measures

on a specialty or multispecialty basis; patients and other interested parties could benefit through the provision of more relevant information on quality and safety within ASCs.

Specialty Centered Quality Reporting Under the Merit-based Incentive Payment System (MIPS)[199]

The Merit-based Incentive Payment System adjusts Medicare Part B payment to a clinician based on the clinician's prior performance on four performance categories.[200] The four performance categories on which clinicians are scored are quality, cost, improvement activities (IA), and Promoting Interoperability.[201] Under MIPS, we have established measure and activity inventories from which clinicians may select measures and activities to report and complete, respectively.[202] While the Traditional MIPS program is being phased out over time,[203] [204] we nonetheless believe that the quality performance category of the program provides an example of a specialty centered approach to quality reporting that is relevant to ASCs as clinically specialized facilities. We believe that quality reporting for ASCs would benefit from measures that:

- Consist of limited, connected, and complementary sets of measures and related activities that are meaningful to clinicians;
- Include measures and activities resulting in comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care;

[199] Centers for Medicare & Medicaid Services. Quality Payment Program Overview. Available at: https://qpp.cms.gov/about/qpp-overview.
[200] *See* Social Security Act section 1848(q).
[201] *See id*. Section 1848(q)(2)(A)(i) and (iii).
[202] *See id*. Section 1848(q)(2)(D); *see also* 42 CFR 414.1355(a).
[203] CY 2022 Physician Fee Schedule final rule (86 FR 65376).
[204] Centers for Medicare & Medicaid Services. MIPS Value Pathways. Available at: https://qpp.cms.gov/mips/mips-value-pathways.

- Promote subgroup reporting that comprehensively reflects the services provided by multispecialty groups;
- Include measures selected using the Meaningful Measures[205] approach and, wherever possible, include the patient voice;

b. Solicitation of Comments on a Potential Future Specialty Centered Approach for the ASCQR Program

We requested comment on the following questions for the ASCQR Program:

- Is the general concept of quality reporting by specialty feasible and desirable for ASCs participating in the ASCQR Program?
- Were we to adopt a specialty centered approach to quality measure reporting for the ASCQR Program, should CMS require that ASCs report a subset of quality measures that apply broadly to all ASCs? An example of potential broadly applicable measures for ASCs based on CY 2022 performance year MIPS quality measures[206] can be found in Table 96.
- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, what would be the appropriate number and type of measures that ASCs should be required to report? Are there minimum and maximum numbers of measures required for ASCs that provide meaningful information while not being overly burdensome? What is the preferred balance of required quality measures that apply broadly to all ASCs and quality measures that apply to a particular area of specialization?

TABLE 96: Potential Broadly Applicable ASCQR Program MIPS Quality Measures

[205] Centers for Medicare & Medicaid Services. Meaningful Measures Hub. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.

[206] Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.

MIPS MEASURE NAME	TYPE	SUMMARY OF MEASURE
Advance Care Plan	Process	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Anesthesiology Smoking Abstinence	Intermediate Outcome	The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.
CAHPS for MIPs Clinician/Group Survey	Patient Engagement Experience	Similar measure currently in ASCQR measure set (ASC-15 a-e).
Closing the Referral Loop: Receipt of Specialist Report	Process	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Documentation of Current Medications in the Medical Record	Process	Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Multimodal Pain Management	Process	Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.
Patient-Centered Surgical Risk Assessment and Communication	Process	Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.
Perioperative Temperature Management	Outcome	Currently in ASCQR measure set as Normothermia (ASC-13).

Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy	Process	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Surgical Site Infection (SSI)	Outcome	Percentage of patients aged 18 years and older who had a surgical site infection (SSI).
Unplanned Hospital Readmission within 30 Days of Principal Procedure	Outcome	Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure (similar to ASC-17 and ASC-18).
Unplanned Reoperation within the 30 Day Postoperative Period	Outcome	Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.
Use of High-Risk Medications in Older Adults	Process	Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.

- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, which area(s) of specialization would benefit from such an approach and which would not?
- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, should CMS define a set of measures for particular areas of specialization (for example, ophthalmology) or should measures be self-selected for individual facilities from selected categories, especially given that an ASC may be multi-specialty?

We have considered several potential measure sets for the ASC setting based on CY 2022 performance year MIPS quality measures.[207] An example of an ophthalmology measure set using quality measures based on CY 2022 performance year MIPS quality measures[208] can be found in Table 97. An example of a gastroenterology measure set can be found in Table 98. We welcome comment on these specific examples as well as comment on potential future measure sets for other specialization areas.

- Were we to adopt a specialty centered approach for quality measure reporting under the ASCQR Program, should ASCs be required to report all measures in such a measure set, or should they be permitted to select a minimum number of measures from their selected measure set?

- Were we to adopt a specialty centered approach for quality measure reporting system under the ASCQR Program, what measures, if any, from the current ASCQR Program measure set should be retained and incorporated in such an approach?

TABLE 97: Example Ophthalmology ASCQR Program MVP Measures

MEASURE NAME	TYPE	SUMMARY OF MEASURE
Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery	Outcome	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	Outcome	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.

[207] Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.
[208] Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.

Cataract Surgery: Difference Between Planned and Final Refraction	Outcome	Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.
Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	Outcome	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Patient Reported Outcome	Similar measure currently in ASCQR measure set (ASC-11).
Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery	Patient Engagement Experience	Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.

TABLE 98: Example Gastroenterology ASCQR Program MVP Measures

MEASURE NAME	TYPE	SUMMARY OF MEASURE
Age Appropriate Screening Colonoscopy	Efficiency	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Anastomotic Leak Intervention	Outcome	Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.
Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Process	Similar measure currently in ASCQR measure set (ASC-9).
Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Process	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.

Photodocumentation of Cecal Intubation	Claims	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.

We invited public comment on this topic.

Comment: Several commenters expressed their support of a potential future specialty centered approach for the ASCQR Program. A few commenters expressed that this approach would allow specialists to report more relevant measures, which would in turn benefit the patient population. Another commenter expressed that the general concept of quality reporting by specialty, in coordination with facility goals and patient population considerations, is feasible and could be desirable for ASCQR interested parties. Many commenters provided input on specific measures that could be included in our potential future specialty centered approach for the ASCQR Program, such as the Toxic Anterior Segment Syndrome (TASS) measure. One commenter recommended the inclusion of a cross-cutting measure on surgical site infection outcomes. Another commenter suggested that we retain current ASCQR Program measures within this specialized approach. Another commenter suggested that we incorporate current MIPS measures which are applicable to ASCs into this approach. A few commenters recommended that we apply additional measure scrutiny to refine and align chosen measures to ensure meaningful measure collection.

Response: We thank the commenters for their support of the potential future specialty centered approach for the ASCQR Program and recommendations for specific measures. We agree that this approach could allow for more meaningful data reporting which will simultaneously benefit the patient population.

Comment: Several commenters expressed concern over potential burden and redundancy of reporting related to this approach. One commenter expressed that physicians are already measured in a more specialty-centered capacity under MIPS, the results of which are publicly reported. Another commenter stated that the potential Ophthalmology-specific ASCQR measure set potential pathway would increase burden, as data that are intended to be reported by ASCs is in the surgeon's office and is, thus, inaccessible; however, this commenter also noted that, in contrast, the exemplary Gastroenterology ASCQR Program MVP measure set contains both process and claims measures that are more accessible to ASCs.

Response: We acknowledge the commenters' concerns regarding redundant reporting, however, our potential future specialty centered approach for the ASCQR Program would not replicate the Quality Performance category of the MIPS. Rather, our approach is informed by the MIPS' specialty centered approach to quality measure selection. Furthermore, MIPS is largely a clinician quality reporting program. Our potential future specialty centered approach used within ASCs would provide important facility-level data that are currently not collected through MIPS. Additionally, this potential future specialty centered approach could be an important way to assess quality measurement in the ASC setting. ASC services for Medicare beneficiaries are limited to certain commonly performed outpatient procedures. Our potential future specialty centered approach would be designed to streamline specialized measure sets, increasing the applicability of measure sets to a given specialized ASC facility. Patients could benefit through the provision of more relevant information on the quality and safety of care provided in ASCs that are primarily focused on specific procedures or areas of care.

We reiterate that facilities are equally responsible for the quality of care provided in ASCs as clinicians. Facilities have an obligation to ensure the best quality of care is provided by the clinicians they employ in their ASCs.

We thank commenters for providing feedback on the areas of specialization that would benefit from such an approach and we will consider this feedback for future rulemaking.

Comment: Several commenters suggested that we consult relevant interested parties and clinicians while creating this approach to reduce potential burden, adopt appropriate measures, and ensure patients are supplied with adequate information to make comparisons between centers.

Response: We thank the commenters for their recommendations and will take them into consideration for future rulemaking. We agree that input from relevant interested parties and clinicians is important.

Comment: Many commenters provided feedback regarding requiring ASCs to report a subset of quality measures that apply broadly to all ASCs, and the preferred balance of required quality measures that apply broadly and those measures that apply to a particular area of specialization. One commenter expressed that potential universally applicable ASCQR Program quality measures would not reflect the specialty focus intended. One commenter suggested restricting the set of general ASC measures to no more than two outcome measures. Some commenters generally agreed with the creation of broadly applicable measures that are risk or case-mix adjusted. One commenter recommended limiting the number of specialty measures to no more than six. One commenter recommended that a given ASC not exceed two measures per specialty.

Regarding the number of required measures, one commenter recommended at least twelve measures, and another recommended around two dozen measures. One commenter recommended that an individual or group report four measures. One commenter suggested that the facility should be required to report all measures in the specialty measure set.

Regarding the self-selection of measures for individual facilities, one commenter expressed that measures should not be self-selected, and stated that ASCs should report on all measures that meet the declared minimum sample size. A few commenters suggested that CMS offer self-selection of measures based on the specialties and strategic opportunities identified by the individual ASCs to add more meaningful measures toward overall quality improvement.

Another commenter suggested that CMS prevent gaming by requiring ASCs that offer patient services for more than one specialty to choose at least one measure for each specialty represented in their practice, instead of only reporting measures on one specialty.

Several commenters raised concern over alignment across quality reporting programs. Several commenters specifically raised concern over misalignment with the Hospital OQR Program if this future specialty centered approach is implemented.

Response: We thank the commenters for their thoughtful recommendations regarding a specialty-centered approach for ASC quality reporting. We note that any changes to the ASCQR Program would require rulemaking and the input of all interested parties would be taken into consideration. We reiterate that currently we are not making any changes to the program's structure. We included this request for comment to get feedback on this potential future approach.

Comment: A few commenters recommended that this future specialty centered approach include digitally reported measures, as opposed to chart-abstracted measures. One commenter

stated that although digital measures are preferable, smaller facilities may not have adequate Electronic Medical Record resources to process these measures.

Response: We thank the commenters for their recommendations and will take them into consideration in future rulemaking. We agree that moving from chart-abstracted measures to digital measures is an important step when working toward interoperability, a goal which we described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45342) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49181).

Comment: One commenter recommended that the OAS CAHPS survey not be included in any future prospective model due to its potential to increase burden. Additionally, one commenter provided feedback on a potential implementation timeline for this potential future specialty centered approach. The commenter suggested an incremental implementation, which would include allowing ASCs to continue reporting their quality performance under the current ASCQR program for at least 5 years.

Response: We thank the commenter for the recommendation to employ a transition period for such a change as the specialty centered approach for the ASCQR Program if implemented and will take it into consideration for future rulemaking. We want to reiterate that currently we are not making any changes to the program. We included this request for comment to get feedback on this potential future approach.

Comment: A few commenters raised concerns about our potential future specialty centered approach incorporating measures which collect data on outcomes that are outside the ASC's control.

Response: We acknowledge that commenters have expressed this concern. However, the statutory charge of the ASCQR Program is to collect and make publicly available quality

measure data for services provided in the ASC setting. Clinicians, regardless of financial relationship to the ASC, are performing services in that ASC. Further, ASCs are responsible for the clinicians allowed to perform procedures upon their premises as well as aspects of the facility that contribute to care, e.g. sterilization, the physical setting, and supporting staff that can contribute to quality of care. Therefore, the complete separation of the clinician from the ASC regarding quality reporting is not consistent with the program's statutory responsibilities. Existing outcome measures, such as ASC-1, ASC-2, ASC-3 and ASC-4, also reflect that ASCs and clinicians work in tandem.

c. Request for Comment: Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC –7) Measure or Other Volume Indicator

(1) Background

ASC services for Medicare beneficiaries are concentrated in a limited number of procedures. Medicare covers surgical procedures represented in about 3,500 Healthcare Common Procedure Coding System (HCPCS) codes under the ASC payment system; however, ASC volume for services covered under Medicare is concentrated in a relatively small number of HCPCS codes. In 2019, for example, 29 HCPCS codes accounted for 75 percent of the ASC volume for surgical services provided to Medicare beneficiaries.[209]

Although ASCs perform procedures under a smaller and more specialized subset of HCPCS codes, the volume within these services continues to increase. Hospital care has been gradually shifting from inpatient to outpatient settings, and since 1983, inpatient stays per capita have fallen by 31 percent.[210] From 2014 to 2018, the volume of ASC services delivered per

[209] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.
[210] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.

Medicare Part B Fee-for-Service (FFS) beneficiary increased by 2.1 percent.[211] During the same time period, the number of Part B FFS beneficiaries who received ASC services increased on average by 1.4 percent annually.[212] Research indicates that volume in ASCs will continue to grow, with some estimates projecting a 25 percent increase in patients between 2019 and 2029.[213]

Volume has a long history as a quality metric, however, quality measurement efforts had moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes.[214] More recent studies suggest that while larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality.[215] The ASCQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509) where we adopted the ASC Facility Volume Data on Selected ASC Surgical Procedures measure (ASC–7) beginning with the CY 2013 reporting period/CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on seven categories of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous

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[211] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.
[212] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.
[213] Sg2. Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. June 4, 2021. Available at: https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/.
[214] Jha AK. Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015.
[215] Ibid.

System, Musculoskeletal, Skin, Respiratory, and Genitourinary.[216] We adopted ASC–7 based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality. We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74507).[217, 218, 219]

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59449 and 59450), we removed ASC–7. We stated our belief based on the available literature that measures on specific procedure types would provide patients with more valuable ASC quality of care information as these types of measures are more strongly associated with desired patient outcomes. Thus, we removed the ASC–7 measure under our second criterion for removal from the program; specifically, that there are other measures available that are more strongly associated with desired patient outcomes for the particular topic. At the time, some commenters supported the proposal to remove the ASC–7 measure and agreed with CMS's rationale that the measure does not add value, however, some commenters opposed this proposal (82 FR 59449). Commenters that opposed removal of the ASC–7 measure emphasized the data's usefulness for comparative research, outcomes research, immediate consumer value, and strategic planning. Some of these commenters also expressed concerns that nonavailability of these data would interfere with the acceptance of ASC-based procedures and noted that the measure is not overly burdensome (82 FR 59449).

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[216] ASC Specifications Manual version 5.1. Available at: https://qualitynet.cms.gov/asc/specifications-manuals#tab6.

[217] Livingston, E.H.; Cao, J ''Procedure Volume as a Predictor of Surgical Outcomes''. Edward H. Livingston, Jing Cao JAMA. 2010;304(1):95–97.

[218] David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. ''Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures''. *JAMA. 2005;294(15):1903–1908.*

[219] Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B '' Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer'' *JAMA. 2000; 284 (23): 3028– 3035.*

We stated in the CY 2023 OPPS/ASC proposed rule that we are considering reimplementing the ASC–7 measure or another volume measure because, in addition to being an important component of quality, the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures (87 FR 44748 through 44749).

Over the past few decades, innovations in the health care system have driven the migration of procedures from the inpatient setting to the outpatient setting. Forty-five percent of percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of surgery itself due to the use of innovative techniques and technologies available in the outpatient setting.[220, 221] Given the relatively small number of HCPCS codes utilized by most ASCs, we believe that patients may benefit from the public reporting of facility-level volume measure data that illuminates which procedures are performed across ASCs, provides the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures. ASC–7 was the only measure in the ASCQR Program measure set that captured facility-level volume within ASCs and volume for Medicare and non-Medicare patients. As a result of its removal, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

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[220] Abrams KD, Balan-Cohen A, Durbha P. Growth in Outpatient Care: The role of quality and value incentives. Deloitte Insights. 2018. Available at: https://www2.deloitte.com/us/en/insights/industry/health-care/outpatient-hospital-services-medicare-incentives-value-quality.html.

[221] Chang AC, Yee J, Orringer MB, Iannettoni MD. Diagnostic thoracoscopic lung biopsy: an outpatient experience. The Annals of Thoracic Surgery. 2002;74:1942–7.

Furthermore, we stated in the CY 2023 OPPS/ASC proposed rule (87 FR 44748 through 44749) that we are considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63902 through 63904). When considering the need for a pain management measure, we analyzed volume data using the methodology established by ASC–7 to determine the proportion of ASC procedures performed for pain management. We found that pain management procedures were the third most common procedure in CYs 2019 and 2020 and concluded that a pain management measure would provide consumers with important quality of care information. Thus, a volume measure would provide Medicare beneficiaries and other interested parties information on numbers and proportions of procedures by category performed by individual facilities, including for ASC procedures related to pain management.

We noted in the CY 2023 OPPS/ASC proposed rule (87 FR 44748 through 44749) that the ASC–7 measure was adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509) and was not reviewed or endorsed by the Measure Applications Partnership (MAP), which first began its pre-rulemaking review of quality measures across Federal programs in February 2012 after the publication of the CY 2012 OPPS/ASC final rule with comment period in November 2011.[222] Therefore, for ASC–7 to be adopted in the ASCQR Program measure set, the measure would need to first undergo the pre-rulemaking process specified in section 1890A(a) of the Act.

[222] Measure Applications Partnership. Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking Final Report. February 2012. Available at: https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.

(2) Solicitation of Comments on the Reimplementation of the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) Measure or Other Volume Indicator in the ASCQR Program

We sought comment on the potential inclusion of a volume measure in the ASCQR Program, either by adopting the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) measure or adopting another volume indicator. We also sought comment on what volume data ASCs currently collect and if it is feasible to submit these data to the ASCQR Program, to minimize the collection and reporting burden of an alternative, new volume measure. Additionally, we sought comment on an appropriate timeline for implementing and publicly reporting the measure data.

Specifically, we invited public comment on the following:

- The usefulness of including a volume indicator in the ASCQR Program measure set and publicly reporting volume data;
- Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission;
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy;
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting; and
- The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

Comment: One commenter supported the reintroduction of a volume measure, stating that the measure would provide critical data about ASC quality to consumers.

Response: We thank the commenter for supporting the reimplementation of a procedure volume measure in the ASCQR Program. We will take this comment into consideration as part of future notice-and-comment rulemaking.

Comment: Some commenters did not support the potential future reimplementation of ASC–7 or adoption of another volume measure. Several commenters expressed their belief that volume is not a clear indicator, or never is an indicator, of quality care and procedure volume data would not be useful to consumers. A few commenters also noted that the procedure categories for ASC–7 are too broad to provide meaningful information to consumers who want to know a facility's experience with a specific procedure. A few other commenters stated that the lack of evidence linking volume and clinical quality would make a volume measure inconsistent with the Meaningful Measures 2.0 Framework goal to "promote innovation and modernization of all aspects of quality." A few commenters also expressed their concern with the high reporting burden.

Some commenters expressed concern that reporting procedure volume for the ASCQR Program would lead to an unnecessary duplication of data because CMS can determine facility volumes using existing claims data.

Another commenter did not support the implementation of any additional measures during a public health emergency.

Response: We thank the commenters for their feedback and acknowledge their concerns. We agree that CMS can determine facility volumes for procedures performed using Medicare FFS claims. However, the specifications for the ASC–7 measure include reporting data for non-

Medicare patients. We refer readers to the specifications for ASC–7 which are available in the ASC Specifications Manual version 5.1 available at: https://qualitynet.cms.gov/asc/specifications-manuals#tab6. As stated in the Specifications Manual, ASC–7 measures the aggregate count of the most commonly performed surgical procedures for seven categories: Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.

We reiterate our belief grounded in the published scientific literature that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and assist consumers in making informed decisions about where they receive care, acknowledging that many studies have shown that volume does serve as an indicator of quality of care.[223, 224] One study found that patients who had total hip arthroplasties performed at high-volume hospitals had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[225] Another study found that congestive heart failure (CHF) patients who stayed in hospitals with more experience in managing CHF received higher quality care and experienced better outcomes.[226]

The adoption of such measure would follow our standard measure adoption process, including our consideration of relevant measures endorsed by a consensus building entity. A

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[223] Ogola, Gerald O. PhD, MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; Shafi, Shahid MD, MPH. High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. Journal of Trauma and Acute Care Surgery: September 2018 - Volume 85 - Issue 3 - p 560-565 doi: 10.1097/TA.0000000000001985

[224] Xu, B., Redfors, B., Yang, Y., Qiao, S., Wu, Y., Chen, J., Liu, H., Chen, J., Xu, L., Zhao, Y., Guan, C., Gao, R., & Généreux, P. (2016). Impact of Operator Experience and Volume on Outcomes After Left Main Coronary Artery Percutaneous Coronary Intervention. JACC. Cardiovascular interventions, 9(20), 2086–2093. https://doi.org/10.1016/j.jcin.2016.08.011

[225] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. *et al.* Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and meta-analysis. *J Orthop Surg Res* **14**, 468 (2019). https://doi.org/10.1186/s13018-019-1531-0

[226] Joynt, K. E., Orav, E. J., & Jha, A. K. (2011). The association between hospital volume and processes, outcomes, and costs of care for congestive heart failure. Annals of internal medicine, 154(2), 94–102. https://doi.org/10.7326/0003-4819-154-2-201101180-00008

volume measure would not be presented to consumers alone, but would be displayed complementary with other program quality measures that are focused on clinical processes and outcomes. We will take the commenters' feedback into consideration as we consider the potential future adoption of a volume measure that is useful to consumers and appropriately assesses the quality of care provided in the outpatient setting.

Comment: Several commenters provided recommendations for improving a potential volume measure in the ASCQR Program. A few commenters recommended that CMS consider volume reporting on a more granular level than the proposed clinical areas, such as by procedure or insurance type. One commenter stated that the volume measure should expand the reporting of clinical areas beyond the existing procedure categories. Another commenter suggested that CMS adopt a volume measure that is limited to a specific set of procedures. A few commenters recommended the adoption of an all-payer volume indicator to provide useful data about facilities that also serve non-Medicare fee-for-service (FFS) patients, and one commenter further noted that volume reporting by insurance type may be useful for monitoring equity or social risk factors.

One commenter stated that if a volume measure is adopted, it should be used only for confidential facility-level feedback. One commenter encouraged CMS to develop a volume electronic clinical quality measure (eCQM) instead of a measure that requires web-based submission through the Hospital Quality Reporting (HQR) portal. Another commenter stated that a volume measure should receive NQF endorsement before being proposed for adoption.

Several other commenters offered alternatives to reimplementing a volume measure. A few commenters encouraged CMS to use volume data that is already available to CMS through claims-based data. A few other commenters recommended that CMS focus on adopting

more meaningful measures of quality and safety of care which have emerged since ASC–7 was removed. Another commenter expressed that a pain management measure should not be developed based on a volume measure because the healthcare system is already overburdened by the ongoing opioid epidemic and the COVID-19 PHE.

Response: We thank the commenters for their recommendations to provide meaningful information to consumers and improve the quality of ASC care and will take these comments into consideration for future rulemaking. We note that the ASC–7 measure, when required for the ASCQR Program, included the submission of Medicare and non-Medicare volume data; conversely, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only this payer.

(3) Request for Comment: Interoperability Initiatives in ASCs

(a) Background

In 2009, under the Health Information Technology for Economic and Clinical Health Act (HITECH Act), financial incentives were authorized for hospitals and clinicians to adopt and meaningfully use certified electronic health record (EHR) technology.[227] We implemented these financial incentives by establishing the Medicare and Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), to encourage health care providers to adopt and meaningfully use certified EHR technology (CEHRT) and improve health care quality, efficiency, and patient safety.[228] The Promoting Interoperability Program also aims to improve care coordination, reduce costs, ensure privacy and security, improve population health, and engage patients and their caregivers in their own healthcare.

[227] Social Security Act section 1848(o)(2), amended by HITECH Act of 2009 section 4101 (February 2009).
[228] Centers for Medicare & Medicaid Services. CMS Finalizes Definition Of Meaningful Use Of Certified Electronic Health Records (EHR) Technology. July 2010. Available at: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-definition-meaningful-use-certified-electronic-health-records-ehr-technology.

ASCs were not included in the HITECH Act and were ineligible for the financial incentives under the Promoting Interoperability Program. This differentiation may contribute to many ASCs continuing to utilize paper-based charts while other healthcare sectors have transitioned to digital records.[229] According to an EHR utilization survey conducted by the Ambulatory Surgical Center Association (ASCA), 54.6 percent of ASCs use an EHR in their facility, indicating that ASCs have a lower adoption rate compared to the 85.9 percent of office-based physicians reported by ONC.[230] Some EHR vendors have developed ASC-specific solutions; however, ASCs still face significant barriers to implementing EHRs as they can be expensive to implement and update, can require many staff hours for training, and may not offer ASCs a meaningful investment given the types of services provided and levels of patient follow-up required.[231]

In the CY 2023 OPPS/ASC proposed rule (87 FR 44750), we referred readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45460 through 45498) where we finalized changes to the Promoting Interoperability Program (87 FR 49319 through 49371), and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28576 through 28612) which proposed additional changes to the Promoting Interoperability Program. Currently, eligible hospitals and critical access hospitals (CAHs) are required to report on four scored objectives including electronic

[229] Vail, T. Electronic Health Record Adoption is Essential for Outpatient Surgery. Managed Healthcare Executive. April 2021. Available at: https://www.managedhealthcareexecutive.com/view/electronic-health-record-adoption-is-essential-for-outpatient-surgery.
[230] Taira, A. ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus: The ASCA Journal. June 2021. Available at: https://www.ascfocus.org/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs.
[231] Nelson, H. EHR Usability, User Satisfaction High in Ambulatory Surgery Centers. September 2021. Available at: https://ehrintelligence.com/news/ehr-usability-user-satisfaction-high-in-ambulatory-surgery-centers.

prescribing, health information exchange, provider to patient exchange, and public health and clinical data exchange, and must also attest to the following[232]:

- Security Risk Analysis measure.
- Safety Assurance Factors for EHR Resilience (SAFER) Guides measure.
- Actions to limit or restrict the compatibility or interoperability of CEHRT attestation.
- Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation.

(b) Solicitation of Comments on Interoperability in ASCs

We sought comment in the CY 2023 OPPS/ASC proposed rule to explore how ASCs are implementing tools in their facilities toward the goal of interoperability (87 FR 44750). We are considering the usefulness of eCQMs in ASCs to aid in delivering effective, safe, efficient, patient-centered, equitable, and timely care.[233] Transitioning to eCQMs would increase alignment across quality reporting programs such as the Hospital OQR Program, which adopted the STEMI eCQM in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63822 through 63875). We are interested in learning more about capabilities for reporting such measures in the future for the ASCQR Program. Generally, we sought input on: (a) Barriers to interoperability in the ASC setting; (b) the impact of health IT, including health IT certified under the ONC Health IT Certification Program, on the efficiency and quality of health care services furnished in ASCs; and (c) the ability of ASCs to participate in interoperability or EHR-based quality improvement activities, including the adoption of eCQMs.

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[232] Centers for Medicare & Medicaid Services. 2022 Medicare Promoting Interoperability Program Requirements. March 2022. Available at: https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements.

[233] Centers for Medicare & Medicaid Services. 2022 Electronic Clinical Quality Measures Basics. March 2022. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures

Specifically, we invited comment on:

- What do ASCs perceive as the benefits or risks of implementing interoperability initiatives in their facilities?
- What improvements might be possible with the implementation of interoperability initiatives in ASCs, including EHR utilization (reduced delays, efficiencies, ability to benchmark, etc.)?
- Do ASCs see interoperability initiatives as non-essential or detrimental to their business practices?

Some clinicians practicing in ASCs may voluntarily participate in the MIPS Promoting Interoperability performance category, though they are not required to do so at this time.[234] We have considered several measures from the Promoting Interoperability Program and from the Traditional MIPS Promoting Interoperability measure set for the CY 2022 performance year that may be applicable for the ASC setting.[235,236] An example of Promoting Interoperability measures potentially applicable for the ASC setting can be found in Table 99. We welcomed comment on these specific measure examples, including whether ASCs believe these measures would be appropriate and feasible for use in ASCs.

TABLE 99: Example Promoting Interoperability Measures Applicable to the ASCQR Program

MEASURE NAME		SUMMARY OF MEASURE
e-Prescribing		At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.

[234] Centers for Medicare and Medicaid Services. Quality Payment Program Special Statuses. 2022. Available at: https://qpp.cms.gov/mips/special-statuses.
[235] Centers for Medicare and Medicaid Services. 2022 Medicare Promoting Interoperability Program Requirements. Available at: https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements.
[236] Centers for Medicare and Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022.

Health Information Exchange (HIE) Bi-Directional Exchange		The MIPS eligible clinician or group must establish the technical capacity and workflows to engage in bi-directional exchange via an HIE for all patients seen by the eligible clinician and for any patient record stored or maintained in their EHR.
Provide Patients Electronic Access to Their Health Information		For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's certified electronic health record technology (CEHRT).
Query of the Prescription Drug Monitoring Program (PDMP)		For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.
Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure (eCQM)		Proportion of hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge.
Security Risk Analysis		Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS

		eligible clinician's risk management process.
Support Electronic Referral Loops By Receiving and Reconciling Health Information		For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.
Support Electronic Referral Loops By Sending Health Information		For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider - (1) creates a summary of care record using certified electronic health record technology (CEHRT); and (2) electronically exchanges the summary of care record.

We invited public comment on this topic.

Comment: Several commenters supported our goal of promoting interoperability by transitioning toward eCQMs to promote delivery of effective, safe, patient-centered, and timely care and increase alignment across quality reporting programs.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern regarding our consideration of a future shift in data reporting via the EHR. A few commenters expressed concern about the lack of ASCs currently using EHR systems and the financial and administrative burden of implementing an EHR system. A few commenters expressed concern about the lack of federal requirements for ASCs to procure an EHR system and the lack of financial incentives for EHR adoption for ASCs, unlike hospitals which received such funding under HITECH Act of 2009.

Response: We thank the commenters for their feedback. We sought comment to better understand the barriers to EHR adoption and interoperability in the ASC setting. We reiterate the importance of use of technology and data standards as a way to increase alignment across quality reporting programs, such as the Hospital OQR Program. We believe streamlining the reporting requirements, and aligning and harmonizing measures for the quality reporting programs will significantly ease the reporting burden on clinicians and ASCs, thus allowing clinicians to devote more time to direct patient care. Our goal is to reduce reporting burden for ASCs in the long term and promote patient-centered care.

Establishing such a system will require additional infrastructure development by ASCs, however, once the infrastructure is accomplished, the adoption of many measures that rely on data obtained directly from EHRs would enable us to expand the ASCQR Program measure set with less cost and burden to ASCs. We believe that automatic data collection and streamlined reporting, like those in other quality reporting programs, will continue to minimize burden on other care settings, a goal which we outlined in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49181). We will take commenters feedback into consideration for future rulemaking.

Comment: Many commenters had recommendations regarding CMS' consideration of a future shift in reporting to EHRs. A few commenters recommended that any EHR requirements be gradually phased in to minimize burden on ASCs. One commenter recommended that CMS evaluate a hybrid paper and electronic record model. One commenter recommended that CMS assess the current capabilities of the ASC industry through a detailed environmental scan. One commenter recommended that interoperability initiatives be voluntary, with no penalties or negative ramifications on ASCs that fail to report. One commenter recommended that CMS provide sufficient financial support, resources, and time for ASCs to make the transition to the

EHR. A few commenters recommended the development and use of health information technology, expanding past EHRs, to create a patient's care pathway so that digital data can be shared across all patient care experiences in order to provide access to a complete and comprehensive healthcare record which could improve patient satisfaction, patient outcomes, and affordability of care. One commenter recommended that CMS also consider use of non-certified EHRs in order to encourage innovation and provide EHR systems to smaller provider groups that otherwise would be financially and resourcefully burdened.

Response: We thank the commenters for their recommendations and will take them into consideration for future rulemaking.

Comment: A few commenters recommended specific measure requirements, should we shift to EHR reporting for ASCs in the future. One commenter recommended that CMS use the Meaningful Measures 2.0 Framework when developing eCQMs for ASCs. One commenter recommended that CMS use the May 2022 Officer of Inspector General (OIG) report, which recommended a significant expansion of measures, when developing eCQM measures for ASCs. One commenter recommended aligning eCQM measures across different quality reporting settings.

Response: We thank the commenters for their recommendations and will take them into consideration for future rulemaking.

6. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we modify the ASCQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: https://qualitynet.cms.gov/asc/specifications-manuals. The policy

on maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

7. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Official

We refer readers to the CYs 2014, 2016, and 2021 OPPS/ASC final rules with comment period (78 FR 75132 through 75133; 80 FR 70533; and 85 FR 86189, respectively) for the previously finalized QualityNet [now referred to as the Hospital Quality Reporting (HQR) system] security official requirements, including requirements for setting up a QualityNet account and the associated timelines. These procedural requirements are codified at 42 CFR 416.310(c)(1)(i). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR

Program at 42 CFR 416.305. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

Previously finalized quality measures and information collections discussed in this section were approved by OMB under control number 0938-1270 (expiration date August 31, 2025). An updated PRA package reflecting the updated information collection requirements will be submitted for approval under the same OMB control number.

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310.

b. Requirements for Claims-Based Measures

(1) Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2). We note that the previously finalized data processing and collection period requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

(2) Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We also refer readers to section XVI.D.1.b of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63904 through 63905), where we finalized that our policies for minimum threshold, minimum case volume, and data completeness requirements apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138) for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at 42 CFR 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

c. Requirements for Data Submitted via an Online Data Submission Tool

(1) Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal) to host our CMS online data submission tool, available by securely logging in at: https://hqr.cms.gov/hqrng/login. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at 42 CFR 416.310(c)(1)(i). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery;
- ASC–13: Normothermia Outcome; and
- ASC–14: Unplanned Anterior Vitrectomy.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63883 through 63885), we finalized our proposal to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination for the following four measures:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: All-Cause Hospital Transfer/Admission.

Measure data for these measures would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

(2) Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (specifically, the CDC's National Healthcare Safety Network (NHSN). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2). While we did not finalize any changes to those policies in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we did finalize policies specific to the COVID-19 Vaccination Coverage Among Health Care Personnel measure (ASC-20), for which data will be submitted via the CDC

NHSN. We did not propose any changes to these policies in the CY 2023 OPPS/ASC proposed rule.

e. ASCQR Program Data Submission Deadlines

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191) for a detailed discussion of our data submission deadlines policy, which we codified at 42 CFR 416.310(f). We did not propose any changes to this policy in the CY 2023 OPPS/ASC proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191 through 86192) for a detailed discussion of our review and corrections period policy, which we codified at 42 CFR 416.310(c)(1)(iii). We did not propose any changes to this policy in the CY 2023 OPPS/ASC proposed rule.

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We did not propose any changes to this policy in the CY 2023 OPPS/ASC proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's extraordinary circumstance exceptions (ECE) request policy. We did not propose any changes to this policy in the CY 2023 OPPS/ASC proposed rule.

E. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail to Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2022, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the Internet on the CMS website): "A2", "G2", "P2", "R2" and "Z2", as well as the service portion of device-intensive procedures identified by "J8" (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators "A2", "G2", "J8", "P2", "R2" and "Z2." These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific

services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2022 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We proposed the continuation of these policies for CY 2023. We did not receive any public comments on our proposal, and are finalizing the continuation of these policies for CY 2023.

XVI. Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background

1. Overview

We refer readers to section XIV of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410) for a general overview of our Hospital Outpatient Quality Reporting (OQR) Program and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Framework.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 and 68494) for a detailed discussion of the priorities we consider for other quality programs for outpatient settings including the Hospital OQR and the Ambulatory Surgical Center Quality Reporting (ASCQR) Programs.

2. Statutory History of Quality Reporting for REHs

The Consolidated Appropriations Act (CAA), 2021, was signed into law in December 2020. In this legislation, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs). Section 125 of Division CC of the CAA added section 1861(kkk) to the Social Security Act (the Act). This section defines an REH as a facility that, in relevant part, was as of December 27, 2020: (1) a Critical Access Hospital (CAH) or a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (defined in section 1886(d)(2)(D) of the Act); or (2) was a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area pursuant to section 1886(d)(8)(E) of the Act. Among other requirements, an REH must apply for enrollment in the Medicare program, provide emergency department services and observation care, and, at the election of the

REH, provide certain services furnished on an outpatient basis, and not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)). Payment with respect to REH services may be made on or after January 1, 2023. Generally, a subsection (d) hospital is an acute care hospital—particularly one that receives payments under Medicare's inpatient prospective payment system (IPPS) when providing covered inpatient services to eligible beneficiaries. Similarly, a CAH is (as defined in section 1820 of the Act) a facility with no more than 25 inpatient beds, unless operating a psychiatric and/or a rehabilitation distinct part unit which may have up to 10 beds each.

We refer readers to section XVIII of this final rule with comment period for payment policies, conditions of participation, and provider enrollment for REHs.

Under section 1861(kkk)(7) of the Act, as added by section 125 of Division CC of the CAA, the Secretary is required to establish quality measurement reporting requirements for REHs, which may include the use of a small number of claims-based measures or patient experience surveys. An REH must submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on a CMS website.

3. Scope

The number of hospitals that convert to an REH and their characteristics may inform the selection of quality measures as we seek measures that are useable by REHs and that have sufficient numbers of REHs with sufficient volume of services to have meaningful measurement for individual facilities and, importantly, the public. REHs as defined by statute would be subsection (d) hospitals defined as rural with not more than 50 beds and CAHs that convert in status to REHs. To estimate the number of facilities that are likely to consider conversion to an

REH, one study[237] analyzed 1,673 rural hospitals on three criteria: (1) 3-years negative total margin; (2) average daily census of acute and swing beds being less than three; and (3) net patient revenue less than $20 million.[238] The analysis concluded that 68 would consider converting.[239] In contrast, an industry analysis - based on estimated REH reimbursement and several financial assumptions[240] and four simulation methods - estimated that up to 600 CAHs would benefit from conversion to REH status.[241] Regardless of the exact number of facilities which convert, there may be quality measure challenges due to the low numbers of hospitals and volume of services provided by these facilities. We discussed possible approaches for addressing these low volume concerns in section XVI.B of the CY 2023 OPPS/ASC proposed rule (87 FR 44764).

B. REHQR Program Quality Measures

1. Considerations in the Selection of REHQR Program Quality Measures

We seek to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and further quality improvement efforts in the REH setting. In the CY 2022 OPPS/ASC proposed rule (86 FR 42285 through 42289), we sought comment through a Request for Information on various topics on REHs. Specifically, we sought input on the concerns of rural providers that should be taken into consideration by CMS in establishing quality measures and quality

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[237] Pink, G. H., et al., *How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)* 8 (July 2021), available at https://www.shepscenter.unc.edu/download/23091/.
[238] Ibid. at 5.
[239] Ibid. at 1.
[240] Estimated average facility payment, estimated outpatient fee schedule payment, estimated average skilled nursing facility payment rates by state, presence or loss of swing bed payments, and continuance or cessation of 340B eligibility.
[241] https://www.claconnect.com/resources/articles/2022/a-path-forward-clas-simulations-on-rural-emergency-hospital designation#:~:text=Depending%20on%20resolution%20of%20key,benefit%20from%20the%20new%20designation (Accessed April 8, 2022).

reporting requirements for REHs (86 FR 42288). We included issues raised and suggestions made from that Request for Information in the CY 2023 OPPS/ASC proposed rule (87 FR 44755) as considerations for selecting measures for an REH quality reporting program.

a. Measure Endorsement

Under section 1861(kkk)(7)(C)(i) of the Act, unless the exception of subclause (ii) applies, a measure selected for the REHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Subclause (ii) provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, due to lack of an endorsed measure for a given facility setting, procedure, or other aspect of care, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

b. Accountability and Quality

The overarching goals of this program, in line with other quality programs, are to improve the quality of care provided to beneficiaries, facilitate public transparency, and ensure accountability. We note that many subsection (d) hospitals and CAHs established on or before December 27, 2020 that are eligible for REH conversion are currently reporting outpatient

quality data under the Hospital OQR Program and have publicly available data. We note that while such reporting is required for subsection (d) hospitals in order to avoid a payment penalty, under the Hospital OQR Program data submission and public reporting are voluntary for CAHs. We intend to adopt measures for the REHQR Program that are useful for REHs for their quality improvement efforts, but it is vital that measure information be of sufficient volume to meet case thresholds for facility level public reporting. See Tables 100 and 101 of this final rule for the current number of facilities and their current public reporting of Hospital OQR Program measure data as of January 2022 as well as the most recent data available for certain measures that have been removed from the OQR Program, but that may have continued relevance for an REHQR Program. The Medicare Beneficiary Quality Improvement Project (MBQIP), under the Medicare Rural Hospital Flexibility (Flex) program of the Health Resources and Services Administration, utilizes outpatient quality data voluntarily reported by CAHs through the Hospital OQR Program. We note that per the 2020 MBQIP Quality Measures annual report, 1,353 CAHs (that is, 86.5 percent of those eligible) reported data for at least one OQR measure,[242] which is greater than the number of facilities having data displayed in Table 101 due to the low reporting volume exclusion limitation of Care Compare, indicating a greater capacity for these facilities to report on certain Hospital OQR measures.[243] Table 100 reflects data for reporting by rurally located subsection (d) hospitals with not more than 50 beds, and Table 101 reflects data for reporting by CAHs for the most recent Care Compare results available. These analyses presented a starting place for assessing the extent of quality reporting by CAHs and

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242 https://www.flexmonitoring.org/sites/flexmonitoring.umn.edu/files/media/PA_Annual%20Report_2020.pdf (Accessed June 5, 2022).

243 https://www.hrsa.gov/rural-health/grants/rural-hospitals/medicare-benificiary-quality-improvement (Accessed June 3,2022).

small, rural hospitals for current or relatively recent measures with sufficient data for public reporting that could be considered for an REHQR Program.

TABLE 100: Rural* Subsection (d) Hospitals with not More than 50 Beds Publicly Reporting Selected Hospital Outpatient Measures (Current and those Previously Removed)**

Measure Number	Measure Title	Number Reporting With Measure Displayed on Care Compare	Percent Reporting
Hospital OQR measures on Care Compare, January 2022			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures; total of 191 hospitals	188	
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	4	2.13%
OP-3b	Median Time to Transfer to Another Facility for Acute Coronary Intervention	6	3.19%
OP-8	MRI Lumbar Spine for Low Back Pain	4	2.13%
OP-10	Abdomen CT Use of Contrast Material	124	65.96%
OP-13	Outpatients who got cardiac imaging stress tests before low-risk outpatient surgery	27	14.36%
OP-18b	Average (median) time patients spent in the emergency department before leaving from the visit	152	80.85%
OP-18c	Average (median) time patients spent in the emergency department before leaving from the visit-Psychiatric/Mental Health Patients	92	48.94%
OP-22	Left before being seen	145	77.13%
OP-23	Head CT results	13	6.91%
OP-29	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk	109	57.98%
OP-31	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	2	1.06%
OP-32	Rate of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies)	123	65.43%
OP-35-ADM	Rate of inpatient admissions for patients receiving outpatient chemotherapy	23	12.23%
OP-35-ED	Rate of emergency department (ED) visits for patients receiving outpatient chemotherapy	23	12.23%
OP-36	Ratio of unplanned hospital visits after hospital outpatient surgery	57	30.32%
	No OQR Measures Reported	8	4.26%
Hospital OQR measures on Care Compare, January 2021			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported measures	177	
OP-33	External Beam Radiotherapy for Bone Metastases	5	2.82%
Hospital OQR measures on Care Compare, January 2020			

	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures	175	
OP-5	Median Time to ECG	131	74.86%
OP-9	Mammography Follow-up Rates	121	69.14%
OP-11	Thorax CT Use of Contrast Material	118	67.43%
OP-14	Outpatients with brain CT scans who got a sinus CT scan at the same time	66	37.71%
OP-30	Endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps	110	62.86%
Hospital OQR measures on Care Compare, January 2018			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures	174	
OP-4	Aspirin at Arrival	130	74.71%
OP-20	Door to diagnostic evaluation	144	82.76%

Data sources: Hospital Compare data updated in January 2018, January 2020, January 2021, and January 2022, CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022, and QIO Program Resource System (PRS).
Hospitals are considered eligible to report on Hospital Compare when having a Medicare accept date prior to the latest measure end date and are identified as open as of PRS access date.
*Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.
** A hospital is considered reporting for this data presentation if it has a Hospital OQR measure published on Hospital Compare; a hospital may report data to CMS, but not have data published on Hospital Compare due to not meeting case number requirements.

TABLE 101: Critical Access Hospitals Publicly Reported Selected Hospital Outpatient Measures* (Current and those Previously Removed)**

Measure Number	Measure Tile	Number Reporting With Measure Displayed on Hospital Compare	Percent of Reporting CAHs With Measure Results Displayed
Hospital OQR measures on Care Compare, January 2022			
	CAHs with publicly reported measures; total number 1,354 plus 5 new CAHs not yet with data	1,354	
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	5	0.37%
OP-3b	Median Time to Transfer to Another Facility for Acute Coronary Intervention	17	1.26%
OP-8	MRI Lumbar Spine for Low Back Pain	2	0.15%
OP-10	Abdomen CT Use of Contrast Material	838	61.89%
OP-13	Outpatients who got cardiac imaging stress tests before low-risk outpatient surgery	79	5.83%
OP-18b	Average (median) time patients spent in the emergency department before leaving from the visit	1,085	80.13%

OP-18c	Average (median) time patients spent in the emergency department before leaving from the visit- Psychiatric/Mental Health Patients	543	40.10%
OP-22	Left before being seen	775	57.24%
OP-23	Head CT results	51	3.77%
OP-29	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk	207	15.29%
OP-31	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	7	0.52%
OP-32	Rate of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies)	625	46.16%
OP-35-ADM	Rate of inpatient admissions for patients receiving outpatient chemotherapy	84	6.20%
OP-35-ED	Rate of emergency department (ED) visits for patients receiving outpatient chemotherapy	84	6.20%
OP-36	Ratio of unplanned hospital visits after hospital outpatient surgery	94	6.94%
Hospital OQR measures on Care Compare, January 2021			
	CAHs with publicly reported selected measures	1,347	
OP-33	External Beam Radiotherapy for Bone Metastases	6	0.45%
Hospital OQR measures on Care Compare, January 2020			
	CAHs with publicly reported selected measures	1,343	
OP-5	Median Time to ECG	863	64.26%
OP-9	Mammography Follow-up Rates	904	67.31%
OP-11	Thorax CT Use of Contrast Material	818	60.91%
OP-14	Outpatients with brain CT scans who got a sinus CT scan at the same time	615	45.79%
OP-30	Endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps	188	14.00%
Hospital OQR measures on Care Compare, January 2018			
	CAHs with publicly reported measures	1,325	
OP-4	Aspirin at Arrival	612	46.19%
OP-20	Door to diagnostic eval	726	54.79%

Data sources: Hospital Compare data updated in January 2018, January 2020, January 2021, and January 2022, CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022, and QIO Program Resource System (PRS).

Hospitals are considered eligible to report on Hospital Compare when having a Medicare accept date prior to the latest measure end date and are identified as open as of PRS access date.

*Critical Access Hospital (CAH) is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022.

** A hospital is considered reporting for this data presentation if it has a Hospital OQR measure published on Hospital Compare; a hospital may report data to CMS, but not have data published on Hospital Compare due to not meeting case number requirements

c. Burden

We recognize REHs will be smaller hospitals that have limited resources compared with larger hospitals in metropolitan areas.[244] Certain measures, particularly those that are chart-abstracted, may be more burdensome than other measures to report. Rural facilities often experience shortage of non-clinical staff to perform certain administrative duties, such as collecting and reporting quality measures.[245] For the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. We recognize these challenges faced by the hospitals eligible to convert to REH status may increase reporting burden and may necessitate limiting the number of quality measures in use for the REHQR Program to facilitate success. There are several avenues we can consider for limiting this burden (that is, reducing the costs associated with reporting the data required for quality measurement) including: (1) use of Medicare claims-based measures; and (2) use of digital quality measures in place of chart-abstraction. In addition, we believe that, to the extent possible, existing quality measures should align across quality reporting programs, Medicare, Medicaid, and other payers to minimize reporting burden.

The Hospital Promoting Interoperability Program, which includes a requirement to report certain eCQMs, shows that of 1,308 CAHs, 1,066 (81.5 percent) met eCQM reporting requirements for the first quarter of 2022. This indicates a relatively high level of reporting capability for eCQMs by a hospital type that tends to be smaller and more likely to be situated in more rural areas.

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[244] American Hospital Association, *Rural Report 2019*: *Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care* 3 (February 2019), available at https://www.aha.org/system/files/2019-02/rural-report-2019.pdf.
[245] Ibid at 6 & 7.

d. Rural Relevance

The measures included in an REH quality program should reflect the types of services and care delivered most frequently in that setting, along with areas of care where there may be inappropriate variation or potential quality of care challenges.[246] For example, an REH may provide ambulatory and outpatient procedures with supporting diagnostic services such as laboratory tests and x-rays, and be considered a low-volume emergency department (ED). Larger variation between these smaller providers due to lower case volumes could allow some topped out measures that are no longer meaningful for larger or urban hospitals to be utilized for rural hospital quality reporting. More specifically, topped-out measures could be re-purposed for reporting the quality of their rural counterparts, which have not achieved the level of success in these measures as often as a result of low-case volumes. In addition, we believe that it may be appropriate to include some measures that would apply to all REHs, for example, measures that are tailored to ED and observation services, while instituting additional applicable measures for REHs that choose to provide additional outpatient services.

e. Low Service and Patient Volume

Section 1861(kkk)(7)(C)(iii) of the Act specifies that the Secretary shall, in the selection of measures, take into consideration ways to account for rural emergency hospitals that lack sufficient case volume to ensure that the performance rates for such measures are reliable. Effective quality measurement requires a sufficiently large patient number or service volume to account for level of measure variability. This ensures that the quality measure has the necessary reliability of an individual facility's information as well as to detect meaningful distinctions

[246] National Quality Forum, *Measure Application Partnership: A Core Set of Rural Relevant Measures and Measuring and Improving Access to Care, 2018 Recommendations from the MAP Rural Health Workgroup, Final Report* 24 & 26 (August 2018), available at https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.

between facilities. Possible approaches to quality measurement where low volume is expected are discussed in section XVI.B of the CY 2023 OPPS/ASC proposed rule and section XVI.B of this final rule.

f. Health Equity

We believe methods to examine disparities in health care delivery and quality measurement should include stratified results using, for example, patient dual eligibility and other social vulnerability factors, as well as patient demographic information to capture the breadth of social determinants of health in rural areas.[247] Other factors or indicators to consider for equity measurement include access to care, disability and functional status, veteran status, health literacy, language preference, race and ethnicity, tribal membership, sexual orientation and gender identity, and religious minority status. These demographic characteristics and social determinants of health can enable a more comprehensive assessment of health equity to further identify and develop actionable strategies, including the selection of quality measures and quality improvement, to promote health equity.

One approach being considered to measure equity across our programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. The Request for Information (RFI) included in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 19415), titled "Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs" describes key considerations across all CMS quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address health care disparities and advance health equity across our programs.

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[247] Agency for Healthcare Research and Quality, *Chartbook on Rural Healthcare: National Healthcare Quality and Disparities Report* 8 &13-14 (November 2021) available at https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/2019-qdr-rural-chartbook.pdf.

We refer readers to the full summary of the RFI and comments we received in the FY 2023 IPPS/LTCH PPS final rule for details on these considerations (87 FR 48780). We also refer readers to section XVI.B of this final rule with comment period for a summary of comments received in response to the RFI. In this section of the final rule, we discuss comments and feedback on the application of these principles to a quality reporting program for REHs.

We discussed possible measures of equity for use in a REHQR Program in section XVI.B of the CY 2023 OPPS/ASC proposed rule (87 FR 44760).

2. Request for Comment on Potential Measures for an REHQR Program

a. Selected Hospital OQR Program Measures Recommended by the National Advisory Committee on Rural Health and Human Services for the REHQR Program

The National Advisory Committee on Rural Health and Human Services for the REHQR Program's measure recommendations drew from measures that were currently being reported or were recently reported under CMS' Hospital OQR Program or HRSA's MBQIP.[248] In the CY 2023 OPPS/ASC proposed rule (87 FR 44760), we requested comment on a selection of measures from this report as we review measures for potential future inclusion in the REHQR Program. We sought to better understand how these measures may help achieve our goal of selecting measures for the REHQR Program that focus on REH areas of care, especially ED care. Measures with an OP designation represent current or past Hospital OQR measures; measure specifications are contained in program specifications manuals (current and past back to CY 2013) available on the QualityNet website.[249]

(1) OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

[248] https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/2021-rural-emergency-hospital-policy-brief.pdf (Accessed April 8, 2022).
[249] https://qualitynet.cms.gov/outpatient/specifications-manuals (Accessed May 20, 2022).

This chart-abstracted process measure calculates the percentage of ED acute myocardial AMI patients with ST-segment elevation on the electrocardiogram (ECG) closest to arrival time receiving fibrinolytic therapy during the ED stay and having a time from ED arrival to fibrinolysis of 30 minutes or less. The measure is calculated using chart-abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one calendar year. We have publicly reported this measure under the Hospital OQR Program since 2012. In the CY 2022 OPP/ASC final rule (86 FR 63823 and 63824), OP-2 was finalized for removal from the Hospital OQR Program beginning with the CY 2023 reporting period/CY 2025 payment determination, with planned replacement with an electronic clinical quality measure (eCQM) that combines this measure with OP-3 Median Time to Transfer to Another Facility for Acute Coronary Intervention, the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (86 FR 63823 and 63824). The adoption of the STEMI eCQM and the measure calculation method for the Hospital OQR Program was finalized in this same final rule (86 FR 63837 through 63840). The current level of rurally located subsection (d) hospitals with not more than 50 beds (4 total) and CAHs (5 total) with data publicly displayed on Care Compare for this measure is relatively low (see Tables 101 and 102 of this final rule with comment period). However, the MBQIP (which utilizes data reported through the Hospital OQR Program) reported that about 71 percent of CAHs reported at least one case for the OP-2 measure.

(2) OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention

Time to transfer to receiving facilities delays time to reperfusion in patients with ST segment elevation myocardial infarction (STEMI). There are multiple, critical system practices that minimize transfer time to receiving centers; however, two characteristics of the sending facility have been noted as most important: (1) performance of a prehospital electrocardiogram

and (2) having established transfer protocols.[250] The use of time-to-transfer quality measures in rural areas may raise equity concerns as the geographic isolation of many rural facilities and the lack of uniformity in geographic isolation may be outside the control of the facilities measured.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63458), OP-3 was finalized for removal from the Hospital OQR Program beginning with the CY 2023 reporting period/CY 2025 payment determination due to availability of a more broadly applicable measure that captures the OP-2 and OP-3 measure populations and expand beyond these populations to comprehensively measure the timeliness and appropriateness of STEMI care, with planned replacement of these measures by the OP-40 STEMI eCQM. The current level of subsection (d) hospitals and CAHs with data publicly displayed on Care Compare for this chart-abstracted measure is relatively low possibly due to case numbers below the threshold to allow the data to be publicly reported (see Tables 100 and 101 above). However, about 70 percent of CAHs reported at least one case for this measure through the MBQIP program.

(3) OP-4: Aspirin on Arrival

This chart-abstracted process measure documents the percentage of ED acute myocardial infarction (AMI) patients or chest pain patients (with probable cardiac chest pain) without aspirin contraindications who received aspirin within 24 hours before ED arrival or prior to transfer at the facility level. The early use of aspirin in patients with AMI results in a significant reduction in adverse events and subsequent mortality.

OP-4 was implemented into the Hospital OQR program in CY 2008 and removed for the CY 2020 payment determination and subsequent years due to performance being sufficiently high with little variation between providers (82 FR 52570). While being topped out at the

[250] Mumma, BE, Williamson, C, Diercks, DB. Minimizing transfer time to an ST segment elevation myocardial infarction receiving center: Modified Delphi Consensus. Crit Pathw Cardiol 2014, Mar; 13(1):20-24.

national level and no longer useful for larger or urban providers, this measure could be useful for smaller providers, including those that may convert to REH status, due to sufficient variation between individual facilities to permit the measurement of differences. An analysis (see Table 102 below) of the last publicly reported OP-4 data for small rurally located hospitals and CAHs shows such variation between facilities (both urban and rural) with the lower 10th percentile. The analysis found providers with much lower percentages of proper aspirin administration across urban/rural areas for CAHs and subsection (d) hospital types and slightly higher variation as measured by standard deviation, indicating room for improvement. We note that some CAHs, while considered rural for Medicare payment purposes, are situated in areas that can be considered urban. The analysis in Table 102 below was only to examine for variations by urban versus rural setting. This measure was retired and NQF endorsement removed from the Cardiovascular Project in 2013 with subsequent removal from the Hospital OQR Program for the CY 2018 reporting period/CY 2020 payment determination. A similar measure, Emergency Medicine: Aspirin at Arrival for Acute Myocardial Infarction (AMI) was also retired and NQF endorsement removed in 2017 (82 FR 59439).

TABLE 102: Urban, Rural subsection (d) Hospitals with not more than 50 beds and CAHs Reporting* OP-4: Aspirin on Arrival Reporting (Care Compare 2018)**

Hospital Type	Rural/ Urban	N	Mean	Std Dev	Min	10th PCTL	25th PCTL	Median	75th PCTL	90th PCTL	Max
CAH	Rural	463	94.78	6.65	57	86	92	97	100	100	100
CAH	Urban	149	95.17	6.08	65	87	93	98	100	100	100
Subsection (d) hospital	Rural	130	93.98	6.92	63	86.5	92	96	99	100	100
Subsection (d) hospital	Urban	87	94.26	5.81	70	87	91	96	99	100	100

* Hospitals are considered reporting if measure data are published on Care Compare. Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural.
**The January 2018 release of Care Compare contained the final publicly available data for OP-4.

(4) OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients

Care provided in the ED will be a focus of REH services and we seek measures that assess the quality of care in this setting. OP-18 is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED or ED throughput time. Improving ED throughput times is important for alleviating overcrowding and reducing wait times; conditions which can lead to potential safety events and patient dissatisfaction.[251] OP-18 is a current measure for the Hospital OQR Program and reporting for this measure by hospitals eligible to convert to REH status is relatively high (see Table 100 above). Note that the OP-18 measure is calculated for varying types of patients: the OP-18b measure excludes psychiatric/mental health and transferred patients; alternatively, the OP-18c measure includes information only for psychiatric/mental health patients.

(5) OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional

This chart-abstracted, ED measure measures the mean time between patient presentation to the ED and the first moment the patient is seen by a qualified medical person for patient evaluation and management. As REH's main area of care and associated services provided will be related to their ED, and emergency services can be time-sensitive, this measure provides tailored accountability for this setting type. OP-20 was removed from the Hospital OQR Program in the CY 2018 OPPS/ASC final rule beginning with CY 2020 payment determinations (82 FR 52570). During regular measure maintenance, specific concerns were raised by a Technical Expert Panel (TEP) resulting in removal of this measure from the Hospital OQR Program due to measure performance or improvement not resulting in better patient outcome (82 FR 59431)). However, while some commenters agreed with this reasoning, other

[251] https://www.healthcatalyst.com/wp-content/uploads/2021/05/Data-Driven-Operations-Improve-ED-Efficiency.pdf.

commenters, who expressed concern that there are socioeconomic pressures that can vary by community that cause variation in performance on this measure, noted the value of this measure and recommended that a refined version that stratifies by other factors related to measure performance should be adopted, specifically mentioning hospital size which would be more effective in a specific setting (82 FR 59431). When required for the Hospital OQR Program, a significant number of hospitals eligible for REH conversion that had data publicly reported had sufficient case volumes to have publicly reported data for this measure; 70.69 percent (82) of hospitals and 51.93 percent (5) of CAHs that had any measure publicly reported indicating possible usefulness of this measure for REHs.

(6) OP-22: Left Without Being Seen

This structural measure for the ED setting is focused on reflecting staffing expertise and availability. OP-22 measures the percentage of patients who left the ED before being evaluated by a physician, advanced practice nurse (APN), or physician assistant (PA) and uses all-payer, administrative data (not Medicare claims data) to determine the measure's numerator and denominator populations. This measure is in the current Hospital OQR Program measure set with significant numbers of both hospitals and CAHs eligible for REH conversion that have publicly reported data for this measure.

b. Medicare Beneficiary Quality Improvement Project (MBQIP) Measure Recommended by the National Advisory Committee on Rural Health and Human Services for the REHQR Program

The MBQIP is a quality improvement activity under the Medicare Rural Hospital Flexibility (Flex) program. The MBQIP supports more than 1,350 CAHs in 45 states to improve quality of care. Measures included in the MBQIP that are also included in our selection of measures from those by the National Advisory Committee on Rural Health and Human Services

for the REHQR Program (above) are OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention, OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients, and OP-22: Left Without Being Seen.

The Emergency Department Transfer Communications (EDTC) measure is a core measure in the MBQIP program for CAHs and was included in those measures recommended by the National Advisory Committee on Rural Health and Human Services for their use in a REHQR Program. The EDTC measure assesses how well key patient information is communicated from an ED to any health care facility. The measure is applicable to patients with a wide range of medical conditions (that is, acute myocardial infarction (AMI), heart failure, pneumonia, respiratory compromise, and trauma) and is relevant for both internal quality improvement purposes and external reporting to consumers and purchasers.[252] As REHs are expected to focus on triage and transfer, the adequate and timely sharing of information with the receiving site would be an important quality metric.

c. Other Current, Claims-Based Hospital OQR Quality Measures

Measures calculated using administrative data from Medicare claims and enrollment data limit provider burden and provide valuable information regarding Medicare beneficiary service utilization and care provision. The Hospital OQR Program has several established measures of this type that could be applicable to REHs. At this time, we are focused on two current measures that have publicly reported data and that focus on services expected to be provided by hospitals eligible for REH conversion: (1) OP-10 Abdomen Computed Tomography (CT) - Use of

[252] https://www.ruralcenter.org/resource-library/edtc-measure-data-reporting-resources (Accessed May 12 2022).

Contrast Material and (2) OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

(1) OP-10: Abdomen Computed Tomography (CT) - Use of Contrast Material

This diagnostic imaging measure is based fully on Medicare fee-for-service (FFS) claims and enrollment data. It calculates the percentage of CT abdomen studies performed with and without contrast out of all CT abdomen studies performed (those without contrast, those with contrast, and those with both). A CT study performed with and without contrast doubles the radiation dose to patients, exposing them to the potential harmful side effects of the contrast material itself.[253] Davis et al. (2020) showed that while rural facilities account for 32.2 percent of all facilities, they account for 46.0 percent of the outliers for the OP-10 measure. This indicates considerable variation and possible areas for targeted improvement.

(2) OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

This outcome measure is calculated fully using Medicare FFS claims and enrollment data, estimating a facility-level rate of risk standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older. OP-32 captures and makes more visible to providers and patients all unplanned hospital visits following colonoscopy procedures. Under the Hospital OQR program, of the hospitals eligible for REH conversion that had sufficient case volumes to have publicly reported data for this measure, 65.43 percent (123) of hospitals and 46.16 percent (625) of CAHs had any publicly reported data. While the total numbers of hospitals with publicly reported OP-32 data is somewhat low, this could be an important measure for those REHs providing outpatient services and for patients seeking information regarding complications following this procedure. OP-32

[253] Davis M, McKiernan C, Lama, S, Parzynski C, Bruetman C, Venkatesh A. Trends in publicly reported quality measures of hospital imaging efficiency, 2011-2018. AJR: 215, July: 153-158), 2020.

was adopted in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66963) for the CY 2018 payment determination and subsequent years using CY 2016 data for the initial year's measure calculation.

We sought comment on selected Hospital OQR Program measures recommended by the National Advisory Committee on Rural Health and Human Services as well as additional, claims-based measures for potential inclusion in an REHQR Program.

We received public comments on these topics.

Comment: Many commenters supported CMS' stated efforts to implement quality reporting for REHs and the adoption of Hospital OQR Program measures; specifically, highly reported chart-abstracted and NQF-endorsed measures. Some commenters supported the inclusion of MBQIP measures, as most CAHs already have processes in place for performance improvement initiatives based on measure results. Several commenters supported adoption of limited and claims-based measures to reduce financial and administrative burden associated with collecting quality data, with at least one stating concerns regarding the current, ongoing COVID-19 PHE. Similarly, several commenters supported the use of digital measures as a means of reducing provider burden. Some commenters stated strong support for OP-2, OP-3, and OP-4 with multiple commenters expressing the importance of timeliness and appropriateness of STEMI care, further citing persistent disparities in the outcomes for AMI patients treated in rural facilities. A commenter also supported the use of OP-20 in the REHQR Program; however, they requested detailed guidance if adopted due to concerns over the accuracy of EHR time stamps used to capture information. Some commenters supported adoption of OP-22 and OP-18, as well as additional Hospital OQR measures, OP-5 measure (Median Time to ECG) and OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head

CT or MRI Scan Interpretation Within 45 minutes of ED Arrival, as indicators relating to access and timeliness.

Response: We thank the commenters for their support and suggestions. We agree that inclusion of appropriate quality measures in REHs would promote quality, safety, accessibility, and overall improve patient experience and patient outcomes. We will take all the feedback into consideration for future rulemaking.

Comment: Several commenters neither supported nor opposed CMS' measure recommendations, stating concerns around variables and uncertainties surrounding Conditions of Participation, types of services to be provided, and other logistical expectations for REHs.

Response: We thank the commenters for their feedback. We agree that the standards for REHs as a new Medicare provider type had not been finalizedat the time of the CY 2023 OPPS/ASC proposed rule, and they could impact the implementation of appropriate quality measures for REHs. We will take all REH policies such as those finalized in section XVIII of this final rule with comment period into consideration for future rulemaking.

Comment: Many commenters did not support any of the measures outlined I n the proposed rule for inclusion in the REHQR Program, stated that the Hospital OQR measures were inappropriate due to unique challenges associated with REHs; particularly, uncertainties around types of services that will be provided by this new provider type. Several commenters expressed concerns for adopting measures that are not currently active in other quality programs, not NQF endorsed, or which have not been vetted through consensus building body to ensure relevance for the REHs. Multiple commenters urged CMS to develop REH-specific measures, including ones that may not require aggregation over longer timeframes, as timeliness of results could affect the usefulness of the data in ongoing quality improvement efforts.

Some commenters also expressed concerns for adopting measures that are either removed from the Hospital OQR Program, digital, or chart-abstracted, due to high administrative and financial burden. A few commenters specifically opposed the adoption of OP-2, OP-3, and OP-4 as these measures were removed from the Hospital OQR Program and had low public reporting rates. These commenters also raised concerns regarding high administrative burden associated with chart-abstracted measures. Many commenters opposed the adoption of ED-throughput and volume measures such as OP-18, OP-20, OP-22, and OP-32 questioning the clinical relevance, reliability, and usefulness of these measures in REHs.

Some commenters provided their view that there is significant variation in patient cases presenting at any specific REH in contrast with other types of facilities which could affect performance-related metrics. These commenters also expressed concern regarding the impact of factors outside of facility's control, such as transfer transport or receiving facility capacity. A few commenters in referencing OP-10, acknowledged the importance of avoiding potential service overuse of services, but recognized compounding factors for clinical decision-making.

Response: We thank the commenters for their feedback. We acknowledge the variability in the services REHs could provide and will continue to assess the relevancy of specific quality measures as the number of hospitals that convert to REH status and the types of services provided evolves. We will take the commenters' feedback into consideration for future rulemaking.

Comment: Some commenters urged CMS to focus the REHQR Program on incentives over penalties, with several commenters encouraging the program to be a pay-for-reporting program, at least in the beginning. Other comments suggested at least a one-year reporting delay to give facilities time to transition (that is, develop and become comfortable with their data

collection mechanisms), and implement a potentially phased or slow approach to adding measures. One commenter suggested making the entire program voluntary to reduce burden, while another insisted on it being mandatory to ascertain quality outcomes. Several commenters urged CMS to contextually develop REH-specific measures, including ones that may not require extended performance periods, as timeliness of results could affect the usefulness of the data in ongoing quality improvement efforts. Many commenters also urged CMS to provide support, such as technical assistance and flexibilities, to implement quality measurement in this new setting.

In addition, multiple commenters sought clarification on the intent of the REHQR Program, given the uniqueness of its existence that's more related to providing access to care than aiding patients in determining best places for care.

Response: We thank the commenters for their input related to ensuring successful program outcomes. We will take all suggestions into consideration for future rulemaking.

d. Comments on Additional Measurement Topics and for Suggested Measures for REH Quality Reporting

Our request for information in the CY 2022 OPPS/ASC proposed rule (86 FR 42285 through 42289) yielded suggested additional topics for quality measures appropriate to the REH setting. We requested comment on the below additional topics and requested suggestions for specific measures to assess the patient experience, outcome, and processes related to these topics. In addition, we requested comment on other potential topics not listed that would be applicable to an REH quality reporting program.

(1) Telehealth

REHs can utilize telehealth and other remote service capacities in serving rural communities in their vicinity. Under the COVID-19 PHE, temporary measures to facilitate the provision and receipt of care through telehealth were federally implemented.[254] Additionally, section 301 of Division P of the Consolidated Appropriations Act (CAA), 2022 extended certain telehealth flexibilities for Medicare patients for 151 days after the official end of the federal public health emergency (PHE).[255] The PHE was most recently extended on October 13, 2022 to January 11, 2023.[256] Section 301 of the CAA, 2022 permits certain Medicare beneficiaries to receive telehealth services from their home. This and other flexibilities will facilitate the use of telehealth for 151 days after the expiration of the PHE in rural areas.[257]

In addition, rural emergency telehealth services present unique opportunities for access to quality care in these often time-sensitive and geographically isolated cases. For instance, utilizing provider-to-provider telehealth or telemedicine support, such as in the case of e-consultation or tele-emergency care services, in a rural ED could allow for critical specialist knowledge transfer and reduce patient transfers and wait times.[258] This is particularly impactful in the face of rural facility or departmental closures which can leave gaps in healthcare service access and could contribute or lead to emergency service requirements, such as in the case of obstetric challenges.[259]

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[254] http://telehealth.hhs.gov (Accessed April 8, 2022).
[255] Pub. L. 117-103.
[256] https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx (Accessed Oct. 14, 2022).
[257] https://www.foley.com/en/insights/publications/2022/03/congress-extends-telehealth-flexibilities-7-things (Accessed April 13, 2022).
[258] https://telehealth.hhs.gov/providers/telehealth-for-emergency-departments/ (Accessed May 31, 2022).
[259] Centers for Medicare & Medicaid Services (CMS), *Advancing Rural Maternity Health Equity*, 10 (May 2022), available at https://www.cms.gov/files/document/maternal-health-may-2022.pdf.

(2) Maternal Health

Nearly half of rural U.S. counties lack hospitals with basic capacity to provide emergency obstetric services. In New Mexico, for example, one-third of deaths during pregnancy and in the first year postpartum are from car accidents with increasing maternal mortality and morbidities in rural areas of the state.[260] Similarly, the Illinois Morbidity and Mortality Report identified 175 pregnancy-associated deaths that occurred during 2016-2017 and revealed that the number of pregnancy-associated deaths per 100,000 live births was higher in rural counties.[261] This report identified the greatest (33 percent) underlying cause of pregnancy-associated death in rural counties was attributed to "other injuries," most of which were the result of motor vehicle crashes, as opposed to 'all medical' (31 percent), drug overdose (21 percent), suicide (10 percent), or homicide (5 percent).[262] This was in contrast with the 4 to 10 percent of this category's attribution in the non-rural areas.[263]

REHs could provide valuable emergency care and other outpatient services for preserving and improving maternal health in rural areas, such as providing outpatient OB services in "OB deserts."[264] REHs could also leverage remote patient monitoring. This could include implementing telehealth systems to ensure engagement and timely notification and care among high-risk patients, while also reducing barriers to care, like distance and travel.[265] In addition,

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[260] The Commonwealth Fund. Restoring Access to Maternity Care in Rural America. September 30, 2021. https://www.commonwealthfund.org/publications/2021/sep/restoring-access-maternity-care-rural-america (Accessed April 8, 2022).
[261] Illinois Department of Public Health, *Illinois Maternal Morbidity and Mortality Report, 2016-2017* 25 (April 2021), available at https://dph.illinois.gov/content/dam/soi/en/web/idph/files/maternalmorbiditymortalityreport0421.pdf.
[262] Ibid. at 28.
[263] Ibid. at 28.
[264] https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/bridging-the-gaps-with-telehealth/ (Accessed May 31, 2022).
[265] https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/telehealth-and-high-risk-pregnancy/ (Accessed May 31, 2022).

REHs could possibly fill gaps in the maternity care continuum, or play a critical role in a patient's emergency plan by being identified as their closest medical facility equipped to handle a maternal health emergency.[266]

(3) Behavioral Health

Rural populations are disproportionately affected by mental health concerns including substance use disorders (SUD).[267,268] For example, suicide rates and drug overdose related deaths are especially on the rise among the rural population.[269,270] Roughly 6.5 million individuals, or about one-fifth of the rural population, had a mental illness in 2019.[271] While rates of mental illness and substance use disorder between rural and urban areas are comparable, serious mental illness (SMI) was found to be 1.7 percent greater for rural adults 18 and older than their urban counterparts.[272] Contributing to this problem is the presence of contextual and cultural factors, such as stigma, isolation, and poverty, and the lack of access to trained and specialized mental health providers, with over 60 percent of rural Americans living within a designated shortage area.[273] There are also higher reported rates of prescription opioid misuse among rural residents,

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[266] https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/preparing-patients-and-providers/ (Accessed May 31, 2022).
[267] White B.G. (2015 January 28). Rural America's Silent Housing Crisis. The Atlantic. Retrieved from: https://www.theatlantic.com/business/archive/2015/01/rural-americas-silent-housing-crisis/384885.
[268] Shawnda S. (2017 November). Rural Behavioral Health. Rural Health Research RECAP. Retrieved from: https://www.ruralhealthresearch.org/assets/658-1990/rural-behavioral-health-recap.pdf.
[269] Centers for Disease Control and Prevention. (2018 February 28). Drug Overdose in Rural America. Retrieved from: https://www.cdc.gov/ruralhealth/drug-overdose/index.html.
[270] Centers for Disease Control and Prevention. (2018 March 22). Suicide Policy Brief: Preventing Suicide in Rural America. Retrieved from: https://www.cdc.gov/ruralhealth/suicide/policybrief.html.
[271] Morales, D. A., Barksdale, C. L., & Beckel-Mitchener, A. C. (2020). A call to action to address rural mental health disparities. *Journal of clinical and translational science*, 4(5), 463–467. https://doi.org/10.1017/cts.2020.42
[272] Neylon, K.A. (2020). Strategies for the Delivery of Behavioral Health Crisis Services in Rural and Frontier Areas of the U.S. Alexandria, VA: National Association of State Mental Health Program Directors.
[273] Morales, D. A., Barksdale, C. L., & Beckel-Mitchener, A. C. (2020). A call to action to address rural mental health disparities. *Journal of clinical and translational science*, *4*(5), 463–467. https://doi.org/10.1017/cts.2020.42

but reduced availability of outpatient substance use treatment services, with nearly four times greater likelihood of availability in urban areas than in rural areas.[274]

These high rates of mental health and substance use issues, compounded by lack of access to treatment, underscores the need for an array of behavioral health crisis services in rural areas. REHs could fill this need by providing valuable emergency care and other outpatient services for patients experiencing mental health and substance use crises, and possibly bridging the gaps in the continuum of care. For example, REHs could use telehealth services to reduce care delays,[275] or offer teletherapies which can reduce stigma and privacy concerns.[276]

(4) ED Services

Emergency departments (ED) and the services provided in this setting are expected to be a focus of REHs. OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients, OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP-22: Left Without Being Seen, for example, all measure important aspects of ED care.

ED utilization is another important aspect of ED care and quality measures for Medicare Advantage plans as well as for Medicaid beneficiaries point to this. The Emergency Department Utilization (EDU) Health Effectiveness Data and Information Set (HEDIS) measure assesses ED utilization among Medicare Advantage (18 and older) beneficiaries through an observed-to-expected ratio.[277] For this measure, Medicare Advantage plans report observed rates of ED use

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[274] In Brief: Rural Behavioral Health: Telehealth Challenges and Opportunities, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Nov. 2016) https://store.samhsa.gov/product/In-Brief-Rural-BehavioralHealth-Telehealth-Challenges-and-Opportunities/SMA16-4989

[275] https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/tele-treatment-for-substance-use-disorders/ (Accessed May 31, 2022).

[276] https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/individual-teletherapy/ (Accessed May 31, 2022).

[277] All-Cause Emergency Department (ED) Utilization for Medicaid Beneficiaries Public Comment Framing Document. https://cmit.cms.gov/cmit/#/MeasureView?variantId=4867&sectionNumber=1 (Accessed April 8, 2022).

and a predicted rate of ED use based on the health of their member population and factors.[278] Similarly, we recently sought stakeholder comments on a Medicaid measure under development, the All-Cause ED Utilization for Medicaid Beneficiaries measure.[279] This measure is defined as the number of all-cause ED visits per 1,000 beneficiary months among Medicaid beneficiaries aged 18 years and older with at least 10 months of enrollment.

A patient who returns for an unscheduled visit to the emergency department (ED) shortly after initial discharge from the (that is, within 2-30 days) is called a "bounce-back".[280] ED bounce-backs are associated with ED facility and ED patient metrics, including quality of care, patient insurance status, patient age, ED overcrowding and patient satisfaction, or an unscheduled return visit. Measures for ED utilization, boarding, and unscheduled ED return visits (bounce-backs) could be useful quality metrics for the REH setting.

(5) Equity

Rural populations, among others, face historic and current disproportionate health impacts that have resulted in the higher prevalence, increased risk, and greater barriers to care for medical conditions.[281] The Hospital Commitment to Health Equity measure,[282] which was finalized in the FY 2023 IPPS rule for the Hospital Inpatient Quality Reporting program (87 FR 48780), has five attestation-based questions that each represent a domain of commitment

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[278] We note that we would not be seeking to propose measures that have been developed for Medicare Advantage plans or for Medicaid beneficiaries as developed for an REHQR Program; we intend only to illustrate that ED utilization is considered an important area for quality measurement.

[279] https://www.cms.gov/files/document/all-cause-ed-utilization-medicaid-beneficiaries-measure-framing-document.pdf (Accessed April 7, 2022).

[280] Curcio J, Little A, Bolyard C, et al. (September 17, 2020) Emergency Department "Bounce-Back" Rates as a Function of Emergency Medicine Training Year. Cureus 12(9): e10503. https://doi.org/10.7759/cureus.10503

[281] https://www.cdc.gov/ruralhealth/about.html (Accessed June 2, 2022).

[282] Centers for Medicare and Medicaid Services (CMS), *Summary of Technical Expert Panel (TEP) Meeting # 1, November 16, 2021: Health Equity Quality Measurement, Hospital Commitment to Health Equity Measure, 2016-2017* (February 2022), available at https://www.cms.gov/files/document/health-equity-quality-measurement-tep-1-summary-report-hospital-commitment-health-equity.pdf.

to health equity: strategic planning, data collection, data analysis, quality improvement, and leadership engagement. Additionally, a potential future measure for health equity could be an attestation-based structural measure of a disparities impact statement (DIS) or organizational pledge that outlines how infrastructure supports the delivery of care that is equitable for all patient populations could provide important information regarding organizational commitment to health equity.

We sought public comment on the above additional measurement topics for potential future quality measures and on the ways to bridge various gaps to render equitable, quality of care in rural and rural emergency settings.

We received public comments on these topics.

Comment: Many commenters provided support and suggestions to collect quality data for a wide range of topics to assess quality of care provided in REHs. Multiple commenters supported collecting quality measure data for telehealth, mental health, substance use disorders, emergency department services, maternal health, patient safety, nutrition, and health equity.

Several commenters emphasized the appropriateness and importance of triage and transfer along with patient experience in the EDs, further recommending the MBQIP measure for Emergency Department Transfer Communication (EDTC) and the adoption of Emergency Department Consumer Assessment of Healthcare Providers and Systems (ED CAHPS) survey in REHs. Some commenters suggested focusing quality measures on emergency services, such as time-sensitive conditions, as the main and consistent care between facilities of this setting, and unscheduled ED return visits. Several commenters encouraged CMS to adopt measures from other programs across the agency in an effort to align and reduce burden. A couple of commenters also recommended National Quality Forum's (NQF) Rural Health Advisory Group

2022 Key Rural Measures, noting relevance to rural setting and resiliency to low volume challenges. Several commenters supported inclusion of quality measures specific to telehealth services to ensure access to specialty care such as behavioral health and maternal health and provide quality of care that is comparable to in-person services in rural setting. Some commenters supported the inclusion of telehealth measures as a means of increasing access to medical expertise and maternal, mental, and behavioral health services. One commenter recommended measures reported in the NQF's Rural Telehealth and Healthcare System Readiness Measurement Framework.

Multiple commenters recommended screening measures for conditions such as depression, substance use disorders, and malnutrition, as well as, structural measures for maternal health and health equity to further align with other quality programs. Many commenters agreed that health equity is an important aspect of healthcare and should be incorporated into the REHQR Program. Several commenters supported measure stratification by income, race, age, ethnicity, and dual-eligibility to increase accountability and advance equitable care in rural setting. Some commenters suggested adjustments to health equity measure stratification, including to address risk and regional variations in community resources, as well as making the reporting of health equity measures voluntary to keep burden low.

One commenter sought to clarify the definition of "ED bounce back".

Response: We thank commenter' for their input on various topics for future quality measures for REHs. We appreciate the considered feedback provided on assessing quality of care provided in the rural setting. We clarify that "ED bounce backs" can be defined as a patient who returns for an unscheduled visit to the ED shortly after initial discharge (that is, within 2-30

days); however, the study cited relied on a shorter timeframe.[283,284] We will take the commenters' feedback into consideration for future rulemaking.

Comment: Some commenters expressed concerns regarding the capabilities of REHs to capture technology-based data, including telehealth and digital measures, given constrained resources. Multiple commenters recognized the capacity for digital measures to improve accuracy and decrease burden, and even encouraged the conversion or use of digital measures in the REHQR Program. Other commenters pointed out potential concerns, such as the financial investment and staff expertise required to successfully report digital measures, particularly as it related to EHR capabilities, which low-resourced facilities may not have.

Several commenters suggested delaying reporting requirements on Social Determinants of Health or Social Drivers of Health (SDOH) to afford REHs sufficient time to develop processes to complete and document screenings. One commenter also sought clarification on how a health equity commitment measure would differentiate between hospitals and utilize stratified measure results to improve care. Similarly, some commenters expressed concerns regarding issues related to data collection, such as resource limitations, lack of standardization, and low case volumes potentially risking patient privacy. Another commenter noted the issue with "bounce-back" measurement, given the uniqueness of care-seeking in an REH that may lead patients to present for routine, follow-up, or new condition needs which could skew performance-based metrics.

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[283] Gabayan, G, et. Al (January 17, 2013) Factors Associated With Short-Term Bounce-Back Admissions After Emergency Department Discharge. Annals of Emergency Medicine, 62(2): 136-144. https://doi.org/10.1016/j.annemergmed.2013.01.017.https://doi.org/10.1016/j.annemergmed.2013.01.017

[284] Hsia, Renee, et. Al (November 2013). Is Emergency Department Crowding Associated With Increased "Bounceback" Admissions? Medical Care, 51(11): 1008-1014. doi: 10.1097/MLR.0b013e3182a98310

Response: We thank the commenters for their input as we continue to evaluate appropriate measures for the REHQR Program. We will take the commenters' feedback into consideration via future rulemaking.

e. Addressing Concerns Regarding Small Case Numbers

In the CY 2023 OPPS/ASC proposed rule (87 FR 44759), we noted that there are significant methodological challenges with measurement in rural and low-volume settings. Measure reliability and validity often hinge on having a sufficient volume of cases to ensure the reported rates are reliable. Determining appropriate approaches to addressing low-volume measurement issues will be imperative for public reporting of REH data given expected low volume of these facilities as evidenced by the numbers of rurally located subsection (d) hospitals with not more than 50 beds and CAHs with sufficient case numbers to have data publicly available on Care Compare. The NQF most recently provided expert panel recommendations for addressing the low volume challenge for performance measurement of rural providers in 2019.[285] The panel recommended, to the extent possible, to "borrow strength" (that is, to aggregate measured data over longer timeframes to ensure sufficient data collection for analysis) and leverage expertise and statistical methodology suited to this type of collection. These approaches have been used to model the number of facilities that could achieve sufficient measure volume to produce reliable quality measures based on Medicare Fee-For-Service (FFS) claims.

Another panel recommendation was to report exceedance probabilities as an alternate to reporting absolute performance values. An exceedance probability is the probability that a

[285] National Quality Forum, *Addressing Low Case-Volume in Healthcare Performance Measurement of Rural Providers: Recommendations from the MAP Rural Health Technical Expert Panel, Final Report* 3 (March 2019) available at https://www.qualityforum.org/Publications/2019/04/MAP_2019_Recommendations_from_the_Rural_Health_Technical_Expert_Panel_Final_Report.aspx.

certain value will be exceeded in a predefined future time period; it is often used for predicting the probability of an event. This approach would better reflect the uncertainty of observed quality measure results.[286] For example, an exceedance probability statement might be: "We can be 84 percent sure that hospital A is performing above the mean on this particular measure."

We requested comment on these recommendations for addressing the low volume issues for performance measurement of rural providers.

The comments and our responses are set forth below.

Comment: Most commenters supported the acknowledgment of low-case volumes when considering measures for the REHQR Program. Several commenters recommended reliance on NQF processes and reports, such as rurally-recommended measures and the "borrowing strength" methodology to adequately address low volume issues. However, some commenters raised concerns regarding the reliability and validity of measures calculated with low volumes, which could lead to misinterpretation of data, if publicly reported. One of these commenters, additionally, noted how low case volumes potentially risk patient privacy. Many of these commenters suggested either aggregating measure data over longer periods of time to ensure adequate data collection, applying appropriate statistical methodology, or removing minimum case thresholds to allow REHs to report all data and publicly report data, annotating low case volume appropriately via footnotes.

Response: We thank commenters for their input on this topic. We acknowledge the critical but complicated nature of addressing low case volumes in the REHQR Program to ensure viable and useful data. We are cognizant of the influence case volumes could have on measure

[286] Shwartz M, Peköz EA, Burgess JF Jr, Christiansen CL, Rosen AK, Berlowitz D. A probability metric for identifying high-performing facilities: An application for pay-for performance programs. Med Care. 2014 Dec; 52(2):1030-1036.

selection for reliability and usefulness for public reporting. We will continue to assess options to ensure the integrity of the program and its measures as we develop it.

C. Quality Reporting Requirements Under the REH Quality Reporting (REHQR) Program

1. Administrative Requirements

Section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023, (or each year beginning on or after the date that is 1 year after one or more measures are first specified under subparagraph (C)), a rural emergency hospital shall submit data to the Secretary in accordance with clause (ii). Clause (ii) states that, with respect to each such year, a rural emergency hospital shall submit to the Secretary data in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph. In section XVI.C of the CY 2023 OPPS/ASC proposed rule, we proposed foundational administrative requirements for REHs participating in the REHQR Program (87 FR 44765).

2. Requirements for Registration on QualityNet and Security Official (SO)

We currently use the CMS QualityNet Secure Portal (referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool. To submit quality measure data to CMS using the HQR system, a hospital must establish a secure account through the QualityNet website and designate a Security Official (SO). For more information regarding the HQR system, we refer readers to CY 2022 OPPS/ASC final rule with comment period (85 FR 86179), as well as https://qualitynet.cms.gov. An SO must establish user account(s) for the purpose of submitting quality measure data to the HQR system, as well as for authorized users to review and correct data submissions and preview measure information prior to public reporting. The term SO refers to the individual(s) who have responsibilities for security and account management requirements for a facility (85 FR 86182).

Hospitals that currently report quality measure data under CMS quality programs including, but not limited to, the Hospital IQR and Hospital OQR Programs have existing QualityNet accounts. For the CY 2022 payment determination under the Hospital OQR Program, 3,268 hospitals met all reporting requirements including data submission, whereas, only 30 hospitals did not meet all requirements.[287] In addition, of 1,354 CAHs, 1,291 reported data through the Hospital OQR Program. Thus, the vast majority of all subsection (d) hospitals and CAHs have an account for reporting data via the HQR system. The QualityNet and SO registration process should therefore be familiar to many hospitals that convert to being an REH. In the CY 2023 OPPS/ASC proposed rule (87 FR 44765), we proposed that for an REH to participate in the REHQR Program, they must: (1) have an account for the purpose of submitting data to the HQR system. If an REH already has an account for a CMS hospital quality reporting program, the REH can fulfill this requirement by updating its existing account with its new REH CMS Certification Number (CCN). If the REH does not have an account, we proposed that it must register a new account. Once an REH has an account, it must then (2) have an SO. Since hospitals in the REHQR Program will have new REH CCNs, these hospitals would have to request SO access for the new CCN following the standard instructions posted on the QualityNet website.

From our experience, an SO typically fulfills a variety of responsibilities related to quality reporting such as creating, approving, editing, and terminating user accounts within an organization, and monitoring account usage to maintain proper security and confidentiality protocols. While an SO is initially required to enable a hospital's QualityNet account for data submission and allows the set-up of basic user accounts with capabilities including data

[287] https://qualitynet.cms.gov/outpatient/oqr/apu.

submission, it will not be necessary or required to maintain an SO. We highly recommend that hospitals have and maintain a Security Official; though after initial set-up, we reiterate, an SO will not be required.

We invited public comment on this proposal.

We did not receive comments on the proposal. For the reasons stated above and in the proposed rule (87 FR 44765), we are finalizing this proposal without modification. We note that we intend to propose additional administrative requirements for the REHQR Program in subsequent rulemaking.

XVII. Organ Acquisition Payment Policy

A. Background of Organ Acquisition Payment Policies

The Medicare Program supports organ transplantation by providing an equitable[288] means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately[289] reimburses transplant hospitals[290] (THs) for their organ acquisition costs under reasonable cost principles[291] under section 1861(v) of the Act, based on the TH's ratio of Medicare usable organs to total usable organs. Medicare authorizes payment to designated independent organ procurement organizations (IOPOs) for kidney acquisition costs, under reasonable cost principles[292] in accordance with section 1861(v) of the Act, based on the

[288] In this context "equitable" means fair and equal to all parties. Medicare recognizes that organ acquisition costs can vary among patients due to different levels of acuity, clinical factors and genetic make-up. Some patients may require different or additional testing and care during the organ acquisition process. Payment under reasonable cost principles accounts for these differences and ensures that providers are paid appropriately for their share of organ acquisition costs.
[289] 42 CFR 412.2(e)(4) and 412.113(d).
[290] Under 42 CFR 482.70, a transplant hospital is a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.
[291] See 42 CFR 412.113(d); HCFA Ruling 87–1 (April 1987); CMS Ruling 1543–R (December 2006).
[292] Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.420(a).

IOPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act). In accordance with 42 CFR 413.24(f), Medicare requires THs and IOPOs to complete a Medicare cost report[293] on an annual basis.

In the FY 2022 Inpatient Prospective Payment System (IPPS)/Long Term Care Hospital (LTCH) PPS proposed rule (86 FR 25070), which appeared in the **Federal Register** on May 10, 2021, we explained the background and history of Medicare's organ acquisition payment policy and proposed to change, clarify, and codify Medicare organ acquisition payment policies relative to OPOs,[294] THs, and donor community hospitals. We proposed to change the manner in which an organ is counted as a Medicare usable organ for purposes of calculating Medicare's share of organ acquisition costs by counting only organs transplanted into Medicare beneficiaries. We also proposed to codify that Medicare does not share in the costs to procure organs used for research, except where explicitly required by law. In addition, we proposed to require donor community (not transplant) hospitals to bill OPOs their customary charges reduced to costs for services provided to deceased organ donors.

In the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73416), which appeared in the **Federal Register** on December 27, 2021, we responded to public comments on the proposed rule, and finalized certain proposals to codify longstanding Medicare organ acquisition payment policies, with some modifications, in new subpart L of part 413. We finalized proposals at § 413.418, with modifications, to require both donor community hospitals and transplant hospitals to bill OPOs for hospital services provided to deceased donors, the lesser of their customary charges that are reduced to cost by applying their most recently available

[293] THs complete the hospital cost report on the CMS 2552-10 (OMB No. 0938-0050) and IOPOs complete their cost report on the CMS-216-94 (OMB No. 0938-0102).
[294] We refer to organ procurement organizations generally as "OPOs" throughout, unless differentiation of IOPO is required for cost reporting purposes for OPOs that file a cost report on the CMS-216-94 (OMB No. 0938-0102).

hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate. We also finalized our proposal to move existing organ acquisition payment regulations, and portions of existing kidney acquisition regulations, within title 42 CFR part 412, subpart G, and part 413, subpart H, to a new subpart L in part 413, so that all organ acquisition payment policies would be housed together.

We did not finalize our proposal to count as Medicare usable organs only organs transplanted into Medicare beneficiaries. We also did not finalize certain provisions of the proposed policy with respect to counting organs procured for research for purposes of calculating Medicare's share of organ acquisition costs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that due to the nature of the public comments received, we would address the organ counting policy in subsequent rulemaking, as appropriate.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44765), we proposed additional revisions, clarifications and codifications pertaining to Medicare's organ acquisition payment policies. In section XVII.B of the CY 2023 OPPS/ASC proposed rule (87 FR 44766), we proposed changes to how organs procured for research are counted for THs and OPOs for purposes of calculating Medicare's share of organ acquisition costs. In section XVII.C of the CY 2023 OPPS/ASC proposed rule (87 FR 44767), we proposed that organ acquisition costs include certain hospital services provided to a deceased donor or a donor whose death is imminent. In section XVII.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44768), we proposed technical corrections to certain regulations. In section XVII.E of the CY 2023 OPPS/ASC proposed rule (87 FR 44768), we proposed to clarify the appropriate allocation of administrative and general costs for THs. Additionally, in section XVII.F of the CY 2023 OPPS/ASC proposed rule (87 FR 44769), we solicited comments on an alternative methodology

for counting organs used in the calculation of Medicare's share of organ acquisition costs; allowing IOPOs to create a standard acquisition charge (SAC) for kidneys; and Medicare's reconciliation of non-renal organs for IOPOs.

B. Counting Research Organs to Calculate Medicare's Share of Organ Acquisition Costs

In the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73470), we clarified that for Medicare payment purposes, Medicare does not include in Medicare's share of organ acquisition costs the costs to procure an organ for research, except where explicitly required by law. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provided Medicare coverage of pancreata for islet cell transplant for beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. An exception for Medicare cost sharing purposes for pancreata for islet cell transplant for these trials is under § 413.406(a). Under 42 CFR §§ 413.5(c)(2) and 413.90(a), costs incurred for research purposes, over and above usual patient care, are not includable as Medicare allowable costs.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25668), we clarified that a "research organ" is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of certain pancreata). We proposed to codify that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except certain pancreata procured for islet cell transplants). We also proposed that OPOs and THs do not count organs intended to be used for research prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs but count as total usable organs. Finally, we proposed that OPOs and THs do not count organs intended for transplant prior to the time the donor entered the hospital's

operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we finalized our proposal to require that organs used for research be excluded from Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)), and kidneys used for research be excluded from Medicare usable kidneys in Medicare's share of kidney acquisition costs under § 413.412(c). However, due to the number and nature of the comments received, we did not finalize our proposal that would have required OPOs and THs to include organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs in the count of total usable organs or our proposal to exclude organs intended for transplant but subsequently determined to be unusable and donated to research from Medicare usable organs or total usable organs. We indicated that we may address these issues in future rulemaking.

Commenters on these proposals overall expressed concern that our proposals would negatively impact the affordability and availability of research organs and hinder the advancement of clinical research (86 FR 73494). Some commenters suggested that including research organs in the count of total usable organs reflected a change in policy for IOPOs that would require assignment of a full SAC (including administrative, general, and overhead costs) to each research organ they procured and would also result in significantly higher acquisition costs that would be borne by the research community. One commenter suggested that our proposal to exclude organs donated for research from the count of Medicare and total usable organs would result in procurement costs being passed on to researchers, which could discourage the use of human organs in research studies. A few commenters reported that IOPOs charge

researchers an agreed-upon fee for furnishing an organ for use in research. They asserted that if our proposal to include organs in the count of total usable organs were finalized, IOPOs would need to charge significantly higher amounts for furnishing research organs to the research community. A few commenters noted that procuring an organ for use in research may involve less extensive testing and evaluation than is necessary when procuring an organ for transplantation. We believe that most THs and OPOs currently charge the research community agreed-upon prices to procure research organs instead of charging a SAC. We have heard from some interested parties in the transplant community that THs and OPOs use agreed-upon pricing because the SAC may include procurement services that are unnecessary to procure research organs.

In the time since we issued the FY 2022 IPPS/LTCH PPS final rule with comment period, we have continued to review the potential impacts of our research organ proposal on interested parties. We agree with the comments on the FY 2022 IPPS/LTCH PPS proposed rule that suggested that including research organs in the count of total usable organs would require the assignment of a full SAC on the Medicare cost report for each research organ procured. We understand that this practice may increase the amount the research community pays for obtaining organs for research. We also recognize that procurement costs may differ for research organs and transplanted organs because organs procured for research may be subject to less extensive testing and evaluation than organs that are to be transplanted. We believe that when THs and OPOs furnish organs for research, they should charge amounts that more accurately reflect the testing and evaluation associated with procuring organs intended for research.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44767), we proposed to require that THs and OPOs exclude organs used for research from the denominator (total usable organs) in

the ratio used to determine Medicare's share of organ acquisition costs on the Medicare cost report. Research organs include any organ (with the exception of certain pancreata as set forth in § 413.406(a)) used for research, regardless of whether the organ was intended for research or intended for transplant under § 413.412(a) but subsequently determined unsuitable for transplant and instead furnished for research. When a research organ is included as a total usable organ, this results in assignment of a full SAC to each research organ. Our proposal would exclude research organs from being included in the count of total usable organs, and as a result would not assign a full SAC on the Medicare cost report for each research organ procured. We would not expect this proposal to increase the amounts charged for research organs. However, when an organ identified as a research organ is transplanted into a patient, the organ is counted as a total usable organ and a full SAC is assigned.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44767) we stated that THs and OPOs are responsible for negotiating the amount charged for an organ used for research with the research entity receiving the research organ. We also proposed that THs and OPOs would be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs. This process would ensure that research organ procurement costs are not allocated across all transplantable organs and, consequently, that Medicare is not paying for non-allowable research activities. Additionally, this practice would ensure that Medicare does not pay for non-allowable research costs in instances where the TH or OPO charges a fee that does not cover the cost it incurred to procure the organ for research.

The availability of organs for research is important for continued innovation in transplant medicine and for the discovery of new treatments for diseases. In order to ensure the research community has access to organs for research and to lower the procurement costs associated with

such organs, we proposed to revise the policy set forth in § 413.412(c) for OPOs and THs for counting organs used for research. Specifically, we proposed to revise § 413.412(c) as follows: first, by redesignating paragraph (c) (after the subparagraph heading) as paragraph (c)(1); second, by revising redesignated paragraph (c)(1) to specify that for Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)); and, third, by striking the language that specifies that kidneys used for research are not counted as Medicare usable kidneys or as total usable kidneys in Medicare's share of kidney acquisition costs (we believe this language is duplicative because the reference to "organs" includes kidneys). We also proposed to amend § 413.412(c) by adding paragraph (c)(2) which would require that OPOs and THs must reduce their costs to procure organs for research from total organ acquisition costs on the Medicare cost report.

Regarding the counting of unusable organs as described in § 413.412(d), we proposed to remove the specification that the determination that an organ is unusable is made by the *excising* surgeon; our proposed amendment would allow this determination to be made by any surgeon. As revised, paragraph (d) – which we proposed to redesignate as paragraph (d)(1) – would provide that an organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable. In addition, we proposed to clarify in § 413.412(d) that Medicare shares in the costs to procure unusable organs through the application of the Medicare ratio and to clarify how OPOs and THs must report these organs on

their Medicare cost reports to ensure that Medicare shares in the costs to procure these organs. Specifically, we proposed to add new paragraph (d)(2), which would specify that OPOs and THs include the costs to procure unusable organs, as described in § 413.412(d)(1), in total organ acquisition costs reported on their Medicare cost reports.

Comment: The majority of commenters were not supportive of our proposal for research organs and requested that we withdraw it. Many commenters mistakenly believed that under our proposal, Medicare would no longer share in the acquisition costs for organs that are initially intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research. A few commenters noted that organs that are intended for transplant undergo more extensive testing and evaluation that results in more acquisition costs being assigned to these organs, as opposed to organs that are intended for research that do not undergo extensive testing and evaluations. Because commenters mistakenly believed that under our proposal Medicare would no longer share in the acquisition costs for research organs that were initially intended for transplant, they also mistakenly believed that these costs would be passed on to researchers, resulting in research organs becoming prohibitively expensive for research organizations. Commenters who believed that our proposal would result in Medicare no longer sharing in the acquisition costs for research organs that were initially intended for transplant asserted that research organizations generally operate on a limited budget and expressed concerns that our proposal could potentially disrupt innovation in research. Many commenters who were not supportive of our proposal also noted that the acquisition costs attributable to organs furnished for research are nominal because the acquisition costs are for limited services such as packaging, preservation solution or courier fees. The commenters indicated that

unusable organs are often furnished to research organizations at no charge or at amounts that reflect only the nominal acquisition costs.

Additionally, commenters expressed concern that our proposal would create an incentive for THs and OPOs to discard organs that were intended for transplant but subsequently determined unsuitable for transplant, rather than furnish those organs for research, because THs and OPOs would suffer a financial loss. A few commenters also believed that our proposal would create an incentive for THs and OPOs to discard organs that might otherwise be used for research because our proposal would allow the acquisition costs of discarded organs to be included in the administrative and general cost center while the acquisition costs of research organs would not be included in the administrative and general cost center. Several commenters believed the perceived disincentive to recover an organ that is unsuitable for transplant so that the organ can instead be used in research could result in donated organs being discarded, and that this might not honor the wishes of the organ donor or the donor's family.

Response: We appreciate the comments received on our research organ proposal for purposes of determining Medicare's share of organ acquisition costs. In the FY 2022 IPPS/LTCH final rule, we added new § 413.412(c) to specify Medicare's longstanding policy that for Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs in the ratio used to determine Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)), and kidneys used for research are not counted as Medicare usable kidneys in the ratio used to determine Medicare's share of kidney acquisition costs. This means that organs intended for research, and organs intended for transplant but subsequently determined to be unsuitable for transplant and furnished for research, are not counted as Medicare usable organs. However, Medicare's cost reporting instructions

relative to counting research organs in total usable organs differs for IOPOs and THs. The IOPO cost reporting instructions currently require IOPOs to *exclude* all research kidneys from the count of total usable kidneys used in the ratio to determine Medicare's share of kidney acquisition costs. The costs for these research kidneys are deducted from total kidney acquisition costs, or reduced by the revenue received for the research kidneys, or identified in a non-reimbursable cost center in accordance with the IOPO's accounting policy.[295] However, the TH cost reporting instructions currently require THs to *include* organs intended for research in the count of total usable organs.[296] This difference in the accounting of organs intended for research between OPOs and THs creates an increase in the costs to procure research organs by assigning a full SAC. Due to these differing cost reporting instructions, in the CY 2023 OPPS proposed rule, we proposed to codify a policy that would align the Medicare cost reporting practices for research organs for THs with the policy for IOPOs. Under our proposed policy, both IOPOs and THs would exclude organs intended for research from the count of total usable organs.

Based on some comments we received on our research organ proposal in the CY 2023 OPPS/ASC proposed rule, we believe that the following statement made in the preamble may have created confusion among commenters: "For the purpose of determining Medicare's share of organ acquisition costs, we intend a 'research organ' to be an organ used for research (with the exception of certain pancreata), regardless of whether the organ was intended for research, or intended for transplant under § 413.412(a) and instead used for research" (87 FR 44767). Many commenters mistakenly believed that under our proposal Medicare would no longer pay for organs initially intended for transplant if those organs were later used for research. We did not

[295] IOPOs complete their cost report on the CMS-216-94 (OMB No. 0938-0102).
[296] THs complete the hospital cost report on the CMS 2552-10 (OMB No. 0938-0050).

mean to imply that Medicare would not continue to share in the acquisition costs of organs that are intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research. To address commenters' concerns, in this final rule we are clarifying that the acquisition costs of organs that are *initially intended for transplant,* but subsequently determined unsuitable for transplant and instead furnished for research, are allowable organ acquisition costs. This is similar to the organ acquisition costs for organs that are initially intended for transplant, but subsequently determined unsuitable for transplant and discarded, which are allowable organ acquisition costs.

Therefore, in this final rule with comment period, we are affirming and reiterating our policy that acquisition costs associated with *organs intended for transplant* continue to be allowable organ acquisition costs and Medicare will continue to share in those acquisition costs for organs intended for transplant but subsequently determined unsuitable for transplant and are instead furnished for research. Additionally, in this final rule, we are also clarifying that the acquisition costs of organs that were initially *intended for research* are non-allowable organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)). Under § 413.90, costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs.

Comment: Several commenters misunderstood our proposal for counting research organs and believed those organs could not be counted for cost finding purposes. Those commenters were not supportive of our proposal and requested CMS require IOPOs to continue following the guidance set forth in CMS-Ruling 1543-R.

Response: We appreciate the commenters' input on our proposal. Our proposal was not intended to impact the process of allocating shared overhead costs (that is costs incurred for a

deceased donor when multiple organs are procured) between renal and non-renal organs as described in CMS Ruling 1543-R. Our proposal was limited to counting research organs used in the ratio for determining Medicare's share of organ acquisition costs. Therefore, we are affirming that OPOs should continue to follow the guidance set forth in CMS Ruling 1543-R, "Allocation of Donor Acquisition Costs Incurred by Organ Procurement Organizations." That is, when an OPO has acquired organs other than kidneys, it would go through proper cost finding to ensure that overhead costs are allocated appropriately. To ensure proper allocation of shared overhead costs, these costs would be allocated to all organs the OPO intends to procure, regardless of whether the OPO actually recovers the organ for transplant. If procurement is attempted, but no organ actually retrieved, the organ would still be counted for purposes of proper cost finding. Organs in this instance are the statistical basis used to apportion shared overhead costs between renal and non-renal cost centers, and all organs the OPO intends to procure would be used in the count.

For example: Hospital A notifies OPO B that a death is imminent in its facility and that the individual is listed as a potential organ donor. OPO B arranges for surgeons to procure the organs, an operating room for the excisions to take place, and services necessary to maintain the organs in a viable state. Prior to calling the liver transplant surgeon, the OPO arranges for a liver function test, which shows that the liver is not viable. Surgeons remove all of the remaining organs, but, upon inspection, the heart surgeon determines that the heart is unsuitable for transplant. The lungs were designated for non-transplant research activities prior to the time the donor entered the operating room. Costs are allocated as follows: The cost of the liver function test is allocated to the liver cost center. No portion of the operating room fees or other services is allocated to the liver cost center, or to the lungs cost center. The costs for the operating room

fees and the other services are allocated equally to the other organ cost centers, including the heart cost center. Surgeon's fees that are specific to a particular organ are allocated directly to that organ.

Comment: A few commenters were concerned with our proposal in the CY 2023 OPPS proposed rule that requires OPOs to "deduct the cost incurred in procuring an organ for research from their total organ acquisition cost." These commenters indicated that under current policy, OPOs exclude organs intended for research at the time of entering the operating room from the count of Medicare usable and total usable organs, which is the ratio used in calculating Medicare's share of organ acquisition costs. They also indicated that costs associated with procuring organs used for research are only included in total organ acquisition costs in circumstances where the organs were considered viable for potential transplant at the time the donor entered the operating room, but the organs were subsequently deemed unsuitable for clinical reasons. These commenters also noted that the acquisition costs associated with these organs are nominal, typically reimbursed either by the TH or the research institution, and OPOs account for any revenues received for research organs through an offset. These commenters stated that to the extent costs incurred for organs intended for transplant, but determined unsuitable for transplant and instead furnished for research, exceed revenues received for such organs, those costs should be included in total acquisition costs. One commenter who expressed support for the proposal noted that the costs associated with these organs not used for transplant are insignificant in comparison to the care and testing needed for transplanted organs. This commenter observed that under § 413.412(c), organs used for research are not counted for Medicare cost allocation purposes; therefore, THs'/OPOs' costs incurred are shared among the usable organs procured from the deceased donor.

Response: We appreciate the commenters' input and agree that the acquisition costs for organs intended for transplant but subsequently determined unsuitable for transplant and furnished for research are allowable costs and are included in total organ acquisition costs. Based on commenters' input, the additional costs associated with these organs furnished for research are nominal and currently addressed by IOPOs through a revenue offset. We are finalizing a modified version of our proposal, under which OPOs and THs would be required to reduce their total organ acquisition costs when the organ is intended for transplant but determined unsuitable for transplant and instead furnished for research by either (i) deducting the costs to furnish organs for research from total organ acquisition costs, or (ii) by offsetting the total organ acquisition costs by the revenue received for these organs. In no event may the reduction in total organ acquisition costs as a result of this deduction or offset exceed the costs incurred to furnish organs for research. When the costs to procure organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center, as in the case of organs that are intended for research and furnished for that purpose, no offset is necessary.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44767) we stated that regardless of amounts charged for an organ used for research, "the costs must be offset against total organ acquisition costs." We believe finalizing a modified version of our proposal to provide that when costs to procure research organs are included in organ acquisition costs, THs and IOPOs must *either* deduct the costs to procure organs for research from total organ acquisition costs, or offset the costs to procure organs for research by the revenues received for furnishing these organs to research organizations will reduce burden by affording THs and IOPOs flexibility to account for research costs consistent with their accounting practices. We also believe this will

mitigate confusion regarding the treatment of organ acquisition costs when an organ is intended for transplant but is subsequently determined unsuitable for transplant and furnished for research. In addition, we believe this will promote the furnishing of organs that are intended for transplant, but subsequently determined unsuitable for transplant to research organizations, rather than discarding these organs. Consistent with finalizing a modified version of our proposal would be that no cost offset is necessary for THs or IOPOs when the costs to procure organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center.

Comment: One commenter agreed with our proposals to (1) exclude organs used for research from the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition costs; and (2) for THs and OPOs to deduct the costs incurred in procuring an organ for research from their total organ acquisition costs. This commenter opined that the proposal would allow for a more accurate reporting of Medicare usable organs while still ensuring the Medicare Trust Fund is not inappropriately paying for research costs. A few commenters supported our proposal to exclude organs from the count of Medicare usable and total usable organs to support payment accuracy.

A few commenters requested CMS provide examples and educational materials to support the accuracy of information on the Medicare cost report, should the proposals be finalized.

Response: We appreciate the commenter's support and acknowledgement of our proposals. To address commenters' request for materials to help them understand how to submit information on Medicare cost reports that is accurate and consistent with the policy we are finalizing in this final rule with comment period, we include the following example.

Example:

Assume the following:

- A TH incurs $500,000 in organ acquisition costs (OAC). This OAC is made up of $100,000 to procure organs used for research ($70,000 for organs intended for transplant but subsequently determined unsuitable and furnished for research plus an additional $5,000 for these organs to be packaged and couriered to the research center plus $25,000 for organs intended for research) and $400,000 for organs transplanted.
- The TH receives $28,000 in revenue for organs provided for research.
- The TH reports 80 Medicare usable organs, 20 non-Medicare organs, and 25 research organs. The TH reports 100 total usable organs, excluding the 25 research organs.
- The TH's Medicare ratio is 0.80 (80 Medicare usable organs / 100 total usable organs = 0.80). The TH determines its allowable organ acquisition costs using its accounting practice of offsetting revenue.
- The TH's allowable organ acquisition cost is $472,000 ($500,000 total OA costs - $28,000 in revenue received for organs provided for research).
- The TH determines Medicare's share of allowable organ acquisition costs as $377,600 by multiplying the allowable organ acquisition costs by its Medicare ratio ($472,000 allowable organ acquisition costs times 0.80 Medicare ratio).

Under the policy we are finalizing in this final rule with comment period, the TH in this example would be permitted to continue to follow its accounting practice and reduce its total organ acquisition costs by the revenue received ($28,000) rather than incur additional burden to identify the additional $5,000 cost for packaging and couriering the organs furnished for

research. We will be updating the Medicare cost report forms and instructions for IOPOs and THs commensurate with this final policy.

Comment: A few commenters indicated that they found the CY 2023 OPPS/ASC proposed rule to be unclear on whether organs that are rehabilitated under a research protocol and subsequently transplanted into a Medicare beneficiary may be counted as Medicare organs, and asked CMS to clarify how the acquisition costs for such organs are accounted for. Commenters believed that we proposed to exclude Medicare coverage for organs transplanted in conjunction with a qualified clinical trial. These commenters believe this is inconsistent with CMS's policy of covering routine costs in qualifying clinical trials (NCD 310.1). Thus, commenters believed that disallowing the costs to procure organs rehabilitated under a research protocol that are subsequently transplanted as a component of clinical care is inconsistent both with Medicare's research policy and with the governing regulations (§§ 413.5(c)(2) and 413.90(b)(2)).

Response: We appreciate the commenters' concerns. As we discussed in the CY 2023 OPPS/ASC proposed rule (75 FR 44767), we expect that when an organ is transplanted into a patient, the organ is counted as a total usable organ and a full SAC is assigned. This includes organs "rehabilitated under a research protocol" that are subsequently transplanted into a patient, as well as organs transplanted under the Medicare clinical trial policy. The transplanted organ would additionally be counted as a Medicare usable organ if the transplanting hospital transplanted the organ into a Medicare beneficiary. Our regulations at § 413.90(b)(2) stipulate that if research is conducted in conjunction with, and as a part of, the care of patients (such as a clinical trial), the costs of usual patient care and studies, analyses, surveys, and related activities

to serve the provider's administrative and program needs are allowable costs in the determination of payment under Medicare.

Because the organ is transplanted into a patient, THs and OPOs would not be required to deduct the cost incurred in procuring the organ from their total organ acquisition costs.

Comment: Several commenters suggested that "surgeon" in proposed § 413.412(d)(1) be replaced with "physician" or "any physician" because "physician" is broader than "surgeon" and covers the multiple types of physicians such as intensivists, cardiologists and pulmonologists who may make organ feasibility decisions. A few commenters supported our proposal and one such commenter suggested the "excising surgeon" should be the one to maintain the discretion in determining initial organ viability.

Response: We agree with commenters' concerns that the practitioner who determines, upon initial inspection or after removal of an organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable, should not be limited to a surgeon because there are other physicians who may determine whether an organ is suitable for transplant. We agree with commenters' suggestion to replace "surgeon" with "physician" in proposed § 413.412(d)(1).

Comment: Commenters indicated confusion with the language "For Medicare cost allocation purposes" as used in §413.412(c) that says "For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)) and kidneys used for research are not counted as Medicare usable kidneys in Medicare's share of kidney acquisition costs" In the CY 2023 OPPS/ASC proposed rule, we proposed to redesignate § 413.412(c) to § 413.412(c)(1), with additional proposals in § 413.412(c)(1) to require that

organs used for research not be counted as total usable organs. Thus, our proposed language for § 413.412(c)(1) was "For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a))." Commenters said they were confused with the phrase "For Medicare cost allocation purposes" in proposed § 413.412(c)(1), because the proposed paragraph concerns organs used for research.

Response: As proposed in the 2023 CY OPPS/ACS proposed rule, § 413.412(c)(1) uses the term "cost allocation" to refer to the ratio used to determine Medicare's share of organ acquisition costs. We understand commenters' confusion with the use of the phrase "cost allocation" in proposed § 413.412(c)(1); our intention was that proposed § 413.412(c)(1) would be understood to mean that, *when calculating Medicare's share of organ acquisition costs*, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)). However, commenters believed the meaning was for cost finding purposes as described in CMS Ruling 1543-R.

After consideration of the public comments received, and to address commenters' concerns and confusion with how to account for the costs to procure organs used for research, we are finalizing our proposal with modifications to § 413.412 to more clearly organize and set forth the policies we proposed and intended to convey in the 2023 OPPS/ASC proposed rule.

We are finalizing our proposal to modify the title of § 413.412 with additional modifications to be "Intent to transplant, intent for research, counting of en bloc, and unusable organs." We are also finalizing § 413.412(a) as "Principles for organs intended for transplant for organ acquisition payment purposes." We are modifying § 413.412(a)(2) for further clarity with respect to costs to specify that "OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type. These costs include the costs associated with an organ intended for transplant, but subsequently determined unsuitable for transplant and furnished to research." We are moving the concepts pertaining to research organs in § 413.412(c) to newly added § 413.412(a)(3) with revisions to more clearly specify that "An organ intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs," as this principle is set forth in § 413.412(c). We are also adding § 413.412(a)(4)(i) and (ii) to specify that OPOs and THs must reduce total organ acquisition costs when the organ is intended for transplant but determined unsuitable for transplant and instead furnished for research as follows: (i) by deducting the costs to furnish organs for research from total organ acquisition costs, or (ii) by offsetting the total organ acquisition costs by the revenue received for these organs. We are also adding § 413.412(a)(4)(iii) to specify that in no event may the reduction in total organ acquisition costs as a result of application § 413.412(a)(4) exceed the costs incurred to furnish organs for research.

We are also adding § 413.412(a)(5) to specify that "when the costs to furnish organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center, no offset is necessary."

We are revising paragraph § 413.412(b) to "Principles for organs intended for research for organ acquisition payment purposes" and including some of the concepts in paragraph § 413.412(c) relative to organs intended for research to this revised paragraph. Specifically, we are revising § 413.412(b)(1) to specify that "An organ is intended for research when the OPO or TH designates it for research prior to the time the donor enters the hospital's operating room for surgical removal of the organ." We are also revising § 413.412(b)(2) to specify that "Medicare does not share in the acquisition costs of an organ intended for research and costs to procure these organs must not be included in organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a))." We are adding § 413.412(b)(3) to specify that "An organ intended for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a))."

We are redesignating paragraphs § 413.412(b), (b)(1) and (b)(2), Counting of en bloc organs as § 413.412(c), (c)(1) and (c)(2), respectively. With this redesignation from § 413.412(b) to § 413.412(c), redesignated § 413.412(c) will read "*Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count -". We are also redesignating paragraph § 413.412(b)(1) to § 413.412(c)(1) so that § 413.412(c)(1) will read "En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney." Additionally, we are redesignating § 413.412(b)(2) to § 413.412(c)(2) so that § 413.412(c)(2) will read "En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each

organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney."

We are also finalizing our proposal with modifications based on comments received to amend § 413.412(d)(1) to specify that an organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a physician determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable. We are also amending the section heading at § 413.412(d), which currently reads "Counting of unusable organs" so that it instead reads "Unusable organs." because, as a result of the changes we are finalizing in this final rule with comment period, amended § 413.412(d) not only refers to counting unusable organs, but also to the cost to procure unusable organs as well. Consistent with finalizing our proposal with modifications, we are also revising § 413.402(a) to more clearly explain that costs related to organ acquisition include allowable costs incurred in the acquisition of organs intended for transplant, including those organs that are subsequently determined unsuitable for transplant and furnished for research. We are also making a technical correction to § 413.402(a) to specify that there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH. Specifically, we are revising § 413.402(a) to specify "*Costs related to organ acquisition*. Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH."

C. Costs of Certain Services Furnished to Potential Deceased Donors

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we codified at § 413.418(a) our longstanding policy that only costs incurred after the declaration of the donor's death and consent to donate are permitted to be included as organ acquisition costs (86 FR 73500 through 73503). However, after finalizing that rule, we received feedback from some interested parties that indicated that OPOs may incur certain costs for donor management prior to declaration of death, but when death is imminent, in accordance with OPTN donation policies.[297] This is typical in cases of donation after cardiac death (DCD). We researched this issue further and found that these costs are for certain services that can only be performed prior to declaration of death, when death is imminent, to evaluate the organs for transplant viability and to prepare the donor for donation. Failure to provide these services to the potential donor whose death is imminent may compromise the viability of organs, limit organ donation, and would not honor the donor or donor family's wishes to donate organs. To avoid these unintended consequences, in the CY 2023 OPPS/ASC proposed rule, we proposed to modify § 413.418(a) to allow a donor community hospital or TH to incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. Specifically, as modified by our proposed amendments, § 413.418(a) would provide that organ acquisition costs include hospital services authorized by the OPO 1) when there is consent to donate, and 2) a declaration of death has been made or, if no declaration of death has been made, where death is imminent and it is necessary that the services be provided prior to declaration of death to avoid compromising the viability of the organs for transplant. These costs must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team.

[297] OPTN Policy Manual, Policy 2, available at https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf, accessed February 4, 2022.

Under this proposal, hospitals would bill the OPO for these services in accordance with § 413.418(b), and the OPO would record those billed amounts as organ acquisition costs on its Medicare cost report. Because these services are intended to determine or maintain the viability of organs for transplant, the patient's health insurance would not be billed for the organ acquisition costs, and the patient or patient's family would not be responsible for those amounts. Stakeholders were concerned that without this clarification, if services authorized by the OPO and provided by the hospital could not be included as organ acquisition costs, hospitals may bill the donor's family or a third-party payor. Doing so could create a barrier to organ donation based on economic means, by forcing costs associated with organ acquisition to be borne by the donor's family or a third-party payor. Making the donor's family responsible for these costs could preclude those of lesser economic means from fulfilling their wishes to donate organs and would be inequitable. It could also be a deterrent to deceased donor organ donation and as a result reduce the supply of organs available for transplant. We are committed to supporting organ donation in an equitable fashion and believe that not including in organ acquisition costs certain donor management costs incurred by a donor whose death is imminent, but who has not been declared dead, creates a potential barrier to organ donation and could compromise organ viability. We believe our proposal to modify § 413.418(a) to allow a donor community hospital or TH to incur costs for certain hospital services attributable to a donor prior to declaration of death, but when death is imminent supports organ donation and organ procurement costs and addresses a potential inequity in the transplant ecosystem.

Comment: All the commenters were supportive of this proposal. Many commenters agreed with our proposal because they believed it would result in reimbursement that appropriately supports clinical situations where failure to provide hospital services to a donor

whose death is imminent may compromise the viability of organs, limit organ donation, and fail to honor the donor or donor family's wishes to donate organs.

Response: We thank commenters for their support of our proposal to modify § 413.418(a) to be more inclusive of incurred costs for certain hospital services attributable to a deceased donor or a donor whose death is imminent.

Comment: Several commenters were concerned that OPOs should provide proper authorization before hospitals incur costs for providing certain donor management services prior to death, but when death is imminent, which hospitals will then bill to OPOs. These commenters asked that we work to ensure that the costs of these services are appropriately authorized by the OPO.

Response: We appreciate these comments and note that our existing regulation at § 413.418(a) requires OPO authorization. We believe that best practices also include authorization by the OPO for hospitals to provide certain donor management services prior to death, but when death is imminent, being in place prior to a donor community hospital or TH incurring costs for these donor management services. Because the hospital will then bill the OPO for those services provided prior to declaration of death, but when death is imminent, the hospital and OPO will want to ensure that their financial/business arrangements include providing that authorization prior to the hospital's incurring costs. Based on these comments, we have amended the regulation at § 413.418(a) to emphasize the authorization requirement by stating that these services "must be authorized by the OPO".

Comment: We received a few comments related to § 413.418(b) from commenters who asked that payments by the OPO to the TH reflect donor management costs incurred prior to death, but when death is imminent. Some commenters asked us to confirm that hospitals and

OPOs can renegotiate their case rates paid to donor hospitals to account for these additional allowable costs, to facilitate the proper recording of these costs as organ acquisition costs. Some commenters noted that the costs would be included in the OPO's standard acquisition charge calculation. A few commenters asked that we clarify which cost-to-charge ratio (CCR) donor community hospitals and THs must use if they bill OPOs for donor services by reducing their charges to cost. Specifically, these commenters asked whether the hospital-specific overall operating CCR or the hospital-specific overall operating and capital CCR should be used.

Response: Donor community hospitals and THs that bill OPOs a negotiated rate are free to renegotiate those rates to account for these added costs. OPOs will be able to include the cost of these donor management services in their organ acquisition costs used in calculating their SACs. Regarding CCRs, we clarify that donor community hospitals and THs must use the hospital-specific inpatient operating CCR to reduce their charges to cost. In this final rule with comment period, we are finalizing § 413.418(b) to specify that when a donor community hospital or TH incurs costs for services furnished to a deceased donor, or a donor whose death is imminent as described in § 413.418(a), as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating CCR for the period in which the service was rendered, or a negotiated rate.

Comment: A commenter asked that we codify in the regulations that certain expenses incurred prior to brain death declaration are reimbursable by Medicare.

Response: The regulation text that we are finalizing in this final rule with comment period at § 413.418 allows a donor community hospital or TH to incur costs for hospital services attributed to a deceased donor or a donor whose death is imminent. The regulation does not

specify the type of donor death, but includes all deaths (cardiac deaths and brain deaths). Therefore, we do not see a need to modify the regulation text to refer to brain death specifically.

Comment: A few commenters asked whether our proposed amendment to § 413.418(a) to allow a donor community hospital or TH to incur costs for certain hospital services attributable to a donor prior to declaration of death, but when death is imminent would be effective for any open OPO cost reports.

Response: For cost reporting periods beginning prior to February 25, 2022,[298] providers should follow the policy given in sub-regulatory guidance (see Provider Reimbursement Manual 15-1, chapter 31, section 3108.C). Effective for cost reporting periods beginning on or after February 25, 2022, and in accordance with our current regulation at § 413.418(a), a donor community hospital (a Medicare-certified non-transplant hospital) and a TH can incur organ acquisition costs for donor organ procurement services authorized by the OPO, but those costs are limited to costs incurred following declaration of death and consent to donate. Our proposed amendments to § 413.418(a) to permit organ acquisition costs to include certain donor management costs incurred prior to declaration of death, but when death is imminent, would only be effective for cost reporting periods beginning on or after the effective date of this final rule with comment period.

[298] February 25, 2022 was the effective date of the FY 2022 IPPS final rule with comment period (Part 2).

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.418(a), effective for cost reporting periods beginning on or after the effective date of this final rule with comment period, to specify that a donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. We note that the regulation text we are finalizing in this final rule with comment period modifies the proposed regulation text, which specified that, in the case of a potential organ donor whose death is imminent, organ acquisition costs only include those hospital services that "must be provided prior to declaration of death" to instead include the condition that "it is necessary that the services be provided prior to declaration of death in order to avoid compromising the viability of the organs for transplant." Based on comments received, we also strengthened the regulation so that it specifies that these services "must be authorized by the OPO." Specifically, the regulation text that we are finalizing in this final rule with comment period would provide that a donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. These services must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by the healthcare team, must be authorized by the OPO, and are included as organ acquisition costs when: (1) there is consent to donate and (2) a declaration of death has been made or, if a declaration of death has not been made, death is imminent and it is necessary that the services be provided prior to declaration of death in order to avoid compromising the viability of the organs for transplant. In response to comments, in this final rule with comment period, we are also finalizing § 413.418(b) to include the instructions for amounts billed for organ acquisition costs for donors whose declaration of death has not been made, but whose death is imminent, and to more clearly specify the CCR to be used in reducing

charges to costs. Specifically, we are finalizing § 413.418(b) to specify that when a donor community hospital or TH incurs costs for services furnished to a deceased donor, or a donor whose death is imminent as described in paragraph (a), as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating CCR for the period in which the service was rendered, or a negotiated rate.

D. Technical Corrections and Clarifications to 42 CFR 405.1801, 412.100, 413.198, 413.402, 413.404, 413.420 and Nomenclature Changes to 42 CFR 412.100 and 42 CFR Part 413, Subpart L

Technical Corrections and Clarifications. In the FY 2022 IPPS/LTCH PPS final rule with comment period, § 413.200 was reserved and redesignated as § 413.420 with revisions. In the CY 2023 OPPS/ASC proposed rule (87 FR 44768), we proposed to make a technical correction to § 405.1801(b)(2)(ii), by removing the reference to § 413.200(g) and replacing it with a reference to § 413.420(g). We also proposed to make a technical correction to § 413.198(b)(4)(ii), by removing the reference to "Section 413.200, Reimbursement of OPAs and histocompatibility laboratories" and replacing it with a reference to "Section 413.420," and that section's title, "Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs."

We also proposed to clarify §§ 412.100(b) and 413.402(a) by removing "as appropriate" and instead specifying that organ acquisition costs are allowable costs incurred in the acquisition of organs from a living donor or a deceased donor by a hospital, or from a deceased donor by an OPO.

We proposed to revise § 413.404(c)(2)(i)(C) so that it is written in the active voice and not the passive voice. In addition, we proposed to revise this provision to clarify that the kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in § 413.420(d)(1).

We proposed to amend § 413.420(a)(1) by striking "after September 30, 1978," as we believe it is no longer necessary that the regulations specify that the reasonable cost reimbursement principles in part 413 only apply to covered services furnished after that date; and to replace the acronym "OPOs" with "IOPOs". We proposed to amend § 413.420(a)(2) to correct a typographical error by changing "HOPOs" to "IOPOs".

We proposed to amend § 413.420(c)(1)(v) to correct the statutory reference to section 1861 of the Act so that it instead refers to section 1881 of the Act; the original regulation text was in § 413.178, and was redesignated as § 413.200 in 1997[299] before being redesignated as § 413.420 in the FY 2022 IPPS/ LTCH PPS final rule with comment period.[300] The original regulation at § 413.178 referred to section 1881 of the Act, but a typographical error changed "1881" to "1861" when other changes to the regulation were proposed in 1987 (52 FR 28674) and finalized in 1988 (53 FR 6548).

Nomenclature Changes. In the CY 2023 OPPS/ASC proposed rule (87 FR 44768), we proposed to amend §§ 412.100(b); 413.402(a) and (b)(3), (4), (7) and (8)(ii); 413.404(a)(2), (b)(3), and (c)(1)(i) and (ii); and 413.418 (the section title and paragraph (b)), by replacing the term "cadaveric" with "deceased", to be consistent with terminology used within the transplant community when referring to deceased donors, and to promote sensitivity regarding the process and decision of donating organs from deceased donors. In § 413.404(b)(3)(ii), we proposed to

[299] 62 FR 43668, Aug. 15, 1997.
[300] 86 FR 73515, Dec. 27, 2021.

replace "cadaveric SAC" with "deceased donor SAC" and "cadaveric organ(s)" with "deceased donor organ(s)"; and in § 413.404(c)(2), we proposed to replace "cadaveric kidneys" with "deceased donor kidneys".

We proposed to amend §§ 413.404(c)(2)(i)(A), (B), and (D) and 413.414(c)(1) by replacing references to "Medicare contractor" with "contractor", to conform to terminology changes made in the FY 2015 IPPS final rule (79 FR 49854 at 50199) and in accordance with the definition at 42 CFR 405.201(b).[301]

In the CY 2023 OPPS/ASC proposed rule (87 FR 44768), we also proposed to remove the term "discarded" from § 413.412(d) and replace it with "unusable", to promote sensitivity in scenarios where donated organs are unused because they are unsuitable for transplantation.

Finally, in the CY 2023 OPPS/ASC proposed rule (87 FR 44768), we proposed to amend § 413.400 by adding "TH" in parentheses after the defined term "transplant hospital". Throughout subpart L, we proposed to replace the term "transplant hospital" with "TH". We did not receive any public comments on our proposed technical corrections and nomenclature changes, and therefore, we are finalizing our proposals as proposed.

E. Clarification of Allocation of Administrative and General Costs

When a TH procures organs for transplantation, it is required to allocate administrative and general (A&G) costs to the appropriate organ acquisition cost centers on its Medicare hospital cost report (MCR).[302] This practice is in accordance with Medicare's reasonable cost principles under section 1861(v) of the Act and the regulations at §§ 413.20 and 413.24. When a TH receives an organ from an OPO or other TH, it makes payment to the OPO or TH that

[301] 42 CFR 405.201(b) defines contractors as Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.
[302] CMS 2552-10 (OMB No. 0938-0050)

furnished the organ for the cost incurred to procure the organ. We are aware that some THs that receive organs place the "purchase cost" for the organs they receive in the accumulated cost statistic by which A&G is allocated. Under § 413.24(d)(6), including a statistical cost which does not relate to the allocation of A&G expenses causes an improper distribution of overhead and could result in improper Medicare payment. In this scenario, when the receiving TH includes the purchase cost of the organ it received in the statistical cost by which A&G is allocated, overhead is improperly distributed to the receiving TH organ acquisition cost center.

To ensure the appropriate allocation of A&G costs on a TH's MCR, we proposed to clarify that when a TH receives organs from an OPO or other TH, the receiving TH must exclude from its accumulated cost statistic the purchase cost for these organs because these costs already include A&G costs. In accordance with § 413.24(d)(6), purchased services for a department that are directly assigned to the department that include A&G costs result in an excessive allocation of overhead. This duplication of A&G costs results in improper Medicare payment to the provider. In accordance with MCR instructions,[303] if some of the costs in the department that received this direct assignment of purchased services should receive A&G costs, the TH must remove the directly assigned costs (purchased services) from its allocation statistic to assure a proper allocation of overhead. This process facilitates appropriate Medicare payment and ensures that the receiving TH's organ acquisition cost center does not receive an improper distribution of overhead costs that it did not incur. These longstanding Medicare cost finding principles are in accordance with § 413.24(d)(6), and specifically expressed in the MCR instructions for THs.[304]

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[303] Provider Reimbursement Manual, 15-2, chapter 40, section 4020, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.

[304] Provider Reimbursement Manual, 15-2, chapter 40, section 4020, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935

Comment: Many commenters disagreed with our proposal to clarify Medicare's longstanding cost finding principles on the prohibition of cost duplication relative to a TH's allocation of overhead costs associated with their direct costs for purchased services that would instruct THs to remove from their allocation statistics the amounts for purchased services from OPOs. Some commenters asserted that § 413.24(d)(6) was inapplicable to a TH allocating its overhead costs to a purchased service amount from OPOs (or, in the case of living donor paired exchanges, from the donor TH) because this regulation provides an example of the allocation of a hospital's A&G to a management contract for a hospital based rural health clinic. Some commenters asserted that there is no basis for treating the "purchase price of an organ" differently from other items and services purchased by the hospital, and said that CMS allows other cost centers to include the full cost of supplies and purchased services. Some commenters suggested that our proposed clarification inappropriately assumes that 100 percent of costs associated with the purchased services from an OPO and a TH's A&G costs are "like costs." These commenters suggested that IOPOs and THs each have separate and distinct administrative overhead structures where "like costs" would be non-existent or very minimal; whereas "like costs" may be found between a HOPO and its TH. A few commenters said that where "like costs" for A&G definitively exist and can be documented, those duplicative costs should be removed from the TH's accumulated cost statistic. A few commenters said that a hospital that acquires a high-cost medical device for implantation into a patient is similar to an organ furnished by an OPO to a TH. These commenters asserted that the device company has its own overhead cost structure that differs from the TH's overhead costs and there is no cost reporting instruction to remove the cost of the high-cost medical device from a hospital's accumulated cost statistic. Many commenters also said that there is no duplication of cost for the TH to allocate

A&G when the TH receives the organ from the OPO because the TH bears the administrative expense of processing complex invoices from the OPO, the procuring surgeon, the transportation company and many other stakeholders in the transplant process. Commenters believe that the TH's A&G associated with these efforts must be included in the TH's organ acquisition calculation. Many commenters believed that the application of § 413.24(d)(6) to THs would result in the underreporting and under reimbursement of what commenters assert are valid A&G reasonable costs incurred by a TH that is acting as a prudent buyer of goods and services. Most commenters said they would experience a considerable or significant financial loss.

Response: We thank commenters for their comments and appreciate their comments and concerns. We disagree that there is no duplication of A&G costs from the OPO that provides the organ and the TH that receives it. Because organ acquisition costs are not included in the transplant DRG that Medicare pays to THs for Medicare covered transplants, Medicare pays THs for organ acquisition costs at cost, based upon Medicare's reasonable cost principles. Cost finding, as set forth in § 413.24, is a longstanding Medicare reasonable cost principle, and is the process of allocating and prorating the data derived from the accounts ordinarily kept by a provider to determine the provider's costs of the various services provided. Cost finding is applied to items and services that are paid on a reasonable cost basis. An OPO is a supplier of organ acquisition services to the TH that includes providing the TH with the organ for transplant, and is a separate entity from the TH. We agree with commenters that an OPO and a TH each have their own A&G costs. However, as set forth in § 413.24(d)(6), where a provider purchases services and directly assigns the cost to a cost center for that provider, there is a risk of having excess costs in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. We believe

this can similarly occur when a TH purchases an organ from an OPO, (which inherently includes services provided by the OPO), and directly assigns those costs to the TH's cost center for that specific organ resulting in excess overhead from the TH also being allocated. For example, an OPO furnishes a liver to the TH and the TH assigns to the TH's liver acquisition cost center the invoice amount it paid to the OPO. The issue becomes what, if any, A&G costs of the TH are appropriate to allocate to the liver cost center for the invoice amount it paid to the OPO. Specifically, what indirect costs are being allocated based on a beneficial, causal relationship to the projects, contracts or cost objectives to which they are allocated. When costs within a department are composed of subcontracted efforts or purchased services, the allocation of traditional A&G expenses becomes non-compliant. There is no beneficial or causal relationship of the amount of A&G expense allocated to the base over which these expenses are being allocated. We disagree with commenters who believe all of the TH's A&G costs should be allocated to the liver cost center equally based on the purchased service cost incurred. We agree with the few commenters who said that where "like" A&G costs definitively exist and can be documented, those duplicative costs should be removed from the TH's accumulated cost statistic. In this regard, removing the "like costs" that are duplicative of the directly assigned costs (i.e., purchased services from OPOs) from a TH's allocation statistic is necessary to remove a duplication of overhead costs from the TH and the OPO, to achieve an appropriate allocation of overhead, and thus an appropriate payment from Medicare.

After consideration of the public comments we received, we are withdrawing our proposal to clarify that in accordance with § 413.24(d)(6), a TH must remove the directly assigned costs (purchased services) from its allocation statistic to assure a proper allocation of overhead. We believe that clarifying the appropriate allocation of A&G for THs' purchase costs

from OPOs will require additional analysis, evaluation and provider education to ensure indirect costs are being allocated based on a beneficial, causal relationship to the purchased service to which they are allocated, in accordance with Medicare reasonable cost principles. As such, we may revisit the clarification of this issue in future rulemaking.

F. Organ Payment Policy - Request for Information on Counting Organs for Medicare's Share of Organ Acquisition Costs, IOPO Kidney SACs, and Reconciliation of All Organs for IOPOs

In the CY 2023 OPPS/ASC proposed rule (87 FR 44769), we requested information on an alternative methodology for counting organs for purposes of calculating Medicare's share of organ acquisition costs; IOPOs' kidney SACs; and Medicare's reconciliation of all organs for IOPOs. While we are not responding to specific comments submitted in response to this RFI in this final rule with comment period, we intend to use this input to inform future policy development.

XVIII. Rural Emergency Hospitals (REH): Payment Policies, Conditions of Participation, Provider Enrollment, Use of the Medicare Outpatient Observation Notice, and Physician Self-Referral Law Updates

A. Rural Emergency Hospitals (REH) Payment Policies

1. Introduction

Americans who live in rural areas of the nation make up about 20 percent of the United States (U.S.) population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see health care providers, compared to their urban and suburban counterparts.[305] In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian

[305] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf

American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these rural minority groups often and regularly experience several disadvantageous social determinants of health.

The health care inequities that many rural Americans face raise serious concerns that the trend for poor health care access and worse outcomes overall in rural areas will continue unless the potential causes of such health care inequities are addressed.

There have been growing concerns over the closures of rural hospitals and critical access hospitals (CAHs). Between 2010 and February 2022, 138 rural hospitals stopped providing inpatient services, 44 of which were Critical Access Hospitals. There were 75 complete hospital closures where all services ended and 63 hospital conversions where inpatient services ended but some type of health care service continued. Rural hospitals report they continue to face the threat of closure because they lack sufficient patient volume to offer traditional hospital inpatient acute care services required for Medicare payment; however, the demand still exists for emergency and outpatient services in areas served by these hospitals. Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers such as workforce shortages can impact health care access in rural communities and can lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.[306]

The Consolidated Appropriations Act (CAA), 2021, was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department

[306] Healthy People 2020 (n.d.) Access to Health Services. https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services

and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals may convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA.

REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas.

On January 20 and 21, 2021, President Biden issued three executive orders related to issues of health equity: Executive Order 13985 ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government;''[307] Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation;''[308] and Executive Order 13995 ''Ensuring an Equitable Pandemic Response and Recovery.''[309]

Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that

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[307] The White House. (2021). Briefing Room: Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. https://www.whitehouse.gov/ briefing-room/presidential-actions/2021/01/20/ executive-order-advancing-racial-equity-andsupport-for-underserved-communities-through-thefederal-government/.

[308] The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. https://www.whitehouse.gov/ briefing-room/presidential-actions/2021/01/20/ executive-order-preventing-and-combatingdiscrimination-on-basis-of-gender-identity-orsexual-orientation/.

[309] The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. https:// www.whitehouse.gov/briefing-room/presidentialactions/2021/01/21/executive-order-ensuring-anequitable-pandemic-response-and-recovery/.

serve as barriers to equal opportunity. In accordance with this executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation'' requires the Federal Government to prevent and combat discrimination, including when accessing health care, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, ''Ensuring an Equitable Pandemic Response and Recovery,'' the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID–19 and take swift action to prevent and remedy differences in COVID–19 care and outcomes within communities of color and other underserved populations. The executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities. We believe the services furnished by REHs, could be one means of addressing some of the issues raised in these orders, particularly, barriers to access health care in rural communities.

Consistent with these executive orders, in implementing the new REH provider type, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) community, people with

limited English proficiency, people with disabilities, rural populations, and people otherwise adversely affected by persistent poverty or inequality.

2. Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type

Section 125 of Division CC of the CAA was signed into law on December 27, 2020 and establishes REHs as a new Medicare provider type. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act), which sets forth the requirements for REHs. Section 1861(kkk)(2) of the Act defines an REH as a facility that is enrolled in the Medicare program as an REH; does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements of a staffed emergency department; meets staff training and certification requirements established by the Secretary of the Department of Health and Human Services (the Secretary); and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and CAHs with respect to emergency services.

Additionally, section 125(a)(1) of the CAA added section 1861(kkk)(1) of the Act, which requires that REHs provide emergency department services and observation care and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish rural emergency hospital services in the facility 24 hours a day, and meet applicable staffing requirements similar to those for CAHs.[310]

[310] Congress.gov. (2020). H.R.133 - Consolidated Appropriations Act, 2021. https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf

In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act and in this final rule) will receive a Medicare payment for those services pursuant to section 1834(x)(1) of the Act, as added by section 125 of the CAA, that is equal to the amount of payment that would otherwise apply under the Medicare Hospital Outpatient Prospective Payment System (OPPS) for covered outpatient department (OPD) services increased by 5 percent. The beneficiary co-payments for these services will be calculated the same way as under the OPPS for the service, excluding the 5 percent payment increase. In addition, section 1834(x)(2) of the Act provides an additional monthly facility payment to an REH.

To participate in the Medicare program and receive payment for services furnished to Medicare beneficiaries, providers of services such as hospitals, home-health agencies, hospices, SNFs, and now REHs must enter into a provider agreement with CMS, in accordance with section 1866 of the Act. Medicaid providers, likewise, must enter into provider agreements with State Medicaid agencies to be eligible for participation in that program as described in section 1902(a)(27) of the Act. By entering into a provider agreement, a facility agrees that it will

comply with the applicable requirements of the Medicare and Medicaid statutes and the regulations that the Secretary issues under the respective statute.

Section 1861(kkk)(7) of the Act requires the Secretary to establish quality measurement reporting requirements for REHs, which may include claims-based outcome measures and/or patient experience surveys. An REH must submit quality measure data to the Secretary with respect to each year beginning in 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), and the Secretary is required to establish procedures to make the data available to the public on the CMS website. As discussed further in section XVI of the CY 2023 OPPS/ASC proposed rule (87 FR 44755), CMS requested information on certain quality measures and quality reporting requirements for REHs.

The Quality Improvement Organization requirements of the Act shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 1866(a) of the Act (as amended by section 125(b)(1) of the CAA). In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

In accordance with section 1864 of the Act, CMS uses State surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. Additionally, under section 1865 of the Act, some providers or suppliers subject to certification have the option to instead elect to be accredited by private accrediting organizations (AOs) whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements. The survey process for Medicare and Medicaid participating providers and suppliers provides an opportunity

for these providers and suppliers to demonstrate compliance with all of the applicable CoPs, conditions for coverage (CfCs) or requirements. The methods used by CMS to determine compliance with the regulations include surveys conducted by a State survey agency, surveys conducted by AOs that have deeming authority for Medicare providers and suppliers, and self-attestation. CMS would require REHs participating in Medicare to demonstrate and maintain compliance with the provisions included in the CY 2023 OPPS/ASC final rule with comment period.

3. Summary of Comments by Interested Parties in Response to REH Request for Information

In preparation for developing proposed standards and to gain a clear understanding of the challenges faced by facilities providing health care services in rural communities, we published a Request for Information (RFI) on REHs in the proposed rule, "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals" (86 FR 42018) on August 4, 2021. CMS sought public input on a broad range of issues to inform our policymaking in establishing this new provider type. The RFI solicited public input on the concerns of rural providers, including in the areas of health and safety standards, health equity, payment policies, quality measures and quality reporting, and additional considerations and unintended consequences that should be considered during the development of standards for REHs.

Commenters on the RFI generally noted that CMS should take into consideration the challenges associated with the provision of health care services in rural communities. Some commenters noted that, while Congress did not specify the exact steps that CMS should take to calculate the annual facility payment, CMS should do so in a manner that maximizes potential

payment to REHs to ensure these hospitals can continue to operate. Other commenters cautioned CMS against calculating the monthly facility payment in a way that leads to excessive payment. Commenters also encouraged CMS to set forth the details of the payment calculation in rulemaking, so that interested parties could replicate the calculation. With regard to the services provided by REHs, commenters recommended that REHs should provide maternal health, behavioral/mental health services, and telehealth services to further support the communities that they will serve. Commenters recommended that CMS pay for all REH services at the OPPS rate plus 5 percent. A few commenters also suggested that CMS should pay for all services furnished by an REH, including those that are not designated as REH services, at the applicable rate plus 5 percent. With regard to health equity, several interested parties commented that REHs could have significant value for underserved, rural populations by maintaining local access to care, reducing travel times for care, and serving as leaders for community health improvement efforts including efforts to address the social determinants of health. We note that CMS is committed to reducing inequities in rural communities and we are considering the best approach to address health equity in the standards for all Medicare and Medicaid participating providers and suppliers, including REHs.

We reviewed all comments from interested parties and took them into consideration while drafting the CY 2023 OPPS/ASC proposed rule. We appreciate the interested parties' input and responses to our outreach efforts.

During the development of the policies to implement this new provider type, we reviewed the public comments received on the REH RFI, and held public listening sessions with national stakeholder organizations as well as tribal communities. We also gave presentations at CMS's hospital, rural health, and SNF open door forums and sought public feedback.

4. Payment for Services performed by REHs

a. Covered Outpatient Department (OPD) services performed by REHs

(1) Defining "REH Services"

Section 1861(kkk)(1)(A) defines the term "REH services" as emergency department and observation services as well as, at the election of the REH, other medical and health services furnished on an outpatient basis as specified by the Secretary through rulemaking.

We considered how to determine what other covered outpatient medical and health services should be considered "REH services" for purposes of payment under section 1834(x)(1). Section 1834(x)(1) provides that the amount of payment for REH services shall be equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section, which are inpatient hospital services paid under the OPPS)), increased by 5 percent. We interpret this statutory language to mean that the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii)) represents the outer limit of services that CMS may specify as "REH services." 1834(x)(1) frames the services that may receive the 5 percent increase provided under the statute for "REH services" exclusively in terms of covered OPD services, which we believe precludes including any services that are not "covered OPD services" in this definition. Although we interpret 1834(x)(1) to limit the potential scope of REH services to what is included within the definition of "covered OPD services," we are not suggesting that REHs would be unable to furnish, and receive payment for, other services. Rather, we are stating that only services that are covered OPD services can be paid as specified under Section 1834(x)(1). For further discussion of CMS's proposals pertaining to payment for other services performed by

REHs, please see discussion in the below section titled "Services performed by REHs that are not specified REH services."

Within the universe of covered OPD services, in its broadest interpretation, "REH services" could be defined to encompass all services included in the definition of "covered OPD services," as provided in section 1833(t)(1)(B) of the Act, when furnished by an REH, with the exception of services described in clause (ii) of such section, which are hospital inpatient services, as REHs are precluded by section 1861(kkk)(2)(B) of the Act from providing acute inpatient services. Alternatively, CMS could define "REH services" to include only a smaller subset of services. For instance, we considered limiting "REH services" to services that are emergent in nature, such as those services described by the specific HCPCS codes describing emergency department visits and observation services.

We had some concerns, however, about narrowly defining the covered OPD services for which REHs may receive payment as REH services to only services that are emergent in nature. For one, if CMS were to limit the definition of REH services to strictly emergency services, this might cause REHs to cease to furnish other covered OPD services previously provided by the facility upon conversion of the facility to an REH, which could limit access to such services for some beneficiaries. This would seem antithetical to the purpose of section 125 of the CAA, which was created with the goal of ensuring greater access to outpatient services in rural areas. Further, a narrower definition could exclude services that may be desirable for REHs to provide in order to expand or maintain access to outpatient services in rural areas, including behavioral health, routine imaging, or clinic visits.

In light of our concerns with narrowly defining "REH services" and our interest in allowing maximum flexibility for REHs to tailor the services provided to the needs of their

individual communities, for purposes of payment, we proposed to define "REH services," at 42 CFR 419.91, as all covered outpatient department services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the OPPS when provided in a hospital paid under the OPPS for outpatient services, provided that the REH meets the various applicable REH CoPs. In other words, all services that are paid under the OPPS when furnished in an OPPS hospital, with the exception of acute inpatient services, would be REH services when furnished in a REH. We noted that this definition of REH services excludes services described in section 1833(t)(1)(B)(ii) of the Act, which cannot be considered REH services because they are inpatient services, which REHs are not permitted to furnish pursuant to section 1861(kkk)(2)(B) of the Act.

Additionally, we solicited comments on whether CMS should adopt a narrower definition of REH services than the definition we proposed, and if so, how commenters believe we should define these services and what methodology commenters suggest CMS use to determine whether a service meets this definition.

Comment: Multiple commenters supported CMS's proposal to designate all hospital outpatient services furnished by an REH as REH services, provided these services are furnished consistent with the applicable REH COPs. Commenters appreciated CMS taking a more expansive approach to the definition of REH services and accordingly, did not support narrowly limiting the definition of REH services. A few commenters, while supporting the proposed definition, cautioned CMS about the possible unintended consequences of such a broad definition, specifically that REHs could potentially become a point-of-service in larger systems who use the designation as a means of generating higher payment for services that would

otherwise be available at lower prices. The commenter encouraged CMS to monitor the REH program for this concern as the program develops.

A few commenters expressed concerns that the proposed definition of REH services excluded services not paid under the OPPS, particularly services paid off the physician fee schedule. Some commenters specifically requested that, when a CAH converts to an REH, that the REH continue to be able to bill for physician services under the CAH method II payment methodology.

Response: We appreciate commenters' support for our proposal. With regard to classification of services that are not hospital outpatient services paid under the OPPS as REH services, we believe that the statutory language in section 1834(x)(1) means that the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii)) represents the outer limit of services that CMS may specify as "REH services", and as this is the outer limit of the services CMS may specify as "REH services", we do not have the authority to expand this definition further. Given that the reimbursement for CAH method II billing is statutorily defined in Section 1834(g)(2) to only apply to CAHs, we likewise believe that we do not have the authority to apply the same policy to REHs as, once a CAH converts to an REH, it will no longer be a CAH, and therefore the CAH method II billing methodology would no longer be applicable. Instead, consistent with CMS's proposed approach to payment for outpatient services other than covered OPD services furnished by REHs discussed in Section XVIII.A.2.b of the proposed rule, physician services furnished in REHs would be paid off the Physician Fee Schedule. We also appreciate the concern over unintended consequences of adopting a broad definition of REH services, specifically concerns regarding the financial incentives for the

provision of services in a REH rather than another hospital given the higher payment for REH services, and we will monitor utilization of REH services going forward.

After consideration of the public comments we received, and for the reasons described here and in the proposed rule, we are finalizing our definition of REH services at 42 CFR 419.91 as proposed.

(2) Payment for REH Services

Section 1834(x)(1) of the Act states that payment for REH services "…shall be equal to the amount of payment that would otherwise apply under section 1833(t) for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section)), increased by 5 percent to reflect the higher costs incurred by such hospitals, and shall include the application of any copayment amount determined under section 1833(t)(8) as if such increase had not occurred." As a result, we proposed that payments for REH services would be calculated using existing OPPS payment policies and rules. The only differences between the payment for a covered OPD service furnished by an OPPS provider and the payment for an REH service furnished by an REH provider would be that the service payment to the REH would be equal to the applicable OPPS payment for the same service plus an additional 5 percent. Accordingly, we proposed to codify, at 42 CFR 419.92(a)(1), that the payment rate for an REH service would be calculated using the OPPS prospective payment rate for the equivalent covered OPD service increased by 5 percent.

Because we proposed to utilize OPPS payment policies and rules to effectuate payment rates for REH services equivalent to the OPPS payment rates plus five percent, we believed it would be most efficient from a claims processing perspective for the REHs to utilize the OPPS claims processing system to process REH payments. We proposed updating the OPPS claims

processing logic to include an REH-specific payment flag, which an REH provider would utilize to indicate that the provider is an REH and should not be paid at the OPPS payment rates, but should instead be paid at the REH payment rates. Claims from REH providers for REH services would be processed within the OPPS claims processing system. However, when a REH submits a facility claim with the REH-specific payment flag, this payment flag would trigger payment for REH services on the claim at the REH services payment rate, which is the OPPS payment rate plus 5 percent.

We also proposed, consistent with the requirement in section 1834(x)(1) of the Act, that the copayment amount for an REH service would be determined as if the 5 percent payment increase had not occurred. That is, the additional 5 percent payment for REH services, above the amount that would be paid for covered OPD services, would not be subject to a copayment. Therefore, we proposed to codify in the REH payment regulation, at 42 CFR 419.92(a)(2), that the beneficiary copayment amounts for an REH service would be the amounts determined under the OPPS for the equivalent covered OPD service, pursuant to section 1833(t)(8) of the Act, and would exclude the 5 percent payment increase that applies to the REH service payment.

Finally, we noted that section 1834(x)(5)(A) of the Act states that "…except as provided in subparagraph (B), payments under this subsection shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841." The statute makes clear that payments for services rendered by REHs receive payment from the Federal Supplementary Medical Insurance Trust Fund under section 1841. We noted, however, that payments for REH services would have no impact on OPPS budget neutrality because REH services are not covered OPD services under section 1833(t) of the Act to which the OPPS budget neutrality requirements apply. This also means that REH claims would not be used for OPPS rate setting purposes.

Consistent with section 1834(x)(5)(A) of the Act, REH service payments will be paid from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Act.

Comment: Multiple commenters supported excluding payment for REH services from OPPS budget neutrality requirements.

Response: We appreciate the commenters' support of this policy.

Comment: Commenters requested that CMS implement additional measures to support IHS facilities that convert to REHs. Policies suggested by commenters include providing supplemental payments to former IHS facilities that experience a revenue loss after their REH conversion, or allowing IHS facilities that convert to REHs to receive payment for services at the IHS all-inclusive encounter rate plus a 5 percent premium payment to substitute for the OPPS payment rate plus 5 percent additional payment rate for other REH providers. Commenters also requested that IHS facilities that have converted to REHs receive the REH monthly facility payment in addition to the IHS all-inclusive rate payment.

Response: We appreciate the suggestions by the commenters. IHS facilities have limited staff and financial resources, factors which increase the risk of changing payment methodologies for medical services, especially if the new payment approach generates less revenue than anticipated. We understand that targeted supplemental payments or retaining familiar payment methodologies may encourage IHS facilities eligible to become REHs to convert. However, these payment suggestions for IHS facilities that convert to REHs were neither proposed nor discussed in the CY 2023 OPPS/APC proposed rule. Therefore, we will consider policy suggestions for alternative payment methodologies for IHS facilities that convert to REHs in future rulemaking along with consulting with interested tribal parties regarding these policies.

Comment: Multiple commenters asked that eligibility requirements for the 340B Drug Pricing Program (340B Program) be modified so that REHs can participate in the program. Commenters are concerned that excluding REHs from being eligible for the 340B Program will discourage providers from converting to REHs because providers that are currently eligible for the 340B Program would no longer be able to purchase drugs through the 340B Program when they convert to REHs.

Response: These comments are out-of-scope as HRSA, and not CMS regulates the 340B Program. HRSA is responsible for determining whether a healthcare provider is eligible for the 340B Program, and managing the 340B-eligible provider types that are listed in the 340B statute.

Comment: One commenter requested that CMS designate REHs as graduate medical education (GME) eligible facilities similar to the GME designation for CAHs.

Response: We appreciate the commenter's concern regarding residency training at REHs, however, we did not propose a policy to designate REHs as GME eligible facilities. We do not think it would be appropriate to adopt such a policy without describing it in a proposed rule and obtaining public comments from all interested parties. However, we will consider this comment for future rulemaking.

After consideration of the public comments we received, and for the reasons described here and in the proposed rule, we are finalizing our proposals for the payment of REH services without modification. These proposals include:

- Calculating the payment rate for an REH service using the OPPS prospective payment rate for the equivalent covered OPD service increased by 5 percent. We will codify this policy in regulation at 42 CFR 419.92(a)(1);

- Updating the OPPS claims processing logic to include an REH-specific payment flag, which REH providers will utilize to indicate that the provider is an REH and should not be paid at the OPPS payment rates, but instead will be paid at the REH payment rates. Claims from REH providers for REH services will be processed within the OPPS claims processing system; and
- Beneficiary copayment amounts for REH services will be the amounts determined under the OPPS for the equivalent covered OPD service, pursuant to section 1833(t)(8) of the Act, and will exclude the 5 percent payment increase that applies to the REH service payment. We will codify this policy in regulation, at 42 CFR 419.92(a)(2).

b. Services performed by REHs that are not specified REH services

Section 1834(x)(1) specifically addresses the payment rate that applies for "REH services," which, as discussed above, include at most the full range of covered OPD services for which payment can be made under the OPPS. Likewise, as discussed further below, sections 1834(x)(3) and 1834(x)(4) of the Act specifically address payment for ambulance services and post-hospital extended care services that are furnished by an REH. However, section 125 of the CAA is silent on how CMS should pay for other services furnished by an REH, such as services paid under the Clinical Laboratory Fee Schedule (CLFS) or outpatient therapy services, that may be provided on an outpatient basis by hospital outpatient departments, but that are not covered OPD services, as defined under section 1833(t)(1)(B) of the Act, and thus, pursuant to the limiting language in 1834(x)(1) of the Act, would not be payable as REH services when furnished by an REH.

In order for a REH to fulfill the statutory requirements set forth in section 1861(kkk)(2) of the Act, as well as the proposed CoPs for REHs described in the proposed rule "Medicare and

Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospital (REH) and Critical Access Hospital CoP Updates," which appeared in the **Federal Register** on July 6, 2022 (87 FR 40350), REHs must be capable of providing certain types of outpatient services that are not covered OPD services, such as basic laboratory services and certain diagnostic services. Additionally, the proposed REH CoPs state that the REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. For further discussion of the REH COPs, please see section XVIII.B. of this final rule.

As discussed above, section 1834(x)(1) of the Act provides that the amount CMS shall pay for REH services furnished by an REH shall be the same amount that would otherwise apply under section 1833(t) of the Act for covered OPD services plus five percent. However, section 125 of the CAA does not indicate that the additional 5 percent payment described in 1834(x)(1) of the Act would apply to any services other than those within the definition of "REH services." While some of the services described by the proposed REH CoPs would meet the definition of an REH service because they are also covered OPD services under section 1833(t)(1)(B) of the Act and would therefore be eligible for the 5 percent additional payment specified in 1834(x)(1) of the Act, others—such as laboratory services paid off of the CLFS, and outpatient rehabilitation services—are outside the scope of covered OPD services and therefore, for the reasons previously discussed, could not meet the definition of a REH service. However, CMS believes that it is consistent with the statutory requirements for rural emergency hospitals set forth in section 1861(kkk)(2) of the Act for these services to be paid when they are furnished in an REH.

As a result, we proposed to codify, at 42 CFR 419.92(c), that any outpatient service furnished by an REH consistent with the statutory requirements governing this provider type and the proposed REH CoPs, that does not meet the proposed definition of REH services, would be paid at the same rate the service would be paid if performed in a hospital outpatient department and paid under a fee schedule other than the OPPS, provided the requirements for payment under that system are met.

As noted above, section 1834(x)(3) of the Act states that "…for provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l)." Section 1834(l) of the Act establishes the Medicare ambulance fee schedule. Therefore, consistent with section 1834(x)(3) of the Act, we proposed to codify, at 42 CFR 419.92(c)(1), that an entity that is owned and operated by an REH that provides ambulance services will receive payment for such services under the ambulance fee schedule as described in section 1834(l) of the Act and, as described in section VIII.A.7.b of the CY 2023 OPPS/ASC proposed rule (87 FR 44786 through 44787), to revise § 410.40(f) to include an REH as a covered origin and destination for ambulance transport.

Section 1861(kkk)(6)(A) of the Act provides discretion for REHs to include a unit that is a distinct part of the facility licensed as a skilled nursing facility to furnish post-hospital extended care services. Further, section 1834(x)(4) of the Act states that "…for provisions relating to payment for post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility, see section 1888(e)." Section 1888(e) of the Act establishes the skilled nursing facility prospective payment system. Consistent with section 1834(x)(4), we therefore proposed to codify, at 42 CFR 419.92(c)(2), that post-hospital extended care services provided by an REH in such a

unit receive payment through the skilled nursing facility prospective payment system as described at section 1888(e) of the Act.

Comment: Many commenters requested that CMS pay the additional 5 percent for services furnished in an REH that do not meet the definition of REH services, such as laboratory services paid off of the CLFS, and outpatient rehabilitation services. A few commenters supported CMS's proposal, stating that they recognized that CMS was limited in applying the additional 5 percent payment to those services described in section 1833(t)(1)(B) of the Act.

One commenter asked CMS to clarify that its packaging policy for laboratory services will continue to apply to the adjusted OPPS payment made to an REH. The commenter noted that beginning in 2014, CMS packaged most laboratory tests into its OPPS payments on the basis that laboratory tests are integral, ancillary, supportive, dependent or adjunctive to a primary service or services when provided on the same day and ordered by the same physician for a hospital outpatient.

Response: We agree with the commenters that CMS's ability to pay an additional 5 percent for services furnished by an REH that are not designated as REH services is precluded by the statute. Section 125 of the CAA 2021 does not indicate that the additional 5 percent payment described in 1834(x)(1) of the Act would apply to any services other than those within the definition of "REH services" (e.g., covered OPD services other than those described in 1833(t)(1)(B)(ii)). The statute, in particular 1834(x)(3) and 1834(x)(4), as well as the proposed REH CoPs, anticipate that REHs will furnish certain types of services that do not fall within the definition of REH services. CMS believes that it is consistent with the statutory requirements for REHs that these facilities receive payment when they furnish such other services, and therefore that we proposed that such services would be paid at the same rate the service would be paid if

performed in a hospital outpatient department and paid under a fee schedule other than the OPPS, provided the requirements for payment under that system are met. With regard to packaging of laboratory services, the same rules apply for REHs as for OPPS hospitals. If a lab service would be packaged into an OPPS payment for a primary service or services furnished by a hospital that is paid under OPPS, then it will be packaged into the REH payment for the analogous primary service or services when furnished by a REH. If the lab service would have been paid separately under the CLFS if furnished by a hospital that is paid under OPPS, it likewise will be paid under the CLFS at the CLFS rate when furnished by a REH.

Comment: Multiple commenters requested that CAHs with skilled nursing facilities that want to continue to provide skilled nursing services after conversion to an REH should have a transition period of up to 18 months before the skilled nursing facility is required to receive payment for skilled nursing services through the patient driven payment model (PDPM). These commenters suggested that during the transition period the skilled nursing facility should continue to receive payment at prior rates for swing bed payment.

Response: As noted above, section 1834(x)(4) refers, with respect to payment for post-hospital extended care services furnished by an REH, to the provisions relating to payment for such services described in section 1888(e) of the Act. For the reasons previously discussed, CMS reads that provision to require that a skilled nursing facility that is a distinct part unit of an REH, including such a facility that was previously part of a CAH that has converted to a REH, to be paid through the skilled nursing facility prospective payment system . The statute makes no provision for skilled nursing facilities of former CAHs that convert to REHs to receive a period of transition from their former payment rates to payment under the skilled nursing facility

prospective payment system. Nor was such a transitional period contemplated in the proposed rule.

Because the commenter's request for CMS to establish transition payments for a skilled nursing facility that was previously a part of CAH if that CAH converts to an REH goes beyond the scope of the proposed framework for payment for services furnished by an REH, and does not appear to be supported by the REH statute, we are finalizing the policy for payment of post-hospital extended care services furnished by a distinct part unit within an REH as proposed, without a transition period for services furnished by the SNF units of former CAHs.

After consideration of the public comments we received, and for the reasons described here and in the proposed rule, we are finalizing our proposals for payment of services performed by REHs that are not specified REH services, as set forth in 42 CFR 419.92(c), without modification.

c. Payment for an Off-Campus Provider-Based Department of an REH

As discussed above, section 1834(x)(1) of the Act sets forth the amounts that shall be paid for REH services in terms of amounts that would be otherwise apply for "covered OPD services" under 1833(t). Section 1833(t)(1)(B)(v) of the Act, which was added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, ("BBA"), specifically excludes from the definition of "covered OPD services" applicable items and services furnished by an off-campus outpatient department of a provider as defined by sections 1833(t)(21)(A) and (B) of the Act. In light of the exclusion contained in 1833(t)(1)(B)(v) of the Act, CMS has carefully considered how an REH will be paid for items and services furnished by in an off-campus outpatient department of the REH. Section 1861(kkk)(8) of the Act appears to speak to this issue, stating that nothing in that provision, section 1833(a)(10), or section 1834(x) shall affect the application of paragraph (1)(B)(v) of section 1833(t), relating to applicable items

and services (as defined by 1833(t)(21)(A)) that are furnished by an off-campus outpatient department of a provider (as defined by 1833(t)(21)(B)). For the reasons discussed in this section, CMS proposed to interpret this language as stipulating that the new provisions governing payments for services furnished by REHs are not intended to change the existing scope and applicability of the section 603 amendments to section 1833(t) of the Act, and that, as a result, the section 603 amendments would not apply to the determination of the payment rates for services furnished by an off-campus outpatient department of a REH.

Section 603 of the BBA amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of "covered OPD services" applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms "applicable items and services" and "off-campus outpatient department of a provider," and requires the Secretary to make payments for such applicable items and services furnished by an off-campus outpatient department of a provider under an applicable payment system (other than the OPPS). In defining the term "off-campus outpatient department of a provider," section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015) that is not located on the campus (as defined in § 413.65(a)(2)) of the provider, or within the distance (as described in the definition of campus) from a remote location of a hospital facility (as defined in section § 413.65(a)(2)). We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, in the CY 2023 OPPS/ASC

proposed rule (87 FR 44502), we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD."

Sections 1833(t)(21)(B)(ii) through (vi) of the Act except from the definition of "off-campus outpatient department of a provider," for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD services furnished prior to November 2, 2015, as well as off-campus PBDs that meet the "mid build" requirement described in section 1833(t)(21)(B)(v) of the Act and the departments of certain cancer hospitals. Likewise, the department of a provider located on the campus of such provider or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility (as defined in § 413.65(a)(2)), is also excepted from the definition of "off-campus outpatient department of a provider" pursuant to section 1833(t)(21)(B)(i). The items and services furnished on or after January 1, 2017 (or during 2018 or a subsequent year for off-campus PBDs that qualify for the mid-build exception), by the various types of excepted off-campus PBDs described in 1833(t)(21)(B) continue to be paid under the OPPS. In addition, we note that in defining "applicable items and services," section 1833(t)(21)(A) of the Act specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement the section 603 amendments. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and

services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. We specified the Medicare Physician Fee Schedule (PFS) as the applicable payment system for most nonexcepted items and services furnished by nonexcepted off-campus PBDs. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (82 FR 53030).

Section 125(a)(1) of the CAA added the following language, at section 1861(kkk)(8) of the Act, regarding the application of the section 603 amendments to REHs:

"(8) CLARIFICATION REGARDING APPLICATION OF PROVISIONS RELATING TO OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.— Nothing in this subsection, section 1833(a)(10), or section 1834(x) shall affect the application of paragraph (1)(B)(v) of section 1833(t), relating to applicable items and services (as defined in subparagraph (A) of paragraph (21) of such section) that are furnished by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph)."

While we proposed to define REH services as the covered OPD services furnished by an REH, REHs are not paid under the OPPS; we do not interpret the language in section 1861(kkk)(8) to indicate that the section 603 amendments to section 1833(t) should apply to off-campus PBDs of a REH. Rather, we believe section 1861(kkk)(8) can reasonably be interpreted as demonstrating an intent that the creation of the REH provider type would not change the existing scope and applicability of the section 603 amendments, such that the exclusion of items

and services furnished by nonexcepted off-campus PBDs from the definition of covered outpatient department services under the section 603 amendments continues to apply only to items and services furnished by the nonexcepted off-campus PBDs of subsection (d) hospitals paid under the OPPS and does not apply to items and services furnished by an off-campus PBD of an REH, because REHs are a different provider type and are not paid under the OPPS.

We noted that interpreting section 1861(kkk)(8) of the Act to instead mean that the section 603 amendments should apply to items and services furnished by off-campus PBDs of REHs appears to be contrary to the Congressional intent for creating this new provider type, as this interpretation would potentially disincentivize some otherwise eligible facilities from choosing to convert to REHs. Specifically, we noted that section 603 does not apply to items and services furnished by the off-campus PBDs of CAHs. However, if the section 603 amendments applied to the off-campus PBDs of a former CAH that becomes an REH, these off-campus PBDs would appear to meet the statutory definition of "off-campus outpatient department of a provider," and items and services furnished by these entities would be excluded from the definition of "covered OPD services" and paid at the alternative applicable payment system as provided under section 1833(t)(21)(C). Thus, if a CAH becomes an REH and as a result becomes subject to the section 603 amendments, it would experience a significant decrease in payment for items and services furnished by its off-campus PBDs, relative to the amount paid for such services when the entity was a CAH (where it is generally paid at 101 percent of reasonable cost). This would create a financial disincentive for CAHs to convert to REHs and would seem to be contrary to the Congressional intent for creating this new provider type.

We proposed to codify in the REH payment regulation, at 42 CFR 419.93(a), that items and services furnished by off-campus PBDs of REHs are not applicable items and services under

sections 1833(t)(1)(B)(v) or (t)(21) of the Act, and thus that items and services furnished by these off-campus PBDs that otherwise meet the definition of "REH services" will receive the REH services payment amount of the OPPS payment plus 5 percent, as provided in section 1834(x)(1) of the Act and described in the proposed regulation text at 42 CFR 419.92(a)(1). Likewise, items and services furnished by the off-campus PBD of a REH that do not meet the definition of "REH services" would be paid under the payment system applicable to that item or service, provided the requirements for payment under the relevant system are met, as described in the proposed regulation text at 42 CFR 419.92(c).

We solicited comment on alternative payment approaches for items and services furnished by the off-campus PBDs of REHs that may be supported by the REH statute, including section 1861(kkk)(8) of the Act. For example, CMS solicited comment on whether application of the section 603 amendments to an off-campus PBD of an REH should depend on whether that provision applied to the entity before it converted to an REH. Under that framework, if a CAH converts to a REH, because section 1833(t)(1)(B)(v) of the Act did not apply to the CAH before converting, REH services furnished by any existing off-campus PBDs of the CAH would be paid at 105 percent of the OPPS rate, rather than at the PFS-equivalent rate required by section 1833(t)(1)(B)(v) and (t)(21) of the Act. However, because sections 1833(t)(1)(B)(v) and (t)(21) of the Act would have applied to any nonexcepted off-campus PBDs of small rural hospital paid under the OPPS before that entity converted to an REH, any existing nonexcepted off-campus PBDs of the small rural hospital would continue to be considered nonexcepted off-campus PBDs and would continue to receive the PFS-equivalent rate under section 1833(t)(21)(C) of the Act. Under this framework, any new off-campus PBDs created by the REH would be subject to the section 603 amendments. We solicited comment on our proposed approach for paying for items

and services furnished by the off-campus PBDs of REHs, as well as any alternative approaches to this issue that interested parties may have.

Comment: Many commenters supported CMS's proposal to exempt both existing off-campus PBDs of entities converting to REHs and any off-campus PBDs created post conversion to an REH from the section 603 amendments to section 1833(t). These commenters encouraged CMS to finalize this proposal, and to not finalize the alternative payment approach.

Response: We thank commenters for their support.

Comment: We received multiple requests to clarify whether certain provider-based rural health clinics (RHCs) will maintain their excepted status under section 1861(kkk)(6)(B) of the Act after their associated hospital or CAH converts to an REH. Provider-based RHCs that meet specified criteria under this statute are entitled to special payment rules. Beginning April 1, 2021, an excepted RHC had their payment-limit per-visit established on their all-inclusive rate instead of the national statutory payment-limit of $100.

Response: We agree with the commenters and believe that section 1861(kkk)(6)(B) of the Act may be read to mean that if a provider-based RHC was entitled to "grandfathering" by virtue of being in existence on December 31, 2020 and forward, then that RHC could continue to utilize the exceptions set out in section 1833(f) of the Act if its associated hospital converts to an REH. We are finalizing our policy that provider-based RHCs may maintain their excepted status under section 1861(kkk)(6)(B) of the Act when their associated hospital converts to an REH.

After consideration of the public comments we received, and for the reasons discussed here, we are finalizing our proposals for payment of services furnished by an off-campus Provider-Based Department of an REH, as set forth in 42 CFR 419.93, as proposed, while clarifying that provider-based RHCs that were previously entitled to excepted status under

section 1833(f) of the Act may maintain this status when their associated hospital converts to an REH.

5. Monthly REH Facility Payment

a. Overview of the Monthly REH Facility Payment

Section 1834(x)(2) of the Act establishes an additional facility payment that is paid monthly to an REH. Section 1834(x)(5)(B) specifies that this monthly facility payment shall be made from the Federal Hospital Insurance Trust Fund under section 1817. Sections 1834(x)(2)(B) and 1834(x)(2)(C) of the Act require that, for 2023, the monthly payment is determined by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during 2019. The difference is divided by the number of CAHs enrolled in Medicare in 2019 to calculate the annual amount of this additional facility payment per individual REH for 2023. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive. For 2024 and subsequent years, the monthly facility payment will be the amount of the monthly facility payment for the previous year increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

We interpreted the references to the year 2019 in sections 1834(x)(2)(C)(i) and 1834(x)(2)(C)(ii) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) because, in the absence of language implicitly or explicitly denoting the year as fiscal, we believe calendar year is the most logical reading. The REH payment system is based on the

OPPS, which sets its payment rates and rules on a CY schedule. Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the CY. Accordingly, we proposed to codify the calculation of the REH monthly facility payment, under 42 CFR 419.92(b)(1), to specifically refer to the amounts that were and would have been paid to CAHs in calendar year 2019. Under this proposal, we would apply the CY schedule even when the sections refer to the inpatient hospital prospective payment system or the skilled nursing facility prospective payment system where substantial policy changes are implemented on a fiscal year schedule. Therefore, when we calculate the total amount that would have been paid to CAHs if inpatient hospital services, outpatient hospital services, and skilled nursing facility services were paid under their respective prospective payment systems, we would use claims data from the last nine months of FY 2019 and the first three months of FY 2020 to calculate payment data for CY 2019 for both inpatient hospital services and skilled nursing facility services and claims data from CY 2019 for outpatient hospital services.

When determining "the total amount that . . . was paid under this title to all critical access hospitals," as described in section 1834(x)(2)(C)(i)(I) of the Act, we proposed to include both amounts paid to CAHs from the Medicare program and from beneficiary copayments. Likewise, we proposed to include both projected payments from the Medicare program and projected beneficiary copayments when determining the estimated total amount that would have been paid to CAHs had they been paid on a prospective basis, as described in section 1834(x)(2)(C)(i)(II) of the Act. By including both Medicare trust fund payments and beneficiary copayments, we believe that the resulting calculations will reflect the actual payments CAHs received for services provided in CY 2019 and ensure that the full amount of additional payments made to CAHs are reflected in the determination of the monthly REH facility payment. Because CAHs are generally

paid at 101 percent of reasonable cost, a 2014 report found that in 2012 beneficiary copayments consisted of around 47 percent of the total Medicare-related outpatient hospital spending for CAHs.[311]

As discussed in the proposed rule, excluding around 47 percent of the payment CAHs received in 2019 for Medicare services from the REH monthly facility payment calculation would generate a monthly facility payment that would cover a substantially smaller share of the costs REHs face. We believed that if the calculation of the monthly facility payment does not reflect payments from beneficiaries, CAHs and small rural hospitals could be discouraged from converting into REHs because the monthly facility payment would be too small.

Using our calculations, which we will discuss in more detail in sections XVIII.A.5.b and XVIII.A.5.c of this final rule with comment period,[312] we estimated in the proposed rule that the estimated prospective payment for CAHs in 2019 is 58.2 percent of total CAH spending in 2019 when copayments are included for both total CAH spending and the estimated prospective payment for CAHs. Thus, in the proposed rule we estimated that the aggregate REH monthly facility payment would be 72 percent of the estimated prospective payment for CAHs in 2019. The combination of the estimated prospective payment for CAHs and the aggregate REH monthly facility payment where copayments are included in the calculation for an REH would be

[311] Office of Inspector General, Department of Health and Human Services. 2014. Medicare beneficiaries paid nearly half of the costs for outpatient services at critical access hospitals. OEI-05-12-00085. Washington, DC: OIG.
[312] In the CY 2023 OPPS proposed rule, we provided calculations for the total amount paid under title XVIII to CAHs in CY 2019 (as described in section 1834(x)(2)(C)(I)), which assumed that the beneficiary copayment share of CAH payment for Medicare services was 47 percent. As discussed further below, commenters noted in response to the proposed rule that although around 47 percent of CAH outpatient hospital payment spending consists of beneficiary copayment dollars, the beneficiary copayment share for inpatient hospital services and skilled nursing services in CAHs is around 20 percent of total spending rather than the around 47 percent of total Medicare spending for these services that we claimed in the CY 2023 OPPS proposed rule. In addition, commenters noted that CMS's estimate of total estimated prospective payment for CAHs in CY 2019 in our copayment discussion incorrectly excluded inpatient hospital supplemental payments that CAHs would receive if they were paid on a prospective basis. In response to these comments, CMS has provided revised calculations in this final rule that more accurately reflect the beneficiary copayment share of spending for inpatient hospital services and skilled nursing services furnished by CAHs in CY 2019, as well as the estimated total prospective payment for CAHs in CY 2019.

close to the amount that an REH would have received from Medicare if it had decided to stay as a CAH and not convert to an REH. Therefore, it less likely that a CAH would lose revenue if it converted to an REH in the future, which may encourage a CAH to convert to an REH. In the proposed rule, we also estimated that if copayments are removed from both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019, the aggregate monthly facility payment for all providers only would be 11.1 percent of the estimated prospective payment for CAHs in 2019 where the estimated prospective payment amount includes copayments. That means a CAH converting to an REH would face a substantial reduction in Medicare payment if it converted to an REH. Please see the detailed calculations from the proposed rule below:

Step 1: Total estimated CAH spending in CY 2019 with copayments: $12,083,666,636

Total estimated prospective payment for CAHs in CY 2019 with copayments: $7,033,248,418

Difference: $12,083,666,636 - $7,033,248,418 = $5,050,418,218

Aggregate REH monthly facility payment with copayments: $5,050,418,218

Share of the aggregate REH monthly facility payment with copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments: $5,050,418,218 / $7,033,248,418 = 72 percent

Step 2: Total estimated CAH spending in CY 2019 removing copayments: $12,083,666,636 x 0.53 = $6,404,343,317

Total estimated prospective payment for CAHs in CY 2019 removing copayments: $5,626,598,734

Difference: $6,404,343,317 - $5,626,598,734 = $777,744,583

Aggregate REH monthly facility payment without copayments: $777,744,583

Total estimated prospective payment for CAHs in CY 2019 with copayments: $7,033,248,418

Share of the aggregate REH monthly facility payment without copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments: $777,744,583 / $7,033,248,418 = 11.1 percent

We believed that including both Medicare trust fund payments and beneficiary copayments in the calculation of the monthly facility payment reflected the intent of the statute to provide incentives for CAHs and small rural hospitals that might otherwise close to convert to REHs and continue to provide outpatient hospital care in rural communities. We proposed to codify including payments from the Medicare program and beneficiary copayments for CAHs to calculate the monthly facility payment under 42 CFR 419.92(b)(1)(i) and (ii).

Finally, section 1834(x)(2)(D) of the Act states that "[a] rural emergency hospital receiving the additional facility payment under this paragraph shall maintain detailed information as specified by the Secretary as to how the facility has used the additional facility payments. Such information shall be made available to the Secretary upon request." Accordingly, we proposed to codify this reporting requirement, under 42 CFR 419.92(b)(3), to state that an REH receiving the additional monthly facility payment must maintain detailed information as to how the facility has used the monthly facility payments and must make this information available upon request. We believe that this requirement can be met using existing cost reporting requirements for outpatient hospital facilities that would include REHs. The cost reports track spending on outpatient hospital services as a part of overall provider spending. This information will show if a sufficient share of revenue to the REH, which includes the monthly facility

payment, is being directed to outpatient care. For CY 2023, we therefore did not propose to establish any new reporting or data collection requirements for REHs related to their use of the REH monthly facility payments. However, we will monitor this issue in CY 2023 to see if we may need to propose new reporting or data collection requirements for REHs in future rulemaking.

Comment: Multiple commenters, including MedPAC, noticed that we reported two different amounts for the total estimated prospective payment for CAHs in CY 2019. For the comparison of the monthly facility payment aggregate amount as a share of total estimated prospective payment when including or excluding copayments, we reported a total estimated prospective payment for CAHs in CY 2019 of $7.03 billion. For the calculation of the monthly facility payment for an individual REH, we reported a total estimated prospective payment for CAHs in CY 2019 of $7.68 billion. The commenters wanted know which number was the correct amount, and for us to correct the calculation with the incorrect amount.

In addition, one commenter, MedPAC, disagreed with our determination that 47 percent of total Medicare payments to CAHs are beneficiary copayments. MedPAC stated that the 47 percent figure only applies to hospital outpatient services, and that copayment percentages for inpatient hospital services and skilled nursing services are much lower than outpatient hospitals services for CAHs. MedPAC noted that the copayment amounts for inpatient hospital and skilled nursing services are same for a CAH as it would be for a hospital receiving prospective payment.

Response: The correct amount of total estimated prospective payment for CAHs in CY 2019 is $7.68 billion. The $7.03 billion amount mistakenly excluded supplemental inpatient hospital payments that are made to prospectively paid hospitals. In response to this comment, CMS has updated the calculations comparing the monthly facility payment aggregate amount as

a share of total estimated prospective payment when including or excluding copayments presented in the CY 2023 OPPS/ASC proposed rule, as provided below.

In addition, we agree with the copayment information stated by MedPAC, and have revised the calculations on this topic that were provided in the CY 2023 OPPS/ASC proposed rule, as shown below. For our revised calculations that compare the monthly facility payment aggregate amount as a share of total estimated prospective payment when including or excluding copayments we have made the below revised assumptions:

1) The copayment percentage of CAH outpatient hospital payment is approximately 47 percent;
2) The copayment percentage of prospective payment outpatient hospital payment is slightly under 20 percent because some preventive services have no copayment, and the copayment for a few high-cost outpatient services is capped at the cost of the inpatient hospital deductible; and
3) The copayment amounts for inpatient hospital services and skilled nursing services are the same whether the provider is a CAH or a prospectively-paid provider. Therefore, the copayment amounts cancel each other out in the equation.

We revised our assumptions to be in agreement with the beneficiary copayment share of CAH Medicare spending and the beneficiary copayment share of Medicare spending for prospectively paid hospitals described by MedPAC.

Our revised calculations are based on the detailed methodology presented in the CY 2023 OPPS/ASC proposed rule (87 FR 44781). These calculations do not include any updates to the detailed methodology that were made in this final rule. Our revised calculations are as follows:

Step 1: Total estimated CAH spending in CY 2019 with copayments: $12,083,666,636

Total estimated prospective payment for CAHs in CY 2019 with copayments: $7,679,358,171

Difference: $12,083,666,636 - $7,679,358,171 = $4,404,308,465

Aggregate REH monthly facility payment with copayments: $4,404,308,465

Share of the aggregate REH monthly facility payment with copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments: $4,404,308,465/ $7,679,358,171= 57 percent

Step 2: Total estimated CAH spending in CY 2019 removing copayments: $9,078,931,318

Total estimated prospective payment for CAHs in CY 2019 removing copayments: $7,002,437,498

Difference: $9,078,931,318 - $7,002,437,498 = $2,076,493,820

Aggregate REH monthly facility payment without copayments: $2,076,493,820

Total estimated prospective payment for CAHs in CY 2019 with copayments: $7,679,358,171

Share of the aggregate REH monthly facility payment without copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments: $2,076,493,820 / $7,679,358,171 = 27 percent

Our revised calculations, using updated assumptions about the percentage of total Medicare spending for CAHs in CY 2019 from beneficiary copayments and corrected estimates about of prospective payment for CAHs in 2019, indicate that the aggregate REH monthly facility payment including copayments would be 57 percent of the estimated prospective payment for CAHs in 2019. In comparison, our prior calculations from the CY 2023 OPPS/ASC

proposed rule found that the aggregate REH monthly facility payment including copayments was 72 percent of the estimated prospective payment for CAHs in 2019.

In our revised calculations, the combination of the estimated prospective payment for CAHs and the aggregate REH monthly facility payment where copayments are included in the calculation for an REH is more than twice the share of the estimated prospective payment amount than if copayments are removed from both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019 to calculate the aggregate monthly facility payment. In comparison, our prior calculations from the CY 2023 OPPS/ASC proposed rule found that the combination of the estimated prospective payment for CAHs and the aggregate REH monthly facility payment where copayments are included in the calculation for an REH is more than 6 times the share of the estimated prospective payment amount than if copayments are removed from both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019 to calculate the aggregate monthly facility payment.

Our updated calculations found a substantially smaller difference between an aggregate monthly facility payment calculated using both Medicare program spending and beneficiary copayment spending and an aggregate monthly facility payment calculated using only Medicare program spending and excluding beneficiary copayment spending than what we calculated in the CY 2023 OPPS/ASC proposed rule. However, the aggregate monthly facility payment calculated using both Medicare program spending and beneficiary copayment spending was still more than twice as large as the aggregate monthly facility payment calculated using only Medicare program spending and excluding beneficiary copayment spending. We believe the intent of creating the REH provider type was to provide financial support to hospitals that want to maintain outpatient hospital services in areas where it is no longer economically feasible to continue providing

inpatient services. In order to do this, we believe the monthly facility payment was intended to help cover the difference in payment for services that a CAH would experience if it transitioned from receiving 101 percent of reasonable costs under the CAH payment methodology to prospective payment under the REH methodology. We believe an aggregate monthly facility payment that is calculated by factoring in both Medicare program spending and beneficiary copayment spending is the best way to address this difference.

Comment: One commenter, MedPAC, stated that the REH monthly facility payment should be calculated by removing copayment dollars from the both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019. MedPAC determined that removing copayment dollars from the calculation of the aggregate monthly facility payment would result in a $1.5 million aggregate monthly payment per facility per year, instead of a proposed $3.2 million aggregate monthly payment per facility per year. MedPAC believes the smaller, $1.5 million aggregate monthly payment per facility per year will provide sufficient financial stability for REHs while also demonstrating that Medicare is a prudent payer of program funds. MedPAC believes a higher aggregate monthly payment is not the best policy considering that REHs will not be required to have a 24/7 emergency department staffed with a clinician as MedPAC believes one of the main purposes of the monthly facility payment would be to staff and support such a department. MedPAC is concerned that the higher monthly aggregate payment amount may result in too many facilities converting to REHs and further limiting access to inpatient hospital care in rural areas.

Response: We thank MedPAC for their comment. We believe the intent of the REH legislation was to provide financial assistance to support existing outpatient hospital and emergency department care in rural areas when it may not be feasible in the future to maintain an

inpatient hospital capacity. We note, based on a July 2021 policy brief from the NC Rural Health Research Program,[313] that the majority of REHs are expected to be former CAHs. We believe the intent of the monthly facility payment was to address the gap in outpatient payment a CAH would experience in converting from receiving 101 percent of reasonable costs to receiving prospective payment. As such, we believe that an REH monthly facility payment that is calculated from both the total amount of Medicare program dollars and beneficiary copayments better reflects the potential gap in outpatient payment a REH would face after converting from a CAH, as the REH would receive not just lower Medicare payments for services, but also lower beneficiary copayments.

Comment: Multiple commenters supported our decision to calculate the REH monthly facility payment using both Medicare program dollars and beneficiary copayment funds.

Response: We appreciate the commenters' support of our proposal.

Comment: Multiple commenters supported our proposal to increase the REH monthly facility payment calculated in CY 2023 by the hospital market basket in subsequent years. However, many of the commenters were concerned that the hospital market basket increase may not be sufficient to capture all of the increased labor, supplies, and equipment costs that REHs may face in the future. These commenters strongly encourage us to monitor the annual market basket increase to ensure it is adequately covering the increased costs REHs are facing year over year.

Some commenters also were concerned that the monthly facility payment was based on CY 2019 payments to CAHs and CY 2019 estimated prospective payments if CAHs were paid like prospective payment hospitals with no market basket adjustment to the payment amounts for

[313] Pink GH, Thompson KW, Howard HA, Holmes GM. *How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?* NC Rural Health Research Program, UNC Sheps Center. July 2021.

the period of 2020 through 2022. These commenters requested that we adjust the REH monthly payment calculated from CY 2019 data by the change in the market basket percentage from 2020 through 2022.

Response: We appreciate the support of the commenters for our proposal to increase the REH monthly facility payment calculated in CY 2023 by the hospital market basket in subsequent years. As described above, section 1834(x)(2)(B)(ii) of the Act requires that we increase the initial monthly facility payment calculated for CY 2023 by the hospital market basket amount in CY 2024 and subsequent years. We intend to regularly monitor the annual increases to the REH monthly payment to ensure the adequacy of the payment in future years. With respect to the request to adjust the REH monthly facility payment amount for CY 2023 by the market basket increase for the period of 2020 through 2022, we note that sections 1834(x)(2)(B)(i) and (C)(i) of the Act specify that the monthly facility payment for CY2023 should be based on the 2019 payment data and includes no provision for adjusting the payment amount to account for payment increases that CAHs and OPPS hospitals have received in the intervening years. Likewise, such an adjustment was not proposed in the proposed rule. Because the commenters' request goes beyond the scope of the proposed framework for calculation of the CY 2023 REH monthly facility payment and is not supported by the REH statute, we are finalizing the policy for calculation of the CY 2023 REH monthly facility payment based on CY payment 2019 data as proposed, without adjusting this data by the market basket increase for the period of 2020 through 2022.

Comment: Multiple commenters supported our use of 2019 calendar year claims rather than 2019 fiscal year claims to calculate the REH monthly facility payment.

Response: We appreciate the commenters' support for this decision.

Comment: Commenters requested additional cost reporting guidance from us. A commenter wants us to develop a cost report for REH providers. The commenter implies that the REH provider cost report should be finalized in time for reporting CY 2023 provider cost data. The commenter suggests that an REH cost report be based on the cost reporting structure for CAHs. The commenter wants interested parties to have time to review the specifications for an REH cost report and provide feedback before an REH cost report is implemented. Another commenter wants guidance on how to report the cost of observation services performed by REHs and whether the cost of emergency care would be separated from the cost of observation services in a cost report.

Response: We appreciate the commenters' suggestions regarding REH-specific cost reporting. However, we are concerned that new reporting requirements might create an additional burden for providers and discourage eligible providers from converting to an REH. For now, we will follow our proposed policy to monitor cost reporting for REHs for CY 2023 and future years. We will allow REH providers to continue to use their current cost reporting formats to report costs. If REH-specific cost reporting is determined to be necessary, we will consider this issue, including the commenters' policy suggestions, in future rulemaking.

Comment: Multiple commenters supported our proposal to not establish new cost reporting requirements for REHs for CY 2023. Some of the commenters also supported our decision not to propose specific requirements for the spending of REH monthly facility payments.

Response: We appreciate commenters' support of our proposals.

After consideration of the public comments we received, we are finalizing our monthly facility payment proposals without modification. We are required by statute, for CY 2023, to

calculate the REH monthly facility payment by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during 2019. The difference is divided by the number of CAHs enrolled in Medicare in 2019 to calculate the annual amount of this additional facility payment per individual REH for 2023. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive. For 2024 and subsequent years, the monthly facility payment will be, as required by statute, the amount of the monthly facility payment for the previous year increased by the hospital market basket percentage increase.

We are finalizing our policy to use both Medicare program spending and beneficiary copayments to calculate the monthly facility payment after correcting errors with our original calculations which gave a more accurate picture of the amount of the aggregate monthly facility payment calculated using both Medicare program spending and beneficiary copayments as compared to the amount of the aggregate monthly facility payment using Medicare program spending alone. We will calculate the monthly facility payment using claims data from calendar year 2019. We will not establish any new reporting or data collection requirements for REHs related to their use of the monthly facility payments for CY 2023. However, we will monitor this issue in CY 2023 to see if we may need to propose new reporting or data collection requirements for REHs in future rulemaking.

b. Methodology to Estimate Medicare CAH Spending in CY 2019

Section 1834(x)(2)(C)(i)(I) of the Act requires that CMS use "the total amount that the Secretary determines was paid under this title to all critical access hospitals in 2019" as part of the calculation used to determine the monthly facility payment that each REH will receive in 2023. Although the statute provides that this amount shall be an amount determined by the Secretary, the statute is silent regarding what data source the Secretary should use in making such determination. We considered whether CAH claims or cost reports would be the most appropriate data source from which to determine the payments made to CAHs in 2019.

Because CAHs are generally paid at 101 percent of their reasonable costs in furnishing services to Medicare beneficiaries and receive an annual cost settlement for all services covered by Medicare, we did not initially believe that CAH claims would reflect all payments that Medicare may have made to CAHs under Title 18 of the Act. We were most concerned about modelling the annual cost settlement using CAH claims data, because the cost settlement is an accounting action that is not linked to payments reported on individual claims. It was not clear how we would identify the payment or recoupment performed for the cost settlement. By contrast, hospital cost reports track not only payments for claims when they are first submitted to Medicare but also track the annual cost settlements made with CAHs. However, some hospital cost report data can take up to 3 years to be received and processed which raises concerns whether the cost report data for CY 2019 is fully complete. We compared our calculation of Medicare CAH spending in CY 2019 using CAH claims data to our calculation of Medicare CAH spending in CY 2019 using CAH cost report data.

We found that CAH claims data reported approximately $450 million more in CAH Medicare spending ($12,083,666,636) compared to CAH cost report data ($11,631,762,706). Also, the CAH claims data identified 42 more CAHs than the CAH hospital cost report data.

Both findings indicated that the CAH claims data may have a more complete report of CAH spending than the CAH cost report data. Finally, we would need to use CAH claims data to estimate prospective Medicare spending for CAHs. CAH claims data is the only payment data source that allows service-specific payment rates to be linked to individual services, which is necessary to estimate Medicare prospective spending. When comparing data for two different sets of calculations, it is generally preferred to use the same data source for both calculations unless an alternate source is clearly superior. Since we are using CAH claims data to estimate prospective Medicare spending for CAHs, we determined that CAH claims data are the best available resource to fulfill the requirements of section 1834(x)(2)(C)(i)(I) of the Act to determine the amount of Medicare payments to all CAHs in CY 2019.

We proposed to use CAH claims data with service dates in CY 2019 to calculate the actual Medicare spending for CAHs for CY 2019 as required under section 1834(x)(2)(C)(i)(I) of the Act. Our calculation of CAH Medicare spending will include CAH claims data for inpatient hospital services, inpatient rehabilitation services, inpatient psychiatric services, outpatient hospital services, and skilled nursing services including both hospital-based and swing bed services. As discussed above, we interpret the references to the year 2019 in sections 1834(x)(2)(C)(i) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) because, in the absence of language implicitly or explicitly denoting the year as fiscal, we believe calendar year is the most logical reading. Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the CY. Therefore, we are using CY 2019 CAH claims data to align with our interpretation of the statute that references to the year 2019 are for the calendar year, and to avoid unintended discrepancies by combining calendar year and fiscal year data. Once we identify the claims that

we will use for the calculation, we will calculate the total CAH Medicare spending for CY 2019 by getting the total of the provider payment, coinsurance amounts, and deductible amounts for all of the claims. We proposed to codify the calculation of total CAH Medicare spending in CY 2019 to create the monthly facility payment for CY 2023 under 42 CFR 419.92(b)(1)(i).

Comment: Multiple commenters wanted to know whether the amount calculated for total Medicare CAH spending in CY 2019 from CAH claims data included data of any Medicare cost report settlements.

Response: The amount calculated for total Medicare CAH spending came from CAH claims data which does not have Medicare cost settlement data. Data on Medicare cost settlements only is found through Medicare cost reports. However as discussed in this section, we compared CAH claims data and Medicare cost report data for CY 2019 and found that the CAH claims data reported more than $450 million in Medicare spending than the Medicare cost report data, and the CAH claims data identified 42 more CAHs for CY 2019 than the Medicare cost report data. These findings indicate the CAH claims data are more complete than the Medicare cost report data even though the CAH claims data do not have cost settlement data.

Comment: Commenters agreed with our decision to use 100 percent Medicare claims data to calculate the Medicare CAH spending amount and the estimated prospective payment amount for CY 2019.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing this proposal without modification. We will use CAH claims data with service dates in CY 2019 to calculate the actual Medicare spending for CAHs for CY 2019. Our calculation of CAH Medicare spending will include CAH claims data for inpatient hospital services, inpatient rehabilitation

services, inpatient psychiatric services, outpatient hospital services, and skilled nursing services including both hospital-based and swing bed services. As discussed above, we interpret the references to the year 2019 in sections 1834(x)(2)(C)(i) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the calendar year. We will calculate the total CAH Medicare spending for CY 2019 by including the total of the provider payment, coinsurance amounts, and deductible amounts for all of the claims. We will codify the calculation of total CAH Medicare spending in CY 2019 to create the monthly facility payment for CY 2023 under 42 CFR 419.92(b)(1)(i).

c. Methodology to Estimate the Projected Prospective Medicare Payment for CAHs for CY 2019

Section 1834(x)(2)(C)(i)(II) of the Act directs CMS to use "the estimated total amount that the Secretary determines would have been paid under this title to such hospitals in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year" as part of the calculation used to determine the monthly facility payment that each REH will receive in 2023. The statute clearly directs us to use policy and payment rules from the IPPS, the IRF-PPS, the IPF-PPS, the OPPS, and the Skilled Nursing Facility PPS (SNF PPS) as they applied in CY 2019 to determine the projected prospective Medicare payment for CAHs for CY 2019.

To determine the estimated prospective Medicare payment that CAHs would have received for CY 2019, CMS will need to use data reflecting the Medicare-covered services rendered by CAHs in CY 2019. However, the statute does not specify what data source should be used for generating this estimation. We researched this issue and determined that CAH claims

would be the only resource available to estimate projected prospective payment as directed by section 1834(x)(2)(C)(i)(II). We are aware of no other data sources that report individual services received by Medicare beneficiaries in CAHs, and the amounts paid to CAHs for those services, that could be used to estimate projected prospective payment for Medicare CAH services. To estimate Medicare CAH spending if CAHs were paid on a prospective basis, we therefore proposed to use CAH claims for inpatient hospital, inpatient rehabilitation, inpatient psychiatric, skilled nursing facilities, and outpatient hospital services. We also proposed to include services and items that are paid through other payment subsystems including clinical lab services; physician services; ambulance services; parenteral and enteral nutrition services; durable medical equipment, prosthetics/orthotics; and supplies; and vaccines and Medicare Part B drugs if those services and items are reported on an inpatient CAH claim, an outpatient CAH claim, or a skilled nursing CAH claim. We proposed to model prospective Medicare payment for CAHs by processing the CAH claims data through the IPPS, IRF-PPS, IPF-PPS, OPPS, or SNF-PPS in a test environment as appropriate following the detailed methodologies described in either Section XVIII.A.5.c.(1) of the proposed rule for all claims except for skilled nursing facility claims or Section XVIII.A.5.c.(2) of the proposed rule for skilled nursing facility claims.

In response to our request for information in the CY 2022 OPPS/ASC proposed rule, which discussed REH payment policies (86 FR 42288 through 42289), MedPAC expressed concerns that, since CAHs are paid based on procedure cost for inpatient hospital services, they have less incentive to fully document a patient's comorbidities than if the inpatient hospital services were paid prospectively where only documented diagnoses can generate payment for a provider. MedPAC was concerned that if the claims used to document CAH inpatient hospital

services do not fully report all relevant patient diagnoses, the amount of projected Medicare prospective payment assigned to CAHs under the IPPS could be underestimated, which would cause the monthly REH facility payment to be larger than the amount that would be paid if CMS made this calculation using a projected Medicare prospective payment that more accurately reflected all relevant diagnoses of patients that received inpatient hospital services from CAHs assuming CAHs have the same distribution of reported primary diagnoses as hospitals receiving prospective payment.[314]

However, we had concerns about adopting a methodology that assigns additional diagnoses for CAH inpatient hospital claims so that these claims are consistent with the distribution of reported primary diagnoses for hospitals receiving prospective payment. The relative health levels of CAH patients compared to patients of hospitals receiving prospective payment would be needed to be able to confirm MedPAC's hypothesis that CAH inpatient hospital claims may be missing some primary diagnosis information because the information is not required for CAHs to receive full payment for the services they render.

As discussed in the proposed rule, we did not have immediately available data describing in aggregate whether Medicare patients receiving care at CAHs are healthier, less healthy, or have a similar level of health compared to Medicare patients receiving care in facilities receiving prospective payment. Also, it would not be feasible to gather these data before the implementation of the REH provider type. Obtaining such data would likely involve identifying a representative sample of the patients of CAHs and hospitals receiving prospective payment to determine if there are similar or different distributions of patients based on health status, age, income, and race, which is beyond the scope of this rulemaking process. Therefore, when

[314] Medicare Payment Advisory Commission. September 10, 2021. Comment Letter. https://www.medpac.gov/wp-content/uploads/2021/10/09102021_OPPS_ASC_2022_MEDPAC_COMMENT_SEC.pdf . Accessed April 4, 2022.

calculating the projected prospective Medicare payment for CAHs, we did not propose to adjust the distribution of reported primary diagnoses on the CAH inpatient hospital claims to reflect the distribution of reported primary diagnoses for hospitals receiving prospective payment.

Another issue with relying on inpatient hospital and outpatient hospital CAH claims to estimate the prospective Medicare payment that CAHs would have received in CY 2019 is that these claims do not report the Medicare supplemental payments that hospitals receive through the inpatient and outpatient prospective payment systems. Supplemental payments include IPPS new technology payments, outlier claims payments, clotting factor payments, indirect medical education (IME) payments, disproportionate-share hospital (DSH) payments, including uncompensated care payments under section 1886(r) of the Act, low-volume hospital payments, hospital value-based purchasing program (VBP) payments, and hospital readmissions reduction program (HRRP) adjustments. However, to accurately model how much CAHs would have received if they had instead been paid for applicable services under the inpatient and outpatient prospective payment systems, as provided by section 1834(x)(2)(C)(i)(II) of the Act, we must estimate the various supplemental payments that CAHs would have received under these prospective payment systems.

We therefore proposed, in addition to medical claims service data, that CAH payment information used to calculate the projected Medicare prospective payment for CAHs include IPPS new technology payments, outlier claims payments in both the IPPS and the OPPS, clotting factor payments, indirect medical education (IME) payments, DSH payments, uncompensated care payments, and low-volume hospital payments. We chose these supplemental payments because these payments are used to determine the payment amount for claims in either the IPPS or the OPPS.

We are able to estimate new technology add-on payments, outlier payments, and clotting factor payments from the existing CAH claims data.

For IME and DSH adjustments, CAHs generally do not have up-to-date entries in the Provider Specific File. Therefore, the IME and DSH adjustments would almost always be zero in the actual calculation. We estimated an aggregate projected prospective payment amount for CAHs, and therefore, we did not need to calculate IME and DSH for each individual CAH. Instead, we estimated an aggregate amount of IME and DSH spending for all CAHs. Our proposed approach was the following:

- First, identify all IPPS hospitals that are classified as rural and calculate the average percentage of additional DSH payment and the average percentage of IME payment for these rural hospitals. We use rural IPPS hospitals as a proxy to estimate the percentage of additional DSH payment and the average percentage of IME payment. Rural IPPS hospitals are more likely to have complete and timely data to allow the calculation of DSH and IME payments than CAHs, because rural IPPS hospitals need to report their data to receive payment. CAHs, where all services are paid at 101 percent of cost, do not have an incentive to report data to generate DSH and IME payments.
- Second, for each CAH, find the closest IPPS hospital to that CAH, even if the IPPS hospital is located in an urban area, and link the additional DSH payment percentage and additional IME payment percentage of the nearby IPPS hospital to the CAH.
- Finally, average the overall rural IPPS DSH payment percentage and IME payment percentage with the modelled DSH payment percentage and IME payment percentage for each individual CAH. These individual average additional DSH and IME payments for each CAH can be aggregated to get a national estimate of DSH and IME spending for CAHs.

We used the methodology described in the CY 2019 IPPS/LTCH PPS final rule to estimate the low-volume hospital adjustment for CAHs (83 FR 41399). For discharges occurring in FYs 2019 through 2022, the low-volume hospital payment adjustment was determined using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges (both Medicare and non-Medicare discharges) to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

For uncompensated care payments, we used a similar approach to the approach we have described earlier in this section for calculating estimated DSH and IME payments for CAHs. The difference was that, for uncompensated care payments, we estimated the share of uninsured patients in each CAH receiving uncompensated care based on a nearby IPPS hospital and adjusted by the average share of uncompensated care patients for all rural IPPS hospitals. These calculations will be performed in addition to calculating the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. We then aggregated the estimated uncompensated care payments for individual CAHs into a national estimate and included that estimate in the CAH estimated projected prospective payment amount.

We also considered modelling hospital value-based purchasing program (VBP) payments, hospital readmissions reduction program (HRRP) adjustments, and hospital-acquired condition (HAC) reduction program. However, we identified no feasible way to estimate these adjustments for either individual CAHs or for all CAHs in aggregate. These payments are made based on the actions of individual hospitals, and there are no trends regarding these payments

based on whether the hospital is located in a rural or urban area or on the size of the hospital. CAHs do not participate in the VBP, HRRP, or HAC reduction program themselves. So, the only way to model these payments would be to identify trends in comparable hospitals. Since there are no payment trends with the VBP, HRRP, and HAC reduction program, we decided to not include these adjustments in the estimate of projected prospective payment for CAHs.

We proposed to codify our proposal to estimate the prospective spending for CAHs in 2019 under 42 CFR 419.92(b)(1)(ii).

(1) Detailed Methodology to Estimate CY 2019 Prospective Payment for CAHs for Inpatient Hospital and Outpatient Hospital Services

In the proposed rule we provided a detailed methodology using inpatient hospital and outpatient hospital CAH claims and estimated supplemental payments to estimate the projected Medicare prospective payment for CAHs for inpatient hospital and outpatient hospital services. For more detailed information regarding the methodology for estimating the projected aggregate prospective payment for inpatient and outpatient CAH services, please refer to the supplementary document "Calculation of Rural Emergency Hospital (REH) Monthly Additional Facility Payment for 2023" on the CMS website (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices). That proposed methodology included the following steps:

Step 1: CAH Inpatient Prospective Payment (IPPS) Calculation

Preparing Inpatient Claims for CAHs:

- Identify CAH inpatient hospital claims by using the provider CCN number.
- Exclude Medicare Advantage encounter claims and claims where Medicare is not the primary payer from the analysis file.

- Feed CAH claims through MS-DRG grouper software to assign MS-DRG code. If the DRG code field on the claim is empty, take the grouper-assigned MS-DRG code as input to calculate payment. Otherwise, take the claim MS-DRG code as input.

- Group CAH claims that have the same Provider CCN, Admission Date, and Beneficiary ID combination into inpatient stays.[315] Take the benefit exhaust date (if present and earlier than discharge date) or discharge date of the last claim in the grouping as the discharge date of the stay. Take the calendar year of the stay discharge date as the calendar year of the stay (and claims making up the stay).

- Identify paid CAH stays by checking if there is at least one paid claim (Type-of-Bill not being "110") within the stay. The non-paid stays or non-discharging claims will be assigned zero payment, and the discharging claim (last claim) will be assigned total PPS payment for the stay.

Calculating PPS Payment for Each Component

The Medicare PPS payment includes the components described in the following sections.

1. DRG Payment

DRG payment is calculated as the sum of operating base rate and capital base rate multiplied by DRG weight and Transfer Fraction and their respective geographic adjustment factor.

- The **operating** and **capital base rates** and **DRG weight** are taken from the relevant Final Rule/Correction Notice for either FY 2019 or FY 2020;

- **Transfer Fraction** is calculated by the covered days of stay and the Geometric **Mean Length of Stay** of the DRG code, per post-acute-care transfer adjustment policy;

[315] PPS payment is made at the stay level instead of the claim level, that is, there will be up to one final claim per inpatient stay. CAHs can split-bill an inpatient stay, that is, multiple claims that make up one stay can have positive payment. In order to calculate PPS payment for CAH claims, stay grouping is necessary

- **Operating geographic adjustment factor** is calculated as the weighted sum of wage index and operation cost-of-living adjustment, the weights being the labor share and one minus labor share;
- **Capital geographic adjustment** for inpatient hospital services is the wage index raised to the power of 0.6848[316], multiplied by capital cost-of-living adjustment;
- **Wage index** is taken from the CMS provider wage index file or impact file. If not found, take wage index from CBSA wage index file or inpatient provider specific file;
- The **covered length of stay** is calculated as the maximum of utilization days and cost report days. If either is 0, take the discharge date minus admission date plus one as the covered days.

2. New Technology Add-On Payments

- Check the applicable relevant Diagnosis, Procedure, and Drug code on the claim to determine if the claim is eligible to receive new-tech add-on payment.
- Calculate the new-tech payment as the maximum amount for the new-tech or the operating loss multiplied by the new-tech factor, whichever is smaller.
- The operating loss is defined as operation cost minus operating DRG payment (defined in the "DRG Payment" section above).
- Perform New-Tech add-on calculation for all applicable new technologies found on claim and sum all eligible New-Tech add-ons as total new-tech add-on.

3. *Outlier Payments*

- Calculate outlier payment as the excess cost over outlier threshold multiplied by the cost sharing factor. **Cost** is defined as the sum of operating cost and capital cost;

[316] This value is set by statute and is the same value every year.

- **Operating cost** is estimated by total covered charges multiplied by operating cost-to-charge ratio;
- **Capital cost** is estimated by total covered charges multiplied by capital cost-to-charge ratio, divided by wage index of provider raised to the power of 0.6848.

4. Clotting Factor Payments

- Calculate the clotting factor payment as the multiplication of revenue unit of clotting factor line and the clotting factor payment rate from the Part B drug ASP file.

5. Adjusting PPS Payment

The following sections describe adjustments to the payment calculation. This methodology includes Disproportionate Share Hospital (DSH) payment, Uncompensated Care Payment (UCP), Indirect Medical Education (IME) payment, and Low-Volume Adjustment (LVA) payment. Performance-based payment adjustments, such as Value-based Purchasing, Hospital Readmission Reduction Program, and Hospital-Acquired Condition Reduction Program, are not included. These performance programs typically exclude CAHs and are of smaller magnitude than IME, DSH, UCP and LVA. As stated previously, there are no payment trends with the VBP, HRRP, and HAC reduction program in the rural IPPS hospital data, and we decided to not include these adjustments in the estimate of projected prospective payment for CAHs.

a. Disproportionate Share Hospital (DSH) and Uncompensated Care Payment (UCP)

The DSH payment adjustment and UCP are both provider-specific add-on payments for IPPS claims. In order to apply these two adjustments to CAHs, we must assess how they are calculated for IPPS hospitals. DSH is a percentage-based adjustment to the IPPS DRG payment that is determined by the sum of: (1) the percentage of Medicare inpatient days attributed to

patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. UCP is determined by the percent of individuals under 65 who are uninsured, and hospitals' amounts of uncompensated care. These calculations are performed in addition to calculating the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but bot Medicare Part A. All of the factors used in determining DSH/UCP are ultimately determined by the demographics of the patient populations hospitals serve. Operationally, CMS collects and calculates these factors from hospitals' cost report data from prior years. If CAHs' cost report data were as complete and timely as that of IPPS hospitals, DSH and UCP could be calculated for CAHs in the same way. However, because CAHs are reimbursed based on reasonable cost, they do not have the same incentives to complete their cost reports as IPPS hospitals. Because of the data availability and validity concerns, we did not propose to calculate DSH/UCP directly from cost report data.

To simplify the calculations, define the DSH UCP ratio as the ratio of a hospital's total DSH and UCP payment amount over its core payment (i.e., inpatient hospital DRG payment before the inclusion of supplemental payments) for 2019. The goal is to calculate a reasonable DSH UCP ratio for CAHs. Starting from the premise that DSH/UCP are determined by the demographics the hospitals serve, we take the following steps:

- Select IPPS hospitals that are located in rural areas.
- For each CAH, identify the IPPS hospital that is closest based on distance from the CAH.

- Identify the closest rural IPPS hospital and then calculate the average DSH UCP ratio for that hospital.

As a validation, we run a linear regression model that predicts an IPPS hospital's DSH UCP ratio using urban/rural indicator, the percentage of population below the poverty line (at zip code level, obtained from American Community Survey) and the percentage of dually enrolled inpatient beneficiaries (calculated from claims and enrollment data). Then, apply the parameter estimates of the model to the CAHs (i.e., out of sample prediction) and calculate the average predicted DSH UCP ratio. The results show all the covariates are significant predictors of DSH UCP ratio. Furthermore, the validation produces very similar DSH UCP ratios for CAHs as the proposed method.

After we calculate and validate the DSH UCP ratios for the CAHs, we multiply the ratios by the core payment amount for each CAH to determine the estimate amount of DSH and UCP payments the CAH would receive. We then add the DSH and UCP payment amounts to the estimated prospective payment for the CAH.

b. Indirect Medical Education (IME)

The IME payment is a provider-specific add-on payment for IPPS claims. The IME adjustment factor is determined by a hospital's ratio of residents to beds. Operationally, CMS collects and calculates the adjustment from hospitals' cost report data from prior years. Because of the data availability and validity concerns (stated above), we did not propose to calculate IME payment directly from cost report data.

Instead, we proposed to define the IME ratio as the ratio of a hospital's total IME payment over its core payment (i.e. DRG payment) for 2019. The goal is to calculate a reasonable IME ratio for CAHs. We take the following steps:

- Select IPPS hospitals that are located in rural areas.
- For each CAH, identify the IPPS hospital that is closest to it.
- Identify the closest rural IPPS hospital and then calculate the IME ratio for the rural IPPS hospital for 2019.

As validation, run a linear regression model that predicts an IPPS hospital's IME ratio using urban/rural indicator and the average IPPS DRG weight per discharge (calculated from claims data). The urban/rural indicator is assumed to be correlated to the likelihood of a hospital to run an approved graduate medical education (GME) program and attractiveness of such program to medical school graduates; the average IPPS DRG weight is a measurement of level of complexity of inpatient care a hospital provides and is assumed to be correlated to the size of and need for GME. The results show both urban/rural indicator and average IPPS DRG weight per discharge are significant predictors of IME ratio.

c. Low Volume Adjustment

The Low-Volume Hospital Payment Adjustment is an additional payment adjustment based on the per discharge amount (including capital, DSH, IME, and outlier payments) to the qualifying IPPS hospitals during CY 2019. For discharges occurring in FYs 2019 through 2022, the qualifying criteria are: (1) the hospital is more than 15 road miles from another subsection (d) hospital, and (2) the hospital has less than 3,800 total discharges during the fiscal year. If these qualifying criteria for the Low-Volume Hospital payment adjustment were also applied to CAHs, they meet the first criterion, as CAHs must be located either more than 35-miles from the nearest hospital or more than 15 miles in areas with mountainous terrain or with only secondary roads. We then check the number of total discharges from each CAH to determine if the CAH

has less than 3,800 total discharges. The adjustment factor is calculated using the following formula for hospitals between 500 and 3,800 total discharges:

Low-Volume Hospital Payment Adjustment = 0.25 – [0.25/3300] X (number of total discharges – 500) = (95/330) – (number of total discharges / 13,200)

If a hospital has less than 500 total discharges, then the low-volume hospital payment adjustment is 25 percent. The number of total discharges of CAHs is obtained from Hospital Cost Report Data, Worksheet S-3, Part I, Line 14, and Column 15.

6. Other Adjustments

- Device credit (if applicable) is deducted from the claims payment.
- Sequestration:
  - ++ Subtract the actual coinsurance and deductible amount from PPS payment, and
  - ++ Remove 2 percent as sequester reduction.
- Subtract the sequester reduction from the PPS payment.

<u>Step 2: CAH Inpatient Rehabilitation Facility (IRF) and Inpatient Psychiatric Facility (IPF) PPS Payment Calculation</u>

- IRF PPS rules that applied in FY 2019 or FY 2020 based on date of service to claims furnished by the rehabilitation units of CAHs.
- IPF PPS rules that applied in FY 2019 or FY 2020 based on date of service to claims furnished by the psychiatric units of CAHs.
- The Rehabilitation and Psychiatric Units of CAH are actually paid by IRF PPS and IPF PPS payment rules; therefore, we calculate their PPS payment by summing up their actual payment.

<u>Step 3: Outpatient PPS Payment Calculation</u>

Preparing Outpatient Claims for CAHs

Identify CAH outpatient hospital claims. Feed CAH claim lines to the IOCE grouper software to assign Status Indicator, Ambulatory Payment Classification (APC) code,[317] and Discount Formula Indicator.

Calculating OPPS Payment for CAHs

• Flag claim lines that have OPPS payable status indicator.[318] For claim lines that have APC assignment, obtain relevant APC payment rate from the OPPS Final Rule/Correction Notice data files. Apply the following APC adjustments, as applicable:

++ Device Credit, taken from value code "FD", is deducted from payment;

++ Off-campus Provider Based Department deduction indicated by modifier PO;

++ Computed tomography reduction (indicated by modifier CT and HCPCS code);

++ Reduction of X-rays taken with film (indicated by modifier FX);

++ 22.5 percent ASP rate reduction for Part B drugs (indicated by modifier JG and status indicator K).

• Adjust APC payment rate with OPPS discount factor based on the Discount Formula Indicator.

• Multiply adjusted APC payment rate with the number of revenue units to get APC payment.

• Adjust APC payment with geographic adjustment factor.

++ Geographic adjustment factor is the sum of labor share multiplied by wage index and non-labor share;

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[317] Since CAH outpatient claims have type of bill "85x", the IOCE software will not assign status indicator or APC code. In order to use the software properly, change the type of bill to "131" (the same bill type OPPS hospitals use to bill) before feeding the claims to the software.

[318] First digit of status indicator to be "F", "G", "H", "J", "K", "L", "P", "Q", "R", "S", "T", "U", "V", and "X".

++ Wage index is determined by the wage index file, CBSA code, and provider specific record of the provider.

• Calculate line outlier payment by multiplying excess line cost over line multiple threshold with OPPS loss share ratio, if line estimated cost is greater than line multiple threshold and line fixed threshold.

++ Estimate claim line cost by adding line covered charge and charges from packaged services;

++ Line fixed threshold is the line OPPS payment plus the OPPS fix threshold of the calendar year

++ Line multiple threshold is line OPPS payment multiplied by the OPPS outlier factor of the calendar year

• Aggregate claim line level payment to claim level and apply sequester reduction to calculate final PPS payment for CAHs.

Calculating Payment for Other Claim Lines

Calculate payment for other claim lines with applicable fee schedule rules (OPPS Status Indicator "A").

- Clinical Lab Fee Schedule lines.
- Physician Fee Schedule lines.
- Ambulance Fee Schedule lines.
- Parenteral and Enteral Nutrition Fee Schedule lines.
- Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee (DMEPOS) Schedule lines.
- Vaccine and Part B drug lines.

(2) Detailed Methodology to Estimate CY 2019 Prospective Payment for CAHs for Provision of Skilled Nursing Facility Services

We also proposed to use CAH claims to make estimates of the prospective payment amounts for skilled nursing swing bed payments. Under the SNF PPS, facilities are paid a pre-determined daily rate for each day of SNF care for each individual provided services, adjusted by each patient's unique medical needs and diagnoses. In order to calculate PPS payment for CAH claims that were not paid under PPS, we proposed to assign a PPS equivalent daily rate to CAH claims factoring in patient case mix. CAH swing bed claims generally do not have minimum data set (MDS) records (that is, assessment data), which are the critical input to the Grouper software for Resource Utilization Group (RUG)/Patient Driven Payment Model (PDPM) code assignment. Therefore, RUG/PDPM codes for the CAH claims cannot be generated by the RUG/PDPM Grouper software. The RUG codes (which have been phased out of the SNF PPS, to be replaced by the PDPM) are determined mainly by the number of therapy minutes provided or expected to be provided to the beneficiary. However, the therapy minute variable is reported only through the MDS and not recorded on claims. Because of the lack of MDS data, RUG/PDPM rates cannot be directly obtained from the CAH swing bed claims. However, RUG/PDPM rates of CAH swing-bed claims can be predicted by modeling the RUG/PDPM per-diem-rates of claims that were actually paid under PPS rules. Under the statute, the SNF benefit must generally be qualified by a preceding inpatient stay. The information on the qualifying inpatient claim can be used to predict the RUG/PDPM per-diem-rate.

On October 1, 2019, a new case-mix classification model, the PDPM, under SNF PPS began. The use of RUG coding assignments ended, and the use of PDPM coding assignments started. We proposed to apply RUG PPS rules for claims with service dates between January 1,

2019, and September 30, 2019, and we proposed to apply PDPM rules for those with service dates between October 1, 2019, and December 31, 2019. The primary steps to estimate the projected prospective skilled nursing payment for CAHs are as follows:

Step 1: Use the PPS payment calculation formula to estimate payment for skilled nursing facility PPS claims.

Step 2: Process claims using the RUG/PDPM rate prediction model.

Step 3: Use the PPS payment calculation formula to estimate payment for CAH swing-bed claims.

For more detailed information regarding the methodology for each of the steps listed to estimate the aggregate projected prospective payment for CAH skilled nursing services, please refer to the supplementary document "Calculation of Rural Emergency Hospital (REH) Monthly Additional Facility Payment for 2023" on the CMS website.

Comment: Commenters wanted us to clarify whether spending for clinical lab, physician services, ambulance services, parenteral and enteral nutrition, durable medical equipment, prosthetics/orthotics, and supplies, and vaccines and Medicare Part B drugs were included in the reported amount for CAH Medicare spending for CY 2019.

Response: As stated in the CY 2023 OPPS/ASC proposed rule, we included all of the services cited by the commenters, including clinical lab, physician services, ambulance services, parenteral and enteral nutrition, durable medical equipment, prosthetics/orthotics, supplies, vaccines, and Medicare Part B drugs, in the Medicare CAH spending amount for CY 2019, for the calculation of the monthly REH facility payment as provided by section 1834(x)(2)(C)(i)(I). . However, the calculation of the estimated prospective payment for CAHs in CY 2019, as described by section 1834(x)(2)(C)(i)(II), does not mention a different payment methodology for

all of the services identified by the commenters except for Medicare Part B drugs administered in the outpatient hospital setting which are payable in the OPPS when paid prospectively. We interpret the omission of a different methodology to pay for clinical lab, physician services, ambulance services, parenteral and enteral nutrition, durable medical equipment, prosthetics/orthotics, supplies, and vaccines to mean that for the estimate of prospective payment for CAHs in CY 2019, as described by section 1834(x)(2)(C)(i)(II), the payment amount for these services will be same amount as the payment for these services used in the calculation of actual Medicare CAH spending for CY 2019, as described in section 1834(x)(2)(C)(i)(I). In the description of our detailed methodology provided in the CY 2023 OPPS/ASC proposed rule we did not specifically address the effect that these equal payment amounts would have on the calculation of the REH monthly facility payment. We are providing additional detail regarding this aspect of our methodology in this final rule in response to these comments. Specifically, payment for the services noted above will cancel each other out when calculating the REH monthly facility payment, which means the spending on these services will not affect the amount of the REH monthly facility payment.

Comment: Commenters agreed with our decision not to attempt to adjust the CAH inpatient hospital claims to account for potential underreporting of patient co-morbidities on those claims. Commenters also agreed with our statement that there is not readily available data to compare the amount of co-morbidities between CAH inpatient hospital population with the prospective payment inpatient hospital population, and they agreed there was not time prior to the implementation of the REH provider type to obtain this data.

Response: We appreciate the support of the commenters regarding this issue.

Comment: Multiple commenters requested that we include Medicare Advantage (MA) payments in our calculation of CY 2019 Medicare CAH spending and CY 2019 estimated prospective payment for CAHs.

Response: Although we did not explicitly address the treatment of MA payments in the description of the detailed methodology used to generate the monthly facility payment the CY 2023 OPPS/ASC proposed rule, we are providing additional detail regarding this aspect of our methodology in this final rule in response to these comments.

Consistent with section 1834(x)(2)(C)(i) of the Act, CMS was required to determine the monthly facility payment based on the difference between the amount paid under Medicare to all CAHs in 2019 and the amount that would have been paid to CAHs if payment had been made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems. MA payments are payments made by private health plans for the care CAHs provide to Medicare beneficiaries enrolled in Medicare Advantage. Medicare pays a per beneficiary capitation amount to the private health plans which in turn are responsible for paying the CAHs. Medicare Advantage organizations are not required to use the Medicare fee-for-service payment methodology to determine payments to CAHs. Rather, the amount of these payments is based upon the arrangement between the MA organization and the CAH. Thus, the amount of MA payments to CAHs would not be affected by a change in the payment methodology under fee-for-service Medicare. Because the amount of Medicare Advantage payments would be the same for both CY 2019 Medicare CAH spending and for the estimate of CY 2019 prospective payments to CAHs, the Medicare Advantage payments were cancelled out and had no impact on the determination of the REH monthly facility payment.

Comment: Commenters requested that we include payments for professional services made to those CAHs that elected Method II billing.

Response: As noted above, Method II billing is a payment approach available to CAHs, which allows physicians employed at CAHs to assign payment for their professional services to be paid to the CAH instead. The commenters imply that because a CAH receives 115 percent of the MPFS rate for professional services reported using Method II billing, we should include the additional 15 percent of the MPFS payment add-on as a part of the calculation to determine the monthly facility payment. However, since the REH statute only mentions prospective payment systems, we believe it is appropriate to limit the scope of the calculation to services that are paid on a prospective basis. Thus, as with other payment items mentioned in this section, the additional 15 percent payment to the CAH for service billed through Method II would be unaffected whether a CAH received reimbursement at 101 percent of cost or received reimbursement through prospective payment. That means the additional 15 percent payment would cancel out in the calculation to determine the REH monthly facility payment, and would have no impact on the final amount.

Comment: Commenters believe that we failed to reduce the CY 2019 CAH estimated prospective payment amount to account for the fact that CAHs are not subject to the 72-hour rule regarding the conversion of an observational service to an inpatient hospital service while hospitals paid on a prospective basis are subject to this rule.

Response: We acknowledge that the 72-hour rule is part of prospective payment system requirements for both inpatient hospital and outpatient hospital payment. The 72-hour requires that payment for all outpatient services that occur with a 72-hour window of an associated

inpatient service shall be packaged with the cost of the prospectively-paid inpatient hospital service.

An example would be a patient who has an inpatient admission for heart surgery, but 48 hours before their hospital admission received a series of imaging services in the outpatient hospital setting. With at-cost payment at the CAH, the outpatient imaging services would be separately paid along with the inpatient heart surgery. With prospective payment, the outpatient imaging services would be packaged with the DRG payment for inpatient heart surgery. Our current methodology to calculate the CY 2019 prospective payment amount for the REH monthly payment does not package the payment for the outpatient hospital imaging services which increases the prospective payment amount and reduces the amount of the monthly facility payment.

CMS has not identified a feasible approach that could be used to model the extent to which an outpatient service furnished by CAHs within 72 hours of an inpatient admission is an associated service that would be packaged under the 72-hour rule if the CAHs were paid prospectively for inpatient hospital and outpatient hospitals services under the IPPS and OPPS. For example, a diagnostic service closely related to the inpatient service received by a patient is quite likely to be associated with the inpatient service and should be packaged. However, there may be limited information on whether a therapeutic outpatient hospital service within the 72-hour window should be associated with the inpatient admission. We were not able to develop a reliable algorithm that works with CAH claims data to determine whether an outpatient service is admission-related or not. Therefore, we decided not to use the 72-hour rule to adjust the amount of the CY 2019 CAH estimated prospective payment as a part of our calculations for the monthly REH facility payment. Comment: Commenters requested that we clarify and publish our

calculations for projecting supplemental payments under the IPPS and OPPS. Commenters noted that because CAHs are paid based on a cost-basis, their claims do not include supplemental payments that are normally paid under IPPS, such as indirect medical education (IME), disproportionate share hospital (DSH), and uncompensated care payments, and we need to estimate those payments to more accurately reflect the estimated prospective payment amount for CAH providers.

Response: We have proposed a detailed methodology describing how we will model inpatient hospital supplemental payments for prospectively-paid hospitals to generate a more representative estimate of the payment CAHs would receive if these providers were paid on a prospective basis. Our detailed methodology spells out the steps we have taken to calculate the REH monthly facility payment. We reviewed the rules to pay inpatient hospital services on a prospective basis to identify the supplemental payments applied to base service payment rates including low-volume adjustments, quality measures reporting, DSH and uncompensated care payments, and the use of electronic health records. Commenters provided multiple suggestions on how our detailed methodology could be improved. These suggestions will be addressed in the upcoming comments in this section. We have provided the final amount of the monthly facility payment along with the aggregate payment amounts for both Medicare CAH spending for CY 2019 and the estimated prospective payment amount for CAHs for 2019, which allows interested parties to compare the final results of their analyses with our final results. Estimates of the inpatient hospital supplemental payments are included in the total estimated prospective payment amount for CAHs.

Comment: Commenters stated that it appears that we assumed all CAHs would have met the Hospital Inpatient Quality Reporting (IQR) Program. The commenters feel that it would be

appropriate to assume all CAHs would be subject to the hospital inpatient quality reporting reduction because CAHs are not covered by the quality reporting requirements, and would not be familiar with how to submit the reports.

Response: We do not believe it would be appropriate to assume CAHs would not comply with the IQR program because CAHs were not subject to the Quality Reporting program. The share of IPPS hospitals that are subject to the quality reporting program penalty is low, and we anticipate that CAHs would have had a similar level of compliance to IPPS hospitals for the Quality Reporting program had they been subject to the program. We assume that the number of CAHs that would fail to comply with the Quality Reporting program would be very low and the reduction in CY 2019 CAH estimated prospective payment would not be significant enough to have a substantial impact on the REH monthly facility payment. Therefore, we believe it is more appropriate to assume CAHs would comply with the Quality Reporting program requirements, and would not experience a reduction in their estimated prospective inpatient hospital payments.

Comment: Commenters noted that we did not consider reducing the CY 2019 CAH estimated prospective payment to account for payment reductions associated with the Promoting Interoperability Program. The commenters support assuming that every CAH would not be a meaningful electronic health records user and would be subject to a 2 percent decrease in the amount of their inpatient hospital payment if receiving prospective payment.

Response: The Promoting Interoperability Program is an initiative to incentivize hospitals to be meaningful electronic health records (EHR) users. Providers whose EHR systems do not meet the requirements of the Promoting Interoperability Program are subject to a 2 percent decrease to their inpatient hospital payments. We disagree with the commenters' recommendation to update our proposed calculation of the REH monthly facility payment based

on the assumption that every CAH would not be a meaningful electronic health user and would be subject to the Promoting Interoperability Program 2 percent decrease to their projected inpatient hospital payments. It is challenging to anticipate CAH behavior regarding meaningful use of electronic health records when these providers are not subject to this performance requirement. However, we believe that if CAHs relied on prospective payment to pay for inpatient hospital services, most CAHs would comply with the meaningful use requirements for electronic health records as providers generally try to comply with incentive programs to avoid payment penalties. In addition, CAHs would be more likely to qualify for existing hardship exemptions to the payment reductions than subsection (d) hospitals because CAHs are small providers with limited financial resources. These hardship exemptions are available where an eligible facility can show that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for reasons including the facility's use of decertified EHR technology, insufficient internet connectivity, and extreme and uncontrollable circumstances.[319] These hardships are more likely to occur for CAHs than most hospitals because their limited financial resources make it more challenging for CAHs to obtain up-to-date EHR technology. Also, internet connectivity issues are more common in rural areas where CAHs are located. We assume that the number of CAHs that would fail to comply with the Promoting Interoperability Program would be very low and the reduction in CY 2019 CAH estimated prospective payment would not be significant enough to have a substantial impact on the REH monthly facility payment. For these reasons, we believe that it is more reasonable to assume that all CAHs would comply with the meaningful use requirements for electronic health records for our calculations for the monthly facility payment.

[319] "Medicare Promoting Interoperability Program Frequently Asked Questions (FAQs)." Centers for Medicare and Medicaid Services. Accessed October 20, 2022.

Comment: Commenters wanted us to confirm that we did not reduce the DRG payment if the beneficiary was transferred to a swing bed and that the transfer fraction was applied only for those DRGs to which the post-acute transfer adjustment policy applies.

Response: We can confirm that the transfer fraction was applied only for those DRGs to which the post-acute transfer adjustment policy applies; we checked if the discharge status code and DRG on the claim satisfy the condition of the adjustment.

Comment: Commenters stated that the low-volume adjustment should not apply to CAHs that are within 15 miles of another provider, regardless of whether that facility is presently a CAH or subsection (d) hospital. They encouraged CMS to identify the CAHs that do not meet the criteria and eliminate the low-volume adjustment applied to those CAHs.

Response: As the commenters note, our proposed methodology does not consider whether a CAH is within 15 miles of another CAH or subsection (d) hospital, and thus under the proposed methodology the low-volume adjustment was applied to all CAHs, regardless of whether the facility is located within 15 miles of another provider. It was our understanding is that few CAHs are likely to be within 15 miles of another hospital provider because in order for a hospital to become a CAH, a provider has to be more than 35 miles away from another hospital. In response to the commenters' request, we attempted to identify CAHs that were less than 15 road miles from another CAH or subsection (d) hospital. We found that some CAHs were within 15 road miles from other CAHs or subsection (d) hospitals and not eligible for the low-volume adjustment. Based on our analysis, we will revise our estimate of the low-volume adjustment to exclude CAHs that do not meet the 15 road miles distance requirement. This revision to our detailed methodology will increase, by a few thousand dollars, the REH monthly facility

payment. We analyze the financial impact of this change in detail in section XVIII.A.5.e. of this final rule with comment period.

Comment: Commenters raised concerns with our proposal to project the amount of DSH and uncompensated care add-on payments CAHs would have received if paid prospectively, noting that factors other than demographics determine the amount of DSH and uncompensated care. They recommend excluding the amount of DSH and uncompensated care add-on payments from the estimated prospective payment amount since there is not a reliable method to make projections. They believe only small rural hospitals that receive prospective payment and have less than 50 beds with a geographic location assignment in a rural area should be identified for this purpose.

Response: We acknowledge that interested parties are concerned about possible distinctions between rural subsection (d) hospitals versus CAHs for purposes of projecting the amount of DSH and uncompensated care add-on payments that CAHs would receive if they were paid prospectively. As discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44784), our proposed methodology includes elements intended to accurately reflect the amount of such add-on payments that CAHs would receive. We identified the subsection (d) hospital that was closest to an individual CAH and determined its ratio of DSH and uncompensated care payments to core inpatient hospital payments excluding any supplemental payments. We also identified the closest subsection (d) rural hospital to an individual CAH and determined the rural hospital's ratio of DSH and uncompensated care payments to core inpatient hospital payments excluding any supplemental payments. Then we averaged the two percentages to estimate the share of DSH and uncompensated care payments for the CAH. This calculation is repeated for all CAHs throughout the United States to generate a national average percentage of DSH and uncompensated care

payments for CAHs. Additionally, to further corroborate the proposed approach, Acumen also created a model that predicts the percentage of a prospective payment hospital's DSH and uncompensated care from its DRG payment. Three predictors were included in the model:

- A hospital's rural/urban indicator based on actual geographic location;
- The percentage of population below poverty line of the hospital's zip code area; and
- The percentage of the hospital's dually eligible Medicare beneficiaries.

The three coefficients are all statistically significant. A location in a rural area reduces the amount of DSH and uncompensated care a hospital receives. According to MACPAC, only 11.5 percent of DSH spending in 2016 was for rural hospitals.[320] Having a larger percentage of the population of a hospital's zip code area living below the poverty level increases the amount of DSH and uncompensated care a hospital receives. Likewise, having more dually eligible Medicare beneficiaries receive care at a hospital increases the amount of DSH and uncompensated care the hospital receives. Both of these variables are predictive of the share of people in a community who may lack the resources to pay for their medical care, and where hospitals would need more DSH and uncompensated care payments to make up for lost patient revenue. When applying this model to CAHs, the projected DSH and uncompensated care payment is very similar to the result based on proximity to providers in rural areas. Based on this analysis, we believe that the approach described in the proposed rule will produce a reasonably accurate projection of the amount of DSH and uncompensated care add-on payments that CAHs would have received if they had been paid prospectively in CY 2019.

[320] Report to Congress on Medicaid and CHIP. "Chapter 5: Annual Analysis of Disproportionate Share Hospital Allotments to States". Medicaid and CHIP Payment and Access Commission. March 2021. Accessed October 20, 2022.

Comment: Commenters stated that no IME add-on payments should be included for any CAH that did not have a residency program in CY 2019. Commenters believe that cost report data can be used to identify which CAHs had IME payments in 2019.

Response: As we discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44784), cost report data are not a reliable source to determine IME spending by CAHs. CAHs are paid by reasonable cost and there is limited incentive for CAHs to report their medical education spending. To address issues with the completeness of CAH cost report data for IME spending, we used IME spending from nearby rural subsection (d) hospitals to model CAH IME spending. Similar to our approach to DSH and uncompensated care payments, we calculate an estimate share of IME spending for each individual CAH. We then repeat this calculation for all CAHs throughout the United States to generate a national average percentage of IME payments for CAHs.

Even though IME add-on payment is determined by the size of a residency program, rural/urban status and proximity to CAHs are highly associated with the percentage of IME payments that subsection (d) hospitals receive. CAHs are rural hospitals and few rural hospitals offer medical education programs. In the comparable group of rural subsection (d) hospitals, less than 10 percent of hospitals receive any IME payment. In other words, the projected IME add-on payment already factors the concerns of the commenters and treats most CAHs as if they do not receive IME payment. Our model of CAH IME spending estimates that IME spending is less than 1 percent of overall CAH spending.

Comment: Multiple commenters supported our decision not to require CAHs to submit additional information in order to help us project payments for skilled nursing facilities such as

the Minimum Data Set (MDS) 3.0 assessments for their SNF swing bed patients. The commenters agreed with our proposal to predict per-diem rates of claims through modeling.

Response: We appreciate the support of our proposal by the commenters.

After consideration of the public comments we received, and for the reasons discussed, we are implementing most of our proposals without modification. We modified our proposal regarding how we model the use of the low-volume adjustment to estimate the CY 2019 estimated prospective payment for CAHs to exclude from the low-volume adjustment any CAH within 15 road miles of another CAH or subsection (d) hospital. We use the detailed methodology described in this section to calculate the estimated prospective payment amount for CAHs for the REH monthly facility payment calculation.

d. Determination of the total number of CAHs in CY 2019

We proposed to use the CAH claims data to determine the total number of CAHs in CY 2019, which is required to determine the amount of the monthly facility payment pursuant to section 1834(x)(2)(C)(ii) of the Act. We proposed that the number of CAHs in 2019 should be calculated as the distinct count of CAH CMS certification numbers (CCNs) that have any paid Medicare FFS claims from January 1, 2019 to December 31, 2019, based on service date. We proposed that the number of distinct CAH CCNs includes providers that may have either been open or closed during CY 2019. We proposed that CAHs that were open for only part of the year in CY 2019 will be reported as full providers in our count of distinct CAHs and will not be weighted in the count by the portion of the year they were open. Section 1834(x)(2)(C)(ii) of the Act provides that we use the total number of CAHs in 2019 and does not make any provision for counting CAHs only open for a part of the year differently from CAHs open the entire year. We proposed to check the CCNs to ensure that if a CAH reports claims data from rehabilitation,

psychiatric, skilled nursing facility or swing bed units in addition to the primary hospital unit, that only one facility is included in the count of total CAHs. We proposed to codify our methodology to calculate the number of CAHs in CY 2019 under 42 CFR 419.92(b)(1)(iii).

Comment: Commenters requested that we adjust the count of the number of CAHs to remove any CAHs that either opened or closed during CY 2019 and do not have a full year of data. Commenters are concerned that including CAHs that were only open for a part of 2019 when the monthly facility payment calculation is based on an annual payment total will lead to an REH facility payment that may underestimate monthly costs.

Response: As noted above, section 1834(x)(2)(C)(ii) of the Act provides that CMS use the total number of CAHs in 2019 to calculate the monthly facility payment. In the proposed rule, we therefore proposed to determine the number of CAHs in 2019 for purposes of the monthly facility payment calculation described in 1834(x)(2)(C) by tallying the total number of CAH CMS certification numbers (CCNs) that have any paid Medicare FFS claims from January 1, 2019 to December 31, 2019, based on service date. As the commenters note, this approach includes any CAHs that operated during 2019 in the total described in section 1834(x)(2)(C)(ii), including such facilities that only operated for part of the year. This approach complies with the plain language of the statute which has no special provisions for counting CAHs that opened or closed during 2019. Accordingly, we are finalizing this aspect of our policy as proposed.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal for determining the total number of CAHs in CY 2019, as codified in 42 CFR 419.92(b)(1)(iii), without modification.

e. Calculation of the Monthly REH Facility Payment for CY 2023

As stated above, section 1834(x)(2) of the Act requires an additional facility payment be paid monthly to an REH. For CY 2023, we proposed that this facility payment be determined, per the requirements of the CAA and consistent with our proposed regulation text at 42 CFR 419.92(b)(1), using the following calculation:

Step 1: The total amount of Medicare spending for CAHs in CY 2019 (as described in section 1834(x)(2)(C)(i)(I) of the Act) minus the projected Medicare spending for CAHs in CY 2019 if inpatient hospital services, outpatient hospital services, and skilled nursing services had been paid on a prospective basis rather than at 101 percent of total cost (as described in section 1834(x)(2)(C)(i)(II) of the Act) and calculated according to the methodology described above.

Total Amount of Medicare Spending for CAHs in CY 2019: $12.08 billion

Total Projected Amount of Medicare Spending for CAHs if Paid Prospectively in CY 2019: $7.68 billion

Step1 Difference: $12.08 billion – $7.68 billion = $4.40 billion

Step 2: The difference in Step 1 would be divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual payment per individual REH. The annual payment amount would be divided by 12 to calculate the monthly REH facility payment. Each REH would receive the same facility payment.

Step 1 Difference: $ 4,404,308,465

Number of Medicare CAHs in CY 2019: 1,368

REH Monthly Facility Payment: ($4,404,308,465/ 1,368) / 12 = $268,294

Using this calculation, we proposed that the monthly facility payment for REHs for CY 2023 would be $268,294. We requested public comments on our methodology to determine

the total amount was paid by Medicare to all critical access hospitals in 2019, our methodology to estimate the total amount that would have been paid to CAHs in 2019 for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems, and our overall methodology to calculate the monthly REH facility payment for CY 2023.

Comment: Commenters stated that the low-volume adjustment should not apply to CAHs that are within 15 miles of another provider, regardless of whether that facility is presently a CAH or subsection (d) hospital. They encouraged CMS to identify the CAHs that do not meet the criteria and eliminate the low-volume adjustment applied to those CAHs.

Response: As we stated previously in this final rule, in response to the request of the commenters, we will revise our estimate of the low-volume adjustment to exclude CAHs that do not meet the 15 road miles distance requirement. This revision to our detailed methodology will decrease the estimated prospective payment for CAHs in CY 2019 by $75.1 million and will increase the REH monthly facility payment by $4,573.

Comment: Commenters requested that we include in this final rule more detail regarding our calculations for the monthly REH facility payment for CY 2023. Commenters requested that we report CAH Medicare spending amounts and estimated prospective payment amounts by individual provider categories including: inpatient hospital, inpatient rehabilitation hospital, inpatient psychiatric hospital, outpatient hospital, and skilled nursing facility. Commenters requested we report these spending amounts in addition to the total overall spending amounts for CAH Medicare spending and estimated prospective payments that were reported in the CY 2023 OPPS/ASC proposed rule. The commenters believe that breaking down Medicare spending by

each provider category will help interested parties evaluate our calculations for the monthly facility payment.

Response: In the proposed rule we included a detailed calculation showing the key steps to establish the REH monthly facility payment. We provided the proposed final amount of the monthly facility payment along with the aggregate payment amounts for both Medicare CAH spending for CY 2019 and the estimated prospective payment amount for CAHs for CY 2019. By providing these figures, along with the detailed description of CMS's methodology included in the proposed rule, which further described e how we proposed to calculate Medicare CAH spending and the estimated prospective payment values described in sections 183(x)(2)(C)(i)(I) and (II) of the Act, as well as the additional clarification about specific aspects of CMS's methodology described in this final rule, we believe we are providing sufficient information for interested parties to assess our calculation of the REH monthly facility payment.

Comment: Multiple commenters requested that all REH payments, or at least the REH monthly facility payment, be exempted from sequestration. The commenters state the sequestration cuts are harmful to future REH providers, and play a role in reducing access to hospital care in rural areas.

Response: Consistent with 2 U.S.C. 906(d)(1), sequestration will apply to all REH payments including the monthly facility payment. We note that the application of sequestration to the monthly facility payment is consistent with the application of sequestration to other types of Medicare payments that are not payments for services furnished to a single beneficiary, including GME and uncompensated care payments to hospitals, and shared savings payments under the Medicare Shared Savings Program.

Comment: One commenter suggested that the monthly facility payment should not be a fixed amount. The commenter said the size of the payment should vary based on the size of the REH facility.

Response: The methodology for determining the amount of the REH monthly facility payment provided by the REH statute at section 1834(x)(2)(B) and (C) of the Act provides for CMS to determine a single amount for this monthly payment that shall apply to all REH providers, and makes no provision for CMS to change the amount of the payment based on the size of the provider. Likewise, such an adjustment was not proposed in the proposed rule. Because the commenter's request goes beyond the scope of the proposed framework for calculation of the CY 2023 REH monthly facility payment and is not supported by the REH statute, we are finalizing this aspect of our proposed calculation of the CY 2023 REH monthly facility payment as proposed.

Comment: Multiple commenters supported our proposal for the REH monthly facility payment.

Response: We appreciate the support of the commenters for our policy.

After consideration of the public comments we received, and for the reasons described here and in the proposed rule, we are finalizing our proposed calculation of the monthly REH facility payment for CY 2023 with the modification described here. Specifically, we are modifying our calculation of the monthly REH facility payment for CY 2023 to reflect the change in our detailed methodology used to calculated the estimated prospective payment amount for CAHs in CY 2019, to exclude CAH inpatient services from the low-volume adjustment if a CAH was within 15 road miles of another CAH or subsection (d) hospital.

Our revised calculations of the monthly REH facility payment for CY 2023 are as follows:

Step 1: The total amount of Medicare spending for CAHs in CY 2019 (as described in section 1834(x)(2)(C)(i)(I) of the Act) minus the projected Medicare spending for CAHs in CY 2019 if inpatient hospital services, outpatient hospital services, and skilled nursing services had been paid on a prospective basis rather than at 101 percent of total cost (as described in section 1834(x)(2)(C)(i)(II) of the Act) and calculated according to the methodology described above.

Total Amount of Medicare Spending for CAHs in CY 2019: $12.08 billion

Total Projected Amount of Medicare Spending for CAHs if Paid Prospectively in CY 2019: $7.60 billion

Step1 Difference: $12.08 billion – $7.60 billion = $4.48 billion

Step 2: The difference in Step 1 would be divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual payment per individual REH. The annual payment amount would be divided by 12 to calculate the monthly REH facility payment. Each REH would receive the same facility payment.

Step 1 Difference: $4,479,370,835

Number of Medicare CAHs in CY 2019: 1,368

REH Monthly Facility Payment: ($4,479,370,835/ 1,368) / 12 = $272,866

Using our finalized calculations, the REH monthly facility payment for CY 2023 will be $272,866.

f. Calculation of the Monthly REH Facility Payment for CY 2024 and Subsequent Calendar Years

Section 1834(x)(2)(B) of the Act states that "[t]he annual additional facility payment amount specified in this subparagraph is… for 2024 and each subsequent year, the amount determined under this subparagraph for the preceding year, increased by the hospital market basket percentage increase." Accordingly, we proposed to codify, at 42 CFR 419.92(b)(2), that for CY 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

Comment: Commenters supported our proposal to codify the increase the REH monthly facility payment calculated in CY 2023 by the hospital market basket in subsequent years.

Response: We appreciate the support of the commenters for our proposal.

After consideration of the public comments we received, we are finalizing without modification our proposal to codify at 42 CFR 419.92(b)(2) the calculation of the REH monthly facility payment in CY 2024 and subsequent years based on the value of the preceding year increased by the hospital market basket percentage increase.

6. Preclusion of Administrative or Judicial Review

Section 1861(kkk)(9) of the Act explicitly precludes administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the establishment of requirements by the Secretary under subsection 1861(kkk) of the Act; (2) the determination of payment amounts under section 1834(x) of the Act, including the determination of additional facility payments; and (3) the determination of whether a rural emergency hospital meets the requirements of subsection 1861(kkk) of the Act.

Consequently, we proposed to codify, at § 419.94, the preclusion of administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the determination of whether a rural emergency hospital meets the requirements established by CMS's proposed regulations at 42 CFR part 419, subpart K ("Subpart K"); (2) the determination of payment amounts under proposed Subpart K; and (3) the requirements of proposed Subpart K.

Comment: One commenter requested that we not codify the preclusion of administrative or judicial review of the requirements established by proposed Subpart K, the determination of payment amounts under proposed Subpart K, and the determination of whether an REH meets the requirements of proposed Subpart K at this time. The commenter maintains that that the preclusion established by the statute constitutes a "complete hands-off approach" which is highly unusual for a new program and which does not foster a transparent, accountable, and equitable system. The commenter believes this creates a precarious position for CMS and for REHs because aspects of the program such as the REH monthly facility payment, other payment provisions and conditions of participation will likely be subject to future review and possible revisions.

Response: As acknowledged by the commenter, the preclusion of administrative and judicial review that we proposed to codify at § 419.94 derives from section 1861(kkk)(9) of the Act, which states that there shall be no administrative or judicial review of the establishment of requirements under 1861(kkk) by the Secretary, the determination of whether a REH meets the requirements of 1861(kkk) or the determination of payment amounts under section 1834(x), including additional facility payments. The proposed regulatory text at § 419.94 simply codifies the statutorily mandated preclusion, and would apply to Subpart K whether we codify it or not.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to codify, at § 419.94, the preclusion of administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the determination of whether an REH meets the requirements established by proposed Subpart K; (2) the determination of payment amounts under proposed Subpart K; and (3) the requirements of proposed Subpart K.

7. Conforming Revisions to 42 CFR 410 and 413

In addition to proposing to codify the requirements of section 1861(kkk) and 1834(x) of the Act at 42 CFR 419 as described above, we proposed to make conforming changes to 42 CFR 410, which describes the origin and destination requirements for the coverage of ambulance services, and 42 CFR 413, which specifies principles of reasonable cost reimbursement.

a. Rural Emergency Hospitals Ambulance Services Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggests that the Congress intended:

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is

covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility. Since April 1, 2002, payment for ambulance services is made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act.

We have established regulations at § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. The origin and destination requirements for coverage of ambulance services are addressed in our regulations at § 410.40(f).

b. Revision to the Origin and Destination Requirements under the AFS (42 CFR 410.40(f))

Section 125 of the Consolidated Appropriations Act, 2021, added section 1834(x)(3) of the Act for payment for ambulance services. Specifically, newly added section 1834(x)(3) of the Act states: "For provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l) of the Act." Accordingly, the statute makes clear that the ambulance provisions under section 1834(l) of the Act apply to REHs that owns and operates an ambulance transportation in the same manner that they do for other ambulance providers and suppliers that receive AFS payment for ambulance services. The previous section includes a discussion about this provision, including CMS's proposal, consistent with section 1834(x)(3) of the Act, to codify, at 42 CFR 419.92(c)(1), that an entity that is owned

and operated by an REH that provides ambulance services will receive payment for such services under the ambulance fee schedule as described in section 1834(l) of the Act.

The REH is an appropriate destination for an ambulance transport if furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. the beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. We proposed to revise our regulations at § 410.40(f) to include REH as a covered origin and destination for ambulance transport.

There are several different types of ambulance providers and suppliers that are enrolled in Medicare and furnished ambulance services payable under the AFS, such as a hospital provider. We proposed that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

We invited comments on our proposals to include REHs as a covered origin and destination for ambulance transport under the AFS and that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

Comment: We received several comments in support of our proposal to include REHs as a covered origin and destination for ambulance transport under the AFS. A commenter supported our proposal that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if coverage and payment requirements are met. The commenter further stated that high quality ambulance

service is an essential component of emergency medical services and rural hospitals, and by extension, REHs often are the sole providers of those services in their communities.

Response: We appreciate the commenters' support.

Comment: Several commenters recommended two additional subsections be added to the regulation at § 410.40(f): (1) A new subsection addressing coverage for facility-to-facility transfers for emergency services: "From a hospital, CAH, or REH to a hospital or CAH for emergency services not available at the hospital, CAH, or REH to which the patient came", (2) A new subsection addressing coverage for hospital-to-SNF transfers: "For a beneficiary who qualifies for SNF or swing bed services following an inpatient stay, from a hospital or CAH to a hospital, CAH, or SNF in the beneficiary's home community for SNF or swing bed services."

Response: The first recommended subsection seems to be subsumed in what the regulation already states so adding the recommendation is duplicative. Our regulations at § 410.40(f) includes coverage of ambulance services from any point of origin to the nearest hospital, CAH, or SNF and we proposed to add REH that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition. This requirement would cover a medically necessary ambulance transport for a beneficiary that needs to be transported from a hospital, CAH, or REH to a hospital or CAH for emergency services not available at the hospital, CAH, or REH to which the patient came.

The second recommended subsection does not include REHs, and is out of scope because we didn't propose any new ambulance coverage requirements for hospital-to-SNF transports. This recommended subsection seems to circumvent the nearest appropriate facility requirement if the beneficiary gets ill and is hospitalized not near the beneficiary's home. Under the AFS,

Medicare Part B covers ambulance services furnished to a Medicare beneficiary that meet the following requirements: There is medically necessary transportation of the beneficiary to the nearest appropriate facility that can treat the patient's condition and any other methods of transportation are contraindicated, meaning that traveling to the destination by any other means would endanger the health of the beneficiary. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

After consideration of the public comments we received, and for the reasons stated here and in the proposed rule, we are finalizing our proposals to revise our regulations at § 410.40(f) to include an REH as a covered origin and destination for ambulance transport under the AFS, and that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

c. Conforming Revisions to 42 CFR §§ 413.1; 413.13 and 413.24

We also proposed to make conforming changes to the regulation text specifying principles of reasonable cost reimbursement in 42 CFR 413 to incorporate references to REHs. Specifically, we proposed to modify § 413.1(a)(1)(ii) by adding subparagraph (L), to state that Section 1834(x) of the Act authorizes payment for services furnished by REHs and establishes the payment methodology. We also proposed to modify § 413.1(a)(2)(i) to add REHs to the listing of provider types covered by the regulations in 42 CFR part 413. Additionally, we proposed to amend § 413.13(c)(2) by adding subparagraph (vii) to the listing of services not subject to the lesser of costs or charges principle, to specify that services furnished by REHs are subject to the payment methodology set forth in Part 419, subpart K.

Furthermore, we proposed to amend § 413.24(f)(4)(i) to specify that an REH is required to file annual cost reports, and to amend § 413.24(f)(4)(ii) to specify that effective for cost reporting periods beginning on or after January 1, 2023, REHs are required to submit their cost reports in a standardized electronic format. Finally, we proposed to amend § 413.24(f)(4)(iv)(A), which requires providers to submit a hard copy of a settlement summary, if applicable, and the certification statement described in § 413.24(f)(4)(iv)(B), by adding subparagraph (5) to state that for REHs, these requirements are effective for cost reporting periods beginning on or after January 1, 2023.

We did not receive any public comments on our proposal and, therefore, we are finalizing, without modification, our proposed conforming revisions to 42 CFR §§ 413.1; 413.13 and 413.24.

B. REH Conditions of Participation (CoP) and Critical Access Hospital (CAH) CoP Updates (CMS-3419-F)

Section 125 of Division CC of the Consolidated Appropriations Act, 2021 (CAA) added a new section 1861(kkk) to establish REHs as a new Medicare provider type to address Congress's growing concern over closures of rural hospitals. According to a report by the United States Government Accountability Office published in 2020, over 100 rural hospitals closed from January 2013-February 2020 (*Rural Hospital Closures: Affected Residents Had Reduced Access to Health Care Services;* GAO-21-93, https://www.gao.gov/products/gao-21-93). The CAA created a pathway for certain critical access hospitals (CAHs) and certain rural hospitals to convert to this new provider type, allowing for continued access to emergency care in rural areas. In accordance with the statute, a facility is eligible to be an REH if it was a CAH or rural hospital with not more than 50 beds as of the date of enactment of the CAA (December 27, 2020). REHs

must provide emergency services and observation care and they may not provide inpatient services. Additionally, REHs may provide skilled nursing facility services in a separately certified distinct part skilled nursing facility unit. The statute also allows the Secretary discretion to establish additional requirements for REHs in the interest of health and safety.

1. Provisions of the Proposed Regulations and Responses to Public Comments

We published a Request for Information (RFI) for REHs in the CY 2022 OPPS/ASC proposed rule (86 FR 42018, 42285) on August 4, 2021, and used this information to inform development of the REH health and safety, payment, quality measures, and enrollment policies. The proposed health and safety standards (that is, the Conditions of Participation) for REHs were published in the **Federal Register** on July 6, 2022 in a proposed rule titled, "Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates" (87 FR 40350). All of the final health and safety policies for REHs and the CAH CoP updates are being published in this final rule with comment period.

The comments and our responses to those comments are set forth below.

Comments Out of the Scope of this Rulemaking

Comment: We received many comments regarding issues that were out of scope of this rulemaking, addressing subjects such as Medicare Advantage, home health payments, and Medicare coverage for all.

Response: We have reviewed all of the comments, including those that were out of the scope of this rule. We will not be addressing them in this final rule with comment period; however, we will consider them for future rulemaking.

a. Rural Emergency Hospital Conditions for Participation (Proposed Part 485, Subpart E)

We proposed to add a new subpart E in 42 CFR part 485, to incorporate the REH CoPs. Proposed subpart E would include all the health and safety standards for REHs. Overall, the proposed requirements were modeled closely after the CoPs for CAHs. In some instances, we have also proposed requirements that are similar to the CoPs for hospitals and CfCs for Ambulatory Surgical Centers (ASCs). In each of the sections below, we specify the existing requirements for CAHs, hospitals, or ASCs that we used to guide the proposed requirements.

(1) Basis and Scope (§ 485.500)

We proposed to set forth the basis and scope of part 485, subpart E, at § 485.500. As previously noted, proposed part 485, subpart E, would implement section 1861(kkk) of the Act, which establishes the requirements that an REH must meet in order to participate in the Medicare program. Section 1833(a) of the Act serves as the basis for the establishment of payment of benefits covered under Medicare for REHs.

Technical assistance (TA) is available to hospitals and CAHs seeking REH designation from the Health Resources and Services Administration's REH TA Center. The REH TA Center, which has been awarded to the Rural Health Redesign Center (https://www.rhrco.org/reh-tac), provides TA to rural hospitals and CAHs exploring REH designation. Their aim is to assist facilities to financially model and assess the feasibility of an REH conversion; helping them complete the application process to CMS for REH designation; assist with strategic planning for REH conversion and identifying alternative care pathways to continue to meet the needs of their community; and provide ongoing support while new REHs implement service changes as a result of the conversion.

We did not receive any public comments on our proposal and therefore, we are finalizing this provision as proposed.

(2) Definitions (§ 485.502)

At § 485.502, we proposed to define certain terms that would be used throughout the REH CoPs. We proposed to define the term "Rural Emergency Hospital or REH" in accordance with the definition set forth in section 1861(kkk) of the Act. In accordance with the Act, we proposed to define "Rural Emergency Hospital or REH" as an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The REH must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or post-hospital extended care services.

Comment: We received several comments on the REH RFI recommending that the average length of stay be increased in certain instances, such as when the REH is providing services to a patient who is need of inpatient psychiatric or inpatient rehabilitation services. The commenters stated that placement of these patients in an inpatient facility could be difficult with some patients potentially remaining in the REH for observation services for weeks. Commenters noted further that attending to these patients could produce an average length of stay that would exceed the proposed 24-hour annual per patient average length of stay. Other commenters requested that CMS be flexible in recognizing bed capacity issues for those patients awaiting placement in an inpatient facility and practice enforcement discretion related to the proposed length-of-stay requirement. Other commenters asked that CMS increase the length of stay, noting that in some instances patients may require a longer stay, potentially affecting compliance with this requirement.

Response: We appreciate the comments received on this provision. The 24-hour annual per patient average length of stay is a statutory requirement and cannot be modified. We note that this is an annual average per patient requirement for all patients, and we expect that some patients will receive services for longer periods of time, while others will receive services there for a minimal amount of time throughout the year.

Comment: Commenters suggested that we allow exemptions for the length of stay, particularly for low-risk labor and delivery, behavioral health and surgical services. Commenters stated that in some situations, a patient may require a longer stay or may not be able to be transferred in a timely fashion, if necessary. Allowing for exemptions will help to avoid non-compliance due to occasional situations in which the patient may require a longer stay. Some commenters also recommended that we exclude the length of stay for a patient whose transfer was delayed for more than 12 hours.

Response: We understand that there may be situations in which a patient may have to stay in the facility for longer periods of time. However, since this is a statutory requirement we do not have the ability to make exceptions. We recommend that facilities maintain documentation of instances in which a patient is unable to be transferred timely or when there are specific situations in which the patient's stay may exceed 24 hours. If for any reason the REH exceeds an average annual per patient length of stay of 24 hours, the REH is expected to have documentation showing instances in which there were attempt(s) to transfer or reasons for an extended length of stay so that the information can be reviewed and considered by CMS when making determinations regarding the REH's compliance with the length of stay requirement. If the services being provided by the REH are appropriate for this provider type (such as outpatient low-risk labor and delivery and outpatient behavioral health services), the REH should not

routinely exceed the length of stay. If more complex patients present to the REH, they would be expected to be transferred to a facility that is able to provide a higher level of care. We also reiterate that the length of stay requirement is an average, such that if an REH exceeds the length of stay requirement with greater frequency, it might suggest that the facility is not in compliance with the definition of an REH.

Comment: Many commenters asked that we clarify how the length of stay will be calculated.

Response: The method used to calculate the average annual per patient length of stay in an REH takes into account the outpatient-only nature of the REH. The time calculation for determining the length of stay of a patient receiving services at the REH is similar to the approach used in ASCs and begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH. The discharge occurs when the physician or other appropriate clinician has signed the discharge order, or at the time the outpatient service is completed and documented in the medical record. The REH length of stay requirement is applicable to all patients receiving services provided by the REH.

After consideration of the public comments we received, we are finalizing § 485.502 with modifications. We are revising § 485.502 by incorporating the methodology used to determine the annual per patient average length of stay for the REH.

(3) Basic Requirements (§ 485.504)

At § 485.504, we proposed to set forth the basic requirements for REHs in accordance with section 1861(kkk) of the Act. Participating REHs would be limited to those facilities that meet the definition in proposed § 485.502 and have in effect a provider agreement as defined at 42 CFR 489.3. This final rule adds REHs to the list of providers required to obtain a provider

agreement at § 489.2(b) in the "Conforming Amendments and Technical Corrections" section of this rule.

Comment: Section 1861(kkk)(4)(A)(i) requires that a hospital or CAH seeking REH conversion submit a detailed transition plan at the time of the submission of their revised CMS Form 855-A. Several commenters suggested that CMS clarify in the final rule the process for submitting the transition plan.

Response: Details regarding submission of the transition plan and the transition plan requirements will be published in future rulemaking.

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal.

(4) Designation and Certification of REHs (§ 485.506)

At § 485.506, we proposed to set forth the criteria for CMS certification of an REH in accordance with section 1861(kkk) of the Act. We proposed to establish that CMS would certify a facility as an REH if the facility was, as of the date of enactment of the CAA, a CAH, or a hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) considered rural (as defined in section 1886(d)(2)(D) of the Act), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. In addition, to be treated as being located in a rural area for the purpose of REH eligibility, we proposed that a hospital located in a metropolitan county that applies to be an REH must have had an active reclassification from urban to rural status, as specified in section 42 CFR 412.103, as of December 27, 2020.

Comment: Commenters asked if either a rural hospital with not more than 50 beds or a CAH were certified for participation in Medicare and Medicaid as of the date of enactment of the

CAA (December 27, 2020), which subsequently closed after that date, would continue to be eligible to seek designation as an REH.

Response: Section 1861(kkk)(3) describes an eligible facility that was a CAH or a rural hospital with not more than 50 beds as of the date of enactment of the CAA (December 27, 2020). Therefore, facilities that were CAHs or rural hospitals with not more than 50 beds as of the date of enactment of the CAA and then subsequently closed after that date, would be eligible to seek REH designation after the closure of the facility. However, the facility would have to meet all the CoPs for REHs in order to re-open as an REH.

Comment: Commenters additionally inquired about the methodology used to determine if a rural hospital with not more than 50 beds meets the bed count requirement to seek REH designation.

Response: The bed count will be determined by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period. We use this methodology to determine if Medicare-dependent small rural hospitals meet the required bed count for that program. We believe this is an appropriate methodology for determining if a rural hospital meets the bed count requirement to seek REH designation, as this is a known and existing methodology for small rural hospitals seeking to determine bed count for eligibility in Medicare programs.

After consideration of the public comments we received, we are finalizing § 485.506 as proposed.

(5) Compliance With Federal, State, and Local Laws and Regulations (§ 485.508)

Consistent with the requirements for all Medicare- and Medicaid-participating providers and suppliers, we proposed to require REHs to comply with Federal, state, and local laws and

regulations. At §485.508(a) we proposed to require the REH to be in compliance with applicable Federal laws, state, and local laws and regulations. In accordance with section 1861(kkk)(5) of the Act, we also proposed to require at § 485.508(b) that the REH be located in a state that provides for the licensing of such hospitals under state or applicable local law. In addition, under § 485.508(b)(1) and (2), we proposed that the REH be licensed in the state as an REH or be approved as meeting standards for licensing by the agency in the state or locality responsible for licensing hospitals. We note that in many instances, states and localities, have more stringent laws and regulations than the Federal requirements. In cases in which state law or regulations are more stringent, the REH would need to comply with the more stringent state or local requirements to meet the proposed requirements at § 485.508(a).

At § 485.508(c), we proposed to require that the REH ensure that personnel are licensed or meet other applicable standards required by state or local laws to provide services within their respective applicable scope of practice.

Comment: Some commenters on the REH RFI recommended that CMS encourage licensure portability among health care practitioners. Commenters on the RFI indicated that allowing practitioners to practice in multiple states would greatly support both in-person and virtual care models in rural areas where the closest health care provider could be across the state line.

Response: This proposed standard does not prohibit a practitioner that is licensed in one state from providing care at an REH in another state; state laws govern whether this is permissible. Other than the comment provided in response to the RFI, e did not receive any public comments on our proposal and therefore, we are finalizing our proposal without change.

(6) Condition of Participation: Governing Body and Organizational Structure of the REH (§ 485.510)

To ensure appropriate oversight of the REH, we proposed at § 485.510 to require the REH to have an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. This aligns with the CAH CoP for organizational structure at § 485.627(a). In addition to oversight, we expect the responsibilities of the governing body or responsible individual to include ensuring that the REH is effectively executing its policies and decision-making about the REH's vision, mission, and strategies. If an REH does not have an organized governing body, we proposed to require that the person or persons legally responsible for the conduct of the REH carry out the functions specified in this part that pertain to the governing body.

Consistent with the hospital governing body CoPs at § 482.12, we proposed at § 485.510(a)(1) to require the governing body, in accordance with state law, to determine which categories of practitioners are eligible candidates for appointment to the medical staff. Additionally, consistent with the interpretive guidelines for CAHs in Appendix W of the State Operations Manual for the standard for *Governing Body or Responsible Individual* at § 485.627(a), we proposed to require that the governing body of the REH appoint members of the medical staff after considering the recommendations of the existing members of the medical staff. The role of the medical staff is the promotion of patient safety and the quality of care. This proposal would give maximum flexibility to an REH in determining and granting staff privileges and organizing its medical staff, and it would allow the REH to grant specific privileges related to patient care to various other types of licensed practitioners as needed, in addition to the privileges it would choose to grant to doctors of medicine or osteopathy. For example, an REH

could choose to grant medical staff privileges to nurse practitioners and physician assistants if permissible under state law. We also proposed to require that the REH's governing body ensure that its medical staff be accountable to the governing body for the quality of patient care provided by the REH; organize itself under bylaws; and ensure that the criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

Many rural populations suffer from limited access to care due to a shortage of health care professionals, especially physicians. Often, clinicians other than physicians provide important care services to rural communities with physicians providing oversight. This may occur in different ways, including via the use of mobile health, video and audio technologies, digital photography and remote patient monitoring. With the development of technology that facilitates "telemedicine," a physician could utilize a variety of methods to provide health care services, including being on-site at a facility or at a distant site furnishing services remotely to a patient located at an originating site.

Commenters on the REH RFI noted that REHs should be able to act as an originating site (that is, the location where a Medicare patient receives medical services from a physician or other clinician through a telecommunications system) for the provision of telehealth services. As noted in the CY 2022 Medicare Physician Fee Schedule final rule (86 FR 65057), section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Act to add REHs to the list of permissible telehealth originating sites. In accordance with section 1834(m)(4)(C)(ii)(XI) of the Act, as added by section 125(c) of the CAA, we have already finalized a revision to § 410.78(b)(3) of our regulations to add REH, as defined in section 1861(kkk)(2) of the Act, as a permissible originating site for telehealth services furnished on or after January 1, 2023.

For the purposes of this rule, similar to our interpretation in the policy set out in our 2011 final rule, "Medicare and Medicaid Programs; Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging" (76 FR 25550, May 5, 2011), we see telemedicine as encompassing the overall delivery of health care to the patient through the practice of patient assessment, diagnosis, treatment, consultation, transfer and interpretation of medical data, and patient education all via a telemedicine link (for example, audio, video, and data telecommunications as may be utilized by distant-site physicians and practitioners). Therefore, in order to make clear that the credentialing and privileging provisions proposed for REHs were not limited to the narrower subset of services and sites eligible for Medicare telehealth payment, we chose to use the term, "telemedicine," throughout this rule instead of "telehealth." As noted previously, payment policies for REHs, including for services furnished via telehealth/telemedicine, will be addressed in separate notice and comment rulemaking.

In recognition of the important role that telemedicine can play in the provision of care in rural communities, we believe it is necessary to establish a more efficient process for REHs to credential and privilege clinicians who provide telemedicine services for the REH's patients. We proposed requirements similar to the telemedicine credentialing and privileging process requirements established for hospitals and CAHs that would allow for an optional and more streamlined credentialing and privileging process that REHs may use for practitioners providing telemedicine services for their patients. We believe that REHs might lack the resources to fully carry out the traditional credentialing and privileging process for all of the physicians and practitioners that may be available to provide telemedicine services. Small hospitals and CAHs seeking to provide enhanced access to care through the use of telemedicine services for their

patients have already encountered this issue. In addition to the costs and administrative staff needed for this process, REHs would also most likely not have in-house medical staff with the clinical expertise to adequately evaluate and privilege the wide range of specialty physicians that larger hospitals can provide their patients through the use of telemedicine services.

Therefore, at § 485.510(a)(8) we proposed that the REH's governing body ensure that when telemedicine services are furnished to the REH's patients through an agreement with a Medicare-participating hospital (the "distant-site"—the site at which the physician or practitioner is located at the time the service is provided via a communications system, as defined at section 1834(m)(4)(A) of the Act), the agreement must specify that the governing body of the distant-site hospital providing the telemedicine services must meet the requirements in § 485.510(a)(1) through (7) with regard to its physicians and practitioners who are providing telemedicine services. These provisions cover the distant-site hospital's governing body responsibilities for its medical staff that all Medicare-participating hospitals must currently meet and that REHs would be required to meet when this rule is finalized. The proposed requirements at § 485.510(a)(8) would allow the governing body of the REH whose patients are receiving the telemedicine services to grant privileges based on the recommendations of its medical staff, who would rely on information provided by the distant-site hospital, as a more efficient means of privileging the individual distant-site physicians and practitioners. This provision would be accompanied by the proposed requirement in the "Medical staff" CoP at § 485.510(a), which would provide the basis on which the REH's governing body, through its agreement as noted above, can choose to have its medical staff rely upon information furnished by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. This option would not prohibit an REH's medical staff from continuing to perform its

own periodic appraisals of telemedicine members of its staff, nor would it bar them from continuing to use the proposed traditional credentialing and privileging process proposed at § 485.512(a)(2). The intent of this proposed requirement is to relieve burden for REHs by providing for a less duplicative and more efficient privileging scheme with regard to physicians and practitioners providing telemedicine services. However, in an effort to ensure accountability to the process, we also proposed at (§ 485.512(a)(3) that the REH, in order to choose this less burdensome option for privileging, would have to ensure that (1) the distant-site hospital providing the telemedicine services was a Medicare-participating hospital; (2) the individual distant-site physician or practitioner was privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provided a current list of the physician's or practitioner's privileges; (3) the individual distant-site physician or practitioner held a license issued or recognized by the state in which the REH, whose patients are receiving the telemedicine services, was located; and (4) with respect to a distant-site physician or practitioner granted privileges by the REH, the REH had evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and send the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner. We also proposed that, at a minimum, the information sent for use in the periodic appraisal would have to include a description of all adverse events that could result from telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH had received about the distant-site physician or practitioner. We proposed at § 485.512(c)(5) to require that REH's medical staff bylaws include criteria for determining privileges and a procedure for applying the criteria to individuals requesting privileges. We proposed to add language to stipulate that in cases where distant-site physicians

and practitioners requested privileges to furnish telemedicine services through an agreement with an REH, the criteria for determining those privileges and the procedure for applying the criteria would be subject to the proposed requirements at §§ 485.510(a)(8) and (9) and 485.512(a)(3) and (4).

Similar to the revisions we made in the "Changes Affecting Hospital and Critical Access Hospital Conditions of Participation" final rule (76 FR 25556), we also concluded that it would be important that the medical staff of a distant-site telemedicine entity, which might not be a Medicare-participating hospital, also be included in an optional and streamlined credentialing and privileging process for those REHs electing to enter into agreements for telemedicine services with such entities. However, similar to the situation we faced for hospitals and CAHs in the May 2011 final rule (that is, the inclusion of distant-site telemedicine entities into this streamlined process without CMS having any regulatory or oversight authority over them, we realized that the proposed requirements for REHs would need to hold distant-site telemedicine entities accountable to the originating-site REH for meeting CMS practitioner credentialing and privileging standards. And like the current requirements for hospitals and CAHs using telemedicine services, REHs would need to provide, upon request when surveyed, the most current telemedicine services agreement showing that the distant-site entities providing the services were required to comply with the CMS standards (even though CMS has no direct authority over those entities) in order for the REH to make use of the more streamlined process when credentialing and privileging practitioners from these distant-site telemedicine entities. Similar to our regulations proposed for REHs using the telemedicine services of distant-site Medicare-participating hospitals, the written agreement between the REH and the distant-site telemedicine entity would be the foundation for ensuring accountability on both sides. However,

due to the differences already discussed between Medicare-participating distant-site hospitals providing telemedicine services and distant-site practitioners under section 1834(m) of the Act providing similar services, there would also have to be differences in the way the regulations were written.

Therefore, we also proposed requirements that would apply to the credentialing and privileging process and the agreements between REHs and distant-site telemedicine entities (§§ 485.510(a)(9) and 485.512(a)(4)). These provisions would require the governing body of the REH (or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnished its services in a manner that would enable the REH to comply with all applicable CoPs and standards. For the contracted services, the applicable CoPs and standards would include, but are not limited to, the credentialing and privileging requirements for distant-site physicians and practitioners furnishing telemedicine services.

Comment: Commenters were generally supportive of the provisions in this proposed section. Several commenters suggested that local physicians and/or physicians with rural emergency care experience serve on the governing board of the REHs. Other commenters suggested that a physician with board certification in emergency medicine oversee the care and services provided by the REH given their primary function of providing emergency care.

Response: We want to promote a high degree of flexibility in how REHs handle staffing decisions, including in how REH staff helps in deciding the Board or responsible individual. While we do not speak to whether local physicians or physicians with rural emergency experience must serve on the governing boards of REHs, the REHs themselves have the discretion to develop their own set of best practices regarding the specifics of governance. We

appreciate the suggestion, but do not believe at this time that there should be requirements of which credentials physicians must have to qualify for appointment to an REH's governing board.

Comment: Some commenters wanted to ensure that CMS would not obstruct the ability for REHs to provide services via telemedicine, while other commenters suggested that CMS take steps to ensure that telemedicine was not used in a wasteful or inappropriate manner to substitute for visitation with a local physician.

Response: We thank commenters for their statements regarding telemedicine. The proposed requirements mirror the CAH and hospital requirements regarding telemedicine. The aim of the requirements is to ensure that REHs, like CAHs and hospitals, have a written agreement regarding the provision of services via telemedicine. We will require that the REH have a credentialing and privileging process in place, holding the REH responsible for telemedicine services provided under arrangement and agreement. The requirement includes process to allow for the use of telemedicine by another Medicare-participating facility or a non-Medicare participating entity in the provision of services by the REH.

After consideration of the public comments we received, we are finalizing these provisions as proposed.

(7) Condition of Participation: Provision of Services (§ 485.514)

Consistent with the CAH CoPs at § 485.635(a)(1), we proposed at § 485.514(a) to require that the REH's health care services be furnished in accordance with appropriate written policies consistent with applicable state law and at § 485.514(b) that the REH must have policies that are developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse

practitioners, or clinical nurse specialists, if they are on staff (as defined at 485.528(b)(1)). This requirement would align with the CAH CoPs at § 485.635(a)(2).

At § 485.514(c) we proposed requirements for the written policies to include a description of the services the REH furnishes (including those furnished through agreement or arrangement), policies and procedures for emergency medical services, guidelines for the medical management of health problems, and policies and procedures that address the post-acute care needs of all patients receiving services furnished by an REH. Because the statute prohibits REHs from providing of inpatient services (with the exception of patients receiving SNF services in a distinct part SNF), post-acute care for an REH patient is any care the REH patient receives once they are discharged from the REH. Lastly, at § 485.514(d), we proposed to require the policies to be reviewed at least biennially by the group of professional personnel required at § 485.514(b) and updated as necessary by the REH. These requirements align with the CAH CoPs at § 485.635(a)(3).

Comment: Commenters were supportive of our proposals. After consideration of the public comments we received, we are finalizing as proposed.

(8) Condition of Participation: Emergency Services (§ 485.516)

In accordance with section 1861(kkk)(2)(D)(iv) of the Act, REHs must comply with the CAH emergency services requirements at § 485.618 as well as the hospital emergency services requirements, which are located at § 482.55, as determined to be applicable. As such, at § 485.516 we proposed to require that the REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

Additionally, because the primary function of an REH is to provide emergency services, we proposed at § 485.516(a) that the REH must have emergency services that are organized

under the direction of a qualified member of the medical staff and are integrated with other departments of the REH, similar to the requirements for hospitals. We anticipate that there will be instances in which a patient is receiving outpatient services other than emergency services and may unexpectedly require care in the emergency department. In this instance, having emergency services that are integrated with the other departments of the REH will facilitate care coordination and promote patient-centered care.

At § 485.516(b), we proposed that there be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility. To comply with this requirement, we would expect the REH to conduct an analysis based on the anticipated staffing needs and once the REH begins to provide services, the analysis would include actual staffing needs. Lastly, at § 485.516(c), we proposed to require the REH to provide emergency services that meet the CAH requirements specified at § 485.618(a) through (e), as required by section 1861(kkk)(2)(D)(iv)(I) of the Act.

Comment: Commenters noted that REHs should be required to have at least one physician, nurse practitioner, clinical nurse specialist, or physician assistant with training or experience in emergency care staffing their emergency department at all times and that these clinicians should be required to be physically located on the REH's campus (or in adjacent buildings) to meet the REH staffing requirement. Some commenters noted that because the primary purpose of the REH is emergency access, the facility needs to have a clinician with board certification or at a minimum, training in emergency medicine immediately available to provide the care or oversee the care delivered by non-physician practitioners. Other commenters supported the proposal, noting the appropriateness of not requiring a practitioner to be on-site at

the REH at all times given the expected low volume of patients and services in the rural communities they serve.

Response: We are appreciative of these comments. We believe that given the workforce challenges faced by healthcare facilities providing care and services in rural communities, it would be overly burdensome to require specific expertise of the practitioners who are providing services to patients presenting to the REH for emergency care. However, REHs are expected to have staff that meet the needs of the community they serve. We would also like to highlight that that we are finalizing the requirements for Staffing and Staff Responsibilities at §485.528 with modification, such that the individual who fulfills the requirement that the REH must be staffed at all times must be an individual who is competent in the skills needed to address emergency medical care. This individual must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient. We believe that in doing so, we have sufficiently address the commenters' concerns that the REH's emergency department be appropriately staffed.

Comment: One commenter asks that CMS to provide a waiver that allows REHs to divert patients to a higher-level facility on the continuum if the clinical staff at the REH does not believe the facility can provide the appropriate level of care and the patient is stable enough to transport, with the commenter noting that they believe that CMS has the ability to modify the Emergency Medical Treatment and Labor Act (EMTALA) regulations to provide this flexibility to REHs.

Response: Consistent with the requirements for hospitals and CAHs with emergency departments, we note that section 1867(e)(5) applies the EMTALA requirements to REHs. EMTALA requires hospitals with emergency departments to provide a medical screening

examination to any individual who comes to the emergency department and requests such an examination, and prohibits hospitals with emergency departments from refusing to examine or treat individuals with an emergency medical condition. We note that REHs will be familiar with the EMTALA requirements because they complied with them as either a hospital with an emergency department or a CAH. Section 125 of the CAA does not allow for a waiver of the EMTALA requirements for REHs.

After consideration of the public comments we received, we are finalizing § 485.516 as proposed.

(9) Condition of Participation: Laboratory Services (§ 485.518)

We proposed at § 485.518 that REHs, similar to CAHs (§ 485.635(b)(2)), would be required to provide basic laboratory services essential to the immediate diagnosis and treatment of the patient. The CAH requirements cite specific laboratory services that should be provided by the CAH, such as chemical examination of urine, hemoglobin or hematocrit, blood glucose, examination of stool specimens for occult blood, pregnancy tests, and primary culturing for transmittal to a certified laboratory. However, we believe that given the REH's nature of primarily providing emergency services, it is appropriate that REHs provide laboratory services that are consistent with nationally recognized standards of care for emergency services. In addition to the laboratory services identified in the CAH CoPs, we encourage the REH to provide laboratory services that include a complete blood count, basic metabolic panel (also known as a “chem 7”), magnesium, phosphorus, liver function tests, amylase, lipase, cardiopulmonary tests (troponin, brain natriuretic peptide, and d-dimer), lactate, coagulation studies (prothrombin time, partial thromboplastin time, and international normalized ratio), arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology. In accordance with the

Clinical Laboratory Improvement Amendments of 1988 (CLIA), at § 485.518(a), we proposed to require that the REH must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with the CLIA requirements at 42 CFR part 493. Furthermore, at § 485.518(b) we proposed that REHs must have emergency laboratory services available that would be essential to the immediate diagnosis of the patient, 24 hours a day. This proposal is appropriate given the provision that REHs must provide emergency services 24 hours a day.

Comment: Commenters were generally supportive of our proposals. However, some commenters suggested that the laboratory services provided by REHs should not exceed the laboratory services that must be provided by a CAH. Other commenters suggested that REHs be required to provide specific laboratory services that include those suggested in the preamble, as well as laboratory services that include that blood, urine, cerebrospinal fluid (CSF), and other body fluid cultures; CSF analysis and synovial fluid analysis; serum and urine pregnancy tests; and ammonia level tests.

Response: The proposed standard for laboratory services for REHs requires the REH to provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services. We did not propose to require that the REH provide specific laboratory services beyond ensuring that they are providing such services that are consistent with nationally recognized standards of practice. We believe that REHs should have the flexibility to determine the laboratory services that are appropriate for their scope of services and patient population. Specific laboratory services were highlighted in the proposed rule and include a complete blood count, basic metabolic panel (also known as a “chem 7”), magnesium, phosphorus, liver function tests,

amylase, lipase, cardiopulmonary tests (troponin, brain natriuretic peptide, and d-dimer), lactate, coagulation studies (prothrombin time, partial thromboplastin time, and international normalized ratio), arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology. Based on the current nationally recognized standards for practice, the scope of services provided by the REH, and the patient population receiving REH services, the REH may determine the laboratory services that meet the needs of the community it serves.

After consideration of the public comments we received, we are finalizing this provision with modification by incorporating language into the requirement at § 485.518 that specifically notes that the laboratory services must be consistent with the patient population and services offered.

(10) Condition of Participation: Radiologic Services (§ 485.520)

Radiologic services play an integral role in the provision of emergency services. Commenters on the REH RFI noted that radiologic services, also referred to as imaging services, should be provided at REHs. A study in the American Journal of Roentgenology noted that, "The use of imaging in the emergency department (ED) has increased over time, and by 2010 nearly half of all ED visits in the U.S. included at least one imaging test." [9] These imaging tests include computed tomography (CT), also known as a computerized axial tomography (CAT) scan, magnetic resonance imaging (MRI), and ultrasound. These tests can be used to diagnose bone fractures, infections, arthritis, injuries from trauma, tumors and cancers. They can also be used to monitor and evaluate the growth and development of a fetus, and offer a way to examine many of the body's internal organs such as the liver, gallbladder, kidneys, and bladder.

We expect that REHs will need to provide radiologic services given their focus on emergency services and given the number of emergency department patients who receive

imaging services. Therefore, we proposed that the REH radiologic requirements mirror the hospital radiologic requirements found at § 482.26, which is consistent with the current CAH standard at § 485.635(b)(3) and interpretative guidelines for CAHs in Appendix W of the State Operations Manual (SOM).

The CAH standard for radiology services found at § 485.635(b)(3) requires that these services be furnished by personnel qualified under state law, and that such services do not expose patients or staff to radiation hazards. In addition, we note that the interpretative guidelines for § 485.635(b)(3) in Appendix W of the SOM provides guidance for designating qualified radiologic personnel, developing policies and procedures that ensure safety from radiation hazards, inspecting and maintaining radiologic equipment, and maintaining CAH radiology records.

We proposed to align the REH requirements with the hospital requirements for radiologic services and proposed additional standards related to safety, personnel responsibilities, and record keeping. We believe that facilities that transition to an REH would need to perform these activities to support the delivery of radiology services. We also believe that these proposed requirements are in accordance with the interpretative guidelines that CAHs currently follow for the provision radiological services. We do not expect these requirements to create additional burden for REHs over those applicable to CAHs.

As such, at § 485.520, we proposed to require that the REH provide diagnostic radiologic services. At §485.520(a), we proposed to require that all radiologic services furnished by the REH be provided by qualified personnel in accordance with state law; such services could expose REH patients or personnel to radiation hazards. As with hospitals, we also proposed to require that the REH must have radiologic services that meet the needs of their patients. For

example, we expect an REH that is located in a mining community to offer x-ray services due to the effects of mining on one's lungs or an REH being able to furnish ultrasounds to evaluate the growth and health of a fetus.

At § 485.520(b), we proposed basic factors relating to safety hazard standards for patients and personnel by specifying that the REH must institute proper safety precautions, perform periodic inspections of equipment, periodically check radiation workers for exposure, and only provide radiologic services based on the order of practitioners with clinical privileges or authorization by the medical staff and governing body. We proposed the personnel standard at § 485.520(c) to require that a qualified radiologist, or other personnel qualified under state law either full-time, part-time, or on a consulting basis interpret radiologic tests that require specialized knowledge. This requirement can be fulfilled through arrangements with off-site providers via telehealth. Like hospitals, we proposed that the radiologist in an REH must sign reports only of their interpretations. We proposed to allow the medical staff and the individual responsible for radiological services to designate who is qualified to use radiological equipment. Lastly, at §485.520(d), we also proposed to require that records of departmental activities be maintained and that radiological reports and films be preserved for 5 years, consistent with the proposed requirements for the maintenance and retention of the REH medical records.

Comment: Most commenters supported this requirement. Some commenters stated that radiologic services should not have separate requirements, but should instead be included in the Provision of Services CoP.

Response: We appreciate the comments stating that radiological services should not be a separate requirement. However, Hospital and CAHs requirements have separate provisions for

radiological services so for consistency across providers we will keep them as separate requirements.

After consideration of the public comments we received, we are finalizing as proposed.

(11) Condition of Participation: Pharmaceutical Services (§ 485.522)

While the current CAH requirements do not have a separate CoP for pharmaceutical services, there are standards throughout the CAH CoPs for the oversight, storage, and administration of drugs and biologicals. Regulations at § 485.623(b)(3) requires the CAH to store drugs and biologicals properly, and § 485.635(a)(3)(iv) requires the CAH to develop rules for the storage, handling, dispensation, and administration of drugs and biologicals including a drug storage area administered in accordance with accepted principles. In addition, there are standards throughout the CAH CoPs regarding provisions for infection prevention and control and antibiotic stewardship programs that reference pharmacy leadership and pharmacy services. Therefore, we believe that CAHs and hospitals that transition to an REH would already be in compliance with REH requirements to support the delivery of pharmaceutical services; we do not expect these requirements to create additional burden for REHs.

At § 485.522, we are requiring that the REH's pharmaceutical services meet the needs of the patients. According to the American Society of Health-System Pharmacists Guidelines on Emergency Medicine Pharmacy Services, some factors that an ED is expected to consider when determining how the pharmaceutical services can best meet the needs of the patients include the type and setting of the ED (for example, academic, community, urban, or rural), the size of the ED, the number of annual visits, the patient population served, and any specialty services available.[11] At § 485.522(a), we proposed to require the REH to have a pharmacy or drug storage area administered in accordance with accepted professional principles and state and

Federal laws. Additionally, we proposed to require at § 485.522(a)(1) that a registered pharmacist or other qualified individual in accordance with state scope of practice laws direct the pharmaceutical services or, when appropriate, have a drug storage area that is supervised by an individual who is competent to do so. Rural communities are often challenged by the lack of pharmacists willing to move to rural areas and for this reason, we recognize that there may be REHs that can provide pharmaceutical services only by having a drug storage area that is under the supervision of a qualified individual. In these instances, the facility must establish qualifications for the individual with oversight of the drug storage area for competency purposes and ensure that someone who meets those requirements is fulfilling the role. This is consistent with the interpretive guidelines for the CAH CoPs contained in Appendix W of the SOM for § 485.635(a)(3). We proposed that this individual be available for a sufficient time to provide such oversight based on the scope and complexity of the services offered at the REH. This individual would not be required to be a full-time pharmacist. We believe that requiring "sufficient time" in the regulatory language provides the REH with the flexibility to determine how frequently the pharmacist or other qualified individual is available.

In addition, the CAH interpretive guidelines for § 485.635(a)(3) state that the compounding, packaging, and dispensing of drugs should be consistent with accepted professional principles. In accordance with guidance issued by the Food and Drug Administration, accepted professional principles for compounding, packaging, and dispensing of drugs include having a licensed pharmacist, or in some cases a physician, perform these activities (or having them performed under the supervision of a licensed pharmacist, when appropriate) (https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding#:~:text=Compounding%20is%20generally%20a%20practice,needs%20of%20an

%20individual%20patient). As such, we proposed at § 485.522(b)(1) that all compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or other qualified individual acting in accordance with state scope of practice laws and be performed consistent with state and Federal laws. In addition, we proposed that all drugs and biologicals must be kept in secure areas, and locked when appropriate. All drugs listed in Schedules II, III, IV, and V as outlined in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513, as amended), must be locked within a secure area and only authorized personnel may have access to locked areas. We proposed that outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use and drugs and biologicals can only be removed from the pharmacy or storage area by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with state and Federal law. These proposed requirements are also consistent with the CAH interpretive guidelines for § 485.635(a)(3).

Lastly, at § 485.522(c) we proposed to set forth the standards for the administration of drugs. We note that the existing CAH CoP at § 485.635(a)(3)(iv) requires that the CAH have written policies that include the rules for the storage, handling, dispensation, and administration of drugs and biologicals. The CAH CoPs continue to require that these rules provide that there is a drug storage area that is administrated in accordance with accepted professional principles. Similarly, we proposed to require that drugs be prepared and administered in an REH according to established policies and acceptable standards of practice and consistent with the CAH requirement at § 485.635(a)(3)(v), we proposed to require that any adverse reactions be reported to the physician responsible for the patient and documented in the record. While the CAH CoPs require that the CAH have procedures for reporting adverse drug reactions and errors in the

administration of drugs, we recognize that a nationally recognized standard of practice is to report adverse drug reactions to the physician responsible for the care of the patient. We proposed, that the REH be required to administer blood transfusions, blood products and intravenous medications in accordance with state law and approved medical staff policies and procedures, and that orders given orally for drugs and biologicals be followed by a written order, signed by the prescribing physician or other authorized prescriber at §§ 485.522(c)(2) and (3) respectively. We also proposed at § 485.522(c)(4) to require that the REH have a procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Comment: Several commenters supported this proposed requirement and noted that it afforded flexibilities for providing pharmaceutical services in REHs. We also received some comments stating that this proposed CoP is based on the hospital CoP for pharmaceutical services at 42 CFR 482.25 and requested that the proposal instead only include the provisions of the CAH CoPs at § 485.623(b)(3) and § 485.635(a)(3)(iv) and (v).

Response: As previously noted, we believe that small hospitals and CAHs that transition to the REH provider-type would currently be complying with the proposed REH requirements to support the delivery of pharmaceutical services when they changed provider-type. We do not expect the requirements we are finalizing to create additional burden for REHs. We also note that the proposed REH pharmaceutical services requirements incorporates the CAH requirements at § 485.623(b)(3) and § 485.635(a)(3)(iv) and (v). We have maintained flexibilities afforded to CAHs such as allowing qualified individuals, other than pharmacists, to operate and oversee drug storage areas and allowing physicians to compound, package, and dispense drugs in place of a pharmacist. Therefore, we do not believe it that we should revise the proposed REH requirements for pharmaceutical services.

After consideration of the public comments we received, we are finalizing § 485.522 as proposed.

(12) Condition of Participation: Additional Outpatient Medical and Health Services (§ 485.524)

We proposed at § 485.524 that if the REH chooses to provide additional outpatient medical and health services, that the services would be required to be appropriately organized and to meet the needs of the patients in accordance with acceptable standards of practice. Additionally, at § 485.524(a)(1) we proposed to require that the provision of the additional service be based on nationally recognized guidelines and standards of practice, aligning the proposed requirement with the hospital CoPs for outpatient services at § 482.54. Given that the REH does not provide inpatient services, patients requiring a higher level of care would be required to be transferred to an acute care hospital or CAH. As a result of this, and based on comments received on the REH RFI, we further proposed to require that the REH have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate. Some of the REH RFI comments also indicated that REHs should be required to have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH. Hospital admissions and transfers account for roughly 20 percent of all patient dispositions from emergency departments across the U.S. As a result, we can expect that REHs will transfer at least 20 percent of their patients; we agreed with commenters and proposed to require that REHs have established relationships with hospitals that have the resources and capacity available to deliver care beyond the scope delivered at the REH.

Ensuring effective communication between providers of health care services and patients and their family is a critical element in the provision of care and the discharge or transfer of

patients. We proposed to require that the REH have effective communication systems in place between the REH and patients (or responsible individuals) and their families, ensuring that the REH would be responsive to their needs and preferences. We believe this will assist with effective care coordination as well as improved patient outcomes.

At § 485.524(b), we proposed personnel requirements for REHs that choose to provide additional outpatient medical and health services. These requirements ensure that the additional services provided by the REH are overseen by at least one responsible individual, have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, and are provided by a physician or other clinician with experience and training in the specialty service area.

At § 485.524(c) we proposed to specify standards that REHs must have for ordering outpatient medical and health services; such standards would be consistent with the hospital requirements at 42 CFR 482.54(c). Specifically, we proposed to require outpatient medical and health services to only be ordered by a practitioner who: (1) is responsible for the care of the patient; (2) is licensed in the state where they provide care to the patient; (3) is acting within their scope of practice under state law; and (4) is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. We also proposed that these requirements would apply to those practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services; and those practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the REH for ordering the applicable outpatient services and for referring patients for such services.

Lastly, the importance of allowing REHs to provide outpatient surgical services was especially noted by commenters in response to the REH RFI. A 2011 rural policy brief by the Rural Policy Research Institute (RUPRI) Center for Rural Health Policy Analysis states that, "Like residents of any community, rural residents have surgical needs that range from the predictable (for example, cataract procedures) to the emergent (for example, appendectomy). Innovations in surgery over the past several decades have made possible the provision of many surgical procedures on an outpatient basis, reducing inpatient admissions." [17] The policy brief found that across four states (Colorado, North Carolina, Vermont, and Wisconsin) in 2011, surgeries were performed across 107 CAHs with an average of 522 outpatient procedures performed per year. This is 75 to 80 percent of the total surgical procedure volume in the state for that year and demonstrates that there will be a need for outpatient surgical services in communities in which CAHs convert to an REH. Therefore, we proposed at § 485.524(d) to set forth standards for an REH performing outpatient surgical services that are consistent with the CAH requirements for surgical services at § 485.639. These include proposed standards for ensuring that the services are conducted in a safe manner by qualified practitioners with specific protocols for administering anesthesia.

Given that in accordance with the statutory provision at section1861(kkk)(1)(A) of the Act services furnished by the REH must not exceed an annual per patient average of 24 hours in the REH, we expect REHs, like ASCs, to provide surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.

Comment: Many commenters supported the proposals related to the provision of outpatient and medical health diagnostic and therapeutic items and services in an REH and stated

that REHs should be allowed flexibility in determining the outpatient services that meet the needs of their communities. Commenters also believed that allowing REHs to provide outpatient services could improve the health of rural communities and reduce the reliance on emergency departments for primary care services. Commenters specifically mentioned that REHs should be able to provide services such as outpatient surgeries, behavioral and mental health services, case management and social services, substance use disorder services (including detoxification, counseling, and medication assisted therapy) and post-hospital care and coordination. Numerous commenters mentioned the need for maternal health services to be provided in REHs due to the lack of access to these resources in rural areas. These commenters supported REHs providing pre-natal care, low-risk labor and delivery services, and any outpatient surgical procedures associated with labor and delivery, as appropriate, with the necessary staff, equipment and medications to ensure that the patient can be treated or stabilized and transferred if necessary. Other commenters stated that providing low-risk deliveries and a surgical team to handle these cases would put a financial burden on REHs.

Response: We thank the interested parties for their comments. Section 1861(kkk)(1)(A)(ii) of the Act allows REHs to provide additional outpatient medical and health services as specified by the Secretary through rulemaking. In the proposed rule (87 FR 40391), we specifically mentioned the REH providing outpatient services commonly furnished in a physician's office or at another entry point into the health care delivery system such as radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. We also noted that the REH could provide additional outpatient medical and health services, if the services aligned with the health needs of the community served by the REH as required by §485.524(a). We agree with the numerous commenters who highlighted the need for

comprehensive maternal health services to be provided in REHs. This aligns with a priority of the Biden-Harris Administration to improve access to maternal health care services. Therefore, we expect that REHs will provide various outpatient services suggested by commenters including, but not limited to services such as, low-risk labor and delivery supported by any emergency surgical procedures necessary and substance use disorder treatment, if identified by a health needs assessment of their community and in accordance with the CoPs for additional outpatient medical and health services finalized in this rule.

Comment: We received some comments requesting that REHs be allowed to establish a distinct part inpatient psychiatric and/or inpatient rehabilitation facility to treat patients requiring these services, similar to the allowance for REHs to have distinct part unit licensed as a SNF. These commenters noted that they have experienced difficulty in locating facilities where these patients may be transferred.

Response: Section 1861(kkk)(2)(B) of the Act defines an REH as not providing any inpatient services (other than SNFs distinct part units). Therefore, REHs, are not allowed to operate a distinct part inpatient psychiatric or rehabilitation unit. We would expect the REH to transfer patients requiring these inpatient services to a provider who could offer the appropriate level of care. As stated previously, we recommend that facilities maintain documentation of instances in which a patient is unable to be transferred timely or when there are specific situations where the patient's stay may exceed 24 hours.

Comment: Some commenters requested clarity regarding whether an REH is allowed to operate a provider-based rural health clinic (RHC).

Response: As stated in the CAA of 2021, a rural emergency hospital may be considered a hospital with less than 50 beds for purposes of the exception to the payment limit for rural health

clinics under section 1833(f) of the Act. Therefore, the statute implicitly states that an REH may continue its operation of provider-based RHCs that meet the qualifications detailed under section 1833(f) of the Act.

Comment: We received over 3,000 comments from the CRNA community opposing the proposal that CRNAs be required to be supervised by an operating practitioner.

Response: We thank the CRNA community for their comments. The proposed CRNA supervision requirement is consistent with the hospital, CAH and ambulatory surgical center requirements. Furthermore, the proposal, consistent with the hospital, CAH and ambulatory surgical center requirements, included a requirement that allows states to opt-out of the CRNA supervision requirement. To be exempt from this requirement, CMS requires a letter from the governor of the state requesting the exemption. In the letter, the governor must attest to the following:

- The governor has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State, and
- The governor has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

Lastly, please note the provision of surgical services are optional for REHs and are not are required service in accordance with the CAA.

After consideration of the public comments we received, we are finalizing § 485.524 as proposed.

(13) Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.526)

Similar to the requirements that we finalized with regard to infection prevention and control and antibiotic stewardship programs for hospitals and CAHs in the September 30, 2019 final rule "Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care" (84 FR 51732), we proposed in this rule that each REH has facility-wide infection prevention and control and antibiotic stewardship programs that are coordinated with the REH quality assessment and performance improvement (QAPI) program, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. Further, we proposed in this rule at § 485.526(a)(1) that the REH ensure that an individual (or individuals), who are qualified through education, training, experience, or certified in infection, prevention and control, are appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program at the REH and that the appointment is based on the recommendations of medical staff and nursing leadership.

At § 485.526(a)(2) we proposed that the infection prevention and control program, as documented in its policies and procedures, employ methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings. The program, as documented in its policies and procedures, would have to employ methods for preventing and controlling the transmission of infection within the REH setting (for example, among patients, personnel, and visitors) as well as between the REH (including outpatient services) and other institutions and health care settings. At § 485.526(a)(3) we proposed that the

infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also address any infection control issues identified by public health authorities. We proposed at § 485.526(a)(4) that the infection prevention and control program reflect the scope and complexity of the services provided by the REH.

At § 485.526(b) we proposed to set standards for the organization and policies of the antibiotic stewardship program. Specifically, we proposed at §485.526(b)(1) to require that the REH's governing body ensure that an individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship is appointed as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff and pharmacy leadership. The proposed requirements at § 485.526(b)(2)(i) through (iii) would ensure that certain goals for an antibiotic stewardship program are met. These include: (i) demonstrating coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, and nursing and pharmacy services; (ii) documenting the evidence-based use of antibiotics in all departments and services of the REH; and (iii) documenting improvements, including sustained improvements, in proper antibiotic use. We believe that these three components are essential for an effective program.

The provisions at § 485.526(b)(3) and (4) would require the REH to ensure that the antibiotic stewardship program adhered to nationally recognized guidelines, as well as best practices, for improving antibiotic use, and that the REH's stewardship program reflects the scope and complexity of services offered. We believe these proposed requirements are necessary to promote a facility-wide culture of quality improvement. We reiterate that these requirements

mirror the hospital and CAH requirements for infection prevention and control and antibiotic stewardship and we note that in the proposed rule for those requirements, published on June 16, 2016 (81 FR 39455), our intention to build flexibility into the regulation by requiring hospitals to demonstrate adherence to nationally recognized guidelines rather than any specific guideline or set of guidelines for infection prevention and control and for antibiotic stewardship. While the CDC guidelines represent one set, there are other sets of nationally recognized guidelines from which facilities might choose, such as those established by the Society for Healthcare Epidemiology of America and the Infectious Diseases Society of America. We believe this approach will provide hospitals the flexibility they need to select and integrate those standards that best suit their individual infection prevention and control and antibiotic stewardship programs. We also believe this approach will allow hospitals the flexibility to adapt their policies and procedures in concert with any updates in the guidelines they have elected to follow. This rationale applies to REHs.

We require that the governing body or responsible individual ensure that the infection prevention and control issues identified by the infection prevention and control professionals be addressed in collaboration with REH leadership. Therefore, at § 485.526(c)(1)(i) and (ii), we proposed certain requirements that the governing body or responsible individual must adhere to including—

- Ensuring systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities to demonstrate the implementation, success, and sustainability of such activities; and

- Ensuring all HAIs and other infectious diseases identified by the infection prevention and control program and antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with REH QAPI leadership.

At § 485.526(c)(2)(i) through (vi), we proposed that the responsibilities of the infection prevention and control professionals would include the development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines. The infection preventionist(s)/infection control professional(s) would be responsible for all documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Additionally, the infection preventionist(s)/infection control professional(s) would be responsible for the following—

- Communication and collaboration with the REH's QAPI program on infection prevention and control issues;
- Competency-based training and education of REH personnel and staff including professional health care staff and, as applicable, personnel providing services in the REH under agreement or arrangement, on the practical applications of infection prevention and control guidelines, policies and procedures;
- Prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel; and
- Communication and collaboration with the antibiotic stewardship program.

At § 485.526(c)(3), we proposed requirements for the leader(s) of the antibiotic stewardship program that are similar, but not identical, to the proposed responsibilities for the REH's designated infection preventionist(s)/infection control professional(s) at proposed

§ 485.526(c)(2). We believe that an REH's antibiotic stewardship program is the most effective means for ensuring appropriate antibiotic use. We also believe that such a program requires a leader who is responsible and accountable for its success. Therefore, we proposed that the leader of the antibiotic stewardship program would be responsible for the development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics. We do not expect that each new leader would develop a new antibiotic stewardship program, unless it is determined that a new program is necessary. We also proposed that the leader of the antibiotic stewardship program would be responsible for all documentation, written or electronic, of antibiotic stewardship program activities. The leader would also be responsible for communicating and collaborating with medical and nursing staff, pharmacy leadership, and the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

We also proposed that the leader would be responsible for the competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Similar to a standard in the hospital CoPs, we proposed a standard at § 485.526(d) for REHs that would allow for the governing body of an REH that is part of a system consisting of multiple, separately certified hospitals, CAHs, and/or REHs using a single system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any REHs, after determining that such a decision is in accordance with all applicable state and local laws. We proposed a similar standard

for CAHs at § 485.640(g). The system's single governing body would be responsible for ensuring that each of its separately certified REHs met the requirements of this section. We note that each separately certified REH subject to the system's single governing body would need to demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Were established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;
- Established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration; and
- Had mechanisms in place to ensure that issues localized to particular REHs were duly considered and addressed.

The REH would also need to demonstrate that it had designated a qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship at the REH to be responsible for:

- Communicating with the system's unified infection prevention and control and antibiotic stewardship programs;
- Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs; and
- Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

Finally, in response to the COVID-19 pandemic, on September 2, 2020, CMS published an interim final rule with comment period to track the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives (85 FR 54820). CMS then published a final rule with comment containing reporting requirements for hospitals and CAHs to report acute respiratory illness during the public health emergency (PHE) for COVID-19 (85 FR 86304) on December 4, 2020. Lastly, on November 5, 2021, CMS published an interim final rule with comment establishing COVID-19 vaccination requirements for most Medicare- and Medicaid-certified providers and suppliers (86 FR 61623). Consistent with the recent changes we made to the hospital and CAH infection control CoPs related to COVID-19 (87 FR 28108) and the declared PHE, we proposed the following three standards for REHs:

- Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential, which would require an REH to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency, directly related to such specific pathogens and infectious diseases.
- COVID-19 reporting, which would require an REH to electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary, including the REH's current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the REH and the current usage rate for those therapeutics beginning at the conclusion of the COVID-19 PHE, and continuing until April 30, 2024, unless the Secretary specifies an earlier end date.

- COVID-19 Vaccination of REH staff, which would require the REH to develop and implement policies and procedures to ensure that all staff, with the exception of those with valid exemptions, are fully vaccinated for COVID-19 until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph. Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 establishes a general 3-year timeline for publishing a Medicare final regulation after a proposed regulation or an interim final regulation has been published. The referenced November 4, 2024 date aligns with the statutory 3-year "Section 902" deadline for the IFC that implemented the COVID-19 staff vaccination requirements for the provider and supplier types covered under that rule. Even though this final rule is not itself subject to the section 902 deadline, we are finalizing a policy that will terminate this vaccination requirement at the same time and under the same circumstances as the vaccination requirement applicable to all other provider-types.

Comment: Commenters were very supportive of this proposal. Several commenters did request we consider delaying implementation to allow for additional time to train staff and develop better QAPI standards.

Response: The proposed standards currently mirror those for CAHs and hospitals and have become an industry standard over the years, especially since the COVID-19 pandemic helped spur innovations in infection control nationwide. We believe that a delay in implementation is unnecessary as REHs should be familiar with the infection control standards and techniques given their previous status as a CAH or hospital and the requirement that they comply with the provisions.

After consideration of the public comments we received, we are finalizing these provisions as proposed.

(14) Condition of Participation: Staffing and Staff Responsibilities (§ 485.528)

Sections 1861(kkk)(1)(B)(i) and (ii) of the Act require that the emergency department of the REH be staffed 24 hours a day, 7 days a week. We proposed to implement this requirement at § 485.528(a). The statute does not speak to the type of staff at the REH that is required to fulfill this role. As such, we believe that REHs should have the flexibility to determine how to staff the emergency department at the REH 24 hours, 7 days a week. We expect that the individual(s) staffing the emergency department is competent to receive patients and activate the appropriate medical resources for the treatment of the patient. In our proposed rule, we noted that such staff may include a nurse, nursing assistant, clinical technician, or an emergency medical technician, (EMT).

We proposed for REHs to meet the applicable CAH requirements at § 485.631 for staffing and staff responsibilities. We believe that many of the CAH staffing requirements are appropriate for application to REHs and as a result, at § 485.528(b) through (e), we set for the proposed standards for staffing, responsibilities of the doctor of medicine or osteopathy, physician assistant, nurse practitioner, and clinical nurse specialist responsibilities similar to CAHs. For instance, the CAH CoPs require at § 485.631(a)(5) that a registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients. Since REHs are required to furnish emergency services and observation care, we proposed a similar requirement as CAHs to require that a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the REH has one or more patients receiving emergency services or observation care.

We also proposed to require standards for the periodic review of clinical privileges and performance that are also identical to the CAH standards at § 485.631, with the exception of the CAH standard at § 485.631(b)(1)(iv), which requires that a doctor of medicine or osteopathy periodically review and sign the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants. We did not propose this standard for REHs given that the REHs are providers of outpatient services exclusively.

We did not believe that it was necessary to apply the CAH requirement that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates (§ 485.631(a)(4)) to REHs. Instead, we proposed to require that the REH standards align with the CAH emergency services requirements at § 485.618. The CAH provision at § 485.618(d) requires that there be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within specified timeframes. This allows for the alignment of the REH proposed provisions with the CAH emergency services standards, as required by the statute.

In response to the REH RFI, commenters indicated that CMS should require board-certified emergency physicians to serve as medical directors of the REH. While we agree that having a board-certified emergency physician serving as the medical director of the REH would benefit patients by ensuring that the REH is overseen by a highly qualified physician with a high level of expertise in emergency medicine, we believe that requiring this of REHs would be unduly burdensome due to the challenges faced by rural communities in obtaining and retaining medical professionals to provide health care services. While we did not propose to require that

REHs have a board-certified emergency physician serve as the medical director, we would encourage REHs to have such a physician serve in the capacity of medical director if possible.

Comment: Some commenters agreed with our proposed policy of only having a physician or other practitioner on-call and available on-site within specified timeframes. Other commenters believed a clinician should be on-site at all times and that an EMT or a nurse would not provide sufficient staffing to meet the requirement that an REH be staffed 24 hours a day, 7 days a week. These commenters felt that that this role should be filled by a physician, nurse practitioner, clinical nurse specialist, or physician assistant with training or experience in emergency care.

Response: The statute does not explicitly specify who needs to fill this role. We believe that the intent of the legislation is to ensure that REHs have the flexibility to determine who best meets the needs of their community while ensuring the provision of safe, quality patient care. We expect REHs to determine who is best to fill this role based on the scope of services provided by the REH and the population served.

After consideration of the public comments suggesting that a staff with certain training or experience in emergency care fill the requirement that the emergency department be staffed at all times, we are finalizing our proposal at § 485.528 with modification. We will require that the REH be staffed at all times by an individual who is competent in the skills needed to address emergency medical care. This individual must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient. We believe that this focus on skills needed to address emergency medical care will ensure that the individual staffing the REH at all times is appropriate. We expect that this individual has the ability to effectively communicate information regarding the condition of patients presenting to the emergency department for treatment to the physician or other practitioner notified of the patient's arrival.

We remind readers that the Emergency Services provision at § 485.516 will require the REH to comply with the CAH Emergency Services CoP at § 485.618, such that the REH must have a physician or other practitioner on-call at all times and available on-site within 30 or 60 min (depending on if the facility is located in a frontier area). We also expect the individual staffing the emergency department of the REH to have the ability to recognize life-threatening emergencies and provide cardiopulmonary resuscitation to patients presenting to the emergency department, if necessary.

As noted in the discussion of the Emergency Services requirements at § 485.516, we believe that these revisions sufficiently address commenters concern regarding ensuring the REH's emergency department is appropriately staffed.

(15) Condition of Participation: Nursing Services (§ 485.530)

The CoPs for hospitals and CAHs include a provision for nursing services. However, given that each of these providers offers acute care inpatient services, we do not believe that all nursing services requirements for hospitals and CAHs are appropriate for REHs, which are outpatient-only providers. In evaluating the appropriateness of nursing services requirements for REHs, we also took into consideration the CfCs for ambulatory surgery centers at 42 CFR part 416 since they, like REHs, only offer outpatient services.

Consistent with the hospital requirements, we proposed at § 485.530 to require that REHs have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. We believe that the REH should have a sufficient number of nurses available to provide services, based on the number of patients receiving services in the REH and the level of care required to be provided to those patients.

Similar to the standard for hospitals set out at § 482.23(a), we proposed at § 485.530(a) to require that patient care responsibilities must be delineated for all nursing service personnel and that nursing services must be provided in accordance with recognized standards of practice. Also consistent with the hospital standards for nursing services, we proposed to require at § 485.530(b) that the REH have a director of nursing who is a licensed registered nurse and who is responsible for the operation of the nursing services.

Comment: Commenters were generally supportive of the proposal. One commenter suggested that an RN always be available on-site at the REH.

Response: This provision was modeled after the CAH requirement at § 485.631(a)(5) that a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the CAH has one or more inpatients. Although REHs are outpatient-only facilities, they are required to provide emergency services and observation care. As a result, we believe it is appropriate for them to have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the REH is providing emergency services and observation care to one or more patients, as required at § 485.528(b)(4). We are also requiring the REH to have nursing services that are available to be provided 24-hours a day for the provision of patient care. In cases in which there is not a patient receiving emergency services or observation care, but a patient subsequently presents to the REH for such services or care, the REH would be required to provide nursing services for the patient.

Additionally, the statute requires that the REH be staffed at all times. As discussed in the section for Staffing and Staff Responsibilities (§ 485.528), we are requiring that the individual(s) who fulfills the requirement that the REH must be staffed at all times must be an individual(s) who is competent in the skills needed to address emergency medical care. This individual(s)

must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient. Furthermore, we are incorporating staffing into the REH's QAPI program at § 485.536(a)(1) to further address commenters concerns related to the REH staff and staff responsibilities.

After consideration of the public comments we received, we are finalizing as proposed.

(16) Condition of Participation: Discharge Planning (§ 485.532)

Hospitals and CAHs have very similar discharge planning requirements at §§ 482.43 and 485.642, respectively. These requirements were revised in the final rule entitled "Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care" (84 FR 51836). Many commenters on the REH RFI noted the importance of having in-depth discharge planning requirements for REHs, highlighting the need for REH patients to have safe, well-coordinated discharge processes due to the availability of fewer health care resources in rural environments. As a result, we proposed to closely align the proposed discharge planning requirements for REHs with the requirements for hospitals and CAHs. Specifically, proposed at § 485.532 to require that the patient's discharge plan address the patient's goals of care and treatment preferences. During the discharge planning process, we would expect that the appropriate medical staff would discuss the patient's post-acute care goals and treatment preferences with the patient, the patient's family or their caregiver/ support persons (or both) and subsequently document these goals and preferences in the medical record. We would expect these documented goals and treatment preferences to be taken into account throughout the entire discharge planning process. We note that as a provider of emergency services, the REH may receive patients from nursing homes who

require emergency care. Having a robust discharge planning process in place is imperative for this patient population. There may be instances in which a patient comes to the REH from a nursing home and the nursing home either expresses an intent not to accept the patient or delays the patient's return back to the nursing home after the completion of emergency care by the REH. Under these circumstances, we would encourage the REH to contact their State's long-term care ombudsman or State Survey Agency. We also encourage the REH to inform patients who arrive from or are discharged to a long-term care facility about how to contact the Ombudsman and State Survey Agency, if a patient is having quality of care or quality of life concerns. The Administration of Community Living's Long-Term Care Ombudsman Programs, ". . . work to resolve problems related to the health, safety, welfare, and rights of individuals who live in LTC facilities, such as nursing homes, board and care and assisted living facilities, and other residential care communities. Ombudsman programs promote policies and consumer protections to improve long-term services and supports at the facility, local, state, and national levels." [19]

At § 485.532(a) introductory text and (a)(1), we proposed to require that REHs implement a discharge planning process to begin identifying, early in the provision of services, the anticipated post-discharge goals, preferences, and needs of the patient and begin to develop an appropriate discharge plan for patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning. Timely identification of the patient's goals, preferences, and needs and development of the discharge plan would reduce delays in the overall discharge process. Patient referrals to or consultation with community care organizations will be a key step, for some, in assuring successful patient outcomes. Therefore, we believe that discharge planning for patients is a process that involves the consideration of the

patient's unique circumstances, treatment preferences, and goals of care, and is not solely a documentation process.

In addition, in order to encourage patient engagement and understanding of their discharge plan or instructions, we recommend that providers follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (https://www.thinkculturalhealth.hhs.gov/class/standards), which provide guidance on providing instructions in a culturally and linguistically appropriate manner. We remind providers of their obligations to take reasonable steps to provide meaningful access to individuals with limited English proficiency in accordance with Title VI of the Civil Rights Act of 1964 and section 1557 of the Patient Protection and Affordable Care Act (the Affordable Care Act). In addition, providers are reminded to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services, in accordance with section 504 of the Rehabilitation Act, the Americans with Disabilities Act (ADA), and section 1557 of the Affordable Care Act (see, *https://www.hhs.gov/civil-rights* and *https://www.ada.gov* for more information on these requirements). Discharge planning would be of little value to patients who cannot understand or appropriately follow the discharge plans discussed in this rule. Without appropriate language assistance or auxiliary aids and services, discharge planners would not be able to fully involve the patient and caregiver/support person in the development of the discharge plan. Furthermore, the discharge planner would not be fully aware of the patient's goals for discharge.

Additionally, effective discharge planning would assist REHs in complying with the U.S. Supreme Court's holding in *Olmstead* v. *L.C.* (527 U.S. 581 (1999)), which found that the unjustified segregation of people with disabilities is a form of unlawful discrimination under the

ADA. We note that effective discharge planning may assist REHs in ensuring that individuals being discharged who would otherwise be entitled to institutional services, have access to community-based services when—(1) such placement is appropriate; (2) the affected person does not oppose such treatment; and (3) the placement can be reasonably accommodated. As noted by comments received in response to the REH RFI, discharge planning should focus on returning the patient to a home or community-based setting to the fullest extent possible with necessary supports and service. These proposed discharge planning standards are aimed at achieving this goal.

At § 485.532(a)(2), we proposed to require an REH to perform a discharge planning evaluation which would have to include an evaluation of a patient's likely need for appropriate services following care that has been furnished by an REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

At § 485.532(a)(3) we proposed to require that the patient's discharge needs evaluation and discharge plan be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs, so that appropriate arrangements for post-REH care could be made before discharge. This requirement would prevent the patient's discharge or transfer from being unduly delayed. We expect that in response to this requirement, REHs would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. All relevant patient information would be incorporated into the discharge plan to facilitate its implementation and the discharge plan would have to be included in the patient's medical record. The results of the evaluation would also have to be

discussed with the patient or patient's representative. Furthermore, we believe that REHs would use their evaluation of the discharge planning process, with solicitation of feedback from other providers and suppliers in the community, as well as from patients and caregivers, to revise their timeframes, as needed. We encourage REHs to make use of available health information technology, such as electronic health records, as well as entities that can facilitate exchange, such as health information exchanges, to enhance the efficiency and effectiveness of their discharge process.

At § 485.532(a)(4), we proposed to require the REH to arrange for the development and initial implementation of a discharge plan for those patients so identified as well as for other patients upon the request of the patient's physician. We proposed at § 485.532(a)(5) to require that a registered nurse, social worker, or other personnel qualified in accordance with the REH's discharge planning policy coordinate the discharge needs evaluation and the development of the discharge plan.

At § 485.532(a)(6) we proposed to require that the REH's discharge planning process ensure an ongoing patient evaluation throughout the patient's REH stay or visit to identify any changes in the patient's condition that would require modifications to the discharge plan. The evaluation to determine a patients continued stays at the REH (or in other words, their readiness for discharge or transfer), is a current standard of medical practice.

We proposed to require at § 485.532(a)(7) that the hospital assess its discharge planning process on a regular basis and include, as part of the assessment, an ongoing review of a representative sample of discharge plans. We expect that this would include patients who were emergency department revisits or presented to the emergency department within 30 days of a previous visit, to ensure that the REH is responsive to the discharge needs of patients.

In addition to standards for evaluating the discharge needs of patients and the development of discharge plans, the hospital and CAH discharge planning provisions also require that the hospital and CAH assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), SNF, inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH) data on quality measures and data on resource use measures. Furthermore, the CoPs for those facility-types require the hospital and CAH to ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. We believe these requirements are applicable to REHs, given that we expect some patients of the REH to be discharged to a post-acute care provider. As result, we proposed at § 485.532(a)(8) to require REHs to share data on quality measures and resource use measures of local post-acute care providers with patients to assist them in selecting a post-acute care provider.

We proposed at § 485.532(b) to require that the REH would be required to discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

The Agency for Healthcare Research and Quality (AHRQ) released an environmental scan report on Improving the Emergency Department Discharge Process, that evaluated the state of the emergency department discharge process and ways in which it could be improved.[20] The report found that a high-quality emergency department discharge incorporates the following:

- Informs and educates patients on their diagnosis, prognosis, treatment plan, and expected course of illness. This includes informing patients of the details of their visit (treatments, tests, procedures).
- Supports patients in receiving post-emergency department discharge care. This might include medications, home care of injuries, use of medical devices/equipment, further diagnostic testing, and further health care provider evaluation; and
- Coordinates emergency department care within the context of the health care system (other health care providers, social services, etc.).

We believe discharge planning requirements proposed for REHs address the goals identified in the report.

Comment: Commenters were generally supportive and appreciated the robust requirements proposed for REHs given the rural communities they serve, highlighting the importance of care coordination and transitional care in these communities. One commenter suggested that CMS require REHs to comply with the hospital discharge planning standard at §482.43(c)(2), which requires that the hospital, as part of the discharge planning process, inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express.

Response: We appreciate the commenters' support of our proposal. In response to the commenters' suggestion that CMS require REHs to comply with the hospital discharge planning standard at §482.43(c)(2), this requirement is applicable to hospitals only, and is not applied to CAHs or REHs. The hospital discharge planning statutory requirements for patient choice are

located at sections 1861(ee)(2)(H) and 1861(ee)(3) of the Act, under the definition of "Discharge Planning Process."

We also note that we proposed at § 485.532 to require that REHs have an effective discharge planning process that focused on the patient's goals and treatment preferences and includes the patient and their caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the REH to post-discharge care, and reduce the factors leading to preventable hospital admissions or readmissions. We highlight that this requirement is intended to ensure that the patient and their caregiver/support person(s) are an integral part of the discharge planning process and we expect that to include making the patient aware of their freedom to choose among participating Medicare providers and suppliers of post-discharge services.

After consideration of the public comments we received, we are finalizing this provision as proposed.

(17) Condition of Participation: Patient's Rights (§ 485.534)

It is imperative for patients to have the ability to exercise certain rights and protections while seeking and receiving necessary care and services at an REH. As previously mentioned, the appropriate provision of behavioral health is very important in the treatment and safety of patients and staff. Behavioral health is a challenge in rural areas, due to the accessibility, affordability, acceptability and availability of these services. The demand for mental health is increasing, with 67 percent of organizations seeing an increase in the demand for services (National Council for Mental Wellbeing: https://www.thenationalcouncil.org/press-releases/new-

report-40-of-mental-health-and-addiction-treatment-organizations-will-survive-less-than-a-year-without-additional-financial-support/). According to a 2017 report from the National Council for Behavioral Health, there is a shortage of mental health professionals leading to a gap of up to 15,000 practitioners by 2025. This lack of access to psychiatric services is contributing to an increase in the unitization of hospital emergency departments. Therefore, we anticipate that some patients may rely on REH's to access behavioral health care services, and we believe it is important to have policies and procedures in place for REHs and CAHs (discussed later in this rule) in the event of a mental health crisis and the need for the use of restraints and seclusions. We proposed to establish a CoP for patient's rights at § 485.534 that would set forth the rights of all patients to receive care in a safe setting, and would require the facility to protect the patient's emotional and physical health and safety. Furthermore, we proposed to establish the patient's rights CoP for REHs closely to the patient's rights CoP for hospitals at § 482.13. The REH would be required to inform patients of and permit them to exercise their rights; address privacy and safety; adhere to the confidentiality of patient records; abide by restrictions on the use of restraint and seclusion; and adhere to patient visitation rights. We proposed to add these same patient's rights CoPs for CAHs, as well. Some of these requirements are currently in the SOM for CAHs while some are not explicitly required. We believe that these patient rights provisions are important for hospitals, CAHs, and REHs. However, some of the provisions proposed for REHs and CAHs are less prescriptive than those for hospitals because we proposed to allow for these providers to develop policies and procedures based on the scope of services they provide and patient populations that they serve. For example, we believe that REHs, like CAHs, would have a lower volume of patients than hospitals and the use of restraints and seclusion would not be as frequent as with other providers. REHs would not be providing inpatient services and if a patient

presented at the REH in crisis or needing a level of care so acute that restraints or seclusions became necessary, we would expect the REH to arrange for the transfer of the patient to a higher level of care.

Notice of Rights

At § 485.534(a), we proposed that an REH inform each patient or patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This included a proposal to require the REH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.

Exercise of Rights

At § 485.534(b), we proposed to specify those rights a patient has regarding their medical care, which includes the right to make informed decisions regarding their care, to be fully informed about such care, and the right to request or refuse treatment. We noted that this right was not to be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. In addition, we proposed to specify that the patient also has the right to formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives.

Privacy, Safety, and Confidentiality of Patient Records

At § 485.534(c), we proposed to specify that the patient has the right to personal privacy, receive care in a safe setting, and be free from all forms of abuse or harassment. At § 485.534(d), we proposed to specify that the patient has the right to the confidentiality of their medical records and the right to access their medical records. We also proposed that the REH be required to provide the patient with their records in a form and format requested by the patient, and within a

reasonable timeframe, so as not to frustrate the legitimate efforts of individuals to gain access to their own medical records.

Use of Restraints and Seclusion

At § 485.534(e), we proposed rules relating to the use of restraints and seclusion that would be less burdensome than those for hospitals, because we believe that the likelihood of an REH needing to utilize restraints and seclusion would be relatively low. In addition, in the event that there were patients requiring restraint and seclusion, we would expect them to be transferred quickly to a higher level of care. We note that we have similar expectations for CAHs and are finalizing similar requirements for CAHs in this rule. We proposed to specify that all patients have the right to be free from physical or mental abuse, from corporal punishment, and from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. We proposed that restraint or seclusion would only be imposed to ensure the immediate physical safety of the patient, a staff member, or others, and would have to be discontinued at the earliest possible time. We proposed to define “restraint” as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). We proposed

to define "seclusion" as the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion could only be used for the management of violent or self-destructive behavior.

At § 485.534(e)(2), we proposed to require that the restraint or seclusion only be used when less restrictive interventions had been determined to be ineffective to protect the patient, a staff member, or others from harm, and at § 485.534(e)(3) that the type or technique of restraint or seclusion used would have to be the least restrictive intervention that will be effective to protect the patient, staff member, or others from harm. At § 485.534(e)(4), we proposed that the REH would have to have written policies and procedures regarding the use of restraint and seclusion consistent with current standards of practice. These requirements would allow for the REH to use restraints and seclusion in the event that it was necessary and as a last resort to respond to immediate safety concerns, but would present a lesser burden and allow for more flexibility than existing hospital CoPs. We believe that allowing the REH the flexibility to develop their own policies and procedures for restraints and seclusion based on the scope of services they provide is necessary given their patient volumes, populations, and access to resources. We proposed to require that such policies and procedures be consistent with current standards of practice.

Staff Training Requirements for the Use of Restraints or Seclusion

The following staff training requirements are not as prescriptive as the existing hospital requirements, and we proposed these same requirements for CAHs in the REH NPRM. At § 485.534(f) we proposed to establish staff training requirements for the use of restraints and seclusion. Specifically, we proposed that the patient has the right to safe implementation of restraint or seclusion, when necessary, by trained staff. We proposed at § 485.534(f)(1) that the

REH would have to provide competency-based training and education of REH personnel and staff, including medical staff and contractors, on the use of restraint and seclusion. We proposed to require that the training be patient-centered, meaning that t staff are able to ensure that the use of restraint and seclusion for patients receiving services in an REH is respectful of, and responsive to, individual patient preferences, needs and values. Additionally, to ensure that staff are educated and trained on using the least restrictive intervention necessary for the safety of the patients and REH staff, we proposed at § 485.534(f)(2) to require that the REH staff train their staff in alternatives to the use of restraint and seclusion. For example, we proposed that staff have trauma-informed knowledge competencies and be aware of effective de-escalation techniques that could be used to avoid the use of restraint and seclusion and the trauma that may be associated with their use. Trained peer workers (people who share similar experiences of being diagnosed with mental health conditions, substance use disorders, or both) and community health workers (CHWs) could also serve a useful role in assisting patients and other staff. This could include helping to monitor use of restraint and seclusion, deescalating interactions with patients and contributing to a positive and supportive environment for patients, family members, and REH staff. REHs are encouraged to consider the use of peer workers and CHWs in their staffing plans. For further information, please see the 2007 guidance on use of peers in the Medicaid program (*https://www.medicaid.gov/federal-policy-guidance/downloads/SMD081507A.pdf*) and resources from the Substance Abuse and Mental Health Services Administration (https://www.samhsa.gov/brss-tacs/recovery- *support-tools/peers*). In addition, facilities are encouraged to consider any nutritional needs while a patient is restrained, such as a need to provide food and water.

Death Reporting Requirements

The REH death reporting requirements are similar to the hospital requirements at § 482.13. At § 485.534(g), we proposed to establish requirements that REHs must follow when reporting deaths associated with the use of seclusion or restraint. Specifically, we proposed to require that the REH report to CMS, by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day the following information—(1) Each death that occurs while a patient is in restraint or seclusion; (2) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. We note that "reasonable to assume" in this context would include, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

For instances when no seclusion had been used and when the only restraints used on the patient were those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the REH staff would have to record in an internal log or other system, the following information: (1) Any death that occurs while a patient was in such restraints; (2) Any death that occurred within 24 hours after a patient had been removed from such restraints. Furthermore, we proposed that staff document in the patient's medical record the date and time the death was reported to CMS or recorded in the internal log or other system. Also, for instances when no seclusion had been used and when the only restraints used on the patient were those applied exclusively to the patient's wrist(s),we proposed to require that entries into the internal log or other system must be documented no later than seven days after the date

of death of the patient, include the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es), and to be made available in either written or electronic form to CMS immediately upon request.

Patient Visitation Rights

At § 485.534(h), we proposed to establish requirements related to a patient's visitation rights. These requirements would be consistent with the current hospital and CAH regulations. Specifically, we proposed that an REH have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH would have to inform patients (or support persons, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they were informed of their other rights. Each patient would be informed (or support persons, where appropriate) of the right, subject to their consent, to receive the visitors whom they designated, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend. The patient would also have the right to withdraw or deny such consent at any time. The facility could not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability, and ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Comment: Most commenters supported the proposed patient's rights requirements for REHs. Commenters stated that REHs should have the same patient rights requirements as

hospitals. A commenter suggested that we follow HIPAA requirements for patient confidentiality rights and privacy to avoid any confusion.

Response: We appreciate the support and suggestions from interested parties. Our goal was to establish patient's rights that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. We believe that we have done that and allowed the flexibility for REHs to develop their own policies and procedures in response to the use of restraints and seclusions, in the event that they are necessary.

After consideration of the public comments we received, we are finalizing these provisions as proposed.

(18) Condition of Participation: Quality Assessment and Performance Improvement Program (QAPI program) (§ 485.536)

An effective QAPI program that is engaged in continuous improvement efforts is essential to a provider's ability to deliver high quality and safe care to its patients, while reducing the incidence of medical errors and adverse events. Therefore, we believe the QAPI programs for REHs should conform to the current health care industry standards that require providers to proactively design quality improvement into each program at the outset, monitor data (indicators, measures and reports of staff/residents/families), determine root causes of problems, develop and implement plans that affect system improvement, and monitor the success of this systematic approach to improving quality.

At § 485.536, we proposed to require that every REH develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. This requirement ensures that the REH systematically reviews its operating systems and processes of care to identify and

implement opportunities to deliver effective care to its patients focusing on improving health outcomes and preventing and reducing medical errors.

In the development of the proposed requirements for the REH QAPI program, we reviewed the CAH QAPI requirements at § 485.641, which we note are also closely aligned with the hospital QAPI requirements at § 482.21. We also took into account the comments on the REH RFI and input from other interested parties who requested that CMS consider the clinical and administrative limitations that rural providers experience and, where appropriate, we have proposed requirements that minimize burden while maintaining the ability of the REH to proactively maximize quality improvement activities and programs.

The proposed QAPI program contained the following five parts: (a) Program and scope; (b) Program data collection and analysis; (c) Program activities; (d) Executive responsibilities; and (e) Unified and integrated QAPI program for an REH in a multi-hospital system.

Similar to the program scope standard for hospitals at § 482.21(a)(1) and (2), at § 485.536(a)(1), we proposed to require the REH to have an ongoing QAPI program that reflects improvement in quality indicators related to health outcomes and reductions in medical errors. In proposed paragraph § 485.536(a)(2) we would require REHs to measure, analyze, and track these quality indicators. At § 485.536(b), we proposed to mirror the program data collection and analysis standard for CAHs at § 485.641(e) and require that the REH's QAPI program incorporate quality indicator data including patient care data, quality measures data, and other relevant data in order to attain quality improvement.

Similar to the program activities standard for hospitals at § 482.21(c), at § 485.536(c)(1), we proposed to require the REH to set priorities for its performance improvement activities focused on high-risk, high-volume, or problem-prone areas. We also proposed to require the

REH to consider the incidence, prevalence, and severity of problems in those identified areas and that the set priority areas affect health outcomes, patient safety, and quality of care. At § 485.536(c)(2) and (3), we proposed to require the REH's performance improvement activities to track medical errors and adverse events, analyze their causes, and implement preventive actions. We would expect the REH to conduct analyses at regular intervals to track performance and ensure that improvements were sustained.

We proposed at § 485.536(d), similar to the standard for executive responsibilities for hospitals at § 482.21(e), that the responsibilities for the REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials include ensuring that the QAPI program is implemented and maintained, properly evaluated, and appropriately resourced.

Lastly, consistent with the standard included at § 482.21(f) in the hospital CoPs for QAPI programs, we proposed at § 485.536(e) to allow REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program if in accordance with all applicable state and local laws. Specifically, we proposed to specify that the system's governing body would be responsible and accountable for ensuring that each of its separately certified REHs met the proposed QAPI program requirements. We expect this policy would be beneficial to REHs that may lack time, resources or staff to implement an REH-specific QAPI program. The REH would be able to benefit from the resources and expertise of a multi-hospital system in implementing their QAPI program, as well as potentially reduce the time and labor investments required to enact and maintain the program.

We were interested in input from the public regarding possible unintended consequences that could occur as a result of allowing REHs to participate in a unified and integrated QAPI program. We were interested in feedback regarding how the integrated health system's governing body would ensure that they consider the REH's unique circumstances and any significant differences in patient populations and services offered at the REH. We also sought comments regarding how the integrated health system's governing body would ensure that an REH participating in a unified and integrated QAPI program provided the appropriate level of care to patients being treated in the REH, including being appropriately transferred to another facility when necessary.

Comment: Commenters were generally supportive of the proposals for QAPI programs for REHs. Some commenters specifically noted their support of the proposal to allow REHs that are part of a multi-facility system to elect to have a unified and integrated QAPI program stating that it could help relive administrative burden for REHs. Other commenters noted that REHs may not have the resources to gather and analyze data to inform a QAPI program.

Response: We thank the commenters for their feedback. With regard to providers lacking the resources to implement a QAPI program, as we stated in the proposed rule, the proposed requirements for REH QAPI programs were developed with the intent of being consistent with the CAH QAPI requirements at § 485.641. Many hospitals who may convert to an REH currently adhere to these standards. Therefore, we believe our finalized QAPI requirements will not overburden the REH staff.

Comment: We received two comments regarding the proposed standard at § 485.536(d) for Executive Responsibilities. These commenters noted that this standard mirrored the QAPI

standard for Executive Responsibilities at § 482.21(e) for hospitals and requested that we instead mirror the CAH standard for Governance and Leadership at § 485.641(c) for REHs.

Response: As stated in the proposed rule, when developing the proposed QAPI requirements for REHs we reviewed both the CAH QAPI requirements at § 485.641 and the hospital QAPI requirements at § 482.21. We chose not to mirror the CAH standard for Governance and Leadership at § 485.641(c) for REHs because this standard references a requirement that the CAH's governing body be ultimately responsible for addressing outcome indicators related to readmissions, which is not relevant for REHs because they do not provide inpatient services. Therefore, we instead aligned this requirement with the hospital QAPI regulations at § 482.21 that require the governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials include to ensure that the QAPI program is implemented and maintained, properly evaluated, and appropriately resourced. We believed this standard was reasonable for REHs as well and fairly similar to the CAH requirement at § 485.641(c).

Comment: As discussed in the Staffing and Staff Responsibilities section, some commenters noted concerns regarding the staffing of an REH. Some commenters believed that an EMT or a nurse would not provide sufficient staffing to meet the requirement that an REH be staffed 24 hours a day, 7 days a week. These commenters felt that that this role should be filled by a physician, nurse practitioner, clinical nurse specialist, or physician assistant with training or experience in emergency care. Other commenters stated that if the REH was not sufficiently staffed, it could impact the ability to respond to an obstetrical emergency.

Response: As noted at § 485.528, we are requiring that the individual(s) who fulfills the requirement that the REH must be staffed at all times must be an individual(s) who is competent

in the skills needed to address emergency medical care. This individual(s) must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient. We believe that incorporating staffing into the REH's QAPI program will further address commenters concerns related to the REH staff and staff responsibilities. Therefore, we are revising the standard at § 485.536(a)(2) to specifically require the REH to measure, analyze, and track staffing as a quality indicator to assesses processes of care, REH service and operations.

After consideration of the public comments we received, we are finalizing § 485.536(a)(2) with a modification to require the REH to specifically measure, analyze, and track staffing as a quality indicator.

(19) Condition of Participation: Agreements (§ 485.538)

Section 1861(kkk)(2)(C) of the Act, as added by the CAA, requires an REH to have in effect a transfer agreement with a level I or level II trauma center. In accordance with section 1861(kkk)(2)(C) of the Act, at § 485.538 we proposed to require that REHs have in effect an agreement with at least one Medicare-certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. We would require that the level I or level II trauma center meets certain licensure requirements including being licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state. It is also acceptable for the level I or II trauma center to be located in a state other than the state where the REH is located. In addition, we proposed to require that the level I or level II trauma center must also be licensed or designated by the state or local

government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

We received several comments to the REH RFI regarding transfer agreements between REHs and hospitals that are not designated as a level I or II trauma center. Specifically, commenters stated that due to distance, or the possibility that level I or level II trauma centers may not have available beds, many rural CAHs currently transfer patients to level III or level IV trauma centers based on the patient's specific needs. Commenters requested that CMS allow these facilities to retain these agreements, should they convert to REHs. We would expect REHs to comply with the CoP detailed at § 485.538 and to have a transfer agreement in place with a level I or II trauma center. However, we do not believe that the statute precludes an REH from also having a transfer agreement with a hospital that is not designated as a level I or II trauma center. An REH may have pre-existing relationships with hospitals that are not designated as level I or level II trauma centers. In these instances, the proposed requirement would not preclude them from maintaining those relationships and leveraging resources and capacity that may be available to deliver care that is beyond the scope of care delivered at the REH.

Comment: Many commenters were supportive of the proposed requirement for an REH to have in effect a transfer agreement with at least one Medicare-certified hospital that is a level I or level II trauma center. Commenters noted that agreements with level I or level II trauma centers are vital to ensure that patients requiring serious medical care are able to receive it. Some commenters suggested that REHs that are located more than 50 miles distance from a level I or II trauma center be allowed to meet this requirement by maintaining agreements with closer facilities that may not be designated as a level I or level II trauma center.

Response: We previously noted that REHs are required by section 1861(kkk)(2)(C) of the Act to have in effect a transfer agreement with a level I or level II trauma center. We stated in the proposed rule that we did not believe that the statute precluded an REH from also having a transfer agreement with a hospital that is not designated as a level I or II trauma center. However, we do not have the authority to exempt REHs from this requirement or allow the requirement to be met by only maintaining arrangements with other types of facilities that are not designated as level I or level II trauma centers. Further, we believe that even if an REH rarely transfers a patient to a level I or level II trauma center, having an agreement in place will save critical time and resources if the transfer of a patient is medically necessary.

Comment: One commenter recommended that CMS require REHs to include the capacity for telemedicine capabilities with a physician with, at the minimum, experience in the practice of emergency medicine in the transfer agreement with a level I or level II trauma center. Another commenter recommended that REHs be required to have transfer agreements with a trauma center that has pediatric trauma capability. Other commenters recommended that CMS require REHs to enter into transfer agreements with the closest inpatient psychiatric facility in order to transfer patients who require behavioral health services.

Response: We believe that REHs should have the flexibility to determine the content of the agreements with a level I or level II trauma center based on what will best meet the needs of the patients in their communities as well as the providers involved in the agreement. With regard to transfer agreements with facilities that offer specialties such as pediatric trauma care and inpatient psychiatric services, we also believe that the REH is in the best position to determine the necessity for these agreements without establishing a CoP to require such.

After consideration of the public comments we received, we are finalizing § 485.538 as proposed.

(20) Condition of Participation: Medical Records (§ 485.540)

The maintenance of a medical records system is a longstanding requirement in both the hospital and CAH CoPs. In the development of proposed requirements for medical records for REHs, we reviewed the CoPs for medical records for CAHs established at § 485.638, including the requirements finalized in the May 2020 final rule, "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access" (85 FR 25510 through 25585), focused on electronic patient event notifications of a patient's admission, discharge, and/or transfer to another health care facility or to another community provider. We also considered the comments from the REH RFI that encouraged CMS to closely align the CoPs for REHs with currently established requirements for CAHs. After reviewing the CoPs for medical records for CAHs at § 485.638, we believed that the requirements established for medical records for CAHs are also appropriate for REHs. We also would expect that many facilities that may elect to convert to an REH would presently have these systems in place, which may minimize administrative burden. Therefore, at § 485.540(a), we proposed to require that the REH maintain a medical records system in accordance with written policies and procedures; that such records be legible, complete, accurately documented, readily accessible, and systematically organized and that a designated member of the professional staff be responsible for maintaining the records. We also proposed to require that for each patient receiving health care services, the REH would be required to maintain a record that would include, as applicable, identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the

episode, disposition, and instructions to the patient. We proposed that the record requirements include reports of physical examinations; diagnostic and laboratory test results, including clinical laboratory services; consultative findings and all orders of doctors of medicine or osteopathy or other practitioners; reports of treatments and medications; nursing notes and documentation of complications; and other pertinent information necessary to monitor the patient's progress, such as temperature graphics or progress notes describing the patient's response to treatment. Lastly, we proposed that the record include dated signatures of the doctor of medicine or osteopathy or other health care professional.

At § 485.540(b) and (c), we proposed to require the REH to maintain the confidentiality of patients' medical record information and to ensure that such records would be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

Lastly, at § 485.540(d), we proposed a standard for electronic notifications if the REH utilizes an electronic medical records system or other electronic administrative system that conforms with the content exchange standard at 45 CFR 170.205(d)(2). This requirement was intended to limit the applicability of this CoP to those REHs which currently possess an EHR or other electronic administrative system with the technical capacity to generate information for electronic patient event notifications. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25585), electronic patient event notifications can be an effective tool for improving care coordination across settings, especially when patients are discharged. We proposed to require the REH to demonstrate that the system's notification capacity was fully operational and sends notifications with at least specified patient information, as appropriate, and facilitates the exchange of health information when the patient is registered, discharged, or

transferred from the REH's emergency department. Finally, we proposed to require that the REH make a reasonable effort to ensure that the system would send notifications to specific recipients, including the patient's applicable post-acute care and primary care services providers.

Comment: Commenters supported the proposed requirement for the maintenance of medical records. One commenter asked whether a physician or other health care professional would be required to sign the medical record for patients receiving observation services.

Response: We appreciate the commenters' input. At § 485.540(a)(4)(iv), the REH is required to maintain records that are dated and signed by the doctor of medicine or osteopathy or other health care professional for each patient receiving health care services, including observation services.

After consideration of the public comments we received, we are finalizing § 485.540 as proposed.

(21) Condition of Participation: Emergency Preparedness (§ 485.542)

Over the past several years, the U.S. has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, tornadoes and floods in the spring of 2011, the 2009 H1N1 influenza pandemic, and Hurricane Sandy in 2012 and most recently, the COVID-19 pandemic, readiness for public health emergencies has been put on the national agenda. On September 16, 2016, we published a final rule, "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" (81 FR 63860), to establish emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with

Federal, state, tribal, regional, and local emergency preparedness systems. Disasters can disrupt the health care environment and change the demand for health care services. This makes it essential that health care providers and suppliers ensure that emergency management is integrated into their daily functions and values.

Thus, we proposed emergency preparedness requirements to establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness for REHs that would align with the existing emergency preparedness standards for other Medicare and Medicaid participating providers and suppliers. These proposed requirements mirrored the existing CAH emergency preparedness requirements. The emergency preparedness requirements for all Medicare-participating providers and suppliers are generally consistent, with some differences based on the provider type (such as inpatient versus outpatient).

Consistent with the standards for most other Medicare and Medicaid participating providers and suppliers, we proposed to require REHs to comply with all applicable Federal, state, and local emergency preparedness requirements. In addition, we proposed to require that the REH establish and maintain an emergency preparedness program that addressed four core elements that we believe are central to an effective emergency preparedness system. The four elements are: (1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training and testing.

At § 485.542(a), we proposed to require that REHs develop and maintain an emergency preparedness plan that would have to be reviewed and updated at least every 2 years. Specifically, we proposed to require that the REHs emergency plan —(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach; (2) include strategies for addressing emergency events identified by the risk

assessment; (3) address the patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans; and (4) include a process for cooperation and collaboration with local, tribal, regional, state, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

At § 485.542(b), we proposed to require REHs to develop and implement policies and procedures, based on the emergency plan, risk assessment, and communication plan, which would be reviewed and updated at least every 2 years. Specifically, we proposed to require that the policies and procedures would have to address the following:

- Provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, including, but not limited to food, water, medical and pharmaceutical supplies, other sources of energy to maintain temperatures, emergency lighting, fire detection and sewage and waste disposal;
- A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency; if staff were being relocated the REH would have to document the specific name and location of the receiving facility or other location;
- Safe evacuation from the REH, to include consideration of care and treatment needs of the evacuees, staff responsibilities and transportation and identification of the evacuation location(s);
- A means to shelter in place for any patients, staff and volunteers that remain at the REH;
- A system of medical documentation that would preserve patient information, protects confidentiality of all patient information and secures and maintains the availability of the records;

- The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency; and
- The role of the REH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

We believe that small, rural REHs would be able to develop an appropriate emergency preparedness plan and develop policies and procedures in accordance with our proposed requirements with the assistance of resources in their state and local community guidance.

At § 485.542(c), we proposed to require REHs to develop and maintain an emergency preparedness communication plan that would comply with both Federal and state law; the plan would have to be reviewed and updated at least every 2 years. The communication plan would be required to include the following:

- Names and contact information for staff, entities providing services under agreement, patients' physicians and volunteers;
- Contact information for Federal, state, tribal, regional, and local emergency preparedness staff and other sources of assistance;
- Primary and alternate means for communicating with the REH's staff and Federal, state, tribal, regional, and local emergency management agencies;
- A method for sharing information and medical documentation for patients under the REH's care, as necessary, with other health care providers to maintain the continuity of care;
- A means, in the event of an evacuation, to release patient information;

- A means of providing information about the general condition and location of patients under the facility's care; and
- A means of providing information about the REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

We would expect patient care to be well-coordinated within the REH, across healthcare providers, and with state and local public health departments and emergency management agencies and systems to protect patient health and safety in the event of a disaster. The following link is to FEMA's comprehensive preparedness guide to develop and maintain emergency operations plans:https://www.fema.gov/sites/default/files/2020-05/CPG_101_V2_30NOV2010_FINAL_508.pdf. During an emergency, it would be critical for REHs to have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the facilities and to ensure that these functions were carried out in a safe and effective manner.

At § 485.542(d), we proposed to require the REH to develop and maintain an emergency preparedness training and testing program based on the emergency plan, policies and procedures and communication plan, and reviewed and updated at least every 2 years. We proposed to require at § 485.542(d)(1) that the training program include initial training in the emergency preparedness policies and procedures for new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. We also proposed to require the facility to provide emergency preparedness training at least every 2 years, maintain documentation of all emergency preparedness training, demonstrate staff knowledge of emergency procedures, and if the emergency preparedness policies and procedures

were significantly updated, conduct training on the updated policies and procedures. The Homeland Security Exercise and Evaluation Program (HSEEP), developed by FEMA, includes a section on the establishment of a Training and Exercise Planning Workshop (TEPW). The TEPW section provides guidance to organizations in conducting an annual TEPW and developing a Multi-year Training and Exercise Plan (TEP) in line with the HSEEP (*https://www.fema.gov/sites/default/files/2020-04/Homeland-Security-Exercise-and-Evaluation-Program-Doctrine-2020-Revision-2-2-25.pdf*).

We proposed at § 485.542(d)(2) to require that the REH conduct exercises to test the emergency plan at least annually. Specifically, we proposed to require that the REH conduct two testing exercises, a full-scale or functional exercise and an additional exercise of its choice, every 2 years. First, the REH would be required to participate in a full-scale community-based exercise. If a community-based exercise was not accessible, we proposed that the REH would have to conduct a facility-based functional exercise; or, if the REH experienced an actual natural or man-made emergency that required activation of the emergency plan, the REH would be exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event. Second, the REH would have to conduct an additional exercise, opposite the year the full-scale or functional exercise was conducted, that could include, but would not be limited to, a second full-scale community-based exercise or an individual, facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop led by a facilitator, including a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. Lastly, we proposed to require that

the REH analyze its response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

We proposed at § 485.642(e) that REHs be required to store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. In addition to the emergency power system inspection and testing requirements found in NFPA® 99 and NFPA® 110 and NFPA® 101, we proposed that REHs test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the REH anticipates it will require during an emergency. The NFPA 101®2012 edition of the LSC (including the technical interim amendments (TIAs)) provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies. The NFPA 99® 2012 edition of the Health Care Facilities Code (including the TIAs) provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including other hazards associated with the primary hazards. The NFPA 110 covers performance requirements for emergency and standby power systems providing an alternate source of electrical power in buildings and facilities in the event that the normal electrical power source fails. Systems include power sources, transfer equipment, controls, supervisory equipment, and accessory equipment needed to supply electrical power to the selected circuits.

Finally, at § 485.542(f), we proposed to specify that if an REH was part of a healthcare system consisting of multiple separately certified healthcare facilities that elected to have a unified and integrated emergency preparedness program, the REH could choose to participate in

the healthcare system's coordinated emergency preparedness program. If the REH elected this, we proposed that the unified and integrated emergency preparedness program would have to demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program and be developed and maintained in a manner that took into account each separately certified facility's unique circumstances, patient populations, and services offered.

In addition, we proposed that each separately certified REH in the system would have to be capable of actively using the unified and integrated emergency preparedness program and was in compliance with the program's requirements. We also proposed that the unified and integrated emergency preparedness program would have to include a unified and integrated emergency plan that is based on a documented community-based risk assessment, utilizing an all-hazards approach and a documented individual facility-based risk assessment for each separately certified REH within the health system, utilizing an all-hazards approach. Lastly, we proposed that the unified and integrated emergency preparedness program would have to have integrated policies and procedures, a coordinated communication plan, and training and testing programs.

Incorporation by Reference

This final rule will incorporate by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Technical Interim Amendments issued (TIA) April 16, 2014; the NFPA 99®2012 edition of the Health Care Facilities Code, issued August 11, 2011; NFPA 110® 2010 edition of the Health Care Facilities Code, issues June 11, 2009; and all TIA issued prior to April 16, 2014. (1) NFPA 101, LSC, 2012 edition, issued August 11, 2011; (i) TIA 12-1 to NFPA 101, issued August 11, 2011. (ii) TIA 12-2 to NFPA 101, issued October 30, 2012. (iii) TIA 12-3 to NFPA 101, issued October 22, 2013. (iv) TIA 12-4 to NFPA 101, issued October

22, 2013. (2) NFPA 99, Standards for Health Care Facilities Code of the NFPA 99, 2012 edition, issued August 11, 2011. (i) TIA 12-2 to NFPA 99, issued August 11, 2011. (ii) TIA 12-3 to NFPA 99, issued August 9, 2012. (iii) TIA 12-4 to NFPA 99, issued March 7, 2013. (iv) TIA 12-5 to NFPA 99, issued August 1, 2013. (v) TIA 12-6 to NFPA 99, issued March 3, 2014. (3) NFPA 110® 2010 edition of the Health Care Facilities Code, issued June 11, 2009. (i) TIA 10-1 to NFPA 110, issued August 6, 2009. The materials we proposed to incorporate by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1 (617) 770-3000. If CMS wished to adopt any changes in this edition of the Code, it would submit the revised document to notice and comment rulemaking.

Comment: We received few comments regarding the emergency preparedness requirements. However, the few that we received were supportive and suggested that we continue to review the EP requirements based on experience from the most recent pandemic.

Response: CMS appreciates the support for the EP requirements that we set forth for REHs. CMS has held several listening sessions with interested parties on the existing EP requirements and will use this information to inform any future updates, as needed.

After consideration of the public comments we received, we are finalizing these provisions as proposed.

(22) Condition of Participation: Physical Environment (§ 485.544)

The LSC is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and

Medicaid regulations have historically incorporated these requirements by reference, along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC into the regulations we apply to Medicare and, as applicable, Medicaid providers and suppliers is the Secretary's facility-specific authority to stipulate health and safety regulations for each type of Medicare and (if applicable) Medicaid-participating facility. For REHs, that statutory authority is set out at new section 1861(kkk)(2)(D)(v) of the Act. The following provisions we have proposed are similar to the Hospital, CAH, and ASC LSC and Health Care Facilities Code requirements.

The NFPA 101®2012 edition of the LSC (including the technical interim amendments (TIAs)) provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies. The NFPA 99® 2012 edition of the Health Care Facilities Code (including the TIAs) provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including other hazards associated with the primary hazards. The NFPA 110 2010 edition covers performance requirements for emergency and standby power systems providing an alternate source of electrical power in buildings and facilities in the event that the normal electrical power source fails. Systems include power sources, transfer equipment, controls, supervisory equipment, and accessory equipment needed to supply electrical power to the selected circuits.

We review each new edition of the NFPA 101 and NFPA 99, which are issued every 3 years, to see if there are any significant provisions that we need to adopt. We will continue to review these documents every 3 years to see if there are relevant or updated provisions that we

need to adopt. The 2012 edition of the LSC includes provisions that we believe are vital to the health and safety of all patients and staff. Our intention is to ensure that patients and staff continue to experience the highest degree of fire safety possible. All Medicare and Medicaid participating providers and suppliers are currently subject to the requirements of the 2012 edition of the LSC and the 2012 edition of the Health Care Facilities Code as adopted by CMS (with some minor expectations which are set out in the various facilities' "physical environment" regulations).

Incorporation by Reference

This final rule will incorporate by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Technical Interim Amendments issued (TIA) April 16, 2014; the NFPA 99® 2012 edition of the Health Care Facilities Code, issued August 11, 2011; NFPA 110® 2010 edition of the Health Care Facilities Code, issues June 11, 2009; and all TIA issued prior to April 16, 2014. (1) NFPA 101, LSC, 2012 edition, issued August 11, 2011; (i) TIA 12-1 to NFPA 101, issued August 11, 2011. (ii) TIA 12-2 to NFPA 101, issued October 30, 2012. (iii) TIA 12-3 to NFPA 101, issued October 22, 2013. (iv) TIA 12-4 to NFPA 101, issued October 22, 2013. (2) NFPA 99, Standards for Health Care Facilities Code of the NFPA 99, 2012 edition, issued August 11, 2011. (i) TIA 12-2 to NFPA 99, issued August 11, 2011. (ii) TIA 12-3 to NFPA 99, issued August 9, 2012. (iii) TIA 12-4 to NFPA 99, issued March 7, 2013. (iv) TIA 12-5 to NFPA 99, issued August 1, 2013. (v) TIA 12-6 to NFPA 99, issued March 3, 2014. (3) NFPA 110® 2010 edition of the Health Care Facilities Code, issued June 11, 2009. (i) TIA 10-1 to NFPA 110, issued August 6, 2009. The materials we proposed to incorporate by reference are available to interested parties and can be inspected at the CMS and the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500

Security Boulevard, Baltimore, MD, email: scott.cooper@cms.hhs.gov or call (410) 786-9465. For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1 (617) 770-3000. If CMS wished to adopt any changes in this edition of the Code, it would submit the revised document to notice and comment rulemaking.

In order to ensure the minimum level of protection afforded by NFPA 99 is applicable to all patient and resident care areas within a health care facility, we proposed to adopt the 2012 edition of NFPA 99, with the exception of chapters 7—Information Technology and Communications Systems for Health Care Facilities; 8—Plumbing; 12—Emergency Management; and 13—Security Management.

At § 485.544(a) we proposed that the REH be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. Specifically, we proposed that the condition of the physical plant and the overall REH environment would have to be developed and maintained in such a manner that the safety and well-being of patients would be assured. This would include emergency power and lighting in at least all areas serviced by the emergency supply source, including but not limited to, the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source the REH would be required to have battery lamps and flashlights available. In addition, we proposed to require the REH to have facilities for emergency gas and water supply and a safe and sanitary environment, that is properly constructed, equipped and maintained to protect the health and safety of all patients.

At § 485.544(b), we proposed that the REH be required to maintain adequate facilities for its services that includes diagnostic and therapeutic facilities that are located in a manner that ensures the safety of patients. We also would require the REH to maintain facilities, supplies, and equipment in a manner that ensures an acceptable level of safety and quality. We proposed further that the facility be designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice and that there must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

At § 485.544(c), we proposed that REHs meet the provisions applicable to Ambulatory Health Care Occupancies in the 2012 edition of the LSC, regardless of the number of patients the facility serves. We believe the protection provided in the Ambulatory Health Care Occupancies chapter is necessary to protect the health and safety of patients who are incapable of caring for themselves at any point in time. We proposed at § 485.544(c)(2) to implement requirements related to the Secretary's waiver authority for periods deemed appropriate, which would result in unreasonable hardship, but only if the waiver will not adversely affect the health and safety of patients. We proposed at § 485.544(c)(3) that the provisions of the LSC would not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protected patients. We also proposed at § 485.544(c)(4) requirements related to protection against inappropriate access for alcohol-based hand rub dispensers. At § 485.544(c)(5), we proposed to require that a REH with a sprinkler system that was out of service for more than 10 hours in a 24-hour period would be required to evacuate the building or portion of the building affected by the system outage, or establish a fire watch until the system was back in service, notwithstanding the lower standard of the 2012 LSC.

Lastly, at § 485.544(d) we proposed to require REHs to comply with the 2012 edition of the NFPA 99. We proposed that chapters 7, 8, 12, and 13 would not apply to REHs. We also proposed to allow for waivers of these provisions under the same conditions and procedures that we currently use for waivers of applicable provisions of the LSC.

Comment: We received minimal comments regarding the NFPA 101 and NFPA 99. The comments that we did receive were supportive. We did receive a few comments asking if we anticipated adopting a newer version of the 101 and 99 NFPA codes, since CMS currently requirements the use of the 2012 editions. Some commenters suggested that we follow the same "Physical Environment" requirements as Hospitals or CAHs, as they are similar providers as REHs.

Response: As noted previously, we review any new LSC codes every 3 years to determine if there are substantive changes that would warrant the adoption of these updates through rulemaking. There have not been significant changes to adopt a newer version since the 2012 edition. We plan to review the 2024 edition within the next year and determine whether to adopt the new 2024 NFPA 101 and 99 as a part of future rulemaking. We appreciate the comments about using hospital and CAH requirements for REHs; however, REHs are not inpatient facilities; therefore, ASC requirements are more appropriate for REHs.

After consideration of the public comments we received, we are finalizing these provisions as proposed.

(23) Condition of Participation: Skilled Nursing Facility Distinct Part Unit (§ 485.546)

Section 1861(kkk)(2)(D)(vi) of the Act allows REHs to establish a unit that is a distinct part licensed as a SNF to furnish post-REH or post-hospital (in the event the services were provided at a hospital or a CAH) extended care services (or SNF services). A distinct part SNF is

an area that is separately licensed and certified to provide SNF services at all times. A distinct part SNF must be physically distinguishable from the REH, must be fiscally separate for cost reporting purposes, and the beds in the certified distinct part SNF unit of an REH must meet the requirements applicable to distinct part SNFs at 42 CFR part 483, subpart B. Medicare payment for SNF services furnished in these distinct part SNFs of an REH would be under the SNF prospective payment system as required under section 1834(x)(4) of the Act. We note that a distinct part SNF of an REH is not subject to the REH's length of stay limits of less than an annual per patient average of 24 hours.

We highlight that a distinct part SNF unit is not the same as a CAH or hospital utilizing swing-beds. CAHs and hospitals may provide swing-bed services, allowing them to use their beds for acute inpatient care or for post-hospital or CAH SNF care. These facilities must be certified by CMS to provide swing-bed services. CAHs or hospitals utilizing swing-beds are not required to have their swing-beds in a special unit or area within the facility.

To implement that statutory provision allowing REHs to establish distinct part SNFs, we proposed at § 485.546 to require REHs choosing to establish such a distinct part unit to meet the requirements for long-term care facilities at 42 CFR part 483, subpart B.

Comment: Commenters were supportive of this proposal. Some commenters requested clarification regarding how Medicare beneficiaries can qualify for services in a REH's distinct part SNF unit given that a 3-day prior inpatient care stay is required for beneficiaries to receive Medicare SNF services and an REH visit does not constitute an acute inpatient stay.

Response: In order to receive services in an REH's distinct part SNF unit, a beneficiary must have a 3-day prior inpatient stay at a provider such as an acute care hospital or CAH.

Following the 3-day inpatient stay, the patient can be transferred to the REH's distinct part SNF unit for the provision of SNF services.

After consideration of the public comments we received, we are finalizing § 485.546 as proposed. We are adding clarifying language to the regulatory requirement to indicate that the distinct part SNF must be separately licensed and certified, in addition to complying with the requirements of participation for long-term care facilities specified in part 483, subpart B of this subchapter. This is not an additional requirement and was presented in the discussion for this requirement in our proposed rule. The addition of this requirement in the CoP is for clarification only.

b. Changes for Critical Access Hospital Conditions of Participation (485 Subpart F)

(1) Condition of Participation: Status and Location (§ 485.610(c))

(a) Adding the Definition of "Primary Roads"

Generally, a CAH must meet certain criteria for designation, as set out in section 1820(c)(2)(B) of the Act. These criteria specify certain "distance requirements" relative to other hospitals or CAHs, and specifically require that a CAH be (1) "located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital" or (2) "certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area". The current regulatory requirement at § 485.610(c) sets forth the distance requirements for CAHs relative to other CAHs and hospitals, and specific definitions as related to the distance requirements are found in the SOM, Chapter 2, Section 2256A.

We proposed to incorporate the definition of a "primary road" in the CAH distance requirement regulations, both as part of the 35-mile drive requirement, and as applicable through

the "secondary roads" definition for the 15-mile drive requirement. Specifically, we proposed to revise § 485.610(c) to clarify that the location distance for a CAH is one for more than a 35-mile drive *on* primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH. In addition, at § 485.610(c)(2), we proposed to specify that primary road of travel for determining the driving distance of a CAH and its proximity to other providers as a numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway; or a numbered State highway with two or more lanes each way. We also solicited comments regarding the description of a numbered Federal highway in this proposed definition. Specifically, we requested feedback on whether the definition of "primary roads" should include numbered Federal highways with two or more lanes, similar to the description of numbered State highways, and exclude numbered Federal highways with only one lane in each direction.

We stated that codifying the definition of "primary roads" in the regulations would provide clarity and consistency regarding the distance requirements.

Furthermore, to support these regulatory changes we are planning to establish a centralized, data-driven review procedure that focuses on hospitals being certified in proximity to a CAH, rather than focusing specifically on road classifications. CMS will review all hospitals and CAHs within a 50-mile radius of each CAH during each review of eligibility, and then subsequently on a 3-year cycle. Following the initial review of distance and location, further investigations would focus primarily on expanded healthcare capacity and access to care within the 35-mile radius of the CAH being examined and less on the actual roadway designations used in making the calculations. Those CAHs with no new hospitals within 50 miles would be immediately recertified. Those CAHs with new hospitals within 50 miles will receive additional

review based on the distance from the new hospital and the definitions for "primary roads" and "mountainous terrain". To facilitate this review, the CAH Distance Analysis Committee and the CMS Survey Operations Group (SOG) Locations will utilize the geocoding of hospitals to identify those CAHs that are located within 50 miles of another certified hospital. Those CAHs that do not meet the regulatory distance and location requirements at the time of review would be identified as no longer qualified and may lose their CAH status. We believe this change will help surveyors to make evidence-based and objective determinations of continued CAH eligibility. We expect the new distance review procedure, coupled with regulatory clarity on the proposed primary roads definition, will provide greater consistency in evaluating if CAHs meet the statutory 35 or 15-mile distance requirements from other acute care hospitals and CAHs as well greater adherence to statutory language by ensuring that CAHs operate under the CAH designation until, or unless, a hospital moves within 35 miles or 15 miles of the existing CAH.

Comment: Many commenters supported refining the current definition of "primary roads" and codifying the definition in the regulations. We received numerous comments stating that proposed definition of "primary roads" should be revised to require numbered Federal highways to have two or more lanes each way, similar to the description of numbered State highways, and exclude numbered Federal highways with only one lane in each direction from the "primary roads" definition. These commenters stated that including one-lane numbered Federal highways as primary roads in the CAH distance requirements could prevent their facility from gaining or maintaining eligibility for the CAH designation. We received comments from small, rural hospitals that stated that defining one-lane numbered Federal highways as "primary roads" would impact their ability to pursue a CAH designation because including these roads in the distance calculations puts other hospitals or CAHs within the required 35-mile drive radius. We

also received numerous comments from existing CAHs that were concerned that their eligibility for CAH designation could be in jeopardy if numbered Federal highways with only one lane in each direction were included in the "primary roads" definition. Commenters also claimed that many one-lane numbered Federal highways are not well maintained, difficult to travel on, and more similar to one-lane State highways, which are not included in the "primary roads" definition. Some commenters also suggested that we include a definition of "secondary roads" in the regulations text.

Response: We appreciate the feedback from interested parties regarding the definition of primary roads in the CAH distance requirements. After further review, we agree with the commenters that the proposed definition may have unintended consequences for hospitals interested in applying for CAH designation as well as existing CAHs that could prevent these providers from being eligible to operate as a CAH. Our goal for codifying the definition of primary roads in the regulations language at §485.610(c) was to provide greater flexibility, consistency and clarity to providers with regards to CAH designations. Therefore, we are finalizing the definition of "primary roads" at §485.610(c) to include numbered Federal highways with two or more lanes each way, similar to the description of numbered State highways, and exclude numbered Federal highways with only one lane in each direction.

With regard to adding a "secondary roads" definition in the CAH distance requirements regulations, we do not believe that it is necessary to include a definition of "secondary roads" in the regulations text at this time. As stated, we remain committed to providing reducing burden for providers in meeting the distance criteria. Currently, we believe the language at §485.610(c) coupled with guidance in the SOM, Chapter 2, Section 2256A regarding the application of the 15-mile drive standard based on secondary roads adequately describes how we determine what

constitutes a secondary road. Specifically, this language states that to be eligible for the lesser distance standard due to the secondary road criteria under § 485.610(c), the CAH would have to document that there is a drive of more than 15 miles between the CAH and any hospital or other CAH where there are no primary roads. We also plan to continue to allow a CAH to qualify for application of the "secondary roads" criterion if there is a combination of primary and secondary roads between it and any hospital or other CAH, so long as more than 15 of the total miles from the hospital or other CAH consists of areas in which only secondary roads are available. We will continue to monitor this issue to determine if further refinements to the description of secondary roads are necessary for future rulemaking.

Comment: We received comments requesting clarification about the CAH eligibility review process. Commenters questioned the method that will be used to determine the mileage calculation. One commenter stated that CMS should use a 35-mile radius for the basis of the calculation.

Response: In accordance with § 485.610(c), the CAH review process will measure the driving distance between a CAH-main campus and any other CAH or hospital within a 35-mile distance, using definition of primary roads established in this rule, or a 15-mile distance using secondary roads or mountainous terrain. These regulatory requirements will also continue to be used for initial and recertification reviews for all CAHs. Comment: We received several comments requesting clarification regarding whether the establishment of an REH could prevent an existing or potential CAH from meeting the CAH distance requirements, given that a CAH must be located more than a 35-mile drive (or more than a 15-mile drive on in areas with only secondary roads available or in mountainous terrain) from a hospital or another CAH.

Response: We would like to clarify that an existing or potential CAH may still be eligible for a CAH designation if there is an REH established within less than a 35-mile drive (or less than a 15-mile drive in areas with only secondary roads available or in mountainous terrain). We note that an REH cannot, by statute, provide inpatient services, therefore we believe that the services provided by an REH would not duplicate or overlap with those provided at a CAH and an REH would serve a distinct purpose in the community.

Comment: Some commenters requested that CMS allow existing CAHs to be exempt from the proposed primary roads definition and instead "grandfather in" the CAH designation of existing CAHs based on meeting the distance requirements with the current definition of primary roads. Other commenters stated that CAHs that are certified as "necessary providers" should continue to be exempt from the CAH distance and location requirements.

Response: As stated previously, by statute, the CAH distance requirements must continually be met in order for the hospital to maintain its status as a CAH. While we strive to allow CAHs flexibility in meeting these requirements, we do not believe it is within the statutory authority at section 1820(h)(3) of the Act to allow all existing CAHs, other than those certified as necessary providers, to have their CAH designation grandfathered. Therefore, existing CAHs will be subject to CAH distance requirements, including the primary roads definition, as finalized in this rule. CAHs that are certified as "necessary providers" will continue to be exempt from the distance requirement relative to other CAHs and hospitals as noted at § 485.610(c). "Necessary provider" CAHs are still required to meet the rural location requirement at § 485.610(b).

Comment: We received several other comments related to the CAH distance and location requirements that were separate from the definition of primary roads proposal. We received a

request to codify in the regulations text the guidance from the SOM Chapter 2, at 2256A that the proximity of IHS and Tribal hospitals or CAHs and non-IHS or Tribal hospitals or CAHs to each other is not considered when assessing CAH distance requirements and requests to allow exceptions for hospitals to qualify for CAH designation that do not meet the current or proposed CAH distance requirements.

Response: We thank these commenters for their input, however, we did not propose any changes to these policies. Therefore, these comments are out of scope of this rule.

After consideration of the public comments, we are finalizing the language at § 485.610(c) as proposed. In addition, we are finalizing the language at § 485.610(c)(2) with a modification, to specify a primary road of travel for determining the driving distance of a CAH and its proximity to other providers is a numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway with two or more lanes each way; or a numbered State highway with two or more lanes each way.

(2) Condition of Participation: Patient's Rights (§ 485.614)

We proposed to establish a CoP for patient's rights for CAHs at § 485.614 that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. This would include proposed requirements for the CAH to inform patients of and exercise their rights; address privacy and safety; adhere to the confidentiality of patient records; responsibilities for the use of restraint and seclusion; and adherence to patient visitation rights.

Notice of Rights

At § 485.614(a), we proposed that a CAH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of

furnishing or discontinuing patient care whenever possible. This includes a proposal to require the CAH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.

Exercise of Rights

At § 485.614(b), we proposed to specify those rights a patient has regarding their medical care, which includes the right to participate in the development and implementation of their plan of care, to make informed decisions regarding their care, to be fully informed about such care, and the right to request or refuse treatment, and finally the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital. We note that this right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. In addition, we proposed to specify that the patient also has the right to formulate advance directives and to have CAH staff and practitioners who provide care in the CAH comply with these directives.

Privacy, Safety, and Confidentiality of Patient Records

At § 485.614(c), we proposed to specify that the patient has the right to personal privacy, receive care in a safe setting, and be free from all forms of abuse or harassment. At § 485.614(d), we proposed to specify that patients have the right to the confidentiality of their medical records and the right to access their medical records. We proposed that the CAH must provide the patients with their records in a form and format requested by the requestor when requested and within a reasonable timeframe, as not to frustrate the legitimate efforts of individuals to gain access to their own medical records.

Use of Restraints and Seclusion

At § 485.614(e), we proposed patients' rights relating to the use of restraints and seclusion less burdensome than those for hospitals because given the level of services provided by CAHs and their patient volume, we expect the likelihood of their need to utilize restraints and seclusion to be relatively low.

Specifically, we proposed to specify that all patients would have the right to be free from physical or mental abuse, and from corporal punishment and from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. We proposed that restraint or seclusion could only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and would have to be discontinued at the earliest possible time. We proposed to define "restraint" as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement, and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). We proposed to define "seclusion" as the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

At § 485.614(e)(2), we proposed to require that the restraint or seclusion could only be used when less restrictive interventions had been determined to be ineffective to protect the patient a staff member or others from harm. At § 485.614(e)(3), we proposed to require that the type or technique of restraint or seclusion used would have to be the least restrictive intervention that would be effective to protect the patient, a staff member, or others from harm. At § 485.614(e)(4) we proposed to require the CAH to have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. These requirements will allow for the CAH to use restraints and seclusion in the event that either or both were necessary, and only as a last resort to respond to immediate safety concerns. However, the CAH provision would reduce the burden and allow for more flexibility than the current hospital CoP. We believe that allowing the CAH the flexibility to develop their own policies and procedures for restraints and seclusion based on the scope of services they provide is necessary given their patient volumes, populations, and access to resources. The policies and procedures would have to be consistent with current standards of practice.

Staff Training Requirements for the Use of Restraints or Seclusion

At § 485.614(f) we proposed to establish that the patient would have the right to safe implementation of restraint or seclusion by trained staff. We proposed that the CAH would have to provide competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion. To ensure that the use of restraint and seclusion for patients receiving services in a CAH would be respectful of, and responsive to, individual patient preferences, needs and values, we proposed to require that the training be patient-centered. Additionally, to ensure that staff would be educated and trained on using the least restrictive intervention

necessary for the safety of the patients and CAH staff, we proposed at § 485.614(f)(2) to require that the CAH train their staff in alternatives to the use of restraint and seclusion. Staff should have trauma-informed knowledge competencies and be aware of effective de-escalation techniques that could be used to avoid the use of restraint and seclusion so not to trigger any previous mental health issues because of the use of restraints and seclusion. Trained peer workers (people who share similar experiences of being diagnosed with mental health conditions, substance use disorders, or both) and CHWs could also serve a useful role in assisting patients and other staff. This could include helping to monitor use of restraint and seclusion, deescalating interactions with patients and contributing to a positive and supportive environment for patients, family members, and CAH staff. CAHs are encouraged to consider the use of peer workers and CHWs in their staffing plans. For further information, please see the 2007 guidance on use of peers in the Medicaid program (https://www.medicaid.gov/federal-policy-guidance/downloads/SMD081507A.pdf) and resources from the Substance Abuse and Mental Health Services Administration (https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers). In addition, facilities are encouraged to consider any nutritional needs while a patient is restrained, such as a need to provide food and water.

Death Reporting Requirements

The proposed CAH death reporting requirements were similar to the hospital requirements at § 482.13. At § 485.614(g), we proposed to establish requirements that CAHs must follow when reporting deaths associated with the use of seclusion or restraint. Specifically, we proposed to require that the CAH report to CMS, by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day the following information— (1) Each death that occurs while a patient is in restraint or seclusion; (2) Each

death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the CAH that occurs within 1 week after restraint or seclusion, where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. We note that "reasonable to assume" in this context would include, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

For instances when no seclusion had been used and when the only restraints used on the patient were those applied exclusively to the patient's wrist(s), and composed solely of soft, non-rigid, cloth-like materials, the CAH staff would have to record in an internal log or other system, the following information—(1) Any death that occurred while a patient was in such restraints; (2) Any death that occurred within 24 hours after a patient had been removed from such restraints. Furthermore, we proposed that staff also document in the patient's medical record the date and time the death was reported to CMS or recorded in the internal log or other system. Also, for instances when no seclusion had been used and when the only restraints used on the patient were those applied exclusively to the patient's wrist(s),we proposed to require that entries into the internal log or other system would have to be documented no later than seven days after the date of death of the patient, and include the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es), and be made available in either written or electronic form to CMS immediately upon request.

Patient Visitation Rights

We proposed to redesignate § 485.635(f) as § 485.614(h). At § 485.614(h), we proposed to establish new requirements in addition to the existing requirements for CAHs related to a patient's visitation rights. Specifically, we proposed to require that a CAH would have to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. However, we note that the requirements at § 485.614(f) are existing requirements for CAHs and our intent is to redesignate these existing requirements for patient visitation as § 485.614(h).

Comment: Most commenters supported the new proposed patient's rights CoP for CAHs. Commenters stated that CAHs should have the same patient rights requirements as hospitals, as they are similar. One commenter stated that since the CAH patient rights provisions are brand new, we should delay the effective date to give facilities the time to establish processes and train staff.

Response: We appreciate all the support for this new provision in CAHs. Our goal was to establish patient's rights that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. We are aware that these are new requirements for CAHs and will take time to establish policies, procedures and train staff, therefore this does not take effect until 60 days from the publication date. We did receive information from some commenters stating that some CAHs have already incorporated patient rights into their daily practices.

After consideration of the public comments we received, we are finalizing as proposed.

(3) Condition of Participation: Staffing and Staff Responsibilities (§ 485.631)

Unified and Integrated Medical Staff for a CAH in a Multi-Facility System

In alignment the current standards for hospitals, we proposed at § 485.631(e) to allow for either a unique medical staff for each CAH or for a unified and integrated medical staff shared by multiple hospitals, CAHs, and REHs within a health care system. We proposed to require that a CAH ensure that the medical staff members of each separately certified CAH in the system (that is, all medical staff members who hold specific privileges to practice at that CAH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective CAH.

In addition, we proposed to require that the unified and integrated medical staff have bylaws, rules, and requirements that described its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members of that specific certified CAH to maintain a separate and distinct medical staff for their CAH. We proposed that the unified and integrated medical staff be established in a manner that would take into account each CAH's unique circumstances, and any significant differences in patient populations and services offered in each CAH. Lastly, we proposed that the unified and integrated medical staff give due consideration to the needs and concerns of individual members of the medical staff, regardless of practice or location, and the CAH has mechanisms in place to ensure that issues specific to particular CAHs are duly considered and addressed.

In proposing this allowance for CAHs in the requirements here, we considered this past rulemaking experience with those multi-hospital systems using the single governing body and unified and integrated medical staff model for separately certified hospitals within their systems, as well as our decision to also propose this flexibility for REHs, and applied the same model to CAHs within single governing body systems. As we continue to do with hospitals, we thought it is in the best interest of CAHs, medical staff members, and patients to proposed this requirement allowing for the use of a unified and integrated medical staff for a multi-facility system and its member CAHs, in order to enable the medical staff of each CAH to voluntarily integrate itself into a larger system medical staff.

Comment: Commenters were supportive of our proposals.

Response: We did not receive any comments suggesting edits or changes to our proposal. After consideration of the public comments we received, we are finalizing as proposed.

(4) Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.640)

Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for a CAH in a Multi-Facility System

Similar to our standard in the hospital CoPs, we proposed a standard at § 485.649(h) for CAHs that would allow for the governing body of a CAH that is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a single system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any CAHs, after determining that such a decision would be in accordance with all applicable state and local laws. The system's single

governing body would be responsible for ensuring that each of its separately certified CAHs meets all of the requirements of this section. We note that each separately certified CAH subject to the system's single governing body would need to demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Were established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;
- Established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, were given due consideration; and
- Had mechanisms in place to ensure that issues localized to particular CAHs were duly considered and addressed.

The CAH would also need to demonstrate that it had designated a qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship at the CAH to be responsible for:

- Communicating with the system's unified infection prevention and control and antibiotic stewardship programs;
- Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs; and
- Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

Comment: Commenters suggested that we work with Congress to implement support/funding for electronic surveillance systems in infection control. They believed that the automated systems could help in decreasing costs while helping to follow the infection control standards in the regulation.

Response: Comments regarding the use of electronic systems for infection control fall outside the scope of the rulemaking. We support their use in improving patient care standards, but note that there are flexibilities offered to providers. REHs are responsible maintaining patient care standards which comply with the regulations.

After consideration of the public comments we received, we are finalizing the provisions as proposed.

(5) Condition of Participation: Quality Assessment and Performance Improvement Program (§ 485.641)

Unified and Integrated QAPI Program for a CAH in a Multi-Facility System

Consistent with the standard included at § 482.21(f) in the hospital CoPs for QAPI programs, we proposed at § 485.641(f) to allow CAHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program after determining that such a decision is in accordance with all applicable state and local laws. Specifically, we proposed to specify that the system's governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets the proposed QAPI program requirements. We expected that this would be beneficial to CAHs that may lack time, resources, or staff to implement a QAPI program. The CAH would be able to benefit from the resources and expertise of a multi-hospital system in

implementing their QAPI program, as well as potentially reducing the time and labor investments required to enact and maintain the program.

We did not receive any public comments on our proposal and therefore, we are finalizing our proposal.

c. Conforming Amendments and Technical Corrections

(1) Technical Correction to § 485.635(b)(2)

We proposed to make a technical correction to the laboratory services CAH CoP at § 485.635(b)(2). In the September 1, 1994, final rule entitled ‘‘Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates’’ (59 FR 45403), we revised the CAH laboratory services requirement to require the CAH laboratory services to meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). We inadvertently included an error in the referenced Public Health Service Act standard. The referenced standard at § 485.635(b)(2) should read, ‘‘. . .353 of the Public Health Service Act (42 U.S.C. 263a).’’

(2) Conforming Amendments §§ 489.2(b) and 489.24(b)

The provider agreement and supplier approval requirements for Medicare participating providers and suppliers are located at 42 CFR part 489. Section 489.2 sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare, with the providers that are subject to the provisions of this part listed at § 489.2(b). We proposed to add REHs to the list of applicable providers at § 489.2(b) and therefore require REHs to adhere to the requirements for submittal and acceptance of provider agreements under Medicare as defined by § 489.3. The requirements at 42 CFR part 489 also set forth requirements for Medicare hospitals in emergency cases. These provisions apply to hospitals that have emergency departments.

Under this section, a hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act. The CAA amends section 1867(e)(5) of the Act by including REHs, as defined in 1861(kkk)(2), as hospitals that have emergency departments. As a result, we are proposed to add REHs to the definitions at § 489.24(b) for Medicare hospitals in emergency cases under the hospital definition and to the definition of a participation hospital.

C. REH Provider Enrollment

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overall purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all Federal and State requirements to do so. The process is, to an extent, a "gatekeeper" that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Since 2006, we have taken steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. All enrolling and enrolled Medicare providers and suppliers, irrespective of type and including REHs, must comply with these regulatory provisions.

Section 1861(kkk)(2)(A) of the Act states that REHs must be enrolled under section 1866(j) of the Act. We proposed several regulatory provisions that identify the enrollment requirements with which REHs must comply as part of the enrollment process.

1. General Compliance with Part 424, Subpart P

In addition to the previously mentioned requirement for REHs to enroll in Medicare, section 1861(kkk)(4)(B) of the Act states that an REH's enrollment remains in effect until: (1) the REH elects to convert back to its prior designation as a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act, hereafter occasionally referenced as a "section 1886(d)(1)(B) hospital"); or (2) the Secretary determines that the facility does not meet the requirements for REHs under this subsection. To clarify that our enrollment authority under subpart P applies to REHs to the same extent it does to all other Medicare provider and supplier types, we proposed to add a new § 424.575 to subpart P. Paragraph (a) of § 424.575 would state that an REH (as that term is defined in 42 CFR § 485.502) must comply with all applicable provisions and requirements in subpart P in order to enroll and maintain enrollment in Medicare. We noted that these requirements include, but are not limited to, the following:

- Per § 424.510(a)(1) and (d)(1), completion and submission of the applicable enrollment application, which, for REHs, is the Form CMS-855A (Medicare Enrollment Application: Institutional Providers; OMB control number 0938-0685).
- Submission of all required supporting documentation with the enrollment application per § 424.510(d)(1) and (d)(2)(iii).
- Per § 424.510(d)(5), completion of any applicable State surveys, certifications, and provider agreements.
- Reporting changes to any of the REH's enrollment information per § 424.516.
- Revalidation of enrollment per § 424.515.
- Undergoing risk-based screening per § 424.518.

We did not receive any public comments regarding proposed new § 424.575(a). We are therefore finalizing this proposal.

2. Application Fees, Submission of the Form CMS-855A, and Screening Levels

Another requirement in subpart P pertains to application fees. Section 424.514 states that institutional providers submitting an initial or revalidation application, or adding a new practice location, must submit either or both of the following: (1) the applicable application fee (which, for CY 2022, is $631); or (2) a request for a hardship exception to the application fee. The term "institutional provider" is defined (for purposes of the application fee) in § 424.502. It means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations) (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB control number 0938-1377), Form CMS-855S (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB control number: 0938-1056), or an associated internet-based PECOS enrollment application.

Although an REH must submit a Form CMS-855A to enroll as such, it would not have to pay an application fee with its application. This is because we proposed at new § 424.575(b) that the REH would submit a Form CMS-855A change of information under § 424.516 instead of an initial enrollment application. In other words, the facility would merely be reporting its conversion from a CAH or a section 1886(d)(1)(B) hospital to an REH (as well as submitting any other required information and documentation); it would not be newly enrolling in the Medicare program. We explained in the proposed rule our belief that this would alleviate the burden on prospective REHs and expedite the processing of their Form CMS-855As, for change of information applications typically take less time for Medicare Administrative Contractors (MAC) to process than initial applications. Since this particular REH enrollment transaction

would not be an initial enrollment, revalidation, or practice location addition, the fee payment requirement in § 424.514 would not apply.

In addition, we note that § 424.518 outlines provider enrollment screening categories and requirements based on our assessment of the risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the degree of scrutiny with which we will screen and review enrollment applications submitted by providers or suppliers within that category. There are three levels of screening addressed in § 424.518: limited; moderate; and high. Hospitals currently fall within the limited screening category per § 424.518(a)(1)(viii). This also includes, as stated in § 424.518(a)(1)(viii), CAHs, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities. We have no evidence to suggest that REHs as a category of provider type would present a risk of fraud, waste, and abuse warranting placement in the moderate or high screening level. Accordingly, we proposed to revise § 424.518(a)(1)(viii) to incorporate REHs therein.

3. Effective Date of Billing Privileges

We also mentioned in the proposed rule that 42 CFR § 424.520 lists the effective dates of billing privileges for enrolling Medicare providers and suppliers. For surveyed, certified, or accredited providers and suppliers, § 424.520(a) states that the effective date of billing privileges is that specified in 42 CFR § 489.13. Paragraph (b) of the latter section states, in part, that the provider agreement or approval is effective on the date the state agency, CMS, or CMS contractor survey is completed (or on the effective date of the accreditation decision, as applicable) if, on that date, the provider or supplier meets all applicable federal requirements. Among these federal requirements are the previously referenced enrollment requirements in Part

424, subpart P; as mentioned in 42 CFR § 489.13(b), CMS determines the date on which all enrollment requirements have been met.

Hospitals and CAHs are among the provider types that fall within the scope of § 424.520(a). Since REHs, like other hospitals, would also come within the purview of § 424.520(a), it was unnecessary to revise § 424.520(a) to specifically reference them. We discussed this issue in the proposed rule so that prospective REHs would understand what their effective date of billing privileges would be.

We received the following comments regarding this proposal:

Comment: Numerous commenters expressed support for our proposals to: (1) permit a Form CMS-855A change of information submission rather than an initial enrollment application (and, with this, the inapplicability of the application fee requirement); and (2) revise § 424.518(a) to include REHs within the limited screening category.

Response: We appreciate the commenters' support.

Comment: Several commenters asked whether an REH could convert back to a CAH or a section 1886(d)(1)(B) hospital via a Form CMS-855A change of information application.

Response: We explained in the proposed rule our general, longstanding policy that a provider or supplier that is changing its provider or supplier type (for example, a home health agency (HHA) switching to a home infusion therapy supplier) must terminate its existing enrollment and initially enroll as the new provider or supplier type. Specifically, and using the example in the previous sentence, the entity must submit: (1) a Form CMS-855A application to terminate its existing HHA enrollment; and (2) a separate Form CMS-855B initial enrollment application to enroll as a HIT supplier. While we proposed in § 424.575(b) to permit the submission of a Form CMS-855A change of information for the initial conversion of a CAH or

section 1886(d)(1)(B) hospital to an REH, § 424.575(b) does not (and was not intended to) apply to any future conversion back to a CAH or a section 1886(d)(1)(B) hospital. Once the CAH or section 1886(d)(1)(B) hospital has converted to an REH, any subsequent change to a different provider or supplier type would require an initial enrollment application as well as adherence to all requirements in subpart P associated therewith, such as payment of an application fee.

We stated in the proposed rule that "section 1861(kkk)(4)(B)(i) of the Act references a 'conversion' from an REH back to a CAH or a section 1886(d)(1)(B) hospital (rather than termination as an REH and initial enrollment as a CAH or section 1886(d)(1)(B) hospital)" (87 FR 44788). Upon further reflection, we believe this language could convey the erroneous impression that conversions back to a CAH or section 1886(d)(1)(B) hospital merely require a Form CMS-855A change of information application. This statement was not meant to pronounce such a policy. Instead, we cited section 1861(kkk)(4)(B)(i) merely to illustrate the sufficiently close nexus between REHs and CAHs/section 1886(d)(1)(B) hospitals as justification for our proposal to permit a Form CMS-855A change of information application for the initial conversion to an REH. We did not propose anywhere in new § 424.575 to permit Form CMS-855A changes of information for conversions back to CAHs or section 1886(d)(1)(B) hospitals because it was not our intention to do so. To the contrary, § 424.575(a) was specifically meant to apply to such situations, meaning, as stated in the previous paragraph, that an initial Form CMS-855A application would be required consistent with Part 424, subpart P.

We also wish to clarify that although a CAH or section 1886(d)(1)(B) hospital converting to an REH need not submit a separate Form CMS-855A application to voluntarily terminate its enrollment as a CAH or section 1886(d)(1)(B) hospital, its CAH or section 1886(d)(1)(B)

hospital enrollment is terminated as part of the REH conversion process. Put another way, merely because the CAH or section 1886(d)(1)(B) hospital need not submit a Form CMS-855A voluntary termination application does not mean it can remain enrolled as such after its conversion to an REH. The facility cannot be enrolled as both an REH and a CAH or section 1886(d)(1)(B) hospital.

Comment: A commenter asked whether a prospective payment rural hospital can enroll as an REH by submitting a Form CMS-855A change of information rather than an initial application.

Response: If, by the term "prospective payment rural hospital," the commenter is referencing a facility that (1) is a CAH or a section 1886(d)(1)(B) hospital and (2) is otherwise eligible to convert to an REH under section 1861(kkk) of the Act and all applicable Medicare regulations, the hospital may submit a Form CMS-855A change of information.

Comment: A commenter asked whether a CAH or section 1886(d)(1)(B) hospital that closed after December 27, 2020 but is otherwise eligible under section 1861(kkk) of the Act and all applicable Medicare regulations to convert to an REH can submit a Form CMS-855A change of information rather than an initial application.

Response: As previously discussed, the statute does not prohibit a facility that was eligible to seek REH designation as of the date of enactment of the CAA (December 27, 2020) but subsequently closed after that date from seeking REH designation after the facility's closure. As such, under the circumstances the commenter describes, the facility may submit a Form CMS-855A change of information instead of an initial enrollment. To clarify this, we will revise the opening of our proposed regulatory text of § 424.575(b). The current language reads, "A provider that is currently enrolled in Medicare as a critical access hospital or a hospital (as

defined in section 1886(d)(1)(B) of the Act) converts its existing enrollment to that of a rural emergency hospital….". We will change "is currently enrolled in Medicare" to "was enrolled in Medicare as of December 27, 2020". We believe this revision is consistent with the opening language of 1861(kkk)(3), which explains that 1861(kkk) applies to facilities that were CAHs or section 1886(d)(1)(B) hospitals "as of December 27, 2020".

Comment: Several commenters requested that CMS: (1) disseminate detailed guidance and provide in-depth training to the MACs regarding the REH enrollment process; and (2) identify specific individuals who can assist these facilities regarding any enrollment issues arising with the MACs.

Response: CMS will post information on its website and issue detailed guidance to the MACs regarding the processing of REH enrollment applications. We will also issue a Medicare Learning Network ® Matters article explaining: (1) the enrollment process to prospective REHs; and (2) where REHs can direct any questions they have concerning this process.

Comment: A commenter stated that REH enrollment requirements must be sufficiently broad and flexible to accommodate the diverse needs of rural communities.

Response: We appreciate this comment. We noted previously that our proposal to permit Form CMS-855A change of information submissions was intended in large part to alleviate the burden on REHs and to afford them flexibility in this regard.

After consideration of the public comments we received, we are finalizing our proposals with one minor exception. As a mere technical elucidation, we are inserting the following language in § 424.575(b) immediately following the parenthetical referencing section 1886(d)(1)(B) of the Act: "with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act), or treated as

being located in a rural area pursuant to section 1886(d)(8)(E) of the Act". This language is taken from section 1861(kkk)(3)(B) of the Act, and we believe it will further clarify for readers the types of rural hospitals that are eligible to convert to an REH.

D. Use of the Medicare Outpatient Observation Notice by REHs

REHs are prohibited by section 1866(kkk)(2)(B) of the Act from providing inpatient services, other than those that are provided in a distinct part SNF. Section 2 of the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) (Pub. L. 114-42), amended section 1866(a)(1) of the Act by adding a new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours. The notification must explain the status of the individual as an outpatient, not an inpatient, and the implications of such status. We implemented section 1866(a)(1)(Y), as added by section 2 of the Notice Act, in the FY 2017 IPPS/LTCH final rule (81 FR 57037 through 57052).

REHs will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. There may be instances in which REH patients receive observation services at an REH for a period exceeding 24 hours, but REHs are not required to provide required notification under the NOTICE Act, known as the Medicare Outpatient Observation Notice (MOON), because REHs are excluded from the definition of "hospital" in section 1861(e) and the requirements at section 1866(a)(1)(Y) of the Act apply only to hospitals and CAHs. We understand that there may be occasional circumstances in which a facility is not immediately available to provide a higher level of care, resulting in patients receiving services at an REH for more than 24 hours. Notwithstanding the inapplicability of the NOTICE Act requirements at

section 1866(a)(1)(Y) to REHs and the expected infrequency of individuals receiving observation services in REHs for more than 24 hours, CMS solicited comments on the potential need for REHs to notify beneficiaries of their status as outpatients, the implications of such status, and whether the MOON would be the appropriate notice for communicating this information.

We did not receive any public comments on the use of the MOON by REHs, and given the inapplicability of the NOTICE Act requirements to this new provider type, we are not requiring that the MOON be used by REHs.

E. Physician Self-Referral Law Update

1. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. (For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.)

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule) and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was a final rule with comment period published in the January 4, 2001 **Federal Register** (66 FR 856). The second final rulemaking (Phase II) was an interim final rule with comment period (69 FR 16054) published in the March 26, 2004 **Federal Register**. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published in the April 6, 2004 **Federal Register** (69 FR 17933). The third final rulemaking (Phase III) was a final rule published in the September 5, 2007 **Federal Register** (72 FR 51012).

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain

regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions to the physician self-referral law, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. In the December 2, 2020 **Federal Register**, we published a final rule entitled "Modernizing and Clarifying the Physician Self-Referral Regulations" (the "MCR final rule") (85 FR 77492) that established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as "value-based arrangements," established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law. Most notably, we defined the term "commercially reasonable" in regulation, established an objective test for evaluating whether compensation varies with the volume or value of referrals or other business generated between the parties, and revised the definitions of "fair market value" and "general market value." The MCR final rule also revised the definition of "indirect compensation arrangement," which was further revised in the CY 2022 PFS final rule (86 FR 65343 through 65353).

2. Application of the Physician Self-Referral Law to REHs

The referral and billing prohibitions of the physician self-referral law are implicated only when all six of the following elements are present: a <u>physician</u> makes a <u>referral</u> for <u>designated</u>

health services payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship. Where all six elements exist, the physician self-referral law prohibits the physician from making a referral for designated health services to the entity with which he or she has the financial relationship unless an exception applies and its requirements are satisfied.

Our regulations at § 411.351 define "entity" to mean a person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes designated health services. Section 1877(h)(6) of the Act defines "designated health services" to mean any of the following items or services: clinical laboratory services; physical therapy services; occupational therapy services; outpatient speech-language pathology services; radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Under the regulation at § 411.351, only services payable in whole or in part by Medicare are designated health services. Services that are paid by Medicare as part of a composite rate are excluded from the definition of "designated health services."

The Conditions of Participation (CoPs) for rural emergency hospitals (REH), as finalized in this final rule with comment period, require an REH to furnish radiology and certain imaging services, clinical laboratory services, and outpatient prescription drugs, all of which are designated health services under section 1877(h) of the Act. An REH may elect to provide other designated health services as well. Therefore, with respect to such services furnished to

Medicare beneficiaries, an REH would be an entity that furnishes designated health services payable (in whole or in part) by Medicare for purposes of the physician self-referral law.

For purposes of the physician self-referral law, a physician has the meaning set forth in section 1861(r) of the Act. A physician makes a referral when the physician requests or orders a designated health service, certifies or recertifies the need for a designated health service, or establishes a plan of care that includes the provision of a designated health service. (If the physician personally performs or provides the designated health service, the physician has not made a referral.) Under the regulations at § 411.354, a physician (or an immediate family member of a physician) has a financial relationship with an entity if the physician (or immediate family member) has a direct or indirect ownership or investment interest in the entity or has a direct or indirect compensation arrangement with the entity.

Once an entity is enrolled in Medicare as an REH, the physician self-referral law would prohibit a physician from making a referral for designated health services to the REH if the physician (or an immediate family member of the physician) has a financial relationship with the REH unless an exception to the law's referral and billing prohibitions applies and all its requirements are satisfied. There are numerous statutory and regulatory exceptions to the physician self-referral law's prohibitions.

Although there are more than 40 exceptions to the physician self-referral law's prohibitions, only five permit all specified referrals by a physician to an entity in which the physician (or an immediate family member of the physician) has an ownership or investment interest when all requirements of the exception are satisfied. These are the exceptions for publicly traded securities, mutual funds, rural providers (commonly referred to as the "rural provider exception"), hospitals in Puerto Rico, and hospitals outside of Puerto Rico (commonly

referred to as the "whole hospital exception"). Nine additional "services" exceptions in § 411.355, when applicable, may permit a physician's referral on a service-by-service basis, but the protection from the law's prohibitions requires an analysis of each referral by the physician and the resulting designated health service furnished by the entity.

We believe that most physician-owned entities that are not publicly traded or hospitals located in Puerto Rico rely on the rural provider and whole hospital exceptions in section 1877(d)(2) and (3) of the Act and in our regulations at § 411.356(c)(1) and (3), respectively. An entity that is a "hospital" for purposes of the physician self-referral law, including a critical access hospital or small rural hospital, may use either the rural provider exception (if applicable) or the whole hospital exception to avoid the law's referral and billing prohibitions, provided that all requirements of the selected exception are satisfied, including requirements set forth in the Affordable Care Act and included in our regulations at § 411.362.

The rural provider exception requires that the designated health services are furnished in a rural area and that the entity furnishes not less than 75 percent of the designated health services that it furnishes to residents of a rural area. For purposes of the physician self-referral law, a rural area is an area that is not an urban area, a term further defined elsewhere in CMS regulations to include certain areas defined by the Executive Office of Management and Budget (OMB). OMB regularly publishes updates to the list of areas that CMS considers to be urban areas. The whole hospital exception is available only to entities that are "hospitals" for purposes of the physician self-referral law. Under § 411.351, a hospital is an entity that qualifies as a "hospital" under section 1861(e) of the Act, as a "psychiatric hospital" under section 1861(f) of the Act, or as a "critical access hospital" under section 1861(mm)(1) of the Act.

Whether an entity furnishes designated health services in a rural area is subject to change as OMB updates the list of areas that CMS considers to be urban areas. Therefore, the continuous applicability of the rural provider exception to a particular entity is not guaranteed. Reliance on the rural provider exception also requires the entity to monitor the residence of the patients to whom it furnishes designated health services in order to ensure that the entity furnishes not less than 75 percent of the designated health services that it furnishes to residents of a rural area. As with the location where designated health services are furnished, whether an individual resides in a rural area is subject to change as OMB updates the list of areas that CMS considers to be urban areas, which may increase the monitoring burden.

Satisfaction of the requirements of the whole hospital exception is not dependent on whether the entity—which must be a hospital for purposes of the exception—furnishes designated health services in a rural area or where its patients reside. However, section 1861(e) of the Act, as amended by section 125 of the CAA, expressly excludes REHs from qualifying as a hospital for most Medicare purposes. Although critical access hospitals and small rural hospitals meet the definition of "hospital" in § 411.351, once a critical access hospital or small rural hospital converts to an REH, it will no longer be a "hospital" for purposes of the physician self-referral law and, therefore, the whole hospital exception will no longer be available to it. Although we considered deeming REHs to be hospitals for purposes of the physician self-referral law, which would have continued access to the whole hospital exception for such entities, for the reasons explained in the CY 2023 OPPS/ASC proposed rule (87 FR 44798-44799), we did not propose to do so.

In the CY 2023 OPPS/ASC proposed rule, we stated that we were concerned that, without a broadly-applicable exception to its referral and billing prohibitions for ownership or

investment in REHs, the physician self-referral law could inhibit access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members) and thwart the underlying goal of section 125 of the CAA to safeguard or expand such access. For this reason, using the Secretary's authority under section 1877(b)(4) of the Act to establish exceptions to the physician self-referral law for financial relationships that do not pose a risk or program or patient abuse, we proposed a new exception at § 411.356(c)(4) for ownership or investment interests in an REH for purposes of the designated health services furnished by the REH. For purposes of this preamble, we refer to this exception as "the proposed REH exception." We solicited comment on the proposed exception, including whether we should apply more or fewer of the requirements related to physician-owned hospitals to physician ownership of or investment in an REH. We also solicited comment regarding the appropriateness of such requirements in the context of an REH and whether they are necessary to protect against program and patient abuse.

We did not propose any new exceptions for specific designated health services or for compensation arrangements between REHs and physicians (or immediate family members of physicians). We stated our belief that, for the most part, the existing exceptions in §§ 411.355 and 411.357 are sufficiently comprehensive to allow for nonabusive referrals and compensation arrangements between REHs and physicians (or immediate family members of physicians). We noted, however, that certain of the exceptions in existing § 411.357 are applicable only to compensation arrangements between a hospital (or other specific type of entity) and a physician (or an immediate family member of a physician). Because an REH is not considered a hospital for purposes of the physician self-referral law and is not one of the other specific types of entities to which the exceptions currently apply, for the reasons explained in section XVIII.E.5 of the

CY 2023 OPPS/ASC proposed rule (87 FR 44799-44800), and using the Secretary's authority under section 1877(b)(4) of the Act, we proposed to amend our regulations to permit an REH to use these exceptions where doing so would not be a risk of program or patient abuse and solicited comments on this approach.

3. Proposed Exception for REHs (Proposed § 411.356(c)(4))

a. Scope and structure of the proposed REH exception

The proposed REH exception would have been available only to entities that are "rural emergency hospitals." To delineate the scope of the applicability of the proposed REH exception, we proposed to amend § 411.351 to add a definition of "rural emergency hospital" for purposes of the physician self-referral law. Under proposed § 411.351, the term "rural emergency hospital" would have the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91. As proposed, § 419.91 cross-references § 485.502, which was proposed in a separate rulemaking to define "rural emergency hospital" to mean an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. In addition, under that proposal, the entity must not provide inpatient services, except those in connection with a distinct part unit licensed as a skilled nursing facility to furnish post-hospital extended care services.

We did not receive any comments on the proposed definition of "rural emergency hospital." Although, as explained in our response to comments below, we are not finalizing the proposed REH exception due to our concern that the exception, as proposed, does not satisfy the standard under section 1877(b)(4) of the Act that financial relationships permitted under exceptions established by the Secretary do not pose a risk of program or patient abuse, the term

"rural emergency hospital" is incorporated into the revisions to the exceptions at § 411.357(e), (r), (t), (v), (x), and (y) that we are finalizing in this CY 2023 OPPS/ASC final rule with comment period. Therefore, we are finalizing the definition of "rural emergency hospital" as proposed.

In the CY 2023 OPPS/ASC proposed rule, we explained that section 1877(d) of the Act and § 411.356(c) establish exceptions for ownership of or investment in specific types of providers: rural providers, hospitals located in Puerto Rico, and hospitals located outside of Puerto Rico. These exceptions apply only with respect to referrals for and billing of the specific services identified in the relevant exception. For example, the exception at section 1877(d)(1) of the Act and § 411.356(c)(2) applies to all referrals and billing for designated health services furnished by a hospital located in Puerto Rico. In contrast, the exception at section 1877(d)(2) of the Act and § 411.356(c)(1) applies only to referrals and billing for designated health services that the entity furnishes in a rural area. The proposed REH exception followed the established construct of the existing exceptions for other specific providers and we proposed that it would have applied to all referrals and billing for designated health services furnished by an REH. Thus, if all the requirements of the proposed REH exception were satisfied, the referral and billing prohibitions of the physician self-referral law would not have applied with respect to designated health services referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the REH.

Because all REHs would have been critical access hospitals or small rural hospitals prior to their enrollment in Medicare as an REH, we stated in the CY 2023 OPPS/ASC proposed rule that we believed it was appropriate to include in the proposed REH exception program integrity requirements similar to those that apply to hospitals, including critical access hospitals and small

rural hospitals, under the rural provider and whole hospital exceptions at § 411.356(c)(1) and (3)(iv). We proposed that these requirements would have applied to an REH even if it was not owned or invested in by physicians (or their immediate family members) when it was a critical access hospital or small rural hospital. We did not propose to include every requirement of existing § 411.362 in the proposed REH exception; rather, our focus was on certain requirements in existing § 411.362(b)(4) that relate to ensuring *bona fide* investment as they would apply to an REH. We stated that, in our view, requirements that relate to disclosure of conflicts of interest, prohibition on facility expansion, and prohibition on increasing aggregate physician ownership or investment levels are program integrity policies that the Congress applied specifically to physician-owned hospitals under the Affordable Care Act. If the Congress had intended all of these requirements to also apply to REHs, it could have considered an REH to be a hospital for purposes of section 1877 of the Act or expressly applied them to REHs under section 1877 of the Act. We expressed concern that limitations on facility expansion or the amount of physician investment or ownership in an REH could negatively impact access to needed services in rural and other underserved areas. We noted that the requirement at existing § 411.362(b)(3)(ii)(B), which states that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital, is included under the statutory and regulatory set of requirements related to disclosure of conflict of interests. However, as explained in the Conference Committee report for the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), this requirement was seen as a requirement to ensure *bona fide* ownership and investment (Conference Committee report, H. Rept. No. 443, 111th Cong., 2nd

Sess. 354 (2010)). We agreed that it is a requirement to ensure *bona fide* ownership and investment and proposed to include a similar requirement at proposed § 411.356(c)(4)(iii).

b. Entity enrolled as an REH

We proposed that the entity must be enrolled in Medicare as an REH. If finalized, the requirement at proposed § 411.356(c)(4)(i) would ensure that a hospital (for purposes of the physician self-referral law) that may technically meet the definition of "rural emergency hospital" but is not enrolled in Medicare as such may not avail itself of the proposed REH exception. We stated that a hospital must instead use the rural provider or whole hospital exception, and all of the requirements in § 411.362 would apply, including the prohibitions on facility expansion and exceeding the aggregate percentage of investment interests held by physicians (and their immediate family members) as of March 23, 2010.

c. Ownership in the entire REH

We proposed to require at proposed § 411.356(c)(4)(ii) that the physician's (or immediate family member's) ownership or investment interest is in the entire REH and not merely in a distinct part or department of the REH. This requirement is similar to the requirement at § 411.356(c)(3)(iii) in the whole hospital exception, and we stated that we would interpret it in the same manner for REHs. When the physician self-referral law was first enacted and later amended to apply to referrals of designated health services beyond clinical laboratory services, the Congress included the whole hospital exception to allow physician ownership or investment in hospitals because, at the time, there were a number of rural hospitals in particular where physicians held ownership interests, and avoiding barriers to accessible health care for patients in rural areas was imperative. These hospitals were usually the only hospitals in the area and provided a breadth of services, and therefore, the Congress did not view ownership or investment

in the hospital as a significant incentive for self-referral. Even so, the whole hospital exception explicitly prohibited ownership in a subdivision of a hospital because of the concern that if physicians owned only the particular part of a hospital to which they referred—such as a cardiac wing or department—there would be an incentive for self-referral. (*See* Opening Statement of the Honorable Bill Thomas, Physician Ownership and Referral Arrangements and H.R. 345, "The Comprehensive Physician Ownership and Referral Act of 1993," House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, 145-146; Comments of the Honorable Pete Stark, Hearing before the Committee on Ways and Means of the U.S. House of Representatives 109th Cong., 1st Sess., 4-5 (Mar. 8, 2005) (Ser. No. 109-37); and House Committee on Budget Report on H.R. 3200 and H.R. 4872, H. Rep. No. 443, pt.1, 111th Cong., 2nd Sess., 355-356 (2010).). We stated our similar belief that ownership or investment in only a distinct part or department of an REH—such as an imaging center—would be an incentive for self-referral, and, therefore, that proposed § 411.356(c)(4)(ii) would be necessary to protect against the harms the physician self-referral law was enacted to address, namely, overutilization and patient steering to less convenient, lower quality, or more expensive services and facilities.

d. Conditioning ownership or investment on making or influencing referrals or generating business for the REH

In line with requirements for hospitals under the rural provider and whole hospital exceptions, we proposed to require at § 411.356(c)(4)(iii) that the REH not directly or indirectly condition any ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(3)(ii)(B), which applies to hospitals that use

the rural provider and whole hospital exceptions, and we stated that we would interpret the requirements applicable to REHs and hospitals in the same way.

In the CY 2023 OPPS/ASC proposed rule, we noted our position that an REH might fail to satisfy this proposed requirement if it requires a specified action or achievement with respect to referrals to or the generation of business for the REH prior to the purchase or receipt of the ownership or investment interest, or requires divestiture of an ownership or investment interest following the occurrence or nonoccurrence of a specified action or achievement with respect to referrals to or the generation of business for the REH. We stated that, for example, we would consider an REH to condition the ownership or investment interest to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH if the physician was permitted to purchase an ownership interest in the REH only if the physician had ordered a specific number of advanced imaging services during each of the 2 years prior to the purchase date of the ownership interest. We stated that we would also consider an REH to condition an ownership or investment interest held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH if the REH required the physician to sell their ownership interest back to the REH in the event that they failed to perform a specific percentage of their outpatient surgeries at the REH during the current year or reduced the hours that they work in their private practice below 75 percent of the prior year. Similarly, we stated that the REH may not condition the amount of an ownership or investment interest that a physician (or an immediate family member of a physician) may purchase, receive, or maintain on the occurrence or nonoccurrence of a specified action or achievement under proposed § 411.356(c)(4)(iii). For example, if a physician who performs at least 80 percent of their surgeries at an REH would be permitted to purchase and maintain

20 shares in the REH, while a physician who performs only 25 percent of their surgeries at the REH would be permitted to purchase and maintain only 5 shares in the REH, we would consider the REH to condition an ownership or investment interest held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH. The examples provided in the CY 2023 OPPS/ASC proposed rule were for illustrative purposes only and were not intended to indicate, nor do they indicate, that any particular absolute number, percentage, or other standard is acceptable or unacceptable. We solicited comment on our interpretation of what it means to "condition" an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH under proposed § 411.356(c)(4)(iii). We also solicited comment specifically on whether we should consider an REH's policy or other mandate that a physician (or an immediate family member of a physician) must relinquish their ownership or investment interest in an REH upon the physician's full retirement from the practice of medicine or the relocation of the physician's medical practice to a location outside the REH's service area to fail to satisfy the proposed requirement at § 411.356(c)(4)(iii), as well as other examples of conduct that we should consider to "condition" an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH under proposed § 411.356(c)(4)(iii).

Like existing § 411.362(b)(3)(ii)(B), which applies to hospitals that use the rural provider and whole hospital exceptions, the requirement at proposed § 411.356(c)(4)(iii), if finalized, would have prohibited policies and conduct that *directly or indirectly* condition ownership or investment interests held or to be held by a physician (or an immediate family member of a

physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. We stated that, for purposes of this requirement, an REH *directly* conditions ownership or investment interests by adopting policies that require a specific number, volume, or value of referrals to or other business for the REH during a particular time period. For example, a requirement that a physician owner of an REH must have ordered at least 50 clinical laboratory tests during three of the prior four quarters to maintain their ownership (or level of ownership) would not satisfy the requirement at proposed § 411.356(c)(4)(iii). We further stated that a policy that permits an immediate family member to purchase an ownership or investment interest in an REH only if their child, who is a physician in private practice, increases the number of patients that they refer to the REH by 25 percent during the calendar year prior to the purchase would not satisfy the proposed requirement. We continued that, if the REH directs the referrals of the physician under a *bona fide* employment relationship, personal service arrangement, or managed care contract between the REH and the physician, and the directed referral requirement meets all the conditions of § 411.354(d)(4), we would not consider the directed referral requirement to constitute directly or indirectly conditioning an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH.

For purposes of this proposed requirement, we stated that we would consider an REH to *indirectly* condition ownership or investment interests if it adopted policies or standards of another person or organization to establish qualification criteria for purchasing or maintaining ownership or investment interests in the REH and those policies or standards required the physician to make or influence referrals to or generate business for the REH. For example, if an

REH required that a physician have active medical staff privileges at the REH to hold an ownership or investment interest in the REH, and also approved the medical staff bylaws that required a minimum of 50 outpatient therapeutic services per year performed or supervised by the physician, the REH would likely not satisfy the requirement at proposed § 411.356(c)(4)(iii). This is because the REH would indirectly adopt the policy mandating a minimum of 50 outpatient therapeutic services per year as the REH's own criteria for qualification to hold an ownership or investment interest in the REH. We recognized that the medical staff of an entity, although accountable to the entity's governing body for the quality of patient care provided by medical staff members to the entity's patients, is independently organized under its own bylaws and establishes the criteria for appointment to the medical staff, credentialing, privileging, and oversight. We also recognized that an entity's medical staff is responsible for peer review, which, to be effective, requires the review of a minimum body of a medical staff member's work in order to determine whether to grant or continue active (or some other category of) medical staff privileges. We did not propose, nor would we be able, to establish a bright-line rule applicable in all instances defining an acceptable number of referrals to or amount of business generated for an entity that a medical staff could require in order to complete effective peer review activities. We stated that such medical staff requirements must directly relate to its peer review obligations—including the evaluation of a physician's (or other practitioner's) individual character, competence, training, experience, and judgment—and not be a proxy for referrals to or the generation of business for the entity. We cautioned that, if an REH adopted a requirement that a physician owner of or investor in the REH must have active privileges at the REH, we would consider it to have effectively (albeit indirectly) adopted a condition that the physician owner must make the same number of referrals to or generate the same amount of business for

the REH for purposes of the requirement at proposed § 411.356(c)(4)(iii) as the number of referrals to or amount of business for the REH that is required by the medical staff to hold active privileges at the REH. To illustrate, we stated that, if the REH requires all physician owners or investors to maintain active medical staff privileges, and the REH's medical staff requires a physician to admit and treat a minimum of five patients per year to maintain active privileges, we would consider the REH to require a minimum of five admissions per year for physician owners to hold their ownership interests in the REH. Whether the requirement constitutes prohibited indirect conditioning of ownership or investment in the REH under proposed § 411.356(c)(4)(iii) would have required a case-by-case determination, including a review of the underlying purpose of, need for, and available alternatives to the minimum requirement.

We also stated that there are many ways that an REH could indirectly condition an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. For example, an REH could require a physician to earn a minimum number of "points" in a year to maintain the physician's (or an immediate family member's) ownership interest or level of ownership. We noted that this would not *per se* be prohibited under proposed § 411.356(c)(4)(iii), but if the required points are merely a proxy for referrals to or the generation of business for the REH (for example, if the physician is awarded one point for each designated health service that they order), we would consider the REH to indirectly condition an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. In the CY 2023 OPPS/ASC proposed rule, we stated that an REH could also indirectly condition ownership or investment interests under a

points system if it awards points only for a physician's personally performed services but the personally performed services also result in the furnishing of designated health services by the REH. Whether a point system or other condition for ownership or investment in an REH runs afoul of proposed § 411.356(c)(4)(iii) would have required a case-by-case determination. A point system that allows the awarding of only one point per patient closely ties the referral of the patient or the generation of the business to the physician who ordered the designated health service or other REH service and, therefore, would likely not be permissible. In contrast, a point system that awards points for a variety of physician activities, including activities that are not tied to the physician's own referral of the patient or business generated for the REH (such as points for chairing a committee of the REH, serving as an assistant at surgery, or providing a professional consultation for another physician's patient), may be permissible under proposed § 411.356(c)(4)(iii).

As we explained in the MCR final rule, our policies with respect to determining whether compensation is determined in any manner that takes into account the volume or value of a physician's referrals (the "volume or value standard") or the other business generated by a physician (the "other business generated standard") have never applied and do not to apply for purposes of analyzing ownership or investment interests for compliance with the physician self-referral law, as none of our exceptions in § 411.356 include a requirement identical or analogous to the volume or value standard or other business generated standard (85 FR 77541). Any guidance regarding our interpretation of the volume or value standard or other business generated standard is not relevant for purposes of applying the exceptions at § 411.356(c)(1) and (3), both of which incorporate the requirements of § 411.362, including the requirement at § 411.362(b)(3)(ii)(B) that a hospital must not condition any physician ownership or investment

interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital (85 FR 77541). In the CY 2023 OPPS/ASC proposed rule, we expressly stated that the same is true with respect to the proposed REH exception—our interpretation of the volume or value standard and the other business generated standard is not relevant. Likewise, the interpretations with respect to the proposed REH exception explained in the CY 2023 OPPS/ASC proposed rule (87 FR 44795) are not relevant for purposes of applying the special rules at § 411.354(d)(6) when analyzing compensation arrangements for compliance with the physician self-referral law.

As proposed § 411.356(c)(4)(iii) would have prohibited an REH conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician *making or influencing* referrals to the REH (or otherwise generating business for the REH). For purposes of the physician self-referral law generally, a physician makes a referral (as defined in § 411.351) by ordering the designated health service, writing a prescription for a designated health service, including the provision of a designated health service in a plan of care, certifying or recertifying the need for a designated health service, or otherwise requesting the designated health service. A physician also makes a referral when the physician requests a consultation with another physician and the consulting physician orders a designated health service to be performed by (or under the supervision of) the consulting physician. (A physician who transfers the care of a patient, in whole or in part, to another physician for specialty or other care to be provided by the other physician—as opposed to a request for a consultation with the other physician—does not make a referral for designated health services ordered or otherwise referred by the other physician.) A physician may make a referral orally, in writing, electronically, or in any other form. We stated that, for purposes of

proposed § 411.356(c)(4)(iii), we would have interpreted the making of referrals to an REH in the same way.

In the CY 2023 OPPS/ASC proposed rule, we noted that, with respect to the influencing of referrals to an REH under proposed § 411.356(c)(4)(iii), impactful pressure or persuasion to refer, or an enforceable requirement for or control over the referrals of another, would demonstrate a physician's influence over the referrals of another physician to an REH. We highlighted that, under § 411.351, "referral" is defined in the context of a physician's action or conduct, and stated that we would interpret the term "referral" consistent with its meaning throughout the physician self-referral regulations, and interpret the requirement at proposed § 411.356(c)(4)(iii) to relate only to the influencing of referrals <u>by a physician</u> to the REH. For example, an REH would not satisfy the requirement at proposed § 411.356(c)(4)(iii) if it withheld the opportunity to purchase an ownership or investment interest in the REH from the physician owners of a physician practice unless the practice required all of its employed and contracted physicians to refer all of their patients to the REH for diagnostic testing and clinical laboratory services, or required them to perform all outpatient surgeries at the REH. (We noted that, with respect to the employed and contracted physicians' referrals for designated health services furnished by the physician practice, the requirement for referrals to the REH may be permissible, provided that all requirements of § 411.354(d)(4) are satisfied.)

We proposed that § 411.356(c)(4)(iii) also would prohibit an REH conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician *otherwise generating business* for the REH. We stated that we would interpret the phrase "otherwise generating business" in proposed § 411.356(c)(4)(iii) consistent with our interpretation of the same and similar phrases in our

other regulations. We addressed our interpretation of the phrase "other business generated" and its variations, such as "otherwise generating business," in several of our prior rulemakings. We indicated that other business generated does not include a physician's personally performed services, but does include a referred technical component that corresponds to a physician's personally performed service (69 FR 16067 through 16068). We also indicated that other business generated by a physician includes Federal and private pay business (other than Medicare) (66 FR 877), as well as non-Federal health care business (69 FR 16068). We noted that it is important to highlight that these statements are examples of what is and is not "other business generated" for purposes of the physician self-referral law. Our longstanding interpretation of the phrase "other business generated" is that it means *any* other business or revenues generated by a physician (66 FR 877) (emphasis added). Although such business or revenues may be generated through the furnishing of health care services by the entity, our interpretation is not limited to business or revenue generated through the furnishing of health care services.

In the CY 2023 OPPS/ASC proposed rule, we stated our position that a physician may generate business for an REH in a variety of ways, including, but not limited to, ordering services to be furnished or billed by the REH, writing a prescription for a service to be furnished or billed by the REH, establishing a plan of care for services to be furnished or billed by the REH, certifying or recertifying the need for services to be furnished or billed by the REH, or otherwise requesting services to be furnished or billed by the REH. A physician may also generate business for an REH that is unrelated to the REH's furnishing of health care services. We stated that we interpret the generation of business by a physician to include the physician's

direct actions and the actions of others whom the physician directs or otherwise influences to generate business for the REH.

e. Offer of ownership or investment on more favorable terms

We proposed to require at § 411.356(c)(4)(iv) that the REH does not offer any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(ii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we stated that we would interpret the requirements applicable to REHs and hospitals in the same way. For example, an REH that permits a physician owner or investor to pay for purchased shares in the REH over 5 years while requiring non-physicians to pay the full purchase price in advance of the purchase would not satisfy the proposed requirement. Similarly, an REH could not permit a physician to purchase additional shares in the REH every year while allowing non-physicians to purchase shares only once every 3 years.

We noted that, in the requirement at existing § 411.362(b)(4)(ii) from which this proposed requirement was drawn, the word "who" follows "person." We stated our belief that the statutory requirement on which that regulation is based is intended to prohibit the offering of ownership or investment interests to physicians (or immediate family members of physicians) on terms more favorable than any other owner of or investor in a hospital. For this reason, we proposed to use the word "that" following "person" to indicate that the person to which less favorable terms are offered could be a natural person (that is, an individual) or a non-natural person (that is, a corporation, partnership, or similar organization).

f. Providing loans or financing for ownership or investment

We proposed at § 411.356(c)(4)(v) to prohibit an REH and the owners of or investors in the REH from directly or indirectly providing loans or financing for any investment in the REH by a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(iii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we stated that we would interpret the requirements applicable to REHs and hospitals in the same way. For purposes of this proposed requirement, an REH directly provides loans or financing by lending the funds or other assets of the REH for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH. In such a case, the REH is the lender. Similarly, an individual or corporate owner of or investor in an REH directly provides loans or financing by lending their own funds or other assets for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH.

We also stated that, under our interpretation of the proposed exception, an REH indirectly provides loans or financing for investment in the REH by controlling or meaningfully influencing another person's decision to lend funds or assets for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH. In such a case, the REH is not the lender. For example, if an REH is the sole owner of the corporation that loans money to a physician to purchase an ownership or investment interest in the REH, we would consider the REH to indirectly provide the loan because the REH exercises control over its wholly-owned subsidiary corporation. In contrast, merely introducing a physician (or an immediate family member of a physician) to an individual or corporation that might lend funds or assets for use in purchasing an ownership or investment interest in an REH, in the absence of actual control or meaningful influence over the lender's decision whether a

loan will be provided, would not constitute the indirect provision of a loan or financing for investment in the REH.

g. Guarantee, make a payment on, or otherwise subsidize a loan

At proposed § 411.356(c)(4)(vi), we proposed to prohibit an REH and the owners of or investors in the REH from directly or indirectly guaranteeing a loan, making a payment toward a loan, or otherwise subsidizing a loan for a physician (or an immediate family member of a physician) that is related to acquiring any ownership or investment interest in the REH. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(iv), which applies to hospitals that use the rural provider and whole hospital exceptions, and we stated that we would interpret the requirements applicable to REHs and hospitals in the same way. We noted that existing § 411.362(b)(4)(iv) extends the prohibition on guaranteeing, making a payment toward, or otherwise subsidizing a loan to such activities when they are for a group of physician owners or investors, whereas proposed § 411.356(c)(4)(vi) prohibits these activities as they relate to individual physicians (and immediate family members). A group of physician owners or investors is made up of individual physicians and, therefore, the proposed requirement would have also prohibited guaranteeing, making a payment toward, or otherwise subsidizing a loan for a group of physician owners or investors.

In the CY 2023 OPPS/ASC proposed rule, we stated that, for purposes of proposed § 411.356(c)(4)(vi), an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH guarantees a loan when the REH, owner, or investor formally or informally promises the lender that, should a physician (or an immediate family member of a physician) fail to make a required payment on a loan related to the physician's (or immediate family member's) acquisition of any ownership or investment interest in the REH, the REH,

owner, or investor, respectively, will make or otherwise ensure that the payment will be made to the lender. A direct guarantee would include pledging the guarantor's own funds or assets as collateral for the guaranteed loan, whereas an indirect guarantee would include pledging or arranging for the pledge of the funds or assets of another individual or corporate entity as collateral for the guaranteed loan. We stated that we would also consider the pledge of funds or assets of an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH to guarantee a loan for property that serves as collateral for the loan related to acquiring the physician's (or immediate family member's) ownership or investment interest in the REH to be an indirect guarantee of such loan.

We further stated that we would interpret the direct or indirect making of a payment toward a loan similarly. That is, a person directly makes a payment toward a loan by using the person's own funds or assets to make the payment, and indirectly makes a payment toward a loan by using or arranging for the use of the funds or assets of another individual or corporate entity to make the payment. An REH would not have been prohibited from garnishing the wages or other compensation due to a physician (or an immediate family member of a physician) to make loan payments on behalf of the physician (or immediate family member).

Finally, for purposes of proposed § 411.356(c)(4)(vi), we stated that an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH otherwise subsidizes a loan when the REH, owner, or investor pays part of the cost of a loan for a physician (or an immediate family member of a physician). Subsidies would include, for example, payments to reduce the principal amount of the loan, reduce the interest rate applied to the loan, or cover the cost of fees, such as origination fees, late fees, or early payoff penalties. We stated that, as with guaranteeing or making payments toward a loan, we would interpret directly and

indirectly subsidizing a loan to mean that a person directly subsidizes a loan by using the person's own funds or assets to pay part of the cost of the loan, and indirectly subsidizes a loan by using or arranging for the use of funds or assets of another individual or corporate entity to pay part of the cost of the loan.

h. Proportional distributions

We proposed to require at § 411.356(c)(4)(vii) that ownership or investment returns are distributed to each owner of or investor in an REH in an amount that is directly proportional to the ownership or investment interest in the REH of such owner or investor. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(v), which applies to hospitals that use the rural provider and whole hospital exceptions, and we stated that we would interpret the requirements applicable to REHs and hospitals in the same way. Simply put, distributions of profits, dividend payments, and other payouts on equity may only be tied to the number of shares owned by an investor, and not to their referrals or the other business the investor generates for the REH. We stated that we would interpret "proportional" as it is defined in the dictionary: corresponding in size or amount.

Under the proposed REH exception, to ensure that the ownership or investment return to each owner of or investor in the REH is directly proportional to the particular owner's or investor's interest in the REH, we would have required that all owners and investors must be treated the same. That is, if any owner or investor is eligible to receive or actually receives an ownership or investment return, all other owners or investors must be eligible to receive or actually receive an ownership or investment return, respectively. For example, an REH wholly-owned by physicians would not satisfy this proposed requirement if the REH made distributions only to physicians who generate a minimum amount of business for the REH during the

ownership or investment period. In addition, an REH could not exclude owners or investors that are not physicians (or their immediate family members) from eligibility for ownership or investment returns for the purpose of making distributions only to owners or investors who are physicians in a position to generate business for the REH or their immediate family members. This would be the case even if the distributions were in amounts that are directly proportional to the physician's (or immediate family member's) ownership or investment interest in the REH.

i. Guaranteed receipt of or right to purchase other business interests

We also proposed to require that any physician (or immediate family member of a physician) who has an ownership or investment interest in an REH does not directly or indirectly receive any guaranteed receipt of or right to purchase other business interests related to the REH, including the purchase or lease of any property under the control of any other owner of or investor in the REH or located near the premises of the REH. This requirement at proposed § 411.356(c)(4)(viii) is essentially identical to the requirement at existing § 411.362(b)(4)(vi), which applies to hospitals that use the rural provider and whole hospital exceptions. We stated that we would interpret the requirements applicable to REHs and hospitals in the same way.

For purposes of this proposed requirement, we stated that other business interests related to the REH would include a wide array of investment opportunities, ventures, and interests, as well as the examples of the purchase and lease of property under the control of any other owner of or investor in the REH that are listed in the statutory and regulatory requirements applicable to hospitals that use the rural provider and whole hospital exceptions. We stated that we would consider the business interests of any owner of or investor in the REH to be business interests related to the REH. For example, under the proposed requirement at § 411.356(c)(4)(viii), a physician owner of or investor in an REH may not directly or indirectly receive an interest in

another component of the health care system that includes an REH upon the physician's purchase of their ownership or investment interest in the REH, nor may the physician owner directly or indirectly be guaranteed the right to invest in a venture in which another owner of the REH is also an investor. In these examples, the physician owner would directly receive an interest or be guaranteed the right to invest in a business interest related to an REH if the interest is held or would be held, if purchased, in the physician's name. We further stated that, in contrast, the physician owner would indirectly receive an interest or be guaranteed the right to invest in a business interest related to an REH if the interest is received by, held in the name of, or, if purchased, would be held in the name of a person or corporate entity over which the physician exercises meaningful control or influence, such as a partnership or limited liability company in which the physician holds a substantial interest.

j. Offer to purchase or lease other property on more favorable terms

Finally, at proposed § 411.356(c)(4)(ix), we proposed to require that an REH does not offer a physician (or an immediate family member of a physician) the opportunity to purchase or lease any property under the control of the REH or any other owner of or investor in the REH on more favorable terms than the terms offered to a person that is not a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(vii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we stated that we would interpret the requirements applicable to REHs and hospitals in the same way.

We highlighted that there are two main differences between the requirements at proposed §§ 411.356(c)(4)(viii) and (ix). The former applies to any business interests related to the REH and prohibits the guaranteed receipt of or right to purchase such other business interests. The

latter applies only to property under the control of the REH, an owner of the REH, or an investor in the REH, and prohibits the offering of the opportunity to purchase or lease such property on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician).

With respect to the prohibition on offering an opportunity to purchase or lease property on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician), we stated that we would interpret this requirement in the same way as proposed § 411.356(c)(4)(iv), which, would prohibit an REH from offering any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than those offered to a person that is not a physician (or an immediate family member of a physician). We noted that the requirement at existing § 411.362(b)(4)(vii), from which this proposed requirement is drawn, states that the physician owner may not be offered the opportunity to purchase or lease certain property on more favorable terms than those offered to an "individual" who is not a physician owner or investor, in contrast to the requirement at existing § 411.362(b)(4)(ii), which references "persons" in a similar manner. We stated our belief that the statutory requirement on which existing § 411.362(b)(4)(vii) is based is intended to prohibit the offering of the opportunity to purchase or lease the specified property on terms more favorable than any other owner of or investor in a hospital. For this reason, proposed § 411.356(c)(4)(ix) included the words "person that" in the same way as proposed § 411.356(c)(4)(iv) to indicate that the person to which less favorable terms are offered could be a natural person (that is, an individual) or a non-natural person (that is, a corporation, partnership, or similar organization).

k. Alternative to Proposed REH Exception Considered but not Proposed

Section 1861(e) of the Act excludes critical access hospitals (formerly referred to as rural primary care hospitals) from the definition of "hospital" for most purposes of Title XVIII of the Act unless the context otherwise requires. However, as we explained in the 1998 proposed rule, we believe that the reference to context in this statutory provision indicates that critical access hospitals may be deemed to be hospitals where, in specific contexts, it is consistent with the purpose of the legislation to do so (63 FR 1681). For that reason, we included such entities in our definition of "hospital" at § 411.351 (66 FR 954). We based this policy on our belief that a physician who has a financial relationship with a critical access hospital is in as much of a position to profit from overutilizing referrals to the critical access hospital as they would be if the financial relationship was with an ordinary hospital. In addition, a critical access hospital provides services that are very similar to inpatient hospital services (63 FR 1681).

Section 125 of the CAA amended section 1861(e) of the Act to also exclude REHs from the definition of "hospital" for most Medicare purposes, unless the context otherwise requires. We considered whether to include REHs in the definition of "hospital" in § 411.351 for purposes of the physician self-referral law similar to our treatment of critical access hospitals. We did not propose to do so for two primary reasons. First, REHs are not the same as critical access hospitals (or other hospitals that furnish inpatient care). By definition, an REH may not furnish inpatient care, a fundamental attribute of and requirement for a hospital for purposes of Medicare. (See section 1861(e) of the Act.) Second, if we were to consider an REH to be a hospital for purposes of the physician self-referral law, in order for an REH to avoid the law's referral and billing prohibitions, the ownership or investment interests of physicians (and their immediate family members) would have to satisfy the requirements of one of the existing exceptions applicable to such ownership or investment interests, which could prove challenging,

thus limiting the ability of such potential investors to bring needed resources to underserved and rural communities. We explained that, if we had proposed to include REHs as "hospitals" for purposes of the physician self-referral law, we would not have proposed to establish the exception for ownership or investment in an REH with the requirements described in the proposed rule because we do not believe that the Secretary's authority under section 1877(b)(4) of the Act would permit us to establish an exception that applies to only one type of hospital (for purposes of the physician self-referral law) without including the same (or equally stringent) program integrity requirements established by the Congress in statute.

To avoid the physician self-referral law's referral and billing prohibitions under the rural provider or whole hospital exception, an ownership or investment interest must satisfy the requirements of the applicable exception at the time of the physician's referral and the hospital must meet the requirements of section 1877(i) of the Act and § 411.362 no later than September 23, 2011. Section 1877(i)(1)(A) of the Act and § 411.362(b)(1) require that the hospital had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date (emphasis added). Put another way, for a hospital to bill Medicare (or another individual, entity, or third-party payer) for a designated health service furnished as a result of a physician owner's referral today, the hospital must have had both physician ownership or investment and a Medicare provider agreement on December 31, 2010. Thus, the hospital submitting the claim today must be the same hospital that had both physician ownership or investment and a Medicare provider agreement on December 31, 2010. We stated that, if we were to include REHs as hospitals for purposes of the physician self-referral law, certain REHs would be presumptively excluded from using the rural provider or whole hospital exceptions: REHs that had no physician owners or investors, as

defined at § 411.362(a), on March 23, 2010 or December 31, 2010, and REHs that did not have a Medicare provider agreement in effect on December 31, 2010.

Critical access hospitals and small rural hospitals that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 may avail themselves of the rural provider and whole hospital exceptions, provided that all other requirements of the applicable exception are satisfied. This would continue after conversion to an REH if we deemed REHs to be hospitals for purposes of the physician self-referral law. However, as noted above, the REH/hospital would have to be the same hospital that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 (the "original hospital"). We would consider many factors when determining whether an REH would qualify as the same hospital that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 including, but not limited to: status of, type of, and party to the State license for both the REH and the original hospital, including any lapses in State licensure or operation of either the REH or the original hospital; status of and party to the Medicare provider agreement, including any lapses in Medicare participation of either the REH or the original hospital; whether the REH has the same Medicare provider number as the original hospital; the location and structure of the REH building(s) and those of the original hospital; whether the REH is under the same State's licensure regime as the original hospital; whether the REH serves the same community as the original hospital; whether the REH provides the same scope of services as the original hospital; REH ownership and that of the original hospital; and the number of operating rooms, procedure rooms, and beds operated by the REH and that of the original hospital. No one factor would be dispositive.

Provisions of the Final Rule

As noted above, we are finalizing the definition of "rural emergency hospital" as proposed. For the reasons explained in the following responses to public comments, we are not finalizing our proposal to establish an exception at § 411.356(c)(4) for ownership or investment in an REH.

Comment: Several commenters strongly objected to the establishment of the REH exception and urged CMS not to finalize the exception at all or without modification. The commenters were particularly concerned that the REH exception would not protect against the specific types of patient and program abuse that the physician self-referral law is intended to deter, including overutilization, mis-utilization, and patient steering to lower quality, higher cost, or less convenient services. One of these commenters suggested that the exception, if finalized, could actually worsen problems with access to the full range of necessary care in rural areas because CAHs and small rural hospitals may abandon inpatient services in favor of higher Medicare reimbursement and potential physician-owner control over referrals for designated health services if they convert to an REH. This commenter, along with others, highlighted the potential impact of financial self-interest on medical decision-making by physicians who invest in REHs.

Some of the commenters that urged CMS not to finalize the REH exception raised concerns regarding the adequacy of the program integrity protections of the proposed REH exception. These commenters asserted that the REH exception, as proposed, falls outside the Secretary's authority under section 1877(b)(4) of the Act to establish regulatory exceptions only for financial relationships that do not pose a risk of program or patient abuse. The commenters disagreed with our rationale for not including certain of the program integrity requirements

imposed on hospitals that use the whole hospital and rural provider exceptions, and opined that the proposed exception would impose less of a burden on REHs than the whole hospital and rural provider exceptions pose for physician ownership or investment in hospitals. One of the commenters maintained that, when relying on the authority provided in section 1877(b)(4) of the Act, CMS should not create an exception for ownership or investment in an REH with requirements that are less rigorous than those set forth by the Congress for the type of entity from which the REH converted. This commenter urged that, if CMS adopts an REH-specific exception for physician ownership or investment, we should include in the final exception all requirements applicable to physician ownership or investment in hospitals under the whole hospital and rural provider exceptions, including prohibitions on facility expansion, transparency requirements, and patient safety requirements. This recommendation was endorsed by other commenters. None of the commenters suggested potential program integrity requirements alternative to the existing requirements in the statute and our regulations applicable to physician ownership or investment in hospitals, although some noted that the REH exception as proposed would not prevent physician-owned REHs from limiting the services they offer to those most likely to be highly reimbursed or profitable ("cherry-picking"), choosing not to offer less profitable services or treat sicker and costlier patients ("lemon dropping"), and engaging in other behaviors that would have negative effects on care for beneficiaries in rural areas. Despite their opposition to the REH-specific exception for ownership or investment in an REH, the commenters did not object to CMS treating REHs as "hospitals" for purposes of the physician self-referral law instead of finalizing the proposed REH exception.

Response: After reviewing comments on a broad array of proposed REH policies, including comments on the physician self-referral law proposals, we are persuaded that financial

relationships permitted under the REH exception, as it was proposed, may present a risk of patient or program abuse. As we noted in the CY 2023 OPPS/ASC proposed rule, REHs may provide a broad range of outpatient services, including various types of designated health services. As one of the commenters suggested, the lure of financial reward from referrals for highly-reimbursed or profitable services could influence the medical decision-making of an REH's physician owners and investors. In light of the flexibilities afforded REHs under the payment and other policies set forth in this final rule with comment period, we agree with the commenters that the potential for cherry-picking and lemon-dropping, as well as other harms the physician self-referral law aims to deter, may persist in the REH context, particularly for REHs with service areas that include a mix of rural and urban areas. We share the commenters' concerns that the ability to capture the referrals of physician owners or investors may provide an incentive for existing CAHs and small rural hospitals that are economically capable of sustaining inpatient beds to nonetheless convert to REHs and avoid the physician self-referral law's more stringent requirements for hospitals.

Any exception to the physician self-referral law established by the Secretary under section 1877(b)(4) of the Act that permits physician ownership or investment in REHs must include sufficient program integrity requirements to ensure that such ownership or investment interests do not pose a risk of program or patient abuse. After reviewing the comments on the CY 2023 OPPS/ASC proposed rule, we believe that the REH exception—as proposed—may not meet the requirement of section 1877(b)(4) of the Act that the physician ownership or investment interests it would permit do not pose no risk of patient or program abuse. We considered the comments that encouraged CMS to include existing requirements for physician-owned hospitals in any final REH exception. We decline to do so because we continue to believe that certain of

the requirements that are currently applicable to hospitals, such as the limitation on expansion of the aggregate number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010, are not suitable for application to REHs. Commenters did not suggest alternative program integrity criteria that, if included in the exception, would satisfy the statutory requirement that permitted financial relationships do not pose a risk of program or patient abuse. Therefore, we are not finalizing the proposed REH exception at this time.

Because they are not "hospitals," REHs located in rural areas, as defined in § 411.351, may use the rural provider exception in section 1877(d)(2) of the Act and codified at § 411.356(c)(1), without application of the additional requirements for hospitals in § 411.362. As set forth in statute and incorporated into our regulations without additional requirements, the rural provider exception is available to entities located in rural areas and has only one substantive requirement. Specifically, the entity must furnish substantially all (not less than 75 percent) of the designated health services it provides to residents of rural areas. We emphasize that the "substantially all" requirement at § 411.356(c)(1) applies only to designated health services furnished by an entity. As applied to an REH, this means that the REH must furnish not less than 75 percent of the designated health services that it furnishes (such as radiology and other imaging services) to residents of a rural area, but would not need to monitor the residence of patients to whom it provides any services that are not considered designated health services under § 411.351.

In the proposed rule, we recognized that monitoring the residence of beneficiaries receiving designated health services could be burdensome for REHs. Even so, we believe that REHs that are located in rural areas and primarily serve beneficiaries who reside in rural areas will have no difficulty meeting this threshold. The monitoring burden would most likely be

limited to REHs that are located in rural areas but have service areas that encompass urban areas as well. As described in section XXIV.G and H of this CY 2023 OPPS/ASC final rule with comment period, we expect only a limited number of CAHs and small rural hospitals will convert to REHs; therefore, any monitoring burden under the rural provider exception would be limited to only those few REHs located in rural areas but that have service areas that encompass urban areas.

Comment: Several commenters offered general support permitting physician ownership of REHs, but did not address specific provisions of the proposal. Some commenters that supported the proposed REH exception recognized the need for program integrity protections in exceptions to the physician self-referral law. None of the commenters expressly addressed whether the requirements of the proposed REH exception are sufficient to ensure that physician ownership or investment in an REH would not pose a risk of program or patient abuse.

Response: We appreciate the commenters' support of policies designed to promote access to care in underserved rural areas. However, based on the concerns raised by other commenters, which were not addressed by the commenters that supported the proposal to establish an exception for ownership or investment in an REH, we are not finalizing the proposed exception. As explained in the response to the previous comment, the rural provider exception remains available to most, if not all, REHs.

Applicability of Certain Exceptions in § 411.357 for Compensation Arrangements Involving REHs

Section 1877(e) of the Act and § 411.357 set forth exceptions to the physician self-referral law's referral and billing prohibitions for compensation arrangements between entities and physicians (or immediate family members of physicians) that satisfy all requirements of the

exception. Some of these exceptions apply only to specified types of compensation, specified types of entities, or both. The exceptions in § 411.357 that are applicable only to compensation arrangements to which one party is a hospital, federally qualified health center, or rural health clinic would not be available to an REH because it is not a hospital under section 1861(e) of the Act or our regulations at § 411.351. We believe that many of these party-limited exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH. Therefore, using the Secretary's authority under section 1877(b)(4) of the Act, we proposed to revise the exceptions at § 411.357(e), (r), (t), (v), (x), and (y) to make them applicable to compensation arrangements to which an REH is a party.

The existing exceptions for physician recruitment (§ 411.357(e)), obstetrical malpractice insurance subsidies (§ 411.357(r)), retention payments in underserved areas (§ 411.357(t)), and assistance to compensate a nonphysician practitioner (§ 411.357(x)) are available to hospitals, federally qualified health centers, and rural health clinics. We proposed to revise these exceptions to also permit an REH to provide remuneration to a physician if all requirements of the applicable exception are satisfied because we believe that REHs will face the same challenges as hospitals, federally qualified health centers, and rural health clinics in recruiting and retaining qualified physicians and other practitioners in their service areas. Consistent with our rationale when expanding the statutory exception for physician recruitment to federally qualified health centers (69 FR 16095), we proposed the extension of these exceptions to REHs to help ensure that the physician self-referral law does not impede efforts by REHs, which will provide substantial services to underserved populations, to recruit, assist with the recruitment of, and retain adequate staffs. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to

satisfy all the requirements of these exceptions would pose a risk of program or patient abuse. We also proposed a technical amendment at proposed § 411.357(t)(5) to cross-reference the definition of the geographic area served by a federally qualified health center or rural health clinic that was previously omitted from this paragraph. As proposed, the cross-referenced definition would also apply to REHs under this proposal.

The existing exception for electronic prescribing items and services at § 411.357(v) is available only to hospitals, group practices that meet the requirements in § 411.352, PDP sponsors, and MA organizations and applies to hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information that is provided to physicians specified in the regulation. For the reasons set forth in the proposed rule and many of our prior rulemakings regarding the benefits of electronic prescribing, we believe that allowing REHs to use the exception at § 411.357(v) would advance our goals to expand the use of electronic prescribing. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to satisfy all the requirements of the exception would pose a risk of program or patient abuse.

The existing exception for timeshare arrangements at § 411.357(y) is available only to hospitals and certain physician organizations (as defined in § 411.351) and applies to arrangements for the use of premises, equipment, personnel, items, supplies, and services. One of the underlying policy considerations for establishing this exception was to facilitate access to care in rural and other underserved areas (80 FR 71326). We believe that timeshare arrangements between REHs and physicians (or physician organizations in whose shoes such physicians stand under § 411.354(c)) may similarly increase access to necessary care for patients

in underserved areas, and that it would be appropriate to extend the availability of the exception for timeshare arrangements to REHs. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to satisfy all the requirements of the exception would pose a risk of program or patient abuse.

We are finalizing without modification our proposal to revise the exceptions at § 411.357(e), (r), (t), (v), (x), and (y) to make them applicable to compensation arrangements to which an REH is a party. Our responses to the public comments we received on these proposals are below.

Comment: A few commenters addressed the proposed changes to the exceptions at § 411.357(e), (r), (t), (v), (x), and (y) that would make these exceptions applicable to compensation arrangements involving REHs. These commenters generally supported the proposed revisions to the exceptions. No commenters identified any concerns related to the proposed revisions, despite specific requests for comments regarding the need for an REH to recruit physicians to establish or join a medical practice in the geographic area served by the REH (and how to define such a service area), provide assistance to compensate a nonphysician practitioner, or offer obstetrical malpractice insurance subsidies.

Response: As we stated in the proposed rule, we believe that many of the party-limited exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH, as well as advance our goals to expand the use of electronic prescribing and the adoption of electronic health records. We remind parties that all requirements of an applicable exception must be satisfied to avoid the referral and billing prohibitions of the physician self-referral law. We do not believe that making the exceptions at § 411.357(e), (r), (t),

(v), (x), and (y) available to compensation arrangements involving REHs would pose a risk of program or patient abuse, and we are finalizing the revisions to the noted exceptions as proposed.

Revised Cross-Reference in Definition of "Rural Area" for Purposes of the Physician Self-Referral Law

As discussed in section XVIII.E of this final rule with comment period, the rural provider exception applies to designated health services furnished in a rural area. Section 1877(d)(2) of the Act defines "rural area" by reference to section 1886(d)(2)(D) of the Act. In the 1992 proposed rule, we proposed to define "rural area" as an area that is not an "urban area," as the term is the term is defined at § 412.62(f)(1)(ii) (57 FR 8598). Section 412.62 established the Federal rates for inpatient operating costs for fiscal year 1984. We finalized the definition of "rural area," including the reference § 412.62(f)(1)(ii), in the 1995 final rule (60 FR 41980). In the FY 2005 IPPS final rule, CMS revised the definitions of urban and rural areas based on OMB's revised standards for defining Metropolitan Statistical Areas (MSAs) (69 FR 49077). The revised definitions of urban and rural areas were codified at § 412.64(b). Section 412.64 establishes Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years. Despite the revised definition of rural and urban areas in the FY 2005 IPPS final rule, the definition of "rural area" as codified in § 411.351 for purposes of the physician self-referral law was never updated to reflect OMB's revised standards for defining MSAs. As a consequence, the current definition of "rural area" in § 411.351 includes, by reference to § 412.62(f)(1)(ii), terminology that is no longer employed by OMB, such as "New England County Metropolitan Area (NECMA)" (see, for example, 65 FR 51065). To ensure that the definition of "rural area" for purposes of the physician self-referral law is aligned with CMS' updated definitions of rural and urban areas at § 412.64 and takes into account OMB's revised

standards for defining MSAs, we proposed to modify the definition of "rural area" in § 411.351 to reference § 412.64(b) instead of § 412.62(f). Specifically, we proposed to define "rural area" as an area that is not an urban area as defined at § 412.64(b) of this chapter. We believe that this technical change will have no effect on the entities that qualify as "rural providers" under § 411.356(c)(1). We solicited comment on this proposal.

We did not receive any public comments on our proposal. We are finalizing without modification the proposed technical change to the definition of "rural area" at § 411.351.

XIX. Request for Information on Use of CMS Data to Drive Competition in Healthcare Marketplaces

In the CY 2023 OPPS/ASC proposed rule (87 FR 44800 through 44802), we included a Request for Information (RFI) related to the use of CMS data to drive competition in healthcare marketplaces. We received approximately 21 timely pieces of correspondence that were submitted in response to the Competition RFI questions. Additionally, we received 180 pieces of correspondence (176 of the 180 submissions were form letters) related to CMS' hospital price transparency efforts and its role in driving competition, generally. We thank all interested parties for their comments and will take them into consideration in the future.

XX. Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop

"a method for controlling unnecessary increases in the volume of covered OPD services."[321] As part of the CY 2021 OPPS/ASC final rule with comment period, we added two additional service categories to the prior authorization process for certain hospital OPD services (85 FR 85866, 86236 through 86248). The regulations governing the prior authorization process for certain hospital OPD services are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89, with the specific service categories listed in § 419.83.

Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained for service dates on or after July 1, 2020, which are: (i) Blepharoplasty; (ii) Botulinum toxin injections; (iii) Panniculectomy; (iv) Rhinoplasty; and (v) Vein ablation. Paragraph (a)(2) of § 419.83 lists two additional service categories for which prior authorization must be obtained for service dates on or after July 1, 2021, which are: (i) Cervical Fusion with Disc Removal; and (ii) Implanted Spinal Neurostimulators. Paragraph (b) states that CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking. Additionally, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Addition of a New Service Category

In accordance with § 419.83(b), we proposed to require prior authorization for a new service category: Facet Joint Interventions. We proposed adding the new service category at

[321] See also Correction Notice issued January 3, 2020 (85 FR 224).

§ 419.83(a)(3). We also proposed that the prior authorization process for this additional service category would be effective for dates of services on or after March 1, 2023. As explained more fully below, the proposed addition of this service category is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services. Because we proposed that prior authorization would be required for this service category at a later date than for the first seven service categories, we proposed to revise paragraph (a)(3) to include this new service category and reflect the March 1, 2023 implementation date for the prior authorization requirement for this additional service category. Specifically, we proposed that paragraph (a)(3) would read, "[t]he Facet Joint Interventions service category requires prior authorization beginning for service dates on or after March 1, 2023." We also proposed that existing paragraph (a)(3) be moved to paragraph (b), and that paragraph (b) be revised by modifying the title to read, "Adoption of the list of services and technical updates." We also proposed to re-designate the current paragraph (b) as subparagraph (b)(1). We proposed that subparagraph (b)(1) would read, "CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking." We proposed that current paragraph (a)(3) would be moved to new paragraph (b)(2) and read, "Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website."

We proposed that the Facet joint interventions service category would consist of facet joint injections, medial branch blocks, and facet joint nerve destruction. Facet joint injections are procedures in which a practitioner injects medication into the facet joints (the connections between the bones of the spine) to help diagnose the cause and location of pain and also to

provide pain relief. Medial branch block is a procedure in which a medication is injected near the medial branch nerve connected to a specific facet joint to achieve pain relief. Facet joint nerve destruction (also known as nerve denervation) is a procedure that uses heat to destroy the small area of the facet joint nerve for pain management.

We proposed that the list of proposed additional OPD services in the Facet joint interventions service category that would require prior authorization beginning on March 1, 2023, are those identified by the CPT codes in Table 103. For ease of review and brevity, we only included in the regulation text in proposed new § 419.83(a)(3) the name of the service category, but not the CPT codes that fall into that service category, which are listed in Table 103. Note that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1) and two additional service categories in § 419.83(a)(2). Again, we proposed that the prior authorization process for the proposed additional service category would be effective for dates of service on or after March 1, 2023. We proposed an effective date slightly earlier in the calendar year (compared to July 1, 2020, and July 1, 2021, effective dates for the service categories previously added to the prior authorization regulation) because Medicare Contractors, CMS, and the OPD providers already have knowledge of and experience with the prior authorization process. Also, this new service category can be performed by some of the same provider types who furnish other services currently subject to the OPD prior authorization process, such as implanted spinal neurostimulators and cervical fusion with disc removal.

2. Basis for Adding a New Service Category

As part of our responsibility to protect the Medicare Trust Funds, we noted in the proposed rule that we continue our routine analysis of data associated with all aspects of the Medicare program. This responsibility includes monitoring the total amount or types of claims

submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

In the proposed rule, we noted that we reviewed approximately 1 billion claims related to OPD services during the 10-year period from 2012 through 2021. We determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 0.6 percent. This equated to an increase from approximately 105 million OPD claims submitted for payment in 2012 to approximately 111 million claims submitted for payment in 2021. The 0.6 percent rate reflects a decrease when compared to the 2.8 percent rate identified in the CY 2021 OPPS/ASC proposed rule when we looked at the period from 2007 through 2018. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 4.2 percent. Again, this is a decrease when compared to the 7.8 percent rate identified in the CY 2021 OPPS/ASC proposed rule for a slightly earlier timeframe. The decrease in the average annual increase in the claim volume and allowed amount from the increases noted in the CY 2021 OPPS/ASC proposed rule is likely due in part to the PHE, as discussed in more detail below. We found that the total Medicare allowed amount for the OPD services claims processed in 2012 was approximately $48 billion and increased to $73 billion in 2021, while during this same 10-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.4 percent.

In the proposed rule, we noted that our analysis of Integrated Data Repository (IDR[322]) data showed that, with regard to the Facet joint interventions, CPT codes 64490-64495 and 64633-64636, claims volume increased by 47 percent between 2012 and 2021, reflecting a 4 percent average annual increase, which is higher than the 0.6 percent annual increase for all OPD services. For the facet joint injection and medial branch block services, CPT codes 64490-64495, we observed an increase of 27 percent between 2012 and 2021, reflecting a 2.5 percent average annual increase. This reflects an increase from approximately 136,000 claims submitted for payment in 2012 to approximately 173,775 claims submitted for payment in 2021. For the nerve destruction services, CPT codes 64633 through 64636, we observed an increase in volume of 102 percent between 2012 and 2021, which was an average annual increase of 7 percent. This accounts for an increase from approximately 48,000 claims submitted for payment in 2012 to approximately 97,000 claims submitted for payment in 2021. Both the facet joint injections/medial branch block CPT codes and nerve destruction CPT codes, with 2.5 and 7 percent annual increases, respectively, demonstrated higher average annual increases in claim submissions between 2012 and 2021 than the 0.6 percent annual increase for all OPD services over the same time period.

As noted in the proposed rule, when analyzing the data, we took the COVID-19 Public Health Emergency (PHE) into consideration. As a result of the PHE, healthcare use and spending dropped sharply due to cancellations of elective and non-emergency care to increase hospital capacity and social distancing measures to reduce the community spread of the coronavirus. Consequently, the claims data for CY 2020 showed a significant decrease in

[322] The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.

volume compared to the previous year, which is likely due to the PHE. However, over the 9-year period of our analysis, services for Facet joint interventions demonstrated increases. These volume increases led us to further research the reasons behind them to determine if they were unnecessary.

We also noted in the proposed rule that the Department of Health and Human Services' Office of the Inspector General (OIG) had published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of Facet joint interventions. An OIG report published in 2020 identified $748,555 in improper payments out of $3.3 million in paid Medicare claims for facet joint injections with an audit period from January 1, 2017, through May 31, 2019. The OIG recommended that CMS and its contractors provide additional oversight on claims for facet joint injections to prevent additional improper payments[323]. In 2021, the OIG published a report on facet denervation procedures. During the audit period from January 2019 through 2020, the OIG reported that Medicare improperly paid physicians $9.5 million for selected facet joint denervation procedures. According to the OIG, these improper payments occurred because CMS's oversight was not adequate to prevent or detect improper payments for selected facet joint denervation procedures[324]. Further, in March 2022, the Department of Justice reported on a $250 million healthcare fraud scheme that took place from 2007 to 2018 involving physicians from multiple states who allegedly subjected their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids. The physicians required patients to receive facet joint injections due to their high reimbursement rates.[325] CMS' data analysis and research show that the increases

[323] https://oig.hhs.gov/oas/reports/region9/92003003.asp
[324] https://oig.hhs.gov/oas/reports/region9/92103002.asp
[325] https://www.justice.gov/opa/pr/16-defendants-including-12-physicians-sentenced-prison-distributing-66-million-opioid-pills

in volume for these procedures are unnecessary, and further program integrity action is warranted.

In the proposed rule, we said that our conclusion that increases in volume for facet joint services are unnecessary was based not only on the data specific to this service category but also on a comparison of the rate of increase for the service category to the overall trends for all OPD services. We noted our belief that comparing the utilization rate for the particular service category to the overall rate of growth for Medicare OPD services generally is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. We researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe that was the case. In the proposed rule, we reaffirmed our belief that prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste, and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We solicited comments on the addition of this service category and specifically requested comments on the potential for any unintended clinical consequences from the addition of this service category.

We received 69 comments on this proposal, including comments from healthcare providers, professional and trade organizations, and device manufacturers. The following is a summary of the comments we received and our responses.

Comment: We received comments in support of the addition of a new service category to the prior authorization process to ensure the appropriateness of payment for Medicare services.

Response: We appreciate the positive responses on the addition of a new service category to our prior authorization process and agree that prior authorization is an effective method for controlling unnecessary increases in the volume of the new service category.

Comment: Commenters conveyed that prior authorization processes can add burden and costs, unnecessary delays or denials of appropriate care, and directly impact the patient's access to timely proper medical care. Additionally, some commenters stated that prior authorization is contrary to CMS's Patients Over Paperwork initiative.

Response: We remain fully committed to the agency's initiative to reduce unnecessary burden while still protecting our programs' sustainability by serving as a responsible steward of public funds. We continue to believe that the hospital outpatient department (HOPD) prior authorization process can expand to include additional services without the referenced delays in patient care. We believe that we have structured the prior authorization processes to effectively account for concerns associated with processing timeframes, patient care, and other administrative concerns. We recognize apprehension resulting from problems with prior authorization in other settings related to the burden, cost, and patient access, but as with our other Medicare Fee-For-Service prior authorization processes, we believe that the HOPD prior authorization process for the new Facet joint interventions service category will not have these problems. We have established timeframes for contractors to render decisions on prior

authorization requests, as well as an expedited review process when the regular review timeframe could seriously jeopardize the beneficiary's health, which enables hospitals to receive timely provisional affirmations.

Additionally, we note that our prior authorization policy does not create any new documentation requirements. Instead, it requires hospitals to submit the same documents needed to support claim payments, just earlier in the process. Therefore, HOPDs should not need to divert resources from patient care. We note that prior authorization has the added benefit of giving hospitals some assurance of payment for services for which they received a provisional affirmation. In addition, beneficiaries have information regarding coverage prior to receiving the service and benefit from knowing in advance of receiving the service if they will incur financial liability because the service is non-covered. CMS will continue tracking MAC timeliness metrics and is confident that the MACs will continue to meet the required review and decision timeframes to avoid causing an additional burden for HOPDs or delaying medically necessary services.

Comment: Several commenters expressed concern about expanding the program while the COVID-19 public health emergency (PHE) is ongoing, noting that as hospitals return to full operations, CMS may not have the necessary resources to handle the increased volume of prior authorization requests. We received several comments recommending extending the March 1, 2023 implementation date until at least July 1, 2023, consistent with the timeline CMS has used when implementing prior authorization for other service categories so that providers, CMS, and MACs have more time to prepare for the process.

Response: CMS provides necessary resources to the MACs and maintains a robust oversight process to ensure the accuracy and consistency of their review decisions. We are

confident that MACs have sufficient resources and the clinical expertise necessary to administer the prior authorization process effectively. Also, no new documentation requirements are created as a result of this process. Instead, currently required documents are submitted earlier in the process.

Although we believe CMS and MACs have sufficient resources to manage additional prior authorization requests, we acknowledge the commenters' concerns about the proposed March 1, 2023, implementation date for the new service category. While we explained in the proposed rule that the effective date for the new service category would be March 1, 2023, because MACs, CMS, and HOPDs already have knowledge of and experience with the prior authorization process, we recognize that all participants would benefit from additional time to prepare for the addition of Facet joint interventions service category to the prior authorization processes. Accordingly, we are finalizing an implementation date for prior authorization for the Facet joint interventions service category of July 1, 2023, which is consistent with previous July 1 implementation dates for current service categories.

Comment: Some commenters specifically said that prior authorization of the Facet joint interventions service category could cause delays in appropriate care and lead patients toward alternative pain relief options like opioids. One commenter stated that Facet joint interventions should not be added as a new category because the services in the proposed category are not cosmetic or elective and are used to treat spinal diagnoses that cannot often be addressed with other procedures or address chronic pain that has been refractory to other conservative treatments.

Response: We thank the commenters for their input. We believe the proposal is in alignment with the Department of Health and Human Services (HHS) Pain Management Best

Practices Inter-Agency Task Force Report[326] that encourages Medicare and other payers to provide timely insurance coverage of such procedures. We continue to believe that the 10-day timeframe for obtaining a decision on a prior authorization request is not significant considering that these are non-emergency procedures that require the beneficiary to undergo conservative treatment prior to the procedure. Additionally, providers may request expedited review of a prior authorization request under the regulation at 42 CFR 419.82(c)(2), where the processing of the request must be expedited due to the beneficiary's life, health, or ability to regain maximum function being in jeopardy. We also note that under the regulation at 42 CFR 419.83(c), CMS may elect to exempt a provider from the prior authorization process upon the provider's demonstration of compliance with Medicare coverage, coding, and payment rules.

Commenters are correct that many services in other categories for which we require prior authorization are cosmetic, while services in the Facet joint intervention service category are not. We also acknowledge the benefits that Facet joint intervention services offer for chronic pain. However, we reiterate that these are non-emergency procedures that require the beneficiary to undergo at least 3 months of conservative treatment prior to the procedure. For that reason, these procedures generally are elective.

Comment: Some of the commenters were also concerned the time estimate provided in the proposed rule only considers the time required by the surgeon's clerical staff.

Response: We typically use a clerical staff rate because the documentation being submitted is the same documentation that should be regularly maintained in support of claims submitted for payment. The prior authorization process does not require anything new with regard to documentation. The prior authorization process merely requires the documentation to

[326] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

be provided earlier in the process. With regard to the time burden, we included 3 hours of training in our burden estimate for each provider. During this time, the staff can be educated on the services that require prior authorization under this program and what documentation is needed as part of the prior authorization request. Moreover, we included the 3 hours each year so that new staff can be trained and current staff can have a refresher course. Given that this process does not create any new documentation requirements and merely necessitates the submission of the documentation earlier in the claims process, we believe the amount estimated is appropriate. As we have noted, we have endeavored to minimize the burden associated with this prior authorization process, and this burden is more than outweighed by the need to control unnecessary increases in the volume of these services.

Comment: Some of the commenters stated that the data for the Facet joint interventions service category do not truly represent "an unnecessary increase in the volume" of these services and that there could be many reasons for the increase in their utilization. The commenters also questioned the methodologies we used to calculate the percentage increase in utilization of these services. Additionally, some commenters asked CMS to release the MACs' prior authorization data, such as how many HOPDs have achieved the exemption, the accuracy rate for exempt providers, average processing timeframes for initial and resubmission requests, and whether there are any changes in the volume of utilization for the services that are required prior authorization.

Response: We thank the commenters for their input. We continue to believe that comparing the utilization rate for services in the proposed service category to the baseline growth rate for all Medicare HOPD services is an appropriate method for identifying unnecessary increases in volume. After reviewing all possible causes, including questionable billing practices

discussed in published in OIG reports, we found no evidence suggesting other plausible reasons for the increases. We believe financial motivation, as opposed to medical necessity reasons, is the most likely cause. With regard to the providers' data, the number of exempt providers varies among MAC jurisdictions. Among all MACs, the average volume of exempt OPD providers is 16.7 percent, with one MAC having as many as 35 percent of OPD providers exempt. While we require the MACs to make decisions within 10 days, the average initial review timeframe is 4.4 days, and the average resubmission review timeframe is 4.3 days. CMS will consider sharing data regarding the changes in the volume of utilization of the HOPD services that require prior authorization. We are unclear what the commenter meant by the accuracy rate for exempt providers, but in order to be exempt, all exempt providers must achieve a provisional affirmation rate threshold of at least 90 percent based on their submitted initial prior authorization requests.

Comment: Several comments asked us to clarify the process for removing and suspending services from the prior authorization requirements.

Response: As stated in paragraph (d), CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website. We communicate and collaborate with interested parties, and when notified of a concern with a specific procedure, we research their concerns. Following feedback from providers, in June 2020, we removed CPT code 21235 (obtaining ear cartilage for grafting) from the list of codes that require prior authorization as a condition of payment because it was more commonly associated with procedures unrelated to rhinoplasty that are not likely to be cosmetic in nature. Similarly, after reviewing the claim processing requirements for CPT codes 63685 (insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) and 63688 (revision or removal of implanted spinal neurostimulator pulse

generator or receiver) in response to interested parties' feedback, we temporarily removed them from the list of OPD services that require prior authorization in May 2021. OPD providers are required to submit one prior authorization request either for trial or permanent insertion procedures. CPT codes 63685 and 63688 would only apply to the permanent insertion procedure, and leaving them on the list would cause claim denials if a provider submits a prior authorization request for the trial procedure (CPT 63650) only. In January 2022, after communications with the interested party, we removed CPT 67911 (correction of lid retraction) from the list of codes that require prior authorization because this service commonly occurred secondary to another condition and medical review criteria applicable to the services under blepharoplasty service category do not apply to CPT 67911.

Comment: Some commenters continue to question our policy to require prior authorization for Botulinum toxin injections, implanted neurostimulators, and cervical fusion with disc removal and urge CMS to remove the prior authorization requirement finalized in the CY 2020 and CY 2021 OPPS/ASC final rules with comment for these services.

Response: We thank the commenters for their feedback. Our rationale for subjecting Botulinum toxin injections and implanted neurostimulator and cervical fusion with disc removal to prior authorization that is included in the CY 2020 OPPS/ASC final rule with comment period[327] and CY 2021 OPPS/ASC final rule with comment period[328], respectively, still applies to the continued prior authorization requirement for these service categories. We refer the commenter to those final rules with comment period for further information about why we believe prior authorization is an effective method to control unnecessary volume increases for these service categories.

[327] See 84 FR 61448-61449
[328] See 85 FR 86237-86238

Comment: Some commenters suggested that prior authorization is unnecessary and we should use the existing tools, such as Local Coverage Determinations (LCDs) and Articles, to inform providers when services can be used. The commenters do not believe our proposal accounts for them.

Response: LCDs are contractor determinations about whether a particular item or service is covered on a contractor-wide basis in accordance with the "reasonable and necessary" standard in section 1862(a)(1) of the Act. Articles are contractor publications that provide relevant coding and billing information. The existence of these documents does not, in and of itself, guarantee compliance with Medicare's coverage requirements. Instead, a broad program integrity strategy must use a variety of tools to reduce overpayments and combat fraud, waste, and abuse. Among other methods, we use prior authorization, prepayment, and postpayment reviews to check for compliance with these policies. Thus, we believe that the use of prior authorization in the HOPD setting is and will continue to be an effective tool in controlling unnecessary increases in the volume of covered HOPD services by ensuring that the correct payments are made for medically necessary HOPD services while at the same time being consistent with our overall strategy of protecting the Medicare Trust Fund from improper payments, reducing the number of Medicare appeals, and improving provider compliance with Medicare program requirements.

Comment: Some commenters continue to question whether section 1833(t)(2)(F) of the Act grants CMS the authority to establish a prior authorization process. They contend that CMS should not add a new service category as the commenters believe we have not demonstrated that increases in the volume of services for which we proposed to require prior authorization are

unnecessary and have not shown there are no other necessary reasons for the increases in Facet joint interventions.

Response: As we conveyed in the CY 2020 OPPS/ASC and CY 2021 OPPS/ASC final rules with comment period, section 1833(t)(2)(F) of the Act gives us the discretion to determine the appropriate methods to control unnecessary increases in the volume of covered OPD services. We carefully considered all available options in choosing to propose the prior authorization process, which has already been shown to be an effective tool in Medicare Fee-for-Service, and which we believe will be effective at controlling unnecessary increases for Facet joint interventions. Our extensive data analysis included in this year's proposed rule demonstrates that there have been unnecessary increases for this proposed service category and that we did not identify other legitimate reasons for the sustained increases.

Comment: A commenter expressed difficulty dealing with third-party auditors, such as Recovery Auditors, retrospectively denying payment for procedures that were granted prior authorization. The comment also mentions that these reviews and denials create a substantial administrative and financial burden for hospitals.

Response: We agree that, generally, claims receiving a provisional affirmation decision should not be subject to additional medical reviews, including by Recovery Auditors. However, claims may be reviewed by the Comprehensive Error Rate Testing (CERT) contractor if chosen as part of the random sample to calculate the improper payment rate or by the Unified Program Integrity Contractor (UPIC) if there are concerns of fraud, waste, and abuse. We encourage hospitals to contact us with specific examples of postpayment reviews of claims with a provisional affirmation prior authorization decision, so we can investigate further.

Comment: We received comments with concerns that reimbursement should not be withheld when the service performed is different from the one that was originally submitted for prior authorization.

Response: We recognize that sometimes a procedure's necessity could not be anticipated before it was furnished; however, when a service requiring prior authorization as a condition of payment is billed without an affirmation decision, it will be denied. Providers may submit prior authorization requests for multiple potential procedures if they believe that this could be a possibility. It may be best to submit a prior authorization request with several potential service codes; however, providers should be aware that this may result in a partial affirmation decision if the documentation does not support the need for all of the services requested.

Comment: Some commenters recommended that CMS include further guidance or information on what must be included in the proposed prior authorization request for facet joint injections in the final rule and asked CMS to clarify specific methodologies used to calculate the affirmation rate for non-exempt providers and the approval rate for the exempt providers if the Facet joint interventions are added to the prior authorization list. Another commenter asked for further clarification about whether, if the Facet joint intervention receives provisional affirmation, would associated anesthesia care also automatically receive provisional affirmation.

Response: We thank the commenter for the recommendation. As we noted above, our prior authorization policy does not create any new documentation or administrative requirements. Instead, it just requires the same documents that are currently required to be submitted earlier in the process. Medicare contractors will calculate the compliance rate by dividing the total number of initial requests with provisional affirmations by the total number of initial requests for all eight service categories and notify providers with a compliance rate of 90

percent or greater. To calculate the claim approval rate, contractors will divide the total number of approved claims in sample by the total number of the claims in that sample for all eight service categories for exempt providers and notify providers with approval rate of 90 percent or greater. Detailed information on the process of submitting documents in support of the final claim and specifics regarding the calculation of the affirmation and approval rates can be found in subregulatory guidance such as OPD Operational Guide, which is available on the CMS OPD Prior Authorization and Pre-claim Review Initiatives website.[329] A provider's MAC may request additional, optional elements for submission of the prior authorization request. While the associated claim for anesthesia care would follow standard claim review guidelines and does not require prior authorization, in accordance with § 419.82(b)(2), CMS or its contractor may deny a claim that has received a provisional affirmation based on either of the following: (i) Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or (ii) Information not available at the time of a prior authorization request. Additionally, in accordance with § 419.83(b)(3), CMS or its contractor may deny claims for services related to services on the list of hospital outpatient department services for which the provider has received a denial. The codes for the associated services can be found in the table located in Appendix B (OPD PA Part B Associated Codes List) of the Operational Guide.

Comment: One commenter emphasized the need to ensure that review of prior authorization requests for Facet joint interventions service category is conducted by board-certified pain medicine specialists. Some commenters suggested that CMS should explore

[329] https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives/prior-authorization-certain-hospital-outpatient-department-opd-services.

requiring electronic approvals across all payers, thereby increasing the speed of the prior authorization process and curtailing unnecessary delays in care provision.

Response: In all Medicare Fee-for-Service medical review programs, we require that MACs utilize clinicians, specifically, registered nurses when reviewing medical documentation. We also require the oversight of a Medical Director and additional clinician engagement if necessary. Medical Directors are physicians from different medical specialties, including anesthesiology and pain management. We are confident that MACs have the requisite expertise to review prior authorization requests effectively. We are committed to incorporating automation into our prior authorization processes and recognize the value of automation in shortening the receipt of prior authorization requests and our response time. We recognize that not all providers have the same level of technology and allow various methods of submission of a prior authorization request. With regard to the hospital OPD prior authorization process, the majority of providers so far continue to submit requests and medical information to the MACs via facsimile. Other providers submit the requests through the United States (U.S.) postal service. We also support a variety of electronic mechanisms used by providers in submitting prior authorization requests, including individual MAC portals and CMS's electronic submission of medical documentation (esMD) system. We continue to monitor other federal and industry initiatives in order to improve the efficiency of our prior authorization processes, increase provider willingness to submit requests electronically, reduce provider burden, decrease delays in patient care, and promote high-quality, affordable health care.

In sum, we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments without adding

onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste, and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary.

After consideration of the public comments we received, we are finalizing our proposal to add the Facet joint interventions service category to the list of hospital outpatient department services requiring prior authorization with modification. In particular, we are finalizing an implementation date for prior authorization for the Facet joint interventions service category of July 1, 2023, rather than the March 1, 2023 implementation date we proposed and making this change in the proposed regulation text at § 419.83(a)(3). Other than this change in the implementation date, we are finalizing the proposed regulation text changes as proposed.

TABLE 103: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair[330]
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach

[330] CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(ii) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(iv) Rhinoplasty, and related services[331]
20912	Cartilage graft; nasal septum
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)

[331] CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020

30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(v) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators [332]
63650	Percutaneous implantation of neurostimulator electrode array, epidural

[332] CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule with comment period.

Beginning for service dates on or after July 1, 2023	
Code	Facet Joint Interventions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

XXI. Overall Hospital Quality Star Rating

A. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars (85 FR 86193). The Overall Hospital Quality Star Rating was first

introduced and reported on our Hospital Compare website in July 2016[333] (now reported on its successor website at https://www.medicare.gov/care-compare and referred to as Care Compare) and has been refreshed multiple times, with the most current refresh planned for 2022. [334, 335, 336, 337, 338, 339, 340]In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating. We refer readers to section XVI (Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years) of the CY 2021 OPPS/ASC final rule with comment period and 42 CFR 412.190 for details.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44807-44809), we: (1) provided information on the previously finalized policy for inclusion of quality measure data from Veterans Health Administration (VHA) hospitals; (2) proposed to amend the language of § 412.190(c) to state that we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior twelve months; and (3) conveyed that

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[333] Centers for Medicare & Medicaid Services. (2016, July 27). First Release of the Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from CMS.gov newsroom at: https:\\www.cms.gov\\newsroom\\fact-sheets\\first-release-overall-hospital-quality-star-rating-hospital-compare.

[334] Centers for Medicare & Medicaid Services. (2016, May). Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.

[335] Centers for Medicare & Medicaid Services. (2016, October). Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.

[336] Centers for Medicare & Medicaid Services. (2017, October). Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.

[337] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.

[338] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2 .

[339] Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.

[340] Centers for Medicare & Medicaid Services. (2022, May 17). Overall Hospital Quality Star Rating on Hospital Compare: July 2022 Updates and Specifications Report. Retrieved from qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.

although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy if applicable.

B. Veterans Health Administration Hospitals

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86197 and 86198), we finalized a policy to include Veterans Health Administration hospitals' (VHA hospitals) quality measure data for the purpose of calculating the Overall Hospital Quality Star Ratings beginning with the 2023 refresh. In that final rule, we also stated that we intended to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule (85 FR 48999). Since the publication of the CY 2021 OPPS/ASC final rule, we conducted an internal analysis from February 28, 2022, through March 30, 2022, with measure data from all VHA hospitals in the calculation of the Overall Hospital Quality Star Ratings methodology. The internal analysis included a period of confidential reporting and feedback during which VHA hospitals reviewed their Overall Hospital Quality Star Ratings internal analysis results, and in addition, further familiarized themselves with the Overall Hospital Quality Star Ratings methodology and had the opportunity to ask questions. All VHA hospitals were made aware of the internal analysis and were provided the opportunity to participate. For the internal analysis, the Overall Hospital Quality Star Ratings were calculated using VHA hospital measure data along with subsection (d) hospitals and CAHs. The internal analysis included the same measures used for the April 2021 refresh of Overall Hospital Quality Star Ratings on our public reporting website, Care Compare. At the time of the 2022 VHA internal analysis, VHA hospitals in each peer group reported a similar number of measures when compared to non-VHA hospitals for most measure groups. VHA hospitals in the five-measure group peer group reported a lower median number of Safety and Readmission

measures. VHA hospitals in all three peer groups reported fewer measures in the Timely and Effective Care measure group. The measurement periods for VHA and non-VHA hospitals were the same, except for the HAI-1, HAI-2, PSI 04, PSI 90, and OP-22 measures. The specific performance periods for these measures were provided to VHA hospitals during the internal analysis. The reasons for the differing measure reporting periods are:

- The HAI-1 and HAI-2 measures were first publicly reported for VHA hospitals in July 2021, but only included one quarter of measure data. Therefore, we chose to use the next public reporting, April 2022, which included four quarters of these measures' data.
- For the PSI 04 and PSI 90 measures, we used measure data that were publicly reported in July 2021. VHA hospitals first publicly reported these measures in October 2020; however, a different software was used for the measure calculations than the software used to calculate subsection (d) hospitals and CAHs measure data. We chose to use measure data publicly reported in 2021 for better comparison.
- For the OP-22 measure, VHA hospitals began submitting their measure data in January 2021 for public reporting.
- For the HIP/KNEE measures (total hip arthroplasty (THA) and total knee arthroplasty (TKA)), we used measure data that were publicly reported in October 2020. These data did not initially include VHA hospitals, so we recalculated to include them. The recalculated results including VHA hospitals was not publicly reported until July 2021.

Using these data from the internal analysis, we compared 2021 Overall Hospital Quality Star Ratings scores for non-VHA hospitals before and after adding VHA hospitals to Overall Hospital Quality Star Ratings. 119 out of 171 VHA hospitals met the requirements to receive a Star Rating. This increased the number of hospitals receiving a star rating from 3,355 to 3,474.

The distribution of Star Ratings was nearly identical for VHA and non-VHA hospitals. As part of the Overall Hospital Quality Star Ratings methodology, hospitals are assigned to peer groups based on the number of measure groups with at least three measures. Peer group assignments were similar across VHA and non-VHA hospitals. In Peer Group 3, assignments were 12 percent VHA vs. 10 percent non-VHA; in Peer Group 4, assignments were 25 percent VHA vs. 16 percent non-VHA; and in Peer Group 5, assignments were 63 percent VHA vs. 74 percent non-VHA). 3,119 (93 percent) non-VHA hospitals maintained the same number of stars after adding VHA hospitals to 2021 Overall Hospital Quality Star Ratings. For the 236 non-VHA hospitals with a different star rating, 23 gained a star and 213 lost a star. No hospital gained or lost more than one star. As with any update to either the underlying measures or the Overall Hospital Quality Star Ratings methodology, we expect that some hospitals would shift star rating categories. However, for this internal analysis, over 90 percent of non-VHA hospitals did not experience a change in their Overall Hospital Quality Star Ratings score, which is consistent with prior changes to the measures or methodology in our experience. As previously finalized, we intend to include VHA hospitals in future Overall Hospital Quality Star Ratings.

While we did not make any proposals for VA hospital data in the proposed rule, we received some comments, which we are summarizing below.

Comment: A few commenters provided support to include Veterans Health Administration (VHA) hospitals in Overall Star Ratings and one commenter expressed support for providing VHA hospitals with increased access to quality measurement data that they can use to compare to non-VHA hospitals.

Response: We thank commenters for their support of including VHA Hospitals in Overall Star Ratings.

Comment: Some commenters expressed opposition to including VHA hospitals in Overall Star Ratings. A few commenters noted concern about how VHA hospitals and non-VHA hospitals can be meaningfully compared due to a distinct case mix and the differing services that are provided to patients at VHA and non-VHA hospitals. Another commenter noted that the fewer number of measures reported by VHA hospitals, particularly in the Safety and Readmission measure groups, prevents comparability among these measures between VHA and non-VHA hospitals. A commenter stated that including VHA hospitals in Overall Star Ratings may cause confusion for VHA patients who are also Medicare beneficiaries and that including VHA hospitals in Overall Star Ratings may not be the best method of providing VHA quality data. Another commenter expressed concern about how peer grouping was affected when VHA hospitals were added to Overall Star Ratings and suggested phasing the VHA hospitals into Overall Star Ratings over many years to attain increased measure reporting and a less sizeable peer group shift. The commenter also noted that creating cohorts of like facilities is important for Overall Star Ratings and the commenter is concerned about how the integration of VHA hospitals affects the overall goal of peer grouping. Similarly, a commenter suggested another alternative approach to including VHA hospital quality data in Overall Star Ratings by recommending that Critical Access Hospitals and VHA hospitals are assigned to their own peer groups specifically for their hospital types. A few other commenters suggested similar approaches where VHA hospitals would be situated in their own cohort as a result of categorizing hospitals through other types of peer grouping.

Response: We acknowledge commenters' concerns, but we believe it is important for veterans to have information about hospital quality for non-VHA hospitals in addition to VHA hospitals to inform their care decisions. Medicare beneficiaries who are also veterans may

choose to seek care outside the VHA system. When we initially considered options for peer grouping in the CY 2021 OPPS/ASC proposed rule (85 FR 49024), we discussed the potential to peer group by hospital characteristics, recognizing that some types of hospitals offer different sets of services. After extensive outreach with our Provider Leadership and Patient & Advocate Workgroups, as well as our Technical Expert Panel, we determined that the best approach to peer grouping was to use measure group count as measure group reporting was closely correlated with hospital type (85 FR 86229). We maintain that VA hospitals should be compared to other hospitals that report similar numbers of measures and we recognize that hospitals may still differ within each peer group regarding the types of services they offer. Additionally, VHA hospital data are already included in individual measure calculations and publicly reported on Care Compare for 15 measures.

While the results of the VHA hospital Star Rating internal analyses demonstrated that VHA hospitals report fewer measures on average, 63 percent of VHA hospitals still reported at least three measures in all five measure groups, which landed them in the five-measure group peer group (87 FR 44808). Many hospitals that report fewer measures than VHA hospitals are included in Overall Star Ratings, and we believe it is important for the public to have access to Overall Star Ratings for as many hospitals as possible, while still adhering to the Overall Star Ratings guiding principles to:

- Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;
- Align with Care Compare or its successor website and CMS programs;
- Provide transparency of the methods for calculating the Overall Star Rating; and
- Be responsive to stakeholder input.

We also disagree that including Overall Star Ratings scores for VHA hospitals will cause confusion among VHA patients who are also Medicare beneficiaries. Publishing Overall Star Ratings for VHA hospitals will allow dual VHA/Medicare beneficiaries to have more complete information about the quality of care for hospitals in their area and empower them to make health care decisions, in part, based on performance on the underlying Overall Star Ratings measures. In our internal analysis, 3,119 (93 percent) of non-VHA hospitals maintained the same number of stars after adding VHA hospitals to the 2021 Overall Star Ratings (87 FR 44808). As with any update to either the underlying measures or the Overall Hospital Quality Star Ratings methodology, we expect that some hospitals will shift Star Ratings with the addition of peer group members. The small shift in the Overall Star Ratings scores observed with the addition of VHA hospitals is consistent with prior changes to the measures or methodology in our experience. Instead of grouping VHA hospitals separately, incorporating them into Overall Star Ratings allows VHA hospitals to be compared to other hospitals with similar measure group reporting rates.

Comment: One commenter appreciated the VHA impact analysis provided in the CY 2023 OPPS/ASC proposed rule while a few commenters recommended that more detailed information about the VHA impact analysis is shared with stakeholders, specifically focused on how non-VA hospitals will be affected with the inclusion of VHA hospitals.

Response: We thank the commenters for their support of the VHA impact analyses. As part of regular Overall Star Ratings work, we routinely conduct analyses to ensure the continued reliability and validity of Overall Star Ratings. Part of this work will include close monitoring of differences in VHA and non-VHA reporting rates and scores for the 2023 Overall Star Ratings

and beyond. If for some reason results would require updates to Overall Star Ratings, we would address this topic through future rulemaking.

Comment: A few commenters provided alternatives to including VHA hospitals in Overall Star Ratings. A few commenters suggested the implementation of a filter on Care Compare where users would choose to include VHA hospitals in the Overall Star Ratings data. Another commenter proposed a similar alternative where VHA hospitals would not receive an Overall Star Rating, but VHA hospitals would still be included in the measure data in order to have access to comparisons between VHA hospitals and non-VHA hospitals.

Response: We thank the commenters for their suggestion and recognize the appeal of being able to tailor Overall Star Ratings to certain types of patients or hospitals. We acknowledge that some individuals or organizations may wish to compare Overall Star Ratings to a very specific group of hospitals, like the VHA, as opposed to all hospitals. However, filtering by VHA versus non-VHA hospitals would pose several implementation and communications challenges that prevent us from incorporating this suggestion. The Overall Star Ratings methodology utilizes a clustering algorithm to assign Overall Star Ratings based on a hospital's performance compared to all other hospitals included in Overall Star Ratings. When a specific group or type of hospital is removed from Overall Star Ratings, the hospitals to which the clustering algorithm is applied to changes and in turn hospitals are compared to different hospitals and some may receive a different Overall Star Rating. As such, adding a filter for VHA hospitals would lead to hospitals having three different Overall Star Ratings scores:(1) Overall Star Ratings for non-VHA hospitals and VHA hospitals when both are included; (2) Overall Star Ratings for non-VHA hospitals only; and (3) Overall Star Ratings for VHA hospitals only. Therefore, the same hospital may appear as 4-star, 3-star, or 5-star depending on

which comparison group is selected. We believe that this would be confusing to consumers and hospitals. Moreover, it would also necessitate sending hospitals three different hospital specific reports that may confuse local quality improvement efforts. Lastly, adopting this suggestion may lead to additional requests to filter by other types of hospitals, resulting in an even greater numbers of Star Ratings scores depending on which filter was applied.

Comment: A commenter suggested that the VHA could potentially implement its own Overall Star Ratings program but acknowledged that this alternative likely falls outside of the scope of CMS's Overall Star Ratings Program.

Response: The VHA previously used its own rating system, however, it was discontinued in 2020 as part of a broader effort to support veteran's health access and choice beyond VHA hospitals alone. Approximately 50 percent of veterans enrolled in the VHA healthcare system are eligible for Medicare. The goal of this collaboration between us and the VHA healthcare system is to present the VHA's quality and safety data to veterans, their families, and the public in a useful and understandable format. Section 206(c) of The Veteran's Access, Choice, and Accountability Act of 2014 requires the Secretary of VA to enter into an agreement with the Secretary of HHS to report and make publicly available patient quality and outcome information concerning the VA medical centers.

While we did not make any proposals for VHA hospital data in the proposed rule, we appreciate related stakeholder feedback that we received.

C. Frequency of Publication and Data Used

In the CY 2023 OPPS/ASC proposed rule (87 FR 44807), we proposed to amend our policy regarding the data periods used to refresh Overall Hospital Quality Star Ratings. In the CY 2021 OPPS final rule with comment period, we stated that "we would use publicly

available measure results on Hospital Compare or its successor websites from a quarter within the prior year" to refresh Overall Hospital Quality Star Ratings (85 FR 86202). As discussed in the CY 2023 OPP/ASC proposed rule, since adopting that policy, it has come to our attention that this wording could be confusing. We intended for the phrase "within the prior year" to refer to any time within the prior 12 months, and not to a Care Compare refresh from the prior calendar year. Therefore, we proposed to change § 412.190(c) to state "The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months." For example, for the Overall Hospital Quality Star Ratings in July 2023, we would use any Care Compare refreshes from the previous 12 months: July 2023, April 2023, January 2023, October 2022, or July 2022.

We invited public comments on this proposal.

Comment: A few commenters supported the clarification of data period refreshes in the CY 2023 OPPS/ASC proposed rule. Several commenters expressed that the clarifications of the potential measurement reporting periods for use in Overall Star Ratings would allow for more consistent and timely Overall Star Ratings releases. A few commenters added that Overall Star Ratings being released different months each calendar year was not ideal, and that consistent annual or biannual Overall Star Ratings releases should be considered. Another commenter noted that the unpredictability of Overall Star Rating releases cause difficulty in projecting trends and suggested that CMS release Overall Star Ratings more consistently, specifically the same month each year.

Response: We thank the commenters for their support of our proposal. We would like to reiterate that we are not finalizing a change in the Care Compare refreshes available to use for any given Overall Star Ratings release. Rather, we are specifying the specific Care Compare data

that would be available and used for any given Overall Star Ratings release. We intend to release Overall Star Ratings at the same time every year but need to be able to accommodate unforeseen circumstances.

Comment: A commenter emphasized the importance of informing the public in a timely manner which dataset will be used for a given Overall Star Ratings release in order for providers to optimize their use of the program. A commenter also thought that the ability for Overall Star Ratings releases to utilize the data period simultaneously refreshed that same exact month as outlined in the proposed rule (for example, a July 2023 Overall Star Ratings release can use July 2023 data) does not allow enough advanced notice for providers to first digest the underlying measure results; an intention that was expressed in the CY 2021 OPPS/ASC final rule with comment period. A few commenters recommended that further clarification is provided regarding which data are used for Overall Star Ratings releases. More specifically, a few commenters also stated that the wording of "previous 12 months" causes confusion because 1 of 5 individual quarterly refreshes could be used for any given Overall Star Ratings release and 4 quarters is traditionally thought of as one full year.

Response: We appreciate these comments and recognize the importance of providing hospitals and the public with as much notice as possible regarding an upcoming Star Ratings release. We would also like to note that while the regulation allows us to use data from the same month the Star Ratings are released, in practice there is usually at least a 6-month delay between the Care Compare data and when Star Ratings are released. This gap between individual measure refreshes and Overall Star Ratings is intentional and is based upon prior public comment in which stakeholders acknowledged the lack of alignment but noted the benefit of allowing for any Care Compare corrections as well as hospital preparation prior to Overall Star

Ratings releases (85 FR 86203). We agree with commenters that the prior language did not make it clear which specific Care Compare refreshes could be used for any Star Ratings release. We would like to acknowledge that the CY 2023 OPPS/ASC proposed rule incorrectly referenced the January 2022 refresh in the example of data that could be used for July 2023 Overall Hospital Quality Star Ratings, when it should have referenced the January 2023 refresh. We believe this contributed to some of the confusion mentioned. We are confirming our interpretation of "previous 12 months" to include Care Compare refreshes that occur in either the first or last month of that 12-month period, and any time in between. For example, for a 2023 Overall Star Ratings release there are five data refreshes that can be used: July 2022, October 2022, January 2023, April 2023, and July 2023.

Comment: A commenter expressed that the use of older data (up to a year old) in calculating Overall Star Ratings has the potential to limit its value to hospitals in addition to possibly leading to misunderstandings among patients. Similarly, another commenter stated their belief that the lag between data collection and public availability prevents patients from making timely decisions related to choosing a facility.

Response: We understand the need for data that are as up to date as possible when reporting on quality of care. However, Overall Star Ratings must balance this goal with the fact that Overall Star Ratings include measures with various measurement periods and refresh cycles. Moreover, there are times where we are required to use less recent Care Compare data due to situations where measure scores or programs are compromised due to unforeseen circumstances like the COVID-19 PHE. Historically, Overall Star Ratings were published simultaneously with Care Compare refreshes, however, since the institution of a lag between Care Compare refreshes and Overall Star Ratings releases, such challenges have been fewer or absent.

After consideration of the public comments we received, we are finalizing the proposal as proposed and thank the commenters for their input.

D. Overall Hospital Quality Star Ratings Suppression

During development of the Overall Hospital Quality Star Ratings, we established guiding principles to use methods that are scientifically valid, inclusive of hospitals and measure information, account for the heterogeneity of available measures and hospital reporting, and accommodate changes in the underlying measures (85 FR 86193).[341] Overall Hospital Quality Star Ratings aggregates performance on underlying measures adopted under certain CMS quality programs, so any changes or updates to the measures from those programs are already included (85 FR 86194).[342] We continue to believe that the robustness of Overall Hospital Quality Star Ratings to changes in the underlying measures enables the methodology to maintain validity even when there are changes in the health system or underlying measure data (85 FR 86203 through 86205).

We discussed in the CY 2023 OPPS/ASC proposed rule (87 FR 44807) that we recognize there may be some concerns with publishing Overall Hospital Quality Star Ratings if the underlying measures reflect some aspect of extenuating circumstances, for example, skewed data or performance related to treating patients with COVID-19. However, we want to balance that with providing important quality information to Medicare beneficiaries and the public during times when hospital care is critical. The goal of the Overall Hospital Quality Star Ratings is to summarize hospital quality information in a way that is simple and easy for patients to

[341] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.

[342] Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.

understand to increase transparency and empower patients to make more informed decisions about their healthcare.

Although Overall Hospital Quality Star Ratings will have been refreshed twice (that is, in 2021 and 2022) since the emergence of COVID-19, almost all measures included in both Overall Hospital Quality Star Ratings refreshes used pre-COVID-19 data to calculate both the 2021 and 2022 Overall Star Ratings. This is because we issued a nationwide Extraordinary Circumstance Exception (ECE) for hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 Public Health Emergency (PHE). The ECE can be found at this website: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf. Among other requirements, this ECE exempted data reporting requirements for Q1 and Q2 2020 data, including excluding the use of claims data and data collected through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for this data period.[343] Because the ECE only applied through Q2 2020, beginning July 1, 2020, any subsequent measure data collected from these programs would be incorporated into the Overall Hospital Quality Star Ratings. This would include measurement periods that are either partially or fully concurrent with the COVID-19 PHE.

If a measure is considered valid and reliable enough to be reported on Care Compare then it meets the criteria to be included in Overall Hospital Quality Star Ratings calculations (85 FR 86193 through 86236). This remains true even for measures that were suppressed in

[343] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf

certain pay-for-performance programs due to the impact of COVID-19 (86 FR 45301 through 45304). Consistent with this policy, we will continue to include measures in the Overall Hospital Quality Star Ratings that might have been suppressed in the Hospital Value-Based Purchasing, Hospital-Acquired Condition Reduction, and Hospital Readmissions Reduction Programs but are still publicly reported (86 FR 44778 through 44779).

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 48996 through 49027), we finalized that we will allow for suppression, but only in limited circumstances. Specifically, for the Overall Hospital Quality Star Rating beginning with the CY 2021 and for subsequent years, we adopted a policy that we would consider suppressing the Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when--

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Hospital Star Rating calculation. For example, there is a CMS quality program level error for one or more measures included within the Overall Star Rating due to incorrect data processing or measure calculations that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or
- A Public Health Emergency substantially affects the underlying measure data.

This is codified at § 412.190(f)(1). Although we intend to publish the Overall Hospital Quality Star Rating in 2023, we may exercise the authority described above should the COVID-19 PHE substantially affect the underlying measure data.

While we did not make any proposals in this section, we are summarizing comments received below.

Comment: A few commenters noted appreciation for CMS's clarification of the potential circumstances that could warrant suppression of Overall Star Ratings, particularly in the case of a PHE that "substantially affects the underlying measure data" (87 FR 44809). A commenter further expressed their support for CMS's acknowledgement that programs should not be negatively affected by factors unrelated to quality of care provided.

Response: We thank commenters for their support regarding the potential suppression of 2023 Overall Star Ratings in the case of a PHE that "substantially affects the underlying measure data" (87 FR 44809).

Comment: A few commenters expressed approval of the language to enable CMS to suppress the Overall Star Ratings when appropriate. Another commenter voiced support of Overall Star Ratings suppression if the impact of COVID-19 significantly affects quality measurement. Multiple commenters requested continued transparency in any future impacts to Overall Star Ratings and one commenter sought further clarification on circumstances where suppression of Overall Star Ratings would be appropriate.

Response: We thank the commenters for their input on the potential suppression of 2023 Overall Star Ratings. We will continue to evaluate the impacts of COVID-19 and the PHE on 2023 Overall Star Ratings and maintain transparency regarding the results. If future data continue to be significantly affected by COVID-19 and the PHE, we will consider exercising the suppression policy to suppress 2023 Overall Star Ratings. We will continue to assess changes in our methodology to improve its robustness and in the future continue to communicate when suppression of Overall Star Ratings may be necessary.

Comment: A commenter expressed the importance of analyzing measures and policies in Medicare that are tied to payment and publicly reported programs given the impact of the COVID-19 pandemic on measures in terms of data suppression and measure reliability.

Response: We agree with the commenter on the importance of continuing to analyze the data, and we continue to assess the impact of the COVID-19 pandemic on quality measures that are tied to payment and publicly reported programs. Different policies have long had impact on healthcare delivery and could impact individual measure score data or calculations. We conduct regular reevaluation of measures as well as ongoing stakeholder engagement for individual measures to support reporting. While Overall Star Ratings are calculated using measure scores publicly reported on Care Compare, Overall Star Ratings does not separately modify measures to further adjust for patient or hospital-level factors. We will continue to conduct analyses examining the reliability and validity of 2023 Overall Star Ratings and we reserve the right to suppress them.

Comment: Several commenters emphasized the importance of CMS transparency related to impacts of COVID-19 on Overall Star Ratings if Overall Star Ratings are released in 2023. More specifically, a few commenters suggested that alongside 2023 Overall Star Ratings, data be provided that demonstrates exact COVID-19 impacts to the Ratings, such as the number of hospitals that no longer meet the minimum threshold to receive an Overall Star Rating, or the number of hospitals that have reduced measurement periods available due to COVID-19 impact, emphasizing reliability concerns. The commenters also suggested that if that Overall Star Ratings are published in 2023, it would be important to gather feedback from beneficiaries about their interpretation of the impact of COVID-19 on Overall Star Ratings to better understand the patient perspective in this context. A commenter expressed concern about how CMS will

determine whether underlying measure data are "substantially affected" to warrant suppression of Overall Star Ratings. The commenter suggested that an analysis to show this effect on Overall Star Ratings is communicated through stakeholder engagement efforts. The commenter emphasized that beneficiaries are still interested in accessing hospital performance data provided through the Overall Star Ratings program during the COIVD-19 pandemic.

Response: We did not propose to publicly post detailed analyses on the COVID-19 impact on Care Compare and are not planning to do so. Should we discover that the impact of COVID-19 on the underlying measures meets the suppression criteria, then we will suppress 2023 Overall Star Ratings.

Comment: Multiple commenters conveyed the importance of reviewing the suppression policy and understanding the effects of the COVID-19 PHE on data prior to making a final decision on 2023 Overall Star Ratings. One commenter opposed suppression of 2023 Overall Star Ratings, suggesting instead that the methodology mature to withstand adverse events, such as public health emergencies. A few commenters disagreed with the approach to include quality measures in Overall Star Ratings that are suppressed for payment programs but still reported on Care Compare. One of the commenters believed that the misalignment of quality measures reported for payment programs and Care Compare will cause confusion and warrants suppression of the 2023 Overall Star Ratings.

Response: We understand that there may be confusion regarding the decision to include quality measures that are reported on Care Compare but suppressed in payment programs. However, as stated in the CY 2021 OPPS Final Rule (85 FR 86195), the goal of Overall Star Ratings is to include measures that "are publicly reported on Hospital Compare or its successor websites." Overall Star Ratings are meant to be a consumer-friendly tool that

summarizes measure scores reported on Care Compare, and as such do not take into consideration the status of these measures in payment programs. Since the inception of Overall Star Ratings, many measures not included in payment programs, such as the Hospital Value-Based Purchasing or Hospital Readmissions Reduction Programs, have been publicly reported as part of the Hospital Inpatient Quality Reporting or Outpatient Quality Reporting Programs on Care Compare, and have been included in Overall Star Ratings based on Technical Expert input and Work Group input. The primary goal of the Overall Star Rating is to "use an established, evidence-based statistical approach to summarize hospital quality measure results reported on Care Compare" (85 FR 86194). Thus, measures that are reported on Care Compare will continue to be included in Overall Star Ratings, even if they have been suppressed in payment programs.

While we did not make any proposals for the suppression of Overall Star Ratings in the proposed rule, we appreciate related stakeholder feedback that we received.

XXIII. Finalization of Certain COVID-19 Interim Final Rules With Comment Period Provisions

A. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC)

In this final rule with comment, we are responding to public comments and stating our final policies for certain provisions in the IFC titled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-1744-IFC), which appeared in the April 6, 2020 **Federal Register** ((85 FR 19230); hereinafter referred to as the April 6, 2020 IFC)..

1. Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency (PHE) for the COVID-19 Pandemic

For purposes of Medicare payment, section 1861(b) of the Act defines inpatient hospital services in part as the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital: (1) bed and board; (2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and (3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements.

Routine services in the hospital setting are those described in sections 1861(b)(1) and (b)(2) of the Act, under the definition of "inpatient hospital services." Under our historical policy for hospital services furnished under arrangements that we adopted in the FY 2012 IPPS/LTCH PPS rulemaking (76 FR 51714), routine services cannot be provided under arrangement outside the hospital. Only the therapeutic and diagnostic services described in section 1861(b)(3) of the Act can be provided under arrangement outside the hospital.

In the April 6, 2020 IFC (85 FR 19278), we provided an overview of the FY 2012 IPPS/LTCH PPS rulemaking, which set forth the rationale and statutory basis for our under arrangements policy. In particular, we stated in the FY 2012 rulemaking that we believe this policy is consistent with the statute because the statutory language specifying that the routine services described in sections 1861(b)(1) and (b)(2) of the Act be provided "by the hospital" suggests that the hospital is required to exercise professional responsibility over the services, including quality controls. In situations in which certain routine services are provided through arrangement "in the hospital," for example, contracted nursing services, we stated that we believe the arrangement generally results in the hospital exercising the same level of control over

those services as the hospital does in situations in which the services are provided by the hospital's salaried employees.

Therefore, if routine services are provided in the hospital to its inpatients, we consider the service as being provided by the hospital. However, if these services are provided to its patients outside the hospital, the services are considered as being provided under arrangement, and not by the hospital. Therefore, consistent with the statute, we stated that only therapeutic and diagnostic services can be provided under arrangement outside the hospital.

Furthermore, we noted that, at the time of the FY 2012 rulemaking, we were aware that some hospitals were furnishing certain routine services, including ICU services, under arrangement, which we believed might result in inappropriate and potentially excessive Medicare payments for such services in certain circumstances. We explained that limiting the furnishing of routine services under arrangements to situations in which the services are furnished in the hospital would reduce the opportunity for gaming and ensure that the hospital exercises sufficient control over the use of hospital resources when furnishing these services.

For additional details on our prior rulemaking, refer to the discussion in section II.CC.2 of the April 6, 2020 IFC (85 FR 19278) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711).

As we noted in the April 6, 2020 IFC (85 FR 19279), while we continue to believe that our historical policy is consistent with the statute and appropriate for the reasons discussed in the FY 2012 IPPS/LTCH PPS rulemaking, we wished to give hospitals that provide services to Medicare beneficiaries additional flexibilities to respond effectively to the serious public health threats posed by the spread of COVID-19. Recognizing the urgency of this situation, and understanding that some pre-existing Medicare payment rules might inhibit use of capacity that

might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we changed our "under arrangements" policy during the PHE for the COVID-19 pandemic beginning March 1, 2020, so that hospitals could be allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital's campus or premises.

We believe that our concerns articulated in the FY 2012 rulemaking regarding gaming of routine services provided outside the hospital for payment reasons are significantly mitigated by the existence of the PHE. As we explained in the April 6, 2020 IFC, we expected that during the PHE for the COVID-19 pandemic, hospitals would be treating patients in locations outside the hospital for a variety of reasons, including limited beds and/or limited specialized equipment such as ventilators, and for a limited time period, and that during this time hospitals would not be treating patients outside the hospital for gaming reasons.

Moreover, we stated that we did not believe that the statute would preclude this temporary change in policy to allow routine services to be provided under arrangements outside the hospital, in light of the compelling circumstances and the need for additional, short-term flexibility during the current PHE for the COVID-19 pandemic. Consistent with this, we noted that we received comments during the FY 2012 rulemaking stating that our policy to limit the services a hospital may provide under arrangements is not required by the statute and that CMS' reading of the statutory definition of "inpatient hospital services" is only one possible interpretation of the statute.

While we changed our under arrangements policy during the PHE for the COVID-19 pandemic to allow hospitals broader flexibilities in furnishing inpatient services, we emphasized in the April 6, 2020 IFC that we were not changing our policy that a hospital needs to exercise

sufficient control and responsibility over the use of hospital resources in treating patients, as discussed in the FY 2012 IPPS/LTCH PPS final rule and Section 10.3 of Chapter 5 of the Medicare General Information, Eligibility, and Entitlement Manual (Pub. 100-01). Nothing in the current PHE for the COVID-19 pandemic has changed our policy or thinking with respect to this issue and we made no modifications to this aspect of the policy. We emphasized that hospitals need to continue to exercise sufficient control and responsibility over the use of hospital resources in treating patients regardless of whether that treatment occurs in the hospital or outside the hospital under arrangements. If a hospital cannot exercise sufficient control and responsibility over the use of hospital resources under arrangements, the hospital should not provide those services outside the hospital under arrangements.

Comment: Commenters expressed support for the modification to our policy concerning routine services provided under arrangements outside the hospital during the COVID-19 PHE. Several commenters noted that these flexibilities would promote patient access to safe alternative care settings while minimizing risk of exposure to COVID-19.

Response: We appreciate the commenters' support for our policy.

Comment: A number of commenters recommended that CMS extend the modification to our under arrangements policy for a reasonable period after the termination of the PHE, for example one year, stating that this would give hospitals time to revert to normal operations while being prepared to respond to a potential subsequent wave of the virus. A few commenters requested that CMS adopt the modification permanently.

Response: As we noted in the April 6, 2020 IFC (85 FR 19278), we adopted this modification to our under arrangements policy in recognition of the urgent and compelling circumstances associated with the COVID-19 PHE and the understanding that some pre-existing

Medicare payment rules might inhibit use of capacity that might otherwise be effective in the efforts to mitigate the impact of the pandemic. We continue to believe that outside of the context of the COVID-19 PHE, our policy prohibiting routine services from being provided under arrangements outside the hospital is consistent with the statute and appropriate for the reasons discussed in the FY 2012 IPPS/LTCH PPS rulemaking. With respect to the recommendation that we maintain these flexibilities for a limited period of time after the termination of the COVID-19 public health emergency, we note that CMS has regularly updated the provider community on the status of the various COVID-19-related flexibilities and reiterated that these flexibilities will expire once the PHE ends. We also believe that, in the absence of widespread capacity issues such as those experienced earlier during the pandemic, the majority of hospitals are experiencing more typical patterns of inpatient care. Thus, we believe that providers will have had time to prepare for a return to normal operations and to wind down those flexibilities that are no longer critical in nature, and that an extension of the modifications to our policy beyond the end of the PHE is unnecessary. In the event that circumstances in a future PHE warrant additional flexibilities, we will address this issue in future rulemaking. For these reasons, we are not adopting the commenters' suggestions that we make this modification permanent or extend the modification past the end of the COVID-19 PHE.

After consideration of the comments received, and for the reasons discussed, we are finalizing without modification our policy that, effective for services provided for discharges for patients admitted to the hospital during the PHE for COVID-19 beginning March 1, 2020 until the end of the PHE, if routine services are provided under arrangements outside the hospital to its inpatients, these services are considered as being provided by the hospital. We are not changing our policy that a hospital needs to exercise sufficient control and responsibility over the use of

hospital resources in treating patients regardless of whether that treatment occurs in the hospital or outside the hospital under arrangements. When the COVID-19 PHE ends, and consistent with the policy adopted in the FY 2012 IPPS/LTCH PPS rulemaking, for purposes of Medicare payment, only the therapeutic and diagnostic items and services described in section 1861(b)(3) of the Act may be furnished under arrangements outside the hospital. If routine services are provided in the hospital to its inpatients, these services will be considered as being provided by the hospital. However, if these services are provided to patients outside the hospital, the services will be considered as being provided under arrangement, and not by the hospital.

2. Counting Resident Time During the PHE for the COVID-19 Pandemic

In the April 6, 2020-IFC (85 FR 19269), we included provisions revising 42 CFR. §§ 415.172, 415.174, 415.180, 415.184 and 415.208 for the duration of the PHE that allowed a hospital to claim a resident for indirect medical education (IME) or direct graduate medical education (DGME) if the resident is performing patient care activities within the scope of his or her approved program via telecommunications, in his or her own home, or in a patient's home. This allowed medical residents to perform their duties in alternate locations, including their own home or a patient's home, as long as the activities meet appropriate physician supervision requirements, which could also be met via telecommunications participation.

In this section of this final rule, we are responding to the public comments that we received on these provisions in the April 6, 2020 IFC and finalizing the interim policies.

Comment: We received overwhelming support for the provisions allowing teaching hospitals to claim DGME and IME for the time a resident performs patient care activities within the scope of their approved program in their own home, or in an established patient's home for the duration of the PHE. A few commenters requested making this change permanent.

Response: We appreciate the commenters' support of this policy during the COVID-19 PHE. Outside of the context of the COVID-19 PHE, performing patient care activities in a patient's home, or in a resident's home for the purpose of a hospital claiming IME or DGME payment is not permissible under the statute's definition of nonprovider setting[344] and the hospital conditions of participation under 42 C.F.R. Part 482. Therefore, once the COVID-19 PHE ends we do not believe it would be appropriate to continue to permit a hospital to claim a resident for IME or DGME if the resident is performing patient care activities in his or her own home, or in a patient's home either on a temporary or permanent basis. In the event circumstances in a future PHE warrant additional flexibilities, we will address this issue in future rulemaking.

In this final rule with comment period, we are finalizing the provisions of the April 6, 2020 IFC without modification, to allow a hospital to claim a resident for IME or DGME if the resident is performing patient care activities within the scope of his or her approved program in his or her own home, or in a patient's home for the duration of the COVID–19 PHE. We note, when the COVID-19 PHE ends, a hospital may not count a resident for purposes of Medicare DGME payments or IME payments if the resident is performing activities with the scope of his/her approved program in his/her own home, or a patient's home. This policy does not require any changes to the regulations text.

3. Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement for the PHE During the COVID-19 Pandemic

Under 42 CFR 412.622(a)(3)(iv), for an inpatient rehabilitation facility (IRF) claim to be considered reasonable and necessary under section 1862(a)(1) of the Act, there must be a

[344] Section 1886(h)(5)(K) of the Act

reasonable expectation at the time of the patient's admission to the IRF that the patient requires physician supervision by a rehabilitation physician, defined as a licensed physician with specialized training and experience in inpatient rehabilitation. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. The purpose of the physician supervision requirement is to ensure that the patient's medical and functional statuses are being continuously monitored as the patient's overall plan of care is being carried out.

We note that, in the FY 2021 IRF PPS final rule (85 FR 48450 through 48453), we amended the IRF coverage requirements to allow, beginning with the second week of admission to the IRF, a nonphysician practitioner who is determined by the IRF to have specialized training and experience in inpatient rehabilitation to conduct 1 of the 3 required face-to-face visits with the patient per week, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law.

We continue to believe that it is in the patient's best interest to be seen in person by a rehabilitation physician (or, in accordance with the revised regulations, a nonphysician practitioner) to assess their medical and functional statuses while at the IRF, and we encourage rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) to continue to visit IRF patients in person as long as all necessary precautions, including the use of PPE, are taken to ensure the health and safety of the patient and the physician. However, in the April 6, 2020 IFC (85 FR 19252), we stated that we would temporarily allow the face-to-face visit requirements at §§ 412.622(a)(3)(iv) and 412.29(e) to be

conducted via telehealth to safeguard the health and safety of Medicare beneficiaries and the rehabilitation physicians (or, in accordance with the revised regulations, the nonphysician practitioners) treating them during the PHE for the COVID-19 pandemic. This provision allowed rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) to use telehealth services, as defined in section 1834(m)(4)(F) of the Act, to conduct the required 3 physician visits per week during the PHE for the COVID–19 pandemic. By increasing access to telehealth, we believe that this provision has provided the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health.

We received several comments on the flexibility allowing rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) to use telehealth services as defined in section 1834(m)(4)(F) of the Act to conduct the required 3 physician visits per week during the COVID-19 PHE, which are addressed below.

Comment: Commenters expressed support for the modification to our policy to allow rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) to use telehealth services as defined in section 1834(m)(4)(F) of the Act to conduct the required 3 physician visits per week during the COVID-19 PHE. The commenters thanked CMS for our rapid response to the pandemic.

Response: We appreciate the commenters' support for our policy, and are finalizing the policy for the duration of the PHE.

Comment: One commenter said that this temporary flexibility should not be made permanent.

Response: We agree with the commenter that this temporary flexibility should expire when the PHE ends. As we said in the IFC, we believe it is in the patient's best interest to be seen in person by a rehabilitation physician (or, in accordance with the revised regulations, a nonphysician practitioner) to assess their medical and functional statuses while at the IRF. Accordingly, this policy will automatically terminate with the end of the PHE, and rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) will be required to visit IRF patients face-to-face at least 3 times per week.

After carefully considering the comments we received, and for the reasons discussed, we are finalizing without modification our policy that during the COVID-19 PHE, rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) may use telehealth services as defined in section 1834(m)(4)(F) of the Act to conduct the 3 physician visits required under §§ 412.622(a)(3)(iv) and 412.29(e). When the COVID-19 PHE ends, rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) will be required to visit IRF patients face-to-face at least 3 times per week. To effectuate these changes, we are finalizing without modification the revisions to the regulations at §§ 412.622(a)(3)(iv) and 412.29(e) described within the April 6, 2020 IFC.

4. Direct Supervision by Interactive Telecommunications Technology

In the April 6, 2020 IFC (85 FR 19245 through 19246) we altered, for the duration of the PHE, the definition of direct supervision at § 410.32(b)(3)(ii) and § 410.28(e), to state that the necessary presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology was indicated to reduce exposure risks for the beneficiary or health care provider. We similarly altered the definition of direct supervision of pulmonary, cardiac and intensive rehabilitation at § 410.27(a)(1)(iv)(D), to state

that the necessary presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

In the CY 2021 PFS final rule (85 FR 84538 through 84540), we revised § 410.32(b)(3)(ii) to extend the duration of the altered definition of direct supervision until the later of December 31st, 2021 or the end of the calendar year in which the PHE ends. In the CY 2021 OPPS final rule (85 FR 86110 through 86113), we revised § 410.27(a)(1)(iv)(D) to extend the duration of the altered definition of direct supervision of pulmonary, cardiac and intensive rehabilitation until the later of December 31st, 2021 or the end of the calendar year in which the PHE ends.

In the CY 2023 OPPS proposed rule (87 FR 44834 through 44835), we proposed to revise § 410.28(e) to extend the duration of the altered definition of direct supervision from the end of the PHE to the end of the calendar year in which the PHE ends for consistency with § 410.32(b)(3)(ii) and § 410.27(a)(1)(iv)(D). In section X.E of this final rule with comment period, we are finalizing the revisions to § 410.28(e) as proposed.

In the CY 2023 OPPS proposed rule (87 FR 44679 through 87 FR 44680), we solicited comment as to whether we should extend the duration of the altered definition of direct supervision of pulmonary, cardiac and intensive rehabilitation through the end of CY 2023. Based on the comments we received in response to our solicitation, in section X.C of this final rule with comment period, we are finalizing revisions to § 410.27(a)(1)(iv)(D) to extend the duration of the altered definition of direct supervision of pulmonary, cardiac and intensive rehabilitation until the later of December 31st, 2023, or the end of the calendar year in which the PHE ends.

We refer readers to the April 6, 2020 IFC (85 FR 19245 through 19246), CY 2021 PFS final rule (85 FR 84538 through 84540), CY 2021 OPPS final rule (85 FR 86110 through 86113) and the above referenced sections of this CY 2023 OPPS final rule for a more detailed discussion of the reasoning behind our revisions to § 410.32(b)(3)(ii), § 410.28(e) and § 410.27(a)(1)(iv)(D).

Comment: We received public comments on the direct supervision definitions that we adopted on an interim basis in the IFC provisions related to § 410.32(b)(3)(ii), § 410.28(e) and § 410.27(a)(1)(iv)(D). Many commenters supported the alteration of the definition of direct supervision at § 410.32(b)(3)(ii), § 410.28(e) and § 410.27(a)(1)(iv)(D) to include the virtual presence of the physician through audio/video real-time communications technology for the duration of the PHE. Several of these commenters encouraged CMS to make the revisions to these definitions permanent. Several commenters expressed appreciation for CMS's acknowledgement in the April 6, 2020 IFC (85 FR 19245 through 19246) that virtual direct supervision facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their own professional services and cited this as a reason for CMS to make the revisions to direct supervision permanent. Finally, a few commenters expressed concern about the safety of allowing virtual supervision of home infusion therapy services.

Response: We appreciate commenters' input on this policy and will consider these comments for future rulemaking. In this final rule with comment period, we are finalizing the proposal to revise the definition of direct supervision in § 410.28(e) for consistency with § 410.32(b)(3)(ii) and § 410.27(a)(1)(iv)(D). We are also finalizing revisions to § 410.27(a)(1)(iv)(D) to extend the duration of the altered definition of direct supervision of pulmonary, cardiac and intensive rehabilitation until the later of December 31st, 2023 or the end

of the calendar year in which the PHE ends. This means that for §410.32(b)(3)(ii), § 410.28(e) and § 410.27(a)(1)(iv)(D), virtual direct supervision will conclude on December 31st of the calendar year in which the PHE ends. We also note that the Secretary renewed the PHE for the COVID-19 pandemic for a 90-day period beginning on October 13, 2022,[345] which will expire on January 11, 2023, absent another renewal of the PHE by the Secretary. As such, direct supervision through a virtual presence will continue to be permitted through at least the end of CY 2023 under our finalized policies.

B. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (CMS-5531-IFC)

In this final rule with comment we are also responding to public comments and stating our final policies for certain provisions in the IFC titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (CMS-5531-IFC), which appeared in the May 8, 2020 **Federal Register** ((85 FR 27550); hereinafter referred to as the May 8, 2020 IFC).

1. Medical Education Payments

a. Indirect Medical Education

(1) Holding Hospitals Harmless from Reductions in Indirect Medical Education (IME) Payments Due to Increases in Bed Counts

[345] https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx

In the May 8, 2020 IFC (85 FR 27567 through 27568), we implemented several policies on an interim final basis related to holding hospitals harmless from reductions in IME payments due to increases in bed counts during the COVID-19 PHE. As discussed later in this section of this CY 2023 OPPS/ASC final rule, we also implemented a policy to hold IRFs and IPFs harmless from reductions to teaching status adjustment payments due to COVID–19. We refer readers to the May 8, 2020 IFC, for an overview of IME (85 FR 27567).

We received public comments on the policies that we adopted on an interim basis in the IFC provisions related to the holding hospitals harmless from reductions in IME payments due to increases in bed counts due to COVID-19 (85 FR 27567 through 27568). The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelming supported the provision allowing the hospital's available bed count to be considered the same as it was on the day before the COVID-19 PHE was declared. A few commenters recommended making the provision a permanent policy whenever there is a PHE declaration.

Response: We appreciate the commenters' support of this policy during the COVID-19 PHE. In the event circumstances in a future PHE warrant additional flexibilities, we will address this issue in future rulemaking.

In this final rule with comment period, we are finalizing the provisions of the May 8, 2020 IFC without modification, allowing a hospital to maintain the same available bed count as it was on the day before the COVID-19 PHE was declared, for the duration of the COVID-19 PHE. When the COVID-19 PHE ends, any added beds will be considered in determining the hospital's IME payments.

(2) Holding IRFs and IPFs Harmless From Reductions to Teaching Status Adjustment Payments Due to COVID–19

As we discussed in the May 8, 2020 IFC (85 FR 27567 through 27568), we were asked by IRFs and IPFs if CMS can hold facilities harmless from a reduction in teaching status adjustment payments resulting from the temporary increase in facilities' ADC due to the influx of COVID–19 patients. We were concerned that, if a teaching IRF or IPF accepts patients from the inpatient acute care hospital to alleviate bed capacity during the PHE for the COVID–19 pandemic, the IRF's or IPF's ADC would increase, which would artificially decrease the IRF's or IPF's ratio of number of interns and residents to ADC and thereby decrease the facility's teaching status adjustment. To ensure that teaching IRFs or teaching IPFs could alleviate bed capacity issues by taking patients from the inpatient acute care hospitals without being penalized by lower teaching status adjustments, we established an interim final policy to freeze the IRFs' or IPFs' teaching status adjustment payments at their values prior to the COVID–19 PHE. Therefore, we stated that for the duration of the COVID–19 PHE, an IRF's or an IPF's teaching status adjustment payment amount would be the same as it was on the day before the COVID–19 PHE was declared.

Comment: We received 6 comments in response to this interim final policy. Commenters generally supported this policy and noted that it would enable hospitals, including IRFs and IPFs, to expand capacity while continuing to support medical education. One commenter requested that CMS clarify that academic medical centers and other facilities who are eligible for teaching status adjustments will not have their IME payments reduced after the PHE, noting that CMS could provide a transition policy to support hospitals as they prepare for future potential surges or attempt to adapt to more regular practices. Another commenter requested that CMS

implement the policy in a manner that achieves the intent without potentially subjecting IRFs and IPFs to unintended consequences as a result of freezing a facility's teaching status adjustment at the level that it was immediately before the COVID-19 PHE, which in some cases could potentially reflect an unusually low ratio of interns and residents to ADC. This commenter requested that CMS allow IRFs and IPFs the option to utilize the cumulative resident full-time equivalent (FTE) count and average daily census count from July 1, 2019 through January 26, 2020 and apply that ratio until the end of the PHE. In addition, this commenter requested that CMS allow IPFs and IRFs that send residents to work in another hospital to claim such resident FTE time spent at another hospital.

Response: We appreciate the support from commenters about this interim final policy. As we explained in the May 8, 2020 IFC, this policy will apply for the duration of the COVID-19 PHE, after which time any IRF's or IPF's teaching adjustment will be based on the ratio of the number of interns and residents to the IRF's or IPF's ADC. We did not establish a transition policy as part of this interim final policy, and we are not finalizing a transition policy in this final rule, as we believe that sufficient time has passed to allow IPFs and IRFs to adapt their business practices at the end of the COVID-19 PHE.

In response to the request that we implement the policy in a manner that achieves the intent without potentially subjecting IRFs and IPFs to unintended consequences, we note that our intent was to hold IRFs and IPFs harmless and not to limit their teaching adjustments to the level prior to the PHE. IPF and IRF teaching status adjustments are made on a claim basis as an interim payment, and the final payment in full for the claim is made during the final settlement of the cost report. In accordance with this hold harmless policy, we intend to clarify in the cost reporting instructions that for cost reporting periods ending on or after March 1, 2020 and

beginning before the end of the COVID-19 Public Health Emergency, if an IRF's or IPF's calculated teaching adjustment factor is below the teaching adjustment factor that was applicable on February 29, 2020, then the IRF's or IPF's teaching adjustment factor is equal to the teaching adjustment factor that was applicable on February 29, 2020.

Lastly, regarding the suggestion that we allow IPFs and IRFs that send residents to work in another hospital to claim such resident FTE time spent at another hospital, we note that we did not include this as part of our interim final policy for IRF and IPF teaching adjustments, and we are not finalizing such a policy in this final rule with comment period.

After consideration of the public comments we received, we are confirming as final this interim final policy to hold IRF and IPF teaching status adjustments harmless for the duration of the COVID-19 PHE. Therefore, we are finalizing that for the duration of the COVID–19 PHE, an IRF's or an IPF's teaching status adjustment payment amount will not be less than it was on the day before the COVID–19 PHE was declared.

b. Time Spent by Residents at Another Hospital During the PHE

In the May 8, 2020 IFC (85 FR 27568 through 27569), we implemented several policies on an interim final basis related to time spent by residents at another hospital during the COVID-19 PHE. We refer readers to the May 8, 2020 IFC, for an overview of GME (85 FR 27568).

We received public comments on policies that we adopted on an interim basis in the IFC provisions related to time spent by residents at another hospital during the COVID-19 PHE (85 FR 27568 through 27569). The following is a summary of the comments we received and our responses.

Comment: All commenters supported allowing teaching hospitals during the COVID-19 PHE to claim for purposes of IME and DGME payments the time spent by residents training at other hospitals. A few commenters suggested making the provision permanent. Additional commenters requested a grace period for hospitals to resume and be subject to existing FTE counting policies, in order to not disrupt patient care activities.

Response: We appreciate the commenters' support of this policy during the COVID-19 PHE. We continue to believe that outside of the context of the COVID-19 PHE our policy that a hospital cannot claim the time spent by residents training at another hospital is consistent with the statute. Therefore, once the COVID-19 PHE ends we do not believe it would be appropriate to continue permitting a hospital to claim the time spent by residents training at another hospital on a permanent basis. In the event circumstances in a future PHE warrant additional flexibilities, we will address this issue in future rulemaking.

Comment: One commenter requested confirmation that the sending hospital can only claim the resident time if both the sending and receiving hospital agree that the sending hospital will claim the time. In addition, the commenter requested confirmation that a new teaching hospital can accept residents as a receiving hospital from a sending hospital without having to include them on its cost report.

Response: While we believe our statements have been clear on this point, we confirm for the duration of the COVID-19 PHE, both the sending and receiving hospital agree that the sending hospital will claim the time and new teaching hospitals can accept residents as a receiving hospital from a sending hospital without having to include them on its cost report. We refer readers to the May 8, 2020 IFC where we discuss requirements for this provision (85 FR 27568 through 27569).

Comment: One commenter stated that the third requirement, which requires the resident be at the sending hospital prior to going to the receiving hospital and return to the sending hospital at the end of PHE is unnecessary, and instead sending and receiving hospitals should be allowed to enter into arrangements on when a resident goes back to the sending hospital.

Response: We disagree with the commenter and continue to believe that the third requirement is necessary. A hospital is required under 42 CFR 413.75(d) to submit supporting documentation in order to receive payment for GME. These documentation requirements apply to hospitals entering into a GME affiliation agreement, therefore, despite the commenters suggestion, the sending and receiving hospital will need to provide documentation listed § 413.75(d). For a detailed discussion on documentation requirements, we refer readers to the September 29, 1989 final rule (54 FR 40291 and 40304) and the August 18, 2006 IPPS final rule (71 FR 48077 through 48080).

In this final rule with comment period, we are finalizing the provisions of the May 8, 2020 IFC without modification, allowing teaching hospitals during the COVID-19 PHE to claim for purposes of IME and DGME payments the time spent by residents training at other hospitals during the COVID-19 PHE. It is important to note that when the COVID-19 PHE ends, the presence of residents in non-teaching hospitals will trigger establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals (and for DGME will trigger establishment of per resident amounts (PRAs) at those non-teaching hospitals).

2. CARES Act Waiver of the ‘‘3-Hour Rule’’

As a condition of payment for IRF services, § 412.622(a)(3)(ii) generally requires that a beneficiary requires and can be reasonably expected to actively participate in, and benefit from, an intensive rehabilitation therapy program on admission to the IRF. Under current industry

standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period, beginning with the date of admission to the IRF. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient's functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

On March 27, 2020, the CARES Act was enacted. Section 3711(a) of the CARES Act requires the Secretary to waive § 412.622(a)(3)(ii) during the emergency period described in section 1135(g)(1)(B) of the Act (the COVID-19 PHE). This waiver was issued on April 15, 2020. The waiver required by section 3711(a) of the CARES Act was not limited to particular IRFs or patients, and therefore, is available during the emergency period described in section 1135(g)(1)(B) of the Act regardless of whether a patient was admitted for standard IRF care or to relieve acute care hospital capacity. In the May 8, 2020 IFC (85 FR 27572),, we therefore waived § 412.622(a)(3)(ii) for all patients during the COVID-19 PHE to reflect the waiver required by section 3711(a) of the CARES Act.

We received several comments on the CARES Act waiver of the "3-hour rule," which are addressed below.

Comment: Commenters generally expressed support for the waiver of the "3-hour rule" during the PHE. However, a commenter expressed concern that this waiver, applied without

exception, could harm beneficiaries and their families and increase costs for the Medicare program, and urged CMS to place additional limits on the use of the waiver.

Response: We appreciate the commenters' support for this temporary waiver to assist IRFs in providing relief to acute care hospitals for the duration of the PHE. As we noted in the IFC, the waiver required by section 3711(a) of the CARES Act is not limited to particular IRFs or patients, and therefore, is available during the emergency period described in section 1135(g)(1)(B) of the Act regardless of whether a patient was admitted for standard IRF care or to relieve acute care hospital capacity. We do not believe that the CARES Act authorizes any exceptions.

Comment: A commenter requested that we provide a "glide path" or transition at the end of this waiver by continuing the waiver for IRF admissions occurring at least 2 months after the end of the PHE. Conversely, another commenter requested that we terminate this waiver at the end of the PHE to ensure that beneficiaries receive the care that they need when the pandemic is over.

Response: As the PHE has lasted for over 2 1/2 years, we believe that IRFs have had sufficient time to prepare for the end of the PHE and the corresponding expiration of this waiver. Thus, we do not agree that it is necessary to continue to provide this waiver for 2 months after the end of the PHE. In addition, we agree with the commenter who said that this policy is important to ensuring that beneficiaries receive the care that they need in an IRF after the PHE ends. However, to ensure that beneficiaries who are admitted under the waiver do not have requirements suddenly changed in the middle of their IRF stay, we are terminating the waiver for all IRF admissions occurring after the PHE expires. Thus, patients who are admitted to the IRF under this waiver will continue to benefit from this waiver until they are discharged.

After carefully considering the comments we received, and for the reasons discussed, we are finalizing the waiver of the requirements in § 412.622(a)(3)(ii) during the COVID-19 PHE, as authorized by section 3711(a) of the CARES Act. We will terminate this waiver for all IRF admissions occurring after the end of the COVID-19 PHE, so that patients who are admitted to IRFs during the PHE will be able to remain under the waiver until they are discharged from the IRFs.

3. Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID–19 Pandemic

IRF care is only considered by Medicare to be reasonable and necessary under section 1862(a)(1) of the Act if the patient meets all of the IRF coverage requirements outlined in § 412.622(a)(3), (4), and (5). These requirements include requiring 2 or more types of therapy, being sufficiently stable to tolerate an intensive rehabilitation therapy program typically provided in IRFs, needing close medical supervision by a rehabilitation physician, and requiring an interdisciplinary approach to care. Failure to meet the IRF coverage criteria in a particular case results in denial of the IRF claim.

We note that the April 6, 2020 IFC removed the requirement at § 412.622(a)(4)(ii) to complete a postadmission physician evaluation during the COVID–19 PHE, as defined in § 400.200. In follow up to this temporary removal of the waiver, the FY 2021 IRF PPS final rule (85 FR 48445 through 48446) removed this requirement permanently, effective for all IRF discharges beginning on or after October 1, 2020.

While we generally believe that all IRFs should have to comply with the requirements at § 412.29(d), (e), (h), and (i) and § 412.622(a)(3), (4), and (5), we recognize that there are certain institutional differences between freestanding IRF hospitals and IRF distinct part units of

hospitals that may impose barriers on freestanding IRF hospitals seeking to admit patients to relieve acute care hospital capacity during the COVID–19 PHE. Specifically, freestanding IRF hospitals do not have the same close affiliations with acute care hospitals that IRF distinct part units of hospitals have, and are not as able to establish billing procedures under the IPPS that IRF distinct part units have established, by virtue of the fact that the distinct part units have access to (or at least affiliations with) their parent hospitals' billing departments. Therefore, in the May 8, 2020 IFC, we amended the requirements at §§ 412.29(d), (e), (h), and (i) and 412.622(a)(3), (4), and (5) to add an exception for care furnished to patients admitted to freestanding IRF hospitals (identified as those facilities with the last 4 digits of their Medicare provider numbers between 3025 through 3099) solely to relieve acute care hospital capacity during the COVID–19 PHE.

We believe that freestanding IRF hospitals have needed the flexibility during the COVID–19 PHE to determine the best care for each patient who is admitted solely to relieve acute care hospital capacity. For the purposes of exercising these IRF flexibilities that are intended to provide broad flexibility for freestanding IRF hospitals to provide surge capacity in support of acute care hospitals in their state or community, CMS considers surge to be alleviated with regard to exercising these flexibilities when the state (or region, as applicable) in which the freestanding IRF is located has moved beyond phase 1 of reopening. Thus, these flexibilities are no longer available to the freestanding IRF hospital when the state is in phase 2 or phase 3 of reopening. In the Guidelines for Opening Up America Again, Phase 1 of reopening is defined specifically as a state (or region, as applicable) that satisfies all of the following, as determined by applicable state and local officials:

- All vulnerable individuals continue to shelter in place.
- Individuals continue social distancing.

- Individuals avoid socializing in groups of more than 10.
- Non-essential travel is minimized.
- Visits to senior living facilities and hospitals are prohibited.
- Schools and organized youth activities remain closed.

These flexibilities apply to specific patients who must be discharged from the acute care hospitals to the freestanding IRFs to provide surge capacity for the acute care hospitals, and therefore apply only when those specific patients are admitted to the freestanding IRF hospitals and continue for the duration of that patient's care. We believe this allows for continuity of care and care planning consistency at admission and throughout a patient's stay if the same flexibilities apply for the duration of a patient's IRF stay. These limitations only apply to the provisions stated in the IFC and not to any blanket waivers issued, which have their own conditions. Freestanding IRF hospitals must document the particular phase for the state when admitting the patient and electing to exercise these flexibilities.

For billing purposes, we have required freestanding IRF hospitals to append the ''DS'' modifier to the end of the IRF's unique patient identifier number (used to identify the patient's medical record in the IRF) to identify patients who are being treated in a freestanding IRF hospital solely to alleviate inpatient bed capacity in a state that is experiencing a surge during the PHE for the COVID– 19 pandemic. The modifier has also been used to identify those patients for whom the requirements in § 412.622(a)(3)(i), (iii), (iv), (4) and (5) do not apply. Freestanding IRF hospitals are paid at the IRF PPS rates for patients with the ''DS'' modifier.

We have expected freestanding IRF hospitals to take advantage of these flexibilities for those beneficiaries who are surge patients from inpatient hospitals, while continuing to provide standard IRF-level care for those beneficiaries who would benefit from IRF-level care and would

otherwise receive such care in the absence of the COVID–19 PHE. This has provided crucial flexibility to allow freestanding IRF hospitals to aid in the response to the COVID–19 pandemic in several ways. First, some of the patients that freestanding IRF hospitals have cared for during the COVID–19 PHE in states experiencing a surge would need high-acuity clinical care but may not need or be able to tolerate the intensive rehabilitation therapy typically provided in an IRF, such as at least two types of therapy. Second, waiving the documentation requirements in § 412.622(a)(4) and (5) for patients alleviating inpatient hospital bed capacity has allowed freestanding IRF hospitals to concentrate on providing care for surge patients from the acute care hospitals in a state that is experiencing a surge, instead of completing documentation that may not be applicable to these acute patients during the PHE. Third, this flexibility has allowed freestanding IRF hospitals to maximize their available beds to take advantage of space where COVID–19 patients or surge patients could be safely managed. We believe this policy has allowed freestanding IRF hospitals to make a clinical determination about what level of care each individual patient needs during the PHE for the COVID–19 pandemic.

We received several comments on the modification of IRF coverage and classification requirements for freestanding IRF hospitals for the PHE during the COVID–19 pandemic, which are addressed below.

Comment: All of the commenters expressed support for CMS's flexibility in waiving these requirements to help freestanding IRFs alleviate acute care hospital capacity during the PHE. A few commenters expressed concern about the fact that this waiver is restricted to states or regions in Phase 1 (or prior to Phase 1) of reopening, especially given the diversity of the states' reopening plans, and requested that we consider applying the waiver to any freestanding IRF patients admitted to alleviate COVID-19 surge capacity.

Response: We appreciate the commenters' support for these temporary flexibilities to assist IRFs in providing relief to acute care hospitals for the duration of the PHE. These flexibilities were specifically targeted to helping alleviate acute care hospital surge capacity issues during the height of the PHE, when the PHE was most significantly testing the capacity of acute care hospitals in state or regions that were overwhelmed with the surge of COVID-19 patients. We believe that the conditions placed on the waiver were effective in targeting the precise hospitals that were in most urgent need of help, and we therefore believe that the limitations that we placed on the waiver were appropriate. .

Comment: A few commenters also requested that CMS provide additional guidance on this waiver, to ensure that providers and contractors have a clear understanding of how it is applied.

Response: We appreciate the commenters' suggestions to provide additional guidance on this waiver. In response to their concerns, we issued Technical Direction Letter #200515 to our contractors and additional information on our COVID-19 flexibilities and waivers website at https://www.cms.gov/coronavirus-waivers.

Comment: One commenter suggested that we consider implementing additional oversight of this waiver to ensure that it is not abused.

Response: We believe that we tailored this waiver narrowly enough to only those states (or regions, as applicable) that were in phase 1 or prior to entering phase 1 of reopening, to minimize the potential for abuse. In addition, we have monitored the use of this waiver during the PHE and have not found any evidence to date of any abuse. We thank the commenter for the suggestion, and we will continue to ensure that we have adequate safeguards in place to minimize abuses of these policies.

Comment: One commenter requested that we terminate this waiver at the end of the PHE to ensure that beneficiaries receive the care that they need when the pandemic is over.

Response: We thank the commenter for this suggestion and agree that the waiver is no longer needed after the PHE ends.

After carefully considering the comments we received, and for the reasons discussed, we are finalizing without modification the waiver of the requirements at § 412.29(d), (e), (h), and (i) and § 412.622(a)(3), (4), and (5) during the COVID-19 PHE for freestanding IRF hospitals admitting patients in support of acute care hospitals when the state (or region, as applicable) is in phase 1 or prior to entering phase 1 of reopening described in the May 8, 2020 IFC. Patients who are admitted to IRFs during the PHE will remain under these waivers until they are discharged from the IRFs. However, these waivers will no longer apply to patients who are admitted to IRFs after the end of COVID-19 PHE.

To effectuate these changes, we are finalizing without modification the revisions to §§ 412.29(d), (e), (h), and (i) and § 412.622(a)(3), (4), and (5) described in the May 8, 2020 IFC. Specifically, in § 412.622(a)(3)(i), (ii), (iii), and (iv) we are finalizing language providing that these IRF coverage criteria continue to be required, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE, as defined in § 400.200. Similarly, in § 412.622(a)(4), we are finalizing this paragraph to state that the IRF documentation requirements must be present in the IRF medical record, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE, as defined in § 400.200. In § 412.622(a)(5), we are finalizing this paragraph to state that an interdisciplinary team approach

to care is required, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE, as defined in § 400.200. We are also finalizing the revisions to § 412.29 paragraphs (d), (e), (h), and (i) to align the provisions we have waived in § 412.622 with the classification criteria for payment to freestanding IRF hospitals under the IRF prospective payment system. Finally, we are finalizing the revisions to § 412.622(c) to add a definition of state (or region, as applicable) that are experiencing a surge and § 412.29 to cross-reference that definition where applicable.

4. Furnishing Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (CMHC) (Including the Patient's Home)

a. Hospital Outpatient and CMHC Therapy, Education, and Training Services

Partial Hospitalization Program (PHP)

A PHP is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression and schizophrenia. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a

program furnished by a hospital to its outpatients or by a CMHC, as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit.

In the May 8, 2020 IFC (85 FR 27563 through 27566), we stated that infection control was a primary goal of CMS initiatives undertaken during the COVID-19 PHE. We also stated that we believe continuity of behavioral health services is critical for those participating in a PHP, particularly at a time of heightened anxiety and uncertainty. As we noted in the May 8, 2020 interim final rule (85 FR 27562), we issued numerous blanket waivers under section 1135 of the Act, including for hospitals and CMHCs providing PHP services, to give health care providers needed flexibility to address the COVID-19 PHE and support the goal of infection control while maintaining access to partial hospitalization services and ensuring continuity of care for patients. Effective as of March 1, 2020, and for the duration of the COVID-19 PHE, we established an interim final policy that a temporary expansion location where the beneficiary may be located, including a beneficiary's home, may be a provider-based department (PBD) of the hospital, or may be a temporary extension of the CMHC (discussed in more detail below).

Consistent with the goals of infection control and maintaining access, for the duration of the COVID-19 PHE only, we established that providers could furnish certain partial hospitalization services remotely to patients in a temporary expansion location of the hospital or CMHC, which could include the patient's home to the extent it was made provider-based to the hospital or an extension of the CMHC. PHP services consist of unique combinations of services designated at section 1861(ff)(2) of the Act, including individual psychotherapy, patient

education, and group psychotherapy. We further noted that certain PHP services such as these require communication and interaction, but do not require the clinical staff or patient to be in the same location, nor do clinical staff need to be in the hospital or CMHC when furnishing these PHP services. Therefore, we established that the following types of services—to the extent they were already billable as PHP services in accordance with existing coding requirements prior to the COVID-19 PHE—could be furnished to beneficiaries by facility staff using telecommunications technology during the COVID-19 PHE: (1) Individual psychotherapy; (2) patient education; and (3) group psychotherapy. Because of the intensive nature of PHP, we stated that we expect PHP services to be furnished using telecommunications technology involving both audio and video. However, we recognized that in some cases beneficiaries might not have access to video communication technology. In order to maintain beneficiary access to PHP services, we stated that only in the case that both audio and video are not possible can the service be furnished exclusively with audio. We further clarified that services that required drug administration could not be furnished using telecommunications technology. To facilitate public understanding of the types of PHP services that could be furnished using telecommunications technology by the hospital to a patient in the hospital (including the patient's home if it was a PBD of the hospital) or by the CMHC to a patient in an expanded CMHC location, we provided on our website[346] a list of the individual psychotherapy, patient education, and group psychotherapy services that hospital or CMHC staff could furnish during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location that functions as a PBD of the hospital or expanded CMHC when the beneficiary was registered as an outpatient. We noted

[346] https://www.cms.gov/coronavirus-waivers

that this list may not have included every service that fell into this category and that we intended to update the list periodically, to the extent that would be helpful for public awareness.

We further explained that although these services can be furnished remotely, all other PHP requirements were unchanged and still in effect, including that all services furnished under the PHP still required an order by a physician, had to be supervised and certified by a physician, and had to be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. We stated that in accordance with the longstanding requirements that are detailed in the Medicare Benefit Policy Manual, Pub 100–02, chapter 6, section 70.3, documentation in the medical record of the reason for the visit and the substance of the visit would continue to be required. We further explained that when these services are provided by clinical staff of the physician or other practitioner and furnished incident to their professional services, and are not provided by staff of the hospital or CMHC, the hospital or CMHC would not bill for the services. The physician or other practitioner would bill for such services incident to their own services and would be paid under the PFS.

(a) Hospital-Based PHP Providers

As detailed in the May 8, 2020 IFC (85 FR 27564), as part of the initiative to promote infection control and maintain access to PHP services, we waived the requirements for being a PBD of the hospital in § 413.65, as well as certain requirements under the Medicare conditions of participation in §§ 482.41 and 485.623, to facilitate the availability of temporary expansion locations. As we noted in that IFC, for purposes of the COVID-19 PHE and effective as of March 1, 2020, a temporary expansion location where the beneficiary may be located, including a beneficiary's home, may be a PBD of the hospital where the location meets the non-waived conditions of participation. We stated that together, these waivers allow hospitals to consider a

temporary expansion location where the beneficiary may be located, including their homes, an HOPD only in the context of the COVID-19 PHE. Thus, we explained that for the duration of the COVID-19 PHE, we would consider the PHP services furnished by hospital clinical staff, when the beneficiary was registered as an outpatient of the hospital and in accordance with the supervising practitioner's scope of practice, to have been furnished in the hospital to the beneficiary in a temporary expansion location, including a beneficiary's home, so long as such temporary expansion location was made provider-based to the hospital. We noted that the hospital was instructed to bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare during the COVID-19 PHE.

(b) Community Mental Health Centers

A CMHC is a provider of PHP services defined under section 1861(ff)(3)(B) of the Act. As we discussed in the May 8, 2020 IFC (85 FR 27564), for the duration of the COVID-19 PHE, we waived the restriction at § 485.918(b)(1)(iii) for the purpose of providing PHP services to CMHC patients in their homes, which we stated would be considered a temporary expansion location of a CMHC. Certain therapeutic services by CMHC staff would be paid when provided for beneficiaries registered as outpatients, in accordance with the supervising practitioner's scope of practice, consistent with any specific requirements for billing Medicare during the COVID-19 PHE.

Comment: We received four comments in response to this interim final policy. One commenter, a national nonprofit organization, expressed support for this flexibility to ensure services were available safely to people with Medicare. Another commenter, a healthcare services company, encouraged CMS to ensure that temporary expansion location policies did not abruptly end at the end of the PHE, and supported a flexible transition policy to better ensure

continuity of care as hospitals and communities continue to fight the spread of COVID-19 and recover from the impacts of the virus.

One national insurance company voiced support for the flexibilities, stating that these flexibilities were necessary to ensure that PHP beneficiaries continue to have access to the level of care they required and prevent potential relapse and overdose. This commenter noted that structured patient engagement is an important component of PHP and they believe the remote and audio-only flexibilities did not diminish this important component. They further noted that for PHP patients and providers, these flexibilities also reduced the risk of contracting or spreading the coronavirus. This commenter also expressed concern about clerical staff lacking the qualifications to provide the services described, and requested further language to clarify the scope of this allowance. Another national insurance company expressed support for the use of live-two-way video interactions via remote technology for PHP services, stating it is comparable to in-person interaction. However, this commenter expressed concern about the use of only audio communication to provide PHP services. The commenter explained that audio-only delivery of services does not lend itself to the structure of group therapy or ongoing assessments. Consequently, the commenter stated that audio-only therapeutic services impede the ability to achieve the clinical benefits of the programs, and cautioned that if PHP services are delivered ineffectively via audio-only communication, the patient risks relapse and inpatient readmission.

Response: We appreciate the support from commenters about this interim final policy. In response to the concerns about audio-only therapeutic services, we noted in the May 8, 2020 IFC that due to the intensive nature of PHP we expected PHP services to be furnished using telecommunications technology involving both audio and video. However, we recognized that in some cases beneficiaries might not have access to video communication technology. In order to

maintain beneficiary access to PHP services, we stated that only in the case that both audio and video are not possible could the service be furnished exclusively with audio (85 FR 27564).

Regarding the concern about clerical staff lacking the qualifications to provide the services described, we note that we explained in the May 8, 2020 IFC that, although these services can be furnished remotely, all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still require an order by a physician, must be supervised by a physician, must be certified by a physician, and must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice (85 FR 27564).

Lastly, regarding the commenter's suggestion of a transition policy, as we explained in the May 8, 2020 IFC, this interim final policy depends on numerous blanket waivers under section 1135 of the Act, and will apply for the duration of the COVID-19 PHE. After those blanket waivers expire at the end of the COVID-19 PHE, section 1861(ff)(3)(A) of the Act limits Medicare's ability to pay for partial hospitalization services furnished to beneficiaries in a home or residential setting.

After consideration of the public comments we received, we are confirming as final this interim final policy. Therefore, for the duration of the COVID-19 PHE only, providers can furnish certain partial hospitalization services remotely to patients in a temporary expansion location of the hospital or CMHC, which may include the patient's home to the extent it is made provider-based to the hospital or an extension of the CMHC.

5. Furnishing Hospital Outpatient Services Remotely for Services Other Than Mental Health

As we explained in the May 8, 2020 IFC (85 FR 27562 through 27566), outpatient education and training services require communication and interaction between the patient and

the clinical staff providing the service. We stated that facility staff can effectively furnish these services using telecommunications technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them.

We further explained that blanket waivers in effect during the COVID–19 PHE allow temporary expansion locations, including beneficiaries' homes, to become provider-based departments (PBDs) of the hospital during the COVID-19 PHE and therapeutic outpatient hospital services furnished to beneficiaries in these provider-based locations can meet the requirement that these services be furnished in the hospital so long as all other requirements are met, including the hospital conditions of participation, to the extent not waived, during the COVID-19 PHE. . In light of the need for infection control and a desire for continuity of care, we recognized the ability of the hospital's clinical staff to continue to deliver these services even when the beneficiary is not physically located in the hospital. Therefore, in the May 8, 2020 IFC (85 FR 27564), we made clear that when a hospital's clinical staff are furnishing hospital outpatient services (such as drug administration, education, and training services) to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We referred to this policy as Hospitals without Walls (HWW). Further, we clarified that when a patient is receiving a professional service via telehealth in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. Finally, we also clarified the applicability of section 603 of the BBA 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion

locations), and whether those locations are considered relocated, partially relocated, or new PBDs.

We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

In section X.A.1 of this Final Rule with Comment period we are finalizing the IFC policy with respect to mental health services furnished remotely to beneficiaries in their homes, through an alternate regulatory authority that does not rely upon the HWW framework.

Comment: We received a number of comments supporting this policy. Commenters stated that this flexibility helps reduce the spread of COVID-19 by allowing beneficiaries to receive outpatient education and training services in their homes when furnished by hospital staff. A few commenters requested that CMS clarify the intersection of Hospitals Without Walls and the expansion of Medicare telehealth services paid under the Physician Fee Schedule.

Response: We thank commenters for their support. With regard to the intersection of Hospitals Without Walls and Medicare telehealth, we have stated in subregulatory guidance issued since the publication of the May 8, 2020 IFC that if a Medicare distant site practitioner furnishes a Medicare telehealth service to a beneficiary whose home has been reclassified as a temporary provider-based department of a hospital, the hospital should bill for the originating site facility fee. However, if the hospital furnishes services to the beneficiary without the involvement of a distant site practitioner furnishing a Medicare telehealth service, the hospital should accordingly bill for whatever service is being furnished as though it occurred within the four walls of the hospital.

Comment: Some commenters requested additional clarification regarding compliance with conditions of participation and life safety code requirements.

Response: We appreciate the requests for clarification. We have continued to update our guidance online and through CMS Office Hours to address provider questions and concerns in real time.

In this final rule, we are finalizing the provisions of the May 8, 2020 IFC (85 FR 27562 through 27566), without modification, including that when a hospital's clinical staff are furnishing hospital outpatient services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met for the duration of the PHE for COVID-19. We are finalizing that when a patient is receiving a professional Medicare telehealth service in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. We are also finalizing the applicability of section 603 of the BBA 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion locations). Once the PHE for COVID-19 ends, these flexibilities will end as well.

6. Treatment of New and Certain Relocating Provider-Based Departments During the PHE

In the May 8, 2020 IFC (85 FR 27567 through 27568), we implemented a policy on an interim final basis related to treatment of new and certain relocating provider-based departments (PBDs) during the PHE. We refer readers to the May 8, 2020 IFC for an overview of that policy (85 FR 27567).

Comment: Many commenters expressed their support for allowing on and off-campus PBDs to temporarily relocate while maintaining their eligibility to bill as excepted off-campus PBDs. Several commenters requested that CMS expand the extraordinary circumstances policy after the PHE. Commenters wrote that excepted PBDs forced to relocate due to unforeseen circumstances beyond their control should be allowed to relocate without losing their excepted status. Other commenters felt that hospital operations may not return to normal on the date the PHE is lifted as many will need to transition back to normal operations and will need to implement new operating policies to address patient treatment and safety in a post COVID-19 world. They recommended that CMS consider extending the ability of temporarily relocated PBDs to bill at the OPPS rate for at least three months following the conclusion of the PHE. This, commenters argued, would help to facilitate their transition back to traditional billing rates and would allow them to transition care of patients as needed.

Response: We thank the commenters for their support. We continue to believe that our current extraordinary circumstance relocation policy is appropriate when the COVID-19 PHE is no longer in effect. We noted in the May 8, 2020 IFC (85 FR 27567 through 27568) that this temporary extraordinary circumstances relocation policy is time-limited to the PHE for COVID-19 to enable short-term hospital relocation of excepted off-campus and on-campus departments to improve access to care for patients during this time. The temporary extraordinary circumstances relocation policy established in the May 8, 2020 IFC (85 FR 27567 through 27568) will end when the PHE for the COVID-19 pandemic ends, and we anticipate that most, if not all, PBDs that relocated during the COVID-19 PHE will relocate back to their original location prior to, or soon after, the end of the COVID-19 PHE. PBDs that hospitals choose to permanently relocate off-campus would be considered new off-campus PBDs billing after

November 2, 2015, and, therefore, would be required to bill using the "PN" modifier for hospital outpatient services furnished from that PBD location and would be paid the PFS-equivalent rate once the COVID-19 PHE ends. Following the COVID-19 PHE, hospitals may seek an extraordinary circumstances relocation exception for excepted off-campus locations that have permanently relocated, but these hospitals would need to follow the standard extraordinary circumstances application process we adopted in CY 2017 and file an updated CMS-855A enrollment form to reflect the new address(es) of the PBD(s). We note that our standard relocation exception policy only applies to excepted off-campus PBDs that relocate; on-campus PBDs that wish to permanently relocate off-campus will not be able to receive an extraordinary circumstances relocation exception under the standard extraordinary circumstances relocation request process after the conclusion of the COVID-19 PHE. We also note that hospitals should not rely on having relocated the off-campus PBD during the COVID-19 PHE as the reason the off-campus PBD should be permanently excepted following the end of the COVID-19 PHE. In other words, the fact that the off-campus PBD relocated in response to the pandemic will not, by itself, be considered an "extraordinary circumstance" for purposes of a permanent relocation exception, although CMS Regional Offices will continue to have discretion to approve or deny relocation requests for hospitals that apply after the COVID-19 PHE, depending on whether the relocation request meets the requirements for the extraordinary circumstances exception. Following the COVID-19 PHE, if temporarily relocated off-campus PBDs do not go back to their original location, they will be considered to be non-excepted PBDs and paid the PFS-equivalent rate.

Comment: Many commenters felt additional clarification was needed on the documentation required on when a PBD relocates to a beneficiary's home. Commenters

expressed the burden of having to provide individual beneficiary addresses to the CMS RO. Commenters requested that CMS further streamline the process and outline the steps and documents needed to establish a temporary PBD at a beneficiary's' home during the COVID-19 PHE.

Response: We believe that the process as outlined in the May 8, 2020 IFC (85 FR 27567 through 27568) sufficiently addresses the flexibility needed by providers while maintaining some program integrity safeguards. We do not believe it is overly burdensome for providers. We have continued to update our guidance online and through CMS Office Hours to address provider questions and concerns in real time.

Comment: The Medicare Payment Advisory Commission (MedPAC) commented that they fully recognize the benefit of modifying regulations to provide hospitals with flexibility to effectively address the COVID-19 PHE. They also commended CMS for creating an application process that allows hospitals to quickly transfer resources to new off-campus locations and also provides CMS with the data necessary to identify the locations of new off-campus PBDs. However, they expressed their concern that most, if not all, PBDs that relocated might not return to their original location when the COVID-19 PHE is over. They encouraged CMS to maintain the information from the application about the excepted PBDs that relocated and to be diligent in identifying which of these excepted PBDs return to their original location and which remain in their new location to ensure these providers are paid at rates that are consistent with Section 603 of BBA 2015.

Response: We thank MedPAC for their support. As the PHE ends, we will monitor those PBDs that submitted relocation requests to ensure that these providers are paid at rates that are consistent with section 603 of BBA 2015 given their post-PHE location.

In this final rule with comment period, we are finalizing the provisions of the May 8, 2020 IFC (85 FR 27567 through 27568) without modification, including a temporary extraordinary circumstances relocation exception policy for excepted off-campus PBDs that relocate off-campus during the COVID-19 PHE. Additionally, we are finalizing without modification the extension of the temporary policy for on-campus PBDs that relocate off-campus during the COVID-19 PHE that permits the relocating PBDs to continue to be paid under the OPPS during the PHE. Finally, we are finalizing without modification the streamlining of the process for relocating PBDs to obtain the temporary extraordinary circumstances policy exception. All of these flexibilities will end when the PHE for COVID-19 ends.

C. OPPS Separate Payment for New COVID–19 Treatments Policy for the Remainder of the PHE (CMS-9912-IFC)

In this final rule with comment period we are also responding to public comments and stating our final policy for a provision titled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-9912-IFC), which appeared in the November 6, 2020 **Federal Register** ((85 FR 71142); hereinafter referred to as the November 6, 2020 IFC regarding separate payment under the OPPS for new COVID-19 treatments for the remainder of the PHE (85 FR 71158 through 71160).

Under the OPPS Comprehensive APC (C-APC) policy, when a service that we have designated as a primary C-APC service is reported on a hospital outpatient claim, with certain exceptions, we make payment for all other items and services reported on the claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service. This results in a single prospective payment for each of the primary comprehensive services based on the costs of all reported services at the

claim level. Under our current policy, payment for drugs or biological products with emergency authorization or approved to treat COVID-19 in the outpatient setting would be packaged into the payment for a primary service when billed on the claim for that service.

In the November 9, 2020 IFC, we stated that although many beneficiaries would likely not receive both a primary C-APC service and a drug or biological for treating COVID-19, we nonetheless believed that, as drugs or biologicals became available and were authorized or approved for the treatment of COVID-19 in the outpatient setting, it would be appropriate to mitigate any potential financial disincentives for hospitals to provide these new treatments during the PHE for COVID-19. Accordingly, effective for services furnished on or after the effective date of the November 9, 2020 IFC and until the end of the PHE for COVID-19, we created an exception to our OPPS C-APC policy to ensure new COVID–19 treatments that meet two criteria would, for the remainder of the PHE for COVID-19, always be separately paid and not packaged into a C-APC when they appear on the same claim as the primary C-APC service.

The first criterion is that the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in section "I. Criteria for Issuance of Authorization" of the letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19. The second criterion is that the EUA for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting. We refer readers to the November 6, 2020 IFC for a full overview of this policy (85 FR 71158 through 71160).

Comment: We received a few comments that supported this policy. Generally, commenters appreciated CMS's recognition of the significant cost associated with new COVID-19 therapies provided to Medicare beneficiaries in the HOPD setting. Commenters believed this would ensure access to these therapies.

Response: We thank the commenters for their support.

Comment: Commenters had some suggestions related to this policy. They requested CMS confirm the exact payment methodology it would use to calculate separate payment for qualifying COVID-19 therapies. Generally, commenters advocated that qualifying COVID-19 therapies be excluded from the OPPS 340B payment adjustment. Commenters also recommended CMS waive the co-insurance associated with COVID-19 therapies Finally, commenters requested CMS make this C-APC exemption permanent and extending it beyond the end of the PHE.

Response: We appreciate the commenters' support of this policy during the COVID-19 PHE. Since this IFC was published, there have been significant changes to the OPPS 340B payment policy and the commenter request for excluding qualifying COVID-19 therapies from the 340B payment adjustment would no longer be applicable for CY 2023. We refer readers to section V.B.6 in this final rule with comment period for further information about the 340B policy changes. Regarding the request to waive co-insurance associated with COVID-19 therapies, we do not believe that CMS has the statutory authority to waive coinsurance for these therapies, as suggested by the commenter. We believe that outside of the context of the COVID-19 PHE, our standard and longstanding policy of packaging adjunctive items and services into payment for primary C-APC services is appropriate for COVID-19 treatments, as they are similar to other treatments that currently can have their payment packaged into the payment for a

primary service under the OPPS. Therefore, once the COVID-19 PHE ends, we do not believe it would be appropriate to continue paying separately for new COVID-19 treatments provided on the same claim as a C-APC on a permanent basis. In the event that future circumstances warrant additional flexibilities, we will reconsider this issue in future rulemaking.

Given the public comments we received, we are finalizing this policy as implemented in the November 6, 2020 IFC. Accordingly, this policy will end with the end of the PHE.

XXII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the Internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled "Copayment Capped at the Inpatient Deductible of $1,364.00" where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2023, we proposed to retain these columns, updated to reflect the amount of the 2023 inpatient deductible. In the CY 2022 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled "Drug Pass-Through Expiration during Calendar Year" where we flagged, through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2023, we proposed to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in CY 2023.

In addition, for CY 2023, we proposed to update the column titled "Drug Pass-Through

Expiration during Calendar Year" to include devices, so that the column reads: "Drug and Device Pass-Through Expiration during Calendar Year" where we proposed to flag, through the use of an asterisk, each drug and device for which pass-through payment would be expiring during the calendar year on a date other than December 31. For CY 2023, we did not receive any public comments and, therefore, are finalizing our proposal to update the column to include devices, so that the column reads: "Drug and Device Pass-Through Expiration during Calendar Year" where we would flag, through the use of an asterisk, each drug and device for which pass-through payment would be expiring during the calendar year on a date other than December 31.

To view the Addenda to the CY 2023 OPPS/ASC proposed rule pertaining to proposed CY 2023 payments under the OPPS, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html; select "CMS-1772-FC" from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled "2023 NFRM OPPS Addenda" in the related links section at the bottom of the page. To view the Addenda to the CY 2023 OPPS/ASC proposed rule pertaining to CY 2023 payments under the ASC payment system, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html; select "CMS-1772-FC" from the list of regulations. The ASC Addenda to the CY 2023 OPPS/ASC proposed rule are contained in a zipped folder titled "2023 NFRM Addendum AA, BB, DD1, DD2, EE, and FF" in the related links section at the bottom of the page.

XXIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of title 44 of the U.S. Code, as added by section 2 of the Paperwork Reduction Act of 1995, requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. ICRs for the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2022 OPPS/ASC final rules (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156;

84 FR 61468 through 61469; 85 FR 86266 through 86267; and 86 FR 63961 through 63968, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938-1109, which expires on February 28, 2025.

In the CY 2022 OPPS/ASC final rule with comment period, our burden estimates were based on an assumption of 3,300 hospitals (86 FR 63961). For the CY 2023 OPPS/ASC final rule, we have updated our assumption to 3,350 hospitals based on recent data from the CY 2022 payment determination which reflects a closer approximation of the total number of hospitals reporting data for the Hospital OQR Program.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52617), we finalized to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. In BLS' most recent set of National Occupational Employment and Wage Estimates published on March 31, 2022, this occupation title has been removed. As a result, we now utilize the "Medical Records Specialists" occupation title. The BLS describes Medical Records Specialists as those responsible for compiling, processing, and maintaining medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system and classifying medical and healthcare concepts, including diagnosis, procedures, medical services, and equipment, into the healthcare industry's numerical coding system[347]; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data from the BLS' May 2021

[347] https://www.bls.gov/oes/current/oes292072.htm (Accessed June 23, 2022). The hourly rate of $46.46 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

Occupational Employment and Wages data reflects a median hourly wage of $23.23 per hour for a Medical Records Specialists. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($23.23 × 2 = $46.46) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In section XIV.B.4 of this final rule with comment period, we are finalizing to: (1) change the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery measure (OP-31) to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) add an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period; and (3) align the patient encounter quarters with the calendar year and update the data submission deadlines for each of these quarters beginning with the Q2 2023 reporting period.

3. Estimated Burden of Hospital OQR Program Requirements for the CY 2025 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for OP-31: Cataracts – Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 through 63846), we finalized to require this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary

reporting of this measure in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014). As discussed in section XIV.B.5.b of this final rule with comment period, we are finalizing to change this measure to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. We continue to estimate it will require hospitals 10 minutes once annually to report this measure using a CMS web-based tool. As a result, we estimate only 20 percent of hospitals will voluntarily submit data, which results in a total annual burden estimate of 112 hours (3,350 hospitals x 20 percent x 0.1667 hours) at a cost of $5,188 (112 hours × $46.46/hour). In addition to reporting the measure, for hospitals that chose to voluntarily submit, we also require hospitals to perform chart abstraction and estimate that each hospital will spend 2.92 minutes (0.049 hours) per case per measure to perform this activity. In the CY 2022 OPPS/ASC final rule with comment period, we used an estimate of 25 minutes per case per measure (86 FR 63963). Upon review, this estimate was erroneous, therefore we are correcting our assumption to 2.92 minutes (0.049 hours) per case per measure as finalized in the CY 2016 OPPS/ASC final rule (80 FR 70582). The currently approved burden estimate assumes 242 cases per measure. For chart abstraction, we estimate an annual burden of 12 hours (0.049 hours × 242 cases) at a cost of $549 (12 hours × $46.46/hour) per hospital and a total annual burden of 7,891 hours (3,350 hospitals x 20 percent x 12 hours) at a cost of $368,028 (7,891 hours × $46.46/hour) for all participating hospitals. In aggregate, we estimate a total annual burden of 8,003 hours (112 hours + 7,891 hours) at a cost of $373,216 ($5,188 + $368,028) for all hospitals. This is a decrease of 325,847 hours and $15,138,852 per year from the currently approved estimate due to the 80 percent of hospitals we assume will no longer report this measure, the updated assumption of the number of hospitals participating in the

Hospital OQR Program, the updated burden estimate for chart abstraction, and the updated wage rate.

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on February 28, 2025.

b. Information Collection Burden Estimate for the Addition of an Additional Targeting Criterion to the Validation Selection Policy

In section XIV.B.4 of this final rule with comment period, we are finalizing to adopt an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period/CY 2025 payment determination. We also are finalizing to codify this targeting criterion at § 419.46(f)(3). We do not believe this policy will increase reporting burden, because it changes neither the total number of hospitals required to submit data nor the amount of data hospitals selected for validation would be required to submit.

c. Information Collection Burden Estimate for the Alignment of Patient Encounter Quarters with the Calendar Year

In section XIV.B.4.b of this final rule with comment period, we are finalizing to align patient encounter quarters with the calendar year (January through December), beginning with the CY 2026 payment determination and subsequent years. This finalized period will not result in any increase in information collection burden because it will not change the amount of data hospitals will be required to submit.

d. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 which expires on February 28, 2025 we estimate that the updated assumptions and policies promulgated in this final rule with

comment period will result in a decrease of 325,847 hours annually for 3,350 OPPS hospitals for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. The total cost decrease related to this information collection is approximately -$15,138,852 (325,847 hours × $46.46/hour) (which also reflects use of an updated hourly wage rate as previously discussed). Table 104 summarizes the estimated total burden change compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. We did not finalize any changes for the CY 2024 reporting period/CY 2026 payment determination, therefore the previously finalized burden estimates for the CY 2024 reporting period/CY 2026 payment determination remain unchanged.

TABLE 104: SUMMARY OF FINALIZED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determination and Subsequent Years							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Finalized annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Voluntary Reporting of OP-31 Measure	10	1	670	1	0.167	112	550	-438
Chart Abstraction for OP-31 Measure	2.9	1	670	242	12	7,891	333,300	-325,409
	Total Change in Information Collection Burden Hours: -325,847							
	Total Cost Estimate: Updated Hourly Wage ($46.46) x Change in Burden Hours (-325,847) = **-$15,138,852**							

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, CY 2020, CY 2021, and CY 2022 OPPS/ASC final rules (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; 85 FR 86267; and 86 FR 63968 through 63971, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938-1270, which expires on July 31, 2024.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52619 through 52620), we finalized to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the BLS, to calculate our burden estimates for the ASCQR Program. In BLS' most recent set of National Occupational Employment and Wage Estimates published on March 31, 2022, this occupation title has been removed. As a result, we now utilize the "Medical Records Specialists" occupation title. The BLS describes Medical Records Specialists as those responsible for compiling, processing, and maintaining medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system and classifying medical and healthcare concepts, including diagnosis, procedures, medical services, and equipment, into the

healthcare industry's numerical coding system[348]; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the ASCQR Program. The latest data from the BLS' May 2021 Occupational Employment and Wages data reflects a median hourly wage of $23.23 per hour for a Medical Records Specialists. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52619 through 52620). This by necessity is a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($23.23 × 2 = $46.46) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2020 payment determination data, we found that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to participate in the Program and did so. In addition, 689 ASCs that were not required to participate due to having low Medicare claims volume (less than 240), did so, for a total of 4,183 participating facilities. As noted in section XXV.C.5.a of the "Regulatory Impact Analysis", for the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's ECE policy in consideration of the COVID-19 PHE; 3,957 of these ASCs would have been required to participate without the PHE exception. Therefore, we estimate that 3,957 plus 689, or 4,646, ASCs will submit data for the ASCQR Program for the CY 2023 payment determination unless otherwise noted.

[348] https://www.bls.gov/oes/current/oes292072.htm (Accessed June 23, 2022). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

2. Summary

In section XV.B.4 of this final rule with comment period, we are finalizing to change the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery measure (ASC-11) to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination.

3. Estimated Burden of ASCQR Program Requirements for the CY 2025 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for Proposal to Change ASC-11: Cataracts – Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure from Mandatory to Voluntary

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63886 through 63887), we finalized to require this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and estimated that 20 percent of ASCs would elect to report it annually (79 FR 67016). As discussed in section XV.B.5.b of this final rule with comment period, we are finalizing to change the ASC-11 measure to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. We continue to estimate it will require ASCs 10 minutes once annually to report this measure using a CMS web-based tool. As a result of our finalized policy, we estimate only 20 percent of ASCs will voluntarily submit data, which results in a total annual burden estimate for all participating ASCs of 155 hours (4,646 ASCs x 20 percent x 0.1667 hours) at a cost of $7,194 (115 hours × $46.46/hour). In addition to reporting the measure, for ASCs that chose to voluntarily submit, we also require ASCs to

perform chart abstraction for a minimum required sample size of 63 cases. In the CY 2022 OPPS/ASC final rule with comment period, we estimated that each ASC would spend 15 minutes (0.25 hours) per case to perform this activity (86 FR 63969). However, upon review, we believe the effort involved with this activity is similar to what is required for the OP-31 measure in the Hospital OQR Program, therefore, we are updating our assumption to 2.92 minutes (0.049 hours) per case per measure. Therefore, we estimate an annual burden of 3.1 hours (0.049 hours × 63 cases) at a cost of $142 (3.1 hours × $46.46/ hour) per ASC and a total annual burden of 2,848 hours (4,646 ASCs x 20 percent x 3.1 hours) at a cost of $132,333 (2,848 hours × $46.46/hour) for all participating ASCs. In aggregate, we estimate a total annual burden of 3,003 hours (155 hours + 2,848 hours) at a cost of $139,527 ($7,194 + $132,333) for all ASCs. This is a decrease of 72,107 hours and $3,350,091 per year from the currently approved estimate due to the 80 percent of ASCs we assume will no longer report this measure, the updated burden estimate per case per measure, and the updated wage rate.

b. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938-1270 which expires on July 31, 2024, we estimate that the policies promulgated in this final rule with comment period will result in a decrease of 72,107 hours annually for 4,646 ASCs for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. The total cost decrease related to this information collection is approximately $3,350,091 (72,107 hours × $46.46/hour). Table 105 summarizes the total burden change compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938-1270.

TABLE 105: SUMMARY OF FINALIZED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027

PAYMENT DETERMINATION AND SUBSEQUENT YEARS

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Payment Determination and Subsequent Years							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Voluntary Reporting of ASC-11 Measure	10	1	929	1	0.167	155	774	-619
Chart Abstraction for ASC-11 Measure	2.9	1	929	63	3.1	2,848	74,336	-71,488
	Total Change in Information Collection Burden Hours: -72,107							
	Total Cost Estimate: Updated Hourly Wage ($46.46) x Change in Burden Hours (-72,107) = **-$3,350,091**							

D. ICRs for Rural Emergency Hospitals (REH) Physician Self-Referral Law Update

As discussed in section XVIII.E of this final rule with comment period, we are finalizing our proposal to revise certain existing exceptions applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party. Specifically, we are finalizing our proposal to revise the exceptions for physician recruitment at § 411.357(e), obstetrical malpractice insurance subsidies at § 411.357(r), retention payments in underserved areas at § 411.357(t), electronic prescribing items and services at § 411.357(v), assistance to compensate a nonphysician practitioner at § 411.357(x), and timeshare arrangements at § 411.357(y) to also permit an REH to provide remuneration to a physician (or an immediate family member of a physician) if all requirements of the applicable exception are satisfied. All of the finalized proposals will ensure that exceptions that may already be utilized by existing hospitals eligible to undergo conversion to an REH remain available to REHs.

The existing exceptions at § 411.357(e), (r), (t), (v), (x), and (y) each require that the compensation arrangements to which the exceptions apply be documented in a writing signed by the parties. The existing exception at § 411.357(t)(2) also requires a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The existing exception at § 411.357(x) also requires that records of the actual amount of remuneration provided by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years. We did not propose, and are not finalizing, any changes to the existing writing, signature, or record retention requirements. The burden associated with writing and signature requirements will be the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements is the time and effort necessary to compile and store the records.

As noted in the CY 2023 OPPS/ASC proposed rule, while the writing, signature, and record retention requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without Federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature, and record retention requirements should be considered usual and customary business practices.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

E. ICRs for Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).[349] As part of the CY 2021 OPPS/ASC final rule with comment period we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we are finalizing our proposal to require prior authorization for a new service category: Facet joint interventions. We are adding the service category to § 419.83(a)(3). We also are finalizing that the prior authorization process for the additional service category will be effective for dates of services on or after July 1, 2023. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare

[349] See also Correction Notice issued January 3, 2020 (85 FR 224).

coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the new category, Facet joint interventions, will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to July 1, 2023 start date, the first year of the prior authorization for the new service category will only include 6 months. Based on CY 2019 data, we estimate that for those first 6 months there will be 41,701initial requests mailed during the year. In addition, we estimate there will be 13,683 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $276,920 (55,384 mailed requests x $5). Based on CY 2019 data for the new service category, we estimate that annually there will be 83,401 initial requests mailed during a year. In addition, we estimate there will be 27,366 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated to be $553,838 (110,786 mailed requests x $5). We also estimate that an additional 3 hours per

provider will be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of $17.13 with a loaded rate of $34.26. The prior authorization program for the new service category will not create any new documentation requirements. Instead, it will just require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff will need to spend more time on completing the documentation than will be needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. CMS believes providers will have provided education to their staff on what services are included in the prior authorization process. Following this education, the staff will know which services need prior authorization and will not need additional time or resources to determine if a service requires prior authorization. We estimate that the total number of submissions for the first year (6 months) will be 184,613(129,229 submissions through fax or electronic means + 55,384 mailed submissions). Therefore, we estimate that the total burden for the first year (6 months) for the new service category, allotted across all providers, will be 99,768 hours (0.5 hours x 184,613 submissions plus 3 hours x 2,487 providers for education). The burden cost for the first year (6 months) is $3,694,954 (99,768 hours x $34.26 plus $276,920 for mailing costs). In addition, we estimate that the total annual number of submissions will be 369,225 (258,458 submissions through fax or electronic means + 110,768 mailed submissions). The annual burden hours for the new service category, allotted across all providers, will be

192,074 hours (0.5 hours x 369,225 submissions plus 3 hours x 2,487 providers for education). The annual burden cost will be $7,134,276 (192,074 hours x $34.26 plus $553,838 for mailing costs). For the total burden and associated costs for the new service category, we estimate the annualized burden to be 161,305 hours and $5,987835 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938-1368 will be revised and submitted to OMB for approval.

Table 106 below is a chart reflecting the total burden and associated costs for the provisions included in this final rule with comment period.

TABLE 106: TOTAL BURDEN FOR NEW SERVICE CATEGORY

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process	+161,305	+$5.9 million

* Numbers rounded.

F. ICRs for Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators

In section X.H of this final rule with comment period, we are finalizing IPPS and OPPS payment adjustments for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. The payment adjustments will be based on the IPPS and OPPS shares of the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic ones. As discussed in section X.H of this final rule with comment period, in order to calculate the N95 payment adjustment for each eligible cost reporting period, we created a new cost report worksheet to collect additional information from hospitals.

Specifically, the new cost report worksheet will collect the following: (1) total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital; (2) total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital; (3) total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital; and (4) total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

This new information will be used along with other information already collected on the Hospitals and Health Care Complex Cost Report (Form CMS-2552-10) approved under OMB control number 0938-0050 to calculate an IPPS payment adjustment amount and an OPPS payment adjustment amount. This new cost report worksheet may be submitted by a provider of service as part of the annual filing of the cost report and make available to its contractor and CMS, documentation to substantiate the data included on this Medicare cost report worksheet. The documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

The burden associated with filling out this new N95 cost report worksheet will be the time and effort necessary for the provider to locate and obtain the relevant supporting documentation to report the quantity and aggregate costs of domestic NIOSH-approved surgical N95 respirators and non-domestic NIOSH-approved surgical N95 respirators purchased by hospital for the period. We estimate the number of respondents to be 4,662. This number is comprised of 3,240 Medicare certified 1886(d) hospitals eligible for the payment adjustment under Part A and Part B (including 30 Indian Health Services Hospitals excluded from the Part B payment adjustment as they are paid an all-inclusive rate for Part B services) plus 1,422

additional hospitals paid for outpatient services under the hospital OPPS.[350] We estimate the average burden hours per facility to be 0.50 hours which breaks down to approximately 0.40 hours per provider for recordkeeping and 0.10 hours per provider for reporting. We recognize this average varies depending on the provider size and complexity.

We estimate the associated labor costs as follows. The estimated 0.40 hours for recordkeeping includes time for bookkeeping activities. Based on the most recent Bureau of Labor Statistics (BLS) in its 2021 Occupation Outlook Handbook, the mean hourly wage for Category 43-3031 is $21.70.[351] We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $43.40 ($21.70 + $21.70) and multiplied it by 0.40 hours, to determine the annual recordkeeping costs per hospital to be $17.36 ($43.40 per hour multiplied by 0.40 hours). The estimated 0.10 hours for reporting includes time for accounting and audit professionals' activities. The mean hourly wage for Category 13-2011[352] is $40.37. We added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $80.74 ($40.37 plus $40.37) and multiplied it by 0.10 hours, to determine the annual reporting costs per hospital to be $8.07 ($80.74 per hour multiplied by 0.10 hours). We calculated the total average annual cost per hospital of $25.43 by adding the recordkeeping costs of $17.36 plus the reporting costs of $8.07. We estimated the total annual cost to be $118,555 ($25.43 cost per hospital multiplied by 4,662 hospitals). In addition to the announcement in this final rule, we will publish a separate 30-day notice in the **Federal Register** to solicit additional comments on this topic. The information collection request is identified as CMS-10821 and titled "Supplemental to Form CMS-2552-10, Payment Adjustment for Domestic NIOSH-Approved

[350] Data sourced from the System for Tracking Audit and Reimbursement (STAR), an internal CMS data system maintained by the Office of Financial Management (OFM).
[351] Bookkeeping, accounting and auditing clerks (https://www.bls.gov/oes/current/oes433031.htm)
[352] www.bls.gov/oes/current/oes132011.htm

Surgical N95 Respirators." The notice will inform the public on where to find the information collection request for which we are seeking OMB approval and how to submit comments on it.

G. ICRs for REH Provider Enrollment Requirements

As stated earlier in section XIX.C.1 of this final rule with comment period, we are finalizing our proposal at § 424.575, as well as existing § 424.510(a)(1) and (d)(1), which require REHs to complete and submit the applicable enrollment application, which, for REHs, will be the Form CMS-855A (OMB control number 0938-0685). The only impacts associated with our REH enrollment policies are those concerning the submission of a Form CMS-855A change of information application to convert from a CAH or hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH. Per a North Carolina Rural Health Research Program[353] study (and as stated in the CMS proposed rule titled "Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates," published in the **Federal Register** on July 6, 2022 (87 FR 40350), we estimate that 68 REHs would convert from either a CAH or section 1886(d)(1)(B) hospital. (However, as we did in the aforementioned July 6, 2022 proposed rule, we acknowledge that the number of conversions could be less than or significantly greater than this estimate.) For purposes of these calculations, we assume that all of these facilities will do so within the first year of our proposed requirements.

Form CMS-855A applications are typically completed by the provider's office or administrative staff. According to the most recent BLS wage data for May 2021, the mean hourly wage for the general category of " Office and Administrative Support Workers, All Other" (the most appropriate BLS category for owners) is $20.47 (see

[353] https://www.shepscenter.unc.edu/product/how-many-hospitals-might-convert-to-a-rural-emergency-hospital-reh/.

http://www.bls.gov/oes/current/oes_nat.htm#43-0000). With fringe benefits and overhead, the figure is $40.94. This will result in an estimated Year 1 burden involving final policy at § 424.575 of 68 hours (68 applications x 1 hour) at a cost of $2,784.

The burden associated with this requirement will be included as part of a resubmission of the information collection previously approved under 0938-0685. In addition to the announcement in this rule, we will also be publishing the required 60-day and 30-day notices to formally announce the aforementioned resubmission request and to both inform the public on where to find the revised PRA package for review and where to submit comments.

H. ICRs for Rural Emergency Hospitals and CAHs CoPs

1. Factors Influencing ICR Burden Estimates

Under this final rule with comment period, an REH's ICR may differ from that of a hospital or CAH, given that REHs would be providers of outpatient services and would not provide inpatient services. We based the ICRs for REHs on the ICRs for hospitals and CAHs in some cases because, in accordance with section 1861(kkk) of the Act, REHs must convert from either a rural hospital with not more than 50 beds or a CAH. In the discussion that follows, we rely heavily on the study of the North Carolina Rural Health Research Program's (NC RHRP's) study titled, "How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?"[354] This study examined data on existing rural hospitals (Medicare-funded through both the prospective payment system and cost-reimbursements to CAHs) to determine how many might meet three key criteria (1) 3 years of negative total financial margins; (2) average daily census of acute and swing beds of less than three persons; and (3) net patient revenue of less than $20 million annually. The study further assumed that all the statutory and regulatory requirements

[354] This study can be accessed here: https://www.shepscenter.unc.edu/product/how-many-hospitals-might-convert-to-a-rural-emergency-hospital-reh /

would be met by every REH. The NC RHRP study assumes that hospitals and CAHs meeting the necessary requirements would apply for election of coverage under the new REH program. The study did not address the potential caseload, cost, or revenue changes from electing conversion and implicitly assumed that the net effects would be positive.

We note that another study from consulting firm CLA also examines the number of facilities likely to convert to REHs titled, "A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation."[355] The CLA study estimated that between 11 and 600 CAHs would benefit from conversion to REH status—based on estimated REH reimbursement and several financial assumptions (estimated average facility payment, estimated outpatient fee schedule payment, estimated average skilled nursing facility payment rates by state, presence or loss of swing bed payments, and continuance or cessation of 340B eligibility) and four simulation methods. A key takeaway from both studies is that available data support a possible wide range of conversion decisions. In addition, we note that these results and the calculations on which they rely are subject to a wide range of uncertainty as illustratively shown in the CLA study's summary estimate and the NC RHRP study makes the same point in describing its central estimate set of results. In the analysis that follows, we use for simplicity of exposition the NC RHRP study results, which depend on data and calculations presented in the study at a level of detail that allows reader analysis and present our summary estimates based on the NC RHRP study's central estimate.

In total, the NC RHRP study estimated that there are 1,673 hospitals (mostly CAHs) eligible to convert to an REH and of these, 68 would convert to REH status. The reasons why

[355] CLA, "A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation", February 8, 2022, at https://www.claconnect.com/resources/articles/2022/a-path-forward-clas-simulations-on-rural-emergency-hospital-designation.

some would convert are presented in the NC RHRP study and include low levels of inpatient revenue, low levels of swing bed nursing care revenue, and negative financial margins over a period of years.

The finances of individual rural hospitals and CAHs vary widely, as do the local economic and demographic circumstances of the communities served by these facilities (for example some rural areas are gaining population even as most face declining populations). Competition from other hospitals either in the rural area or in nearby cities also varies widely, with the only certainty in forecasting REH conversion is that seemingly similar hospitals and CAHs will make widely different decisions. What the NC RHRP did, in essence, was predict that the hospitals and CAHs facing the most severe financial difficulties would be the most likely to convert.

For purposes of our analysis, we use the NC RHRP estimate of 68 conversions though acknowledge that the number of conversions could be less than or significantly greater than this estimate. In addition, when considering the PRA burden for REHs, given that the CoPs align closely with existing standards, we considered both the existing burden estimates for CAHs and hospitals, as well as our ongoing experience with these provider types. We also considered that REHs would only be furnishing outpatient services, which would lessen their burden.

2. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

For the estimated costs contained in the analysis below, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.[356] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating

[356] BLS. *May 2020 National Occupational Employment and Wage Estimates United* States. United States Department of Labor. Accessed at https://www.bls.gov/oes/current/oes_nat.htm. Accessed on August 25, 2021.

procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in Table 107.

TABLE 107: Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	Physician	$105.22	$210
29-1141	Registered Nurses	Registered Nurse, Clinical Trainer	$39.27	$79
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Administrator, Medical director, Director of nursing	$61.22	$122
29-1071	Physician Assistants	Physician Assistant	$55.34	$111
29-1171	Nurse Practitioners	Nurse Practitioner	$53.51	$107
43-6013	Medical Secretaries and Administrative Assistants	Clerical Staff	$18.75	$38
11-3010	Administrative Services and Facilities Managers	Facilities Director	$51.98	$104
29-1000	Healthcare Diagnosing or Treating Practitioners	Mid-Level Practitioner	$50.58	$101

3. Rural Emergency Hospitals

a. ICRs Regarding Condition of Participation: Provision of Services (§ 485.514)

Section 485.514(a) would require REHs to furnish health care services in accordance with appropriate written policies that are consistent with applicable state law. In addition, § 485.514(b) would require REHs to develop the policies with the advice of members of the REH's professional health care staff, while § 485.514(d) would require REHs to conduct a biennial review of all its policies and procedures. We have not designated any specific process or format for REHs to use in developing their policies or conducting a review of their policies because we believe they need the flexibility to determine how best to accomplish these tasks.

In accordance with the section 1861(kkk)(3) of the Act, REHs must have been either a CAH or a rural hospital with not more than 50 beds as of the date of enactment of the CAA, December 27, 2020, to convert to an REH. We estimate that 68 facilities will convert to an REH and we believe that they will be developing REH-specific policies that are based on policies that were utilized when the facility was a rural hospital or CAH. As a result, we estimate that it would take an REH approximately 80 hours for administrative and clinical staff to develop policies. If there are 68 REHs to comply with the policy development requirement and each REH uses 80 hours to comply: (16 hours for a physician + 16 hours for an administrator + 16 hours for a mid-level practitioner + 16 hours for a nurse + 16 hours for a clerical staff person), then the burden hours are 5,440 (68 REHs x 80 hours). The cost is $8,800 per REH ($3,360 for a physician (16 hours x $210) + $1,952 for an administrator (16 hours x $122) + $1,616 for a mid-level practitioner (16 hours x $101) + $1,264 for a nurse (16 hours x $79) + $608 for a clerical staff person (16 hours x $38)). The total cost is 598,400 (68 REHs x $8,800). We estimate that it would take an REH's professional personnel 16 hours to review and make changes to policies and procedures biennially. Therefore, for all 68 REHs to comply with the policy review requirement it would require an estimated 16 burden hours biennially, or 8 hours

annually (1.5 hours for a physician + 2 hours for an administrator + 1.5 hours for a mid-level practitioner + 1.5 hours for a nurse + 1.5 hours for a clerical staff person). The burden hours are 544 (8 hours x 68 REHs). The cost per REH is $886 ($315 for a physician (1.5 hours x $210) + $244 for an administrator (2 hours x $122) + $151.50 for a mid-level practitioner (1.5 hours x $101) + $118.50 for a nurse (1.5 hours x $79) + $57 for a clerical staff person (1.5 hours x $38)). The total cost is $60,248 ($886 x 68 REHs). Therefore, the total cost for each REH to comply with these requirements would be $658,648 annually and 5,984 burden hours.

b. ICRs Regarding Condition of Participation: Infection prevention and control and antibiotic stewardship programs (§ 485.526)

COVID-19 and Seasonal Influenza Reporting

Consistent with the recent changes we made to the hospital and CAH infection control CoPs related to COVID-19 and the declared public health emergency (PHE), we proposed to require REHs, after the conclusion of the current COVID-19 PHE, to report COVID-19 and seasonal influenza-related reporting. The requirements would apply upon conclusion of the COVID-19 PHE and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. The data elements align closely with those COVID-19 reporting requirements for long-term care (LTC) facilities that were finalized on November 9, 2021 (86 FR 62421) and are representative of the guidance provided to hospitals and CAHs for reporting. Therefore, we do not expect that these categories of data elements would require REHs to report any information beyond that which they have already been reporting as existing rural hospitals or CAHs. Furthermore, similar to the requirements for LTC facilities, this

requirement would also allow for the scope and frequency of data collection to be reduced and limited responsive to the evolving clinical and epidemiological circumstances.

Based on our experience with those existing hospitals and CAHs and the current COVID-19 and related reporting requirements, we believe that this will primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of $79. According to the most recent COVID-19 hospital reporting guidance (available at https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf), hospitals are reporting COVID-19 and influenza-related data on a daily basis, with backdating permitted for weekends and holidays, except psychiatric and rehabilitation hospitals who report weekly. Some data element reporting fields are inactive for data collection, and therefore, hospitals can optionally report data for these fields. The inactive fields and active fields together reflect what is listed in this rule for COVID-19 and influenza-related reporting as well as future reporting in the event of a declared PHE, which we discuss next. We do not expect, nor did we propose, daily reporting for COVID-19 or influenza outside of a declared PHE.

If we were to assume a weekly reporting frequency, we would anticipate that there are reduced cases and fewer data elements (with no line level patient data) being reported. Based on these assumptions, we estimate that total annual burden hours for REHs to comply with these requirements would be 5,304 hours based on weekly reporting of the required information by 68 REHs x 52 weeks per year and at an average weekly response time of 1.5 hours for a registered nurse with an average hourly salary of $79. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $419,016 or approximately $6,162 per facility annually. We acknowledge that the data

elements and reporting frequency could increase or decrease over the next two years, and those changes would impact this burden estimate.

We note that this estimate is assumed to be a one-day snapshot of reporting information as opposed to a cumulative weekly report accounting for information based on each day of that week. If we assumed a cumulative weekly account, we can assume reduced burden related to the actual reporting time, but anticipate that the estimate would be slightly higher to account for the need to track closely to daily reporting. We also acknowledge that respondents may have to track and invest in infrastructure in order to timely and accurately report on the specified frequency. Thus, respondents may face ongoing burdens associated with this collection even in the case of reduced frequency of submissions. We solicit comment on this potentiality.

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all REHs will report manually. Efforts are underway to automate reporting that have the potential to significantly decrease reporting burden and improve reliability.

Future Reporting in the Event of a Future PHE Declaration

In addition, we proposed to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring REHs to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential only when the Secretary has declared a PHE directly related to such specific pathogens and infectious diseases. Specifically, when the Secretary has declared a PHE, we proposed to require REHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other

CDC-supported surveillance systems, as determined by the Secretary. The final requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total REH bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

We also proposed to require that, unless the Secretary specifies an alternative format by which a REH must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients, unless the Secretary specifies an alternative format by which the REH would be required report these data elements. We also proposed in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients and staff to items outlined in this section or otherwise specified by the Secretary. We note that

the provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with sections 304, 306, and 308(d) of the Public Health Service Act (42 USC §§ 242b, 242k, and 242m(d)). Lastly, we proposed that a REH would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary.

For purposes of this burden collection, we acknowledge the unknown and the ongoing burdens that may exist even if CMS is not collecting information outside of a declared PHE. We recognize that considerations such as building and maintaining the infrastructure to support readiness are necessary to ensure compliance with this requirement.

CMS will pursue an emergency review of the collection of information in the case of a declared PHE and, if approved, use such burden estimate to inform its approach at that time. CMS will also publish an accompanying **Federal Register** Notice concurrent with its submission of a request to collect information, in addition to all other actions in accordance with the implementing regulations of the PRA at 5 CFR 1320.13. CMS commits to ensuring that respondents are well aware in advance of the intention to collect such information and solicits comment on the appropriate timeline and notification process for such actions.

c. ICRs Regarding Condition of Participation: Staffing and staff responsibilities (§ 485.528)

We proposed that the emergency department of the REH be staffed 24 hours a day, 7 days a week, and we propose this requirement at § 485.6528(a) and that a doctor of medicine

or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant must be available to furnish services in the REH in the facility 24 hours a day. The burden associated with this requirement is the time it takes to review the REH's written policies and make appropriate changes or updates regarding its staffing and staff responsibilities for the services it furnishes. In conjunction with a mid-level practitioner, the physician develops, executes, and periodically reviews the REH's written policies governing the services it furnishes. We estimate that it will take the physician and mid-level practitioner 1 hour each to review the REH written policies and make the appropriate changes. We also estimate that a REH will utilize the services of one clerical person for half an hour to process any changes or updates, for a total of 2.5 burden hours and an estimated cost per REH of $ 330 ((1 hour x $210 for a physician) + (1 hour x $101 for a mid-level practitioner) + (0.5 hours x $38 for clerical staff)). Therefore, the burden associated with this requirement is an estimated 170 burden hours (2.5 hours x 68 REHs) at an estimated cost of $22,440 ($330 x 68 REHs).

d. ICRs Regarding Condition of Participation: Patient's Rights (§ 485.534)

(1) Standard: Notice of Rights: § 485.534(a)(1) and (2)

Proposed § 485.534(a) would require REHs to notify a patient of their rights and of whom to contact to file a grievance. We allow REHs the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance processes, but have not delineated strategies and policies for implementing this system. We believe that in large measure, REHs would be able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not

serve the very purpose intended by the regulation. Costs associated with formalizing a process and modifying any existing notices or processes will most likely be partially offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We asked that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented are estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in hospitals or CAHs each year; however, for REHs, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to modify any existing notices to include the proposed grievance process requirements. We believe that an office assistant may be tasked with drafting or updating the notices and distributing or posting, as appropriate, the information. We estimate that this would require no more than two hours of the clerical staff time. Based on this we estimate that this will create a one-time cost of $5,168 (68 REHs x 2 hours x $38 clerical staff hourly wage). In addition, we estimate that it will require the office assistant 2 minutes (.0333 hours) to provide the notice per REH patient on an annual basis. The number of notices required will depend on the number of patients received at

the REH. Therefore, the per facility burden associated with providing the notice will vary based on the unique factors of the REH. According to an OIG report, there were 2,316,675 outpatient visits in 2011 at CAHs.[357] Based on this estimate, we assume that the REH will have an average of 1,743 outpatient/emergency department visits per year that would require informing each patient of their rights which would take 58 hours (.0333 hours x 1,743 notices). The cost is $149,872($38 clerical staff wage x 58 hours x 68 REHs).

In its resolution of a grievance, a REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each REH 15 minutes to develop and disseminate the required notice and estimate that an REH may have to provide 50 notices on an annual basis for a total annual burden. The burden hours would be 13 hours (0.25 hours x 50 notices). The total burden hours would be 884 hours (13 hours x 68 REHs) at the cost of $33,592 ($38 x 884 hours). Therefore, the total burden associated with this requirement is $188,632 ($5,168 to update notices, $149,872 to provide the notices, and $33,592 to provide the results of a grievance investigation).

(2) Standard: Confidentiality of Patient Records (§ 485.534(d))

Section 485.534(d), which sets forth the patient's right to access information in their records, will involve minimal burden as many states' existing laws cover this point. We have not proposed to require disclosure of all records, inasmuch as we recognize that there are situations

[357] https://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf

where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the REH can charge. In the absence of state law, the REH should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (3) because this requirement is considered standard industry practice and/or is required under state or local law.

(3) Standard: Restraint and Seclusion (§ 485.534(e))

Section 485.534(e) requires that REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. While the requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary state practices based on current standards of practice and the state would impose this standard for efficient utilization of Medicare or Medicaid services in the absence of a federal requirement. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

(4) Standard: Restraint and seclusion: Staff training requirements (§ 485.534(f))

Section 485.534(f) requires facilities to establish staff training requirements for the use of restraints and seclusion. The REH must provide competency-based training and education of

REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion. While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

(5) Standard: Death reporting requirements (§ 485.534(g))

Section 485.534(g) requires the facility to report the death of a resident associated with restraint or seclusion to the CMS regional office. A report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

We estimate it will take 5 minutes to report each death to the CMS regional office and to document that report. We estimate fewer than 10 deaths annually for all 68 facilities. Five (5) minutes x 10 deaths annually would equate to a national burden of 50 minutes per year.
The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of a death a documenting the report is $122/hour. Multiplying the total burden of 0.83 hours by the hourly wage yields an associated cost of about $101.67.

(6) Standard: Patient visitation rights (§ 485.534(h))

Section 485.534(h) requires a REH to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical

restriction or limitation. Specifically, the written policies and procedures must contain the information listed in § 485.534(h)(1) through (4). Given that the statute requires a REH to have been either a CAH or rural hospital as of the date of enactment of the CAA, we expect these facilities to already have a visitation policy in accordance with the CAH and hospital CoPs at § 485.635(f) and § 482.13(h), respectively. Therefore, the ICR burden associated with this requirement would be the time and effort necessary for a REH to review and make any necessary updates given its conversion to an REH and to distribute that information to patients. We expect that an office secretary or other clerical staff would update and distribute, or post as appropriate, the information and could accomplish this task in 15 minutes for an estimated one-time burden total of 17 hours (0.25 hours x 68 REHs) and at the cost of $646 ($38 x 17 hours).

e. ICRs Regarding Condition of participation: Transfer Agreements (Proposed § 485.538)

At § 485.538, we proposed that each REH must have a transfer agreement in effect with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. We estimate that it would require an REH administrator and a clerical person 2 hours each to develop the initial agreement and obtain the appropriate approvals. According to Table 1, the REH administrator's total hourly cost is $122 per hour. The clerical staff person's total hourly cost is $38. We estimate that for each REH to comply with the requirements in this section it would require 4 burden hours which would be a total of 272 hours (4 hours x 68 REHs). The cost is $320 ($244 (2 hours x $122 for an administrator) + $76 (2 hours x $38 for a clerical staff person)) for each REH. The total cost is $21,760 ($320 x 68 REHs). This is a one-time cost.

f. ICRs Regarding Condition of Participation: Medical Records (Proposed § 485.540)

There is no burden attributed to this task. The REH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable state law. The policies include a description of the services the REH furnishes directly and those furnished through agreement or arrangement; policies and procedures for emergency medical services and guidelines for medical management of health problems that include the conditions requiring medical consultation and/or patient referral and the maintenance of health care records.

We are not including burden associated with certain patient related activities such as health care plans, patient records, medical records, etc., because prudent institutions already incur this burden in the course of doing everyday business. As stated in 5 CFR 1320.3(b)(2), the burden associated with usual and customary business practices is exempt from the PRA. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH. Further, state laws require providers to maintain patient records. (For example, the annotated Code of Maryland (10.11.03.13) requires a provider to be responsible for maintaining patient records for services that it provides.) State law requires record information that should include: documentation of personal interviews; diagnosis and treatment recommendations; records of professional visits and consultations; and consultant notes which shall be appropriately initialed or signed.

g. ICRs Regarding Condition of Participation: Quality assessment and performance improvement program (QAPI) (Proposed § 485.536)

At § 485.536, we require REHs to develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI)

program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS. In addition, REHs must comply with all of the requirements set forth in proposed § 485.536(a) through (e). We believe that the REH QAPI leadership (consisting of a physician, and/or administrator, mid-level practitioner, and a nurse) would need to have at least one and potentially two meetings to ensure that the current QAPI program that the provider has established is in accordance with the proposed requirements at § 485.536. The first meeting would be to discuss the current QAPI program and what, if anything, needs to be revised based on the proposed QAPI requirements at § 485.536. The second meeting, if needed, would be to discuss strategies to update the current policies, and then to discuss the process for incorporating those changes. We believe that these meetings would take approximately 2 hours each. We estimate that the physician would have a limited amount of time, approximately 1 hour to devote to the QAPI activities. Additionally, we estimate these activities would require 4 hours of an administrator's time, 4 hours of a mid-level practitioner's time, 8 hours of a nurse's time, and 2 hours of a clerical staff person's time for a total of 19 burden hours. We believe that the REH's QAPI leadership would need to meet periodically to review and discuss the changes that would need to be made to their program. We also believe that a nurse would likely spend more time developing the program with the mid-level practitioner. The physician would likely review and approve the program. The clerical staff member would probably assist with the program's development and ensure that the program was disseminated to all of the necessary parties in the REH.

Based on these factors, we estimate that for each REH to comply with the requirements in this section it would require annually 19 burden hours (1 hour for a physician + 4 hours for an administrator + 4 hours for a mid-level practitioner + 8 hours for a nurse + 2 hours for a clerical staff person) at a cost of $1,810 ($210 for a physician (1 hour x $210) + $488 for an administrator (4 hours x $122) + $404 for a mid-level practitioner (4 hours x $101) + $632 for a nurse (8 hours x $79) + $76 for a clerical staff person (2 hours x $38)). Therefore, for all 68 REHs to comply with these requirements, it would require 1,292 burden hours (19 hours x 68 REHs) at a cost of approximately $123,080 ($1,810 x 68 REHs).

h. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.542)

Section 485.542 sets forth the emergency preparedness requirements for REHs. We note that these emergency preparedness standards are consistent national parameters that all Medicare and Medicaid participating providers and suppliers must meet. This includes both rural hospitals and CAHs and therefore facility that converts to an REH would have already incurred the costs to develop and implement their emergency preparedness plan. Based on this, the burden associated with these requirements would be the on-going costs to review, maintain and implement the emergency preparedness program to ensure ongoing compliance with the requirements and as such we have developed this COI section based largely on the existing COI burden for CAHs and hospitals.

i. Standard: Risk Assessment and Planning (§ 485.542(a))

We proposed to require REHs to develop and maintain an emergency preparedness plan that must be reviewed and updated at least biennially. We expect that each REH facilities director ($104 per hour) would conduct a thorough risk assessment that will consider its location and geographical area; patient population, including those with special needs; and the type of

services they have the ability to provide in an emergency (12 hours biennially or 6 hours annually) based on the services that they are now providing as an REH. They each would also need to review the measures needed to ensure continuity of its operation, including delegations and succession plans. We estimate that ongoing compliance with this requirement would require 6 burden hours annually (12 biennially) from the REH facilities director. Therefore, for all 68 REHs to comply with this requirement, it would require 408 burden hours (6 x 68 REHs) at a cost of approximately $42,432 (408 hours x $104).

(1) Standard: Policies and procedures (§ 485.542(b))

REHs are required to maintain emergency preparedness policies and procedures in accordance with their emergency plan, risk assessment, and communication plan. Each needs to review their emergency preparedness policies and procedures and revise, or in some cases, develop new policies and procedures that would ensure that the emergency preparedness plans address the specific requirements of the regulations.

We believe that the requirement for REHs to review and update their policies and procedures annually constitutes a usual and customary business practice and is not subject to the PRA in accordance with 5 CFR 1320.3(b)(2). However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

(2) Standard: Communication plan (§ 485.542(c))

REHs are required to develop and maintain an emergency preparedness communication plan that complies with both federal and state law and must be reviewed and updated at least annually. The burden associated with this requirement would be the time and effort necessary to review, revise, and if necessary, develop a new communications plan to ensure that it complies

with the requirements of this regulation. However, we believe that most REHs have some type of emergency preparedness communication plan based on their prior status as a CAH or rural hospital. It is standard practice in the health care industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients.

If any revisions or additions are necessary to satisfy the requirements as an REH, we expect the revisions or additions would be those incurred during the course of normal business and thereby impose no additional burden. Thus, the ICRs related to the communication plan would constitute a usual and customary business practice as stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2) and we did not include this activity in the burden analysis. We are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

(3) Standard: Training and testing (§ 485.542(d))

REHs are required to develop and maintain an emergency preparedness training and testing program. The training program must include initial training in emergency preparedness policies and procedures for all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles and must be documented. The testing program must include participation in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If an actual natural or man-made emergency that requires activation of the emergency plan is experienced, then this requirement is exempt for 1 year following the onset of the actual event. In addition,

the testing program must include one additional testing exercise, which may be determined by the REH. The training must be provided biennially and two testing exercises must be conducted annually.

We expect that all REHs will review their current training programs in their current capacity as hospitals or CAHs, and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. The CAHs will need to revise and, if necessary, develop new sections or materials to ensure their training and testing programs complied with our requirements. We anticipate that ongoing compliance with this requirement will require the involvement of an administrator, the mid-level practitioner, the facilities director, and clerical staff. We expect that a mid-level practitioner will perform the initial review of the training program (4 hours), brief the administrator and the director of facilities (2 hours), and clerical staff to revise or develop new sections for the training program (1 hour), based on the group's decisions, if necessary. This will result in a cost of $894 ($404 for a mid-level practitioner (4 hours x $101) + $244 for an administrator (2 hours x $122) + $208 for a director of facilities (2 hours x $104) + $38 for a clerical staff person (1 hour x $38)) for each REH. Therefore, for all REHs to comply with this requirement it will require an estimated 476 burden hours (7 hours x 68 REHs) at a cost of $60,792 ($894 x 68 REHs).

j. ICRs Regarding Conditions of Participation: Physical environment (§ 485.544)

(1) Standard: Life Safety Code (§ 485.544)

The REH must meet the applicable provisions of the 2012 edition of the Life Safety Code (LSC) of the National Fire Protection Association. If CMS finds that the state has a fire and safety code imposed by the state law that adequately protects patients, CMS may allow the state

survey agency to apply the state's fire and safety code instead of the LSC if waiving the provisions of the LSC does not adversely affect the health and safety of patients. This regulation requires a REH to maintain written evidence of regular inspections and approval by state fire control agencies. We estimate that the burden associated with maintaining written evidence of state inspections and approval would be an average of 30 minutes for clerical personnel to file the documentation, for a total of 34 burden hours (0.5 hours x 68 REHs) and a cost of $1,292 (34 hours x $38). The burden will be accounted for in a new information collection request (request for a new OMB control number) submitted for OMB approval.

Table 108 that follows summarizes our estimates of burden hours and costs for REHs. We emphasize that these estimates assume 68 conversions and that the number actually converting could be a fraction of this figure, or much higher, which as discussed earlier is an uncertainty addressed in both the NC RHRP and CLA study that estimated likely conversions. Our estimates of the cost per entity, however, would not be affected by the number of conversions.

TABLE 108: Total COI Burden for Rural Emergency Hospitals

COI Requirement	Burden Hours	Costs
Condition of Participation: Provision of Services (§ 485.514)	5,984	$658,648
Condition of Participation: Infection prevention and control and antibiotic stewardship programs (§ 485.526)	5,304	$419,016
Condition of Participation: Staffing and Staff Responsibilities (§ 485.528)	170	$22,400
Standard: Notice of Rights: (§ 485.534(a)(1) and (2))	4,981	$188,632
Standard: Restraint and Seclusion (§485.534(e))	0	$0

COI Requirement	Burden Hours	Costs
Standard: Restraint and seclusion: Staff training requirements (§ 485.534(f))	0	$0
Standard: Death reporting requirements (§ 485.534(g))	0.83 hours	$101.67
Standard: Patient visitation rights (§ 485.534(h))	17	$646
Condition of participation: Agreements (Proposed § 485.538)	272	$21,760
Condition of Participation: Quality assessment and performance improvement program (QAPI) (Proposed § 485.536)	1292	$123,080
Standard: Risk Assessment and Planning (§485.542(a))	408	$42,432
Standard: Training and testing (§485.542(d))	476	$60,792
Standard: Life Safety Code (§ 485.544)	34	$1,292
TOTALS	18,939	$1,538,800

A summary of the provisions that have been incorporated by reference for these requirements can be found in section XVIII.B(1)(a)(21) and XVIII.B(1)(a)(22) of this rule.

4. Critical Access Hospitals

a. ICRs Regarding Condition of Participation: Patient's Rights (§ 485.614)

(1) Standard: Notice of Rights: § 485.614(a)(1) and (2)

Section 485.614(a) proposed to require CAHs to notify the patient of their rights and of whom to contact to file a grievance. We allow REHs the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance

processes, but have not delineated strategies and policies for implementing this system. We believe that in large measure, CAHs would be able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not serve the very purpose intended by the regulation. Costs associated with formalizing a process and modifying any existing notices or processes will most likely be offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We proposed that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented are estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in CAHs each year; however, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to modify any existing notices to include the grievance process requirements. We believe that an office assistant may be tasked with drafting or updating the notices and distributing or posting, as appropriate, the information. We estimate that this would require no more than two hours of the

clerical staff time. The burden hours are 2,720 (2 hours x 1,360). Based on this we estimate that this will create a one-time cost of $103,360 (2,720 hours x $38). In addition, we estimate that it will require the office assistant 2 minutes (.0333 hours) to provide the notice per CAH patient on an annual basis. The number of notices required will depend on the number of patients received at the CAH. Therefore, the per facility burden associated with providing the notice will vary based on the unique factors of the CAH. According to a 2013 OIG report, there were approximately 1,753 patient visits per CAH in 2011.[358] Based on this estimate, the burden hours would be 58 hours (.0333 hours x 1,753 notices). The total burden hours would be 78,880 hours (58 hours x 1,360 CAHs). Therefore, we estimate that the CAH would have had to inform each of these patient of their rights at a cost of $2,997,440 ($38 x 78,880 hours).

In its resolution of a grievance, a CAH must provide the patient with written notice of its decision that contains the name of the CAH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each REH 15 minutes to develop and disseminate the required notice and estimate that a CAH may have to provide 50 notices on an annual basis. The burden hours for each CAH will be 12.5 (0.25 hour x 50 notices) for a total of 17,000 burden hours (12.5 hours x 1,360 CAHs). The total annual burden cost is $646,000 ($38 x 17,000).

[358] https://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf

Therefore, the total burden hours are 98,600 (78,880 + 17,000 + 2,720) and the total cost associated with this requirement is $3,746,800 ($103,360 to update notices, $2,997,440 to provide the notices, and $646,000 to provide the results of a grievance investigation).

(2) Standard: Confidentiality of Patient Records (§ 485.614(d)).

Section 485.614(d), which sets forth the patient's right to access information in their records, will involve minimal burden as many states' existing laws cover this point. We did not propose to require disclosure of all records, inasmuch as we recognize that there are situations where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the CAH can charge. In the absence of state law, the REH should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (3) because this requirement is considered standard industry practice and/or is required under state or local law.

(3) Standard: Restraint and Seclusion (§ 485.614 (e))

Section 485.614(e) requires that each CAH have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. While the requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary state practices and the state would impose

this standard for efficient utilization of Medicare and Medicaid services in the absence of a federal requirement. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden.

(4) Standard: Restraint and seclusion: Staff training requirements (§ 485.614(f))

Section 485.614(f) requires facilities to establish staff training requirements for the use of restraints and seclusion. The CAH must provide competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion. While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden.

(5) Standard: Death reporting requirements (§ 485.614(g)).

Section 485.614(g) requires the facility to report the death of a resident associated with seclusion or restraint to the CMS regional office. A report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

We estimate it will take 5 minutes to report each death to the CMS regional office and to document that report. We estimate fewer than 10 deaths annually for all 1,360 facilities. Five (5) minutes x 10 deaths annually would equate to a national burden of 50 minutes per year. The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of a death a documenting the report is $122/hour. Multiplying the total

burden of 0.83 hours by the hourly wage yields an associated cost of about $101.26.

Table 109 below lists the total COI burden for CAHs for the patient's rights standards.

TABLE 109: Total COI Burden for Critical Access Hospitals

COI Requirement	Burden Hours	Costs
Standard: Notice of Rights: § 485.614(a)(1) and (2)	98,600	$3,746,800
Standard: Restraint and Seclusion (§ 485.614 (e))	0	$0
Standard: Restraint and seclusion: Staff training requirements (§ 485.614(f))	0	$0
Standard: Death reporting requirements (§ 485.614(g))	0.83 hours	$101
TOTALS	98,601	$3,746,901

The burden for the proposed CAH provisions will be accounted for under OMB control number 0938-1043.

XXIV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We consider all comments we received by the date and time specified in the "DATES" section of this preamble and responded to the comments in the preamble of this final rule with comment period.

XXV. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2023. We are required under

section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2021, through and including December 31, 2021, and processed through June 30, 2022, and June 2020 HCRIS information with cost reporting periods prior to the PHE, consistent with our final policy of using data prior to the start of the PHE.

This final rule with comment period also is necessary to make updates to the ASC payment rates for CY 2023, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2023. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI-U for CY 2019 through 2023. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI-U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

In this final rule with comment period, we received comments on the Request for Information included in the CY 2023 OPPS/ASC proposed rule on possible alternative methodologies for counting organs for transplant hospitals and organ procurement organizations to calculate Medicare's share of organ acquisition costs. We will consider those comments in developing possible future rulemaking or other guidance.

Additionally, we are finalizing our proposal to exclude research organs from total usable organs used in the ratio to calculate Medicare's share of organ acquisition costs, and finalizing with modification our proposal to require an offset of costs for research organs, to provide more flexibility in how THs and OPOs remove or reduce costs associated with research organs. We are unable to estimate the extent to which the final research organ policy may impact the costs to Medicare. We are also finalizing our proposal to clarify that certain costs incurred prior to declaration of death, but when death is imminent, are included as organ acquisition costs; we do not anticipate any significant impact from this final policy. Therefore, there is no impact from the organ acquisition proposals in this final rule with comment period.

B. Overall Impact of Provisions of this Final Rule with Comment Period

We have examined the impacts of this final rule with comment period, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). This section of this final rule with comment

period contains the impact and other economic analyses for the provisions we are finalizing for CY 2023.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact

analysis that, to the best of our ability, presents the costs and benefits of the provisions of this final rule with comment period. We solicited public comments on the regulatory impact analysis in the CY 2023 OPPS/ASC proposed rule, and we address any public comments we received in this final rule with comment period, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2023, compared to CY 2022, due to the changes to the OPPS in this final rule with comment period, will be approximately $2.53 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2023, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2023 will be approximately $86.5 billion, which is approximately $6.5 billion higher than estimated OPPS expenditures in CY 2022. Because the provisions of the OPPS are part of a final rule with comment period that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 110 of this final rule with comment period displays the distributional impact of the CY 2023 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our final CY 2023 policy, drugs and biologicals that are acquired under the 340B Program will generally be paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. The impacts on hospital rates as a result of this final policy are reflected in the discussion of the estimated effects of this final rule with comment period. Because we are reverting to our previous policy of generally paying ASP plus 6 percent for drugs acquired under the 340B program, we are removing the increase to the OPPS conversion factor that was adopted as part of the budget neutral implementation of the 340B policy, consistent with

our longstanding policy of offsetting increases or decreases in particular payments through an adjustment to the OPPS conversion factor.

We estimate that the final update to the conversion factor and other budget neutrality adjustments will increase total OPPS payments by 4.8 percent in CY 2023. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2022 and CY 2023, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, the exception for rural sole community hospitals from the clinic visit policy when provided at off-campus provider based departments, and the payment adjustment for the additional resource costs for domestic NIOSH-approved surgical N95 respirators will increase total estimated OPPS payments by 4.5 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2023 compared to CY 2022, to be approximately $230 million. Tables 111 and 112 of this final rule with comment period display the redistributive impact of the CY 2023 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in this Final Rule with Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the final CY 2023 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2023 on the CMS website with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. On the website, select "Regulations and Notices" from the left side of the page and then select "CMS-1772-FC" from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 110 of this final rule with comment period. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Payment Policy for Drugs and Biologicals Obtained under the 340B Program

In section V.B of this final rule with comment period, we discuss our final policy to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. In this final rule with comment period for CY 2023, for hospitals paid under the OPPS, payment for separately payable drugs and biologicals that are obtained with a 340B discount will generally be ASP plus 6 percent. Additionally, we are decreasing the OPPS conversion factor by the same percentage that we increased the OPPS conversion factor in CY 2018 to implement the 340B policy in a budget neutral manner. After applying this payment methodology for drugs and biologicals purchased under the 340B Program, we currently estimate that we would apply a budget neutrality adjustment of 0.9691 to the OPPS conversion factor to remove the original CY 2018 OPPS budget neutrality adjustment for 340B acquired drugs. More information on the comments received on the 340B policy can be found in section V.B.6 of this final rule with comment period.

c. Effects of the IPPS and OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators

As discussed in section X.H of the preamble of this final rule with comment period, we are finalizing IPPS and OPPS payment adjustments for the additional resource costs that hospitals incur in procuring domestic NIOSH-approved surgical N95 respirators. The payment adjustments will commence for cost reporting periods beginning on or after January 1, 2023.

For the IPPS, we are making this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1886(d)(5)(I) of the Act. To

further support the strategic policy goal of sustaining a level of supply resilience for domestic NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency, we are not making the IPPS payment adjustment budget neutral under the IPPS. The data currently available to calculate a spending estimate for CY 2023 under the IPPS is limited. However, we believe the methodology described next to calculate this spending estimate under the IPPS for CY 2023 is reasonable based on the information available.

To calculate the estimated total spending associated with this policy under the IPPS we multiplied together estimates of the following:

1) Estimate of the total number of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023.

2) Estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators

3) Estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023 that are domestic.

For purposes of this estimate, we believe it is reasonable to assume that on average approximately one NIOSH-approved surgical N95 respirator is used for every day a beneficiary is in the hospital. The FY 2021 MedPAR claims data used for ratesetting in the FY 2023 IPPS/LTCH final rule accounted for approximately 7.3 million IPPS discharges and 38.4 million Medicare covered days. Therefore, for CY 2023, we are estimating that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of IPPS patients will be 38.4 million. Based on available data, our best estimate of the

difference in the average unit costs of domestic and non-domestic NIOSH-approved surgical N95 respirators is $0.20.

It is particularly challenging to estimate the percentage of NIOSH-approved surgical N95 respirators that will be used in the treatment of IPPS patients in CY 2023 that will be domestic. The OMB's Made in America Office recently conducted a data call on capacity in which several entities attested to being able to supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand. We recognize that it may take time for this capacity to be fully reflected in hospital purchases. Therefore, although this would be sufficient capacity to supply the entire hospital industry if it were to be available and focused on this segment of the marketplace in 2023, we believe it is reasonable to assume that this will not happen instantaneously and hospitals in aggregate may in fact be able to purchase less than half of their NIOSH-approved surgical N95 respirators as domestic in 2023. Therefore, for purposes of this IPPS spending estimate, we set the percentage of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023 that are domestic to 40 percent, or slightly less than half. We estimate that total CY 2023 IPPS payments associated with this policy will be $3.1 million (or 38.4 million covered days * $0.20 * 40 percent).

For the OPPS, we are making this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. Consistent with this authority, the final OPPS payment adjustment will be budget neutral. In section X.H of the preamble of this final rule with comment period, we estimate that total CY 2023 OPPS payments associated with

this policy will be $8.7 million. This represents approximately 0.01 percent of the OPPS, which we are budget neutralizing through an adjustment to the OPPS conversion factor.

d. Estimated Effects of OPPS Changes on Hospitals

Table 110 shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 110, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2023, we are continuing to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B of this final rule with comment period.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket

percentage increase applicable to the OPD fee schedule for CY 2023 is 4.1 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 4.1 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.3 percentage point for CY 2023 (which is also the productivity adjustment for FY 2023 in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49056)), resulting in the CY 2023 OPD fee schedule increase factor of 3.8 percent. We are using the OPD fee schedule increase factor of 3.8 percent in the calculation of the CY 2023 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 110 of this final rule with comment period.

To illustrate the impact of the CY 2023 changes, our analysis begins with a baseline simulation model that uses the CY 2022 relative payment weights, the FY 2022 final IPPS wage indexes that include reclassifications, and the final CY 2022 conversion factor. Table 110 shows the estimated redistribution of the increase or decrease in payments for CY 2023 over CY 2022 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2022 and CY 2023 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 3.8 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated differential impact of the rural SCH exception to the Off Campus Provider Based Department Visits Policy (Column 5); the estimated impact taking into account all payments for CY 2023 relative to all payments for CY 2022, including the impact of changes in estimated outlier payments, changes to the pass-through payment estimate,

the change to except rural sole community hospitals from the clinic visit policy when provided at campus provider based departments, and the payment adjustment for the additional resource costs to hospitals of acquiring domestic NIOSH-approved surgical N95 respirators (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2023. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2023 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2022 and CY 2023 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2023 will increase Medicare OPPS payments by an estimated 4.5 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 4.7 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 110 shows the total number of facilities (3,508), including designated cancer and children's hospitals and CMHCs, for which we were able to use

CY 2021 hospital outpatient and CMHC claims data to model CY 2022 and CY 2023 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2022 or CY 2023 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,414), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 27 CMHCs at the bottom of the impact table (Table 110) and discuss that impact separately below.

Column 2: APC Recalibration – All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience a 0.1 increase, with the impact ranging from a decrease of 0.2 percent to an increase of 0.5, depending on the number of beds. Rural hospitals

will experience an estimated decrease of 0.1 overall. Major teaching hospitals will experience an estimated decrease of 0.3 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2023 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2022 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2023 changes in wage index policy, discussed in section II.C of this final rule with comment period. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2023, as described in section II.E of this final rule with comment period. We also did not model a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2023 is 0.89, the same as the ratio that was reported for the CY 2022 OPPS/ASC final rule with comment period (85 FR 85914). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2023 scaled weights and a CY 2022 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2022 and CY 2023.

Column 4: Removal of 340b Drug Payment Policy

Column 4 demonstrates the impact of paying for 340B-acquired drugs at ASP+6 percent and removing the 3.19 percent increase to the conversion factor that was made in CY 2018 to implement the 340B policy in a budget neutral manner.

Column 5: All Budget Neutrality Changes Combined with the Market Basket Update

Column 5 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 3.8 percent. Overall, these changes will increase payments to urban hospitals by 5.3 percent and to rural hospitals by 2.7 percent. Sole community hospitals receive an estimated increase of 1.7 percent while other rural hospitals receive an estimated increase of 4.3 percent.

Column 6: Rural SCH Exception to Off-Campus PBD Clinic Visit Payment Policy

Column 6 displays the estimated effect of the exception for rural sole community hospitals to the volume control method to pay for clinic visit HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier "PO" by an excepted off-campus PBD at 40 percent of the OPPS rate for a clinic visit service for CY 2023. This exception is estimated to increase payments to rural sole community hospitals by 1.1 percent.

Column 7: All Changes for CY 2023

Column 7 depicts the full impact of the final CY 2023 policies on each hospital group by including the effect of all changes for CY 2023 and comparing them to all estimated payments in CY 2021. Column 7 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV of this final rule with comment period); the change to except rural sole community hospitals from the clinic visit policy when provided at excepted off-campus provider-based departments, and the adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2022 update (and assumed, for modeling purposes, to be the same number for CY 2023), we included 20 hospitals in our model because they had both CY 2021 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2023 will increase payments to all facilities by 4.5 percent for CY 2022. We modeled the independent effect of all changes in Column 7 using the final relative payment weights for CY 2022 and the final relative payment weights for CY 2023. We used the final conversion factor for CY 2023 of $85.585 and the final CY 2022 conversion factor of $84.177 discussed in section II.B of this final rule with comment period. While the calculation to determine the conversion factor includes the differences between the amounts carved out for pass-through payment in CYs 2022 and 2023, as this change is implemented in a budget neutral manner, we have excluded it from

the impact calculations displayed in Table 110 below because it has no estimated overall effect on OPPS total payments.

Column 7 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49427) of 6.4 percent (1.06404) to increase charges on the CY 2021 claims, and we used the overall CCR in the July 2022 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2022. Using the CY 2021 claims and a 6.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2022, using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,175, will be approximately 1.26 percent of total payments. The estimated current outlier payments of 1.26 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 13.2 percent (1.13218) and the CCRs in the July 2022 OPSF, with an adjustment of 0.974495 (87 FR 49427), to reflect relative changes in cost and charge inflation between CY 2021 and CY 2023, to model the final CY 2023 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $8,625. The charge inflation and CCR inflation factors are discussed in detail in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49422 through 49429).

Overall, we estimate that facilities will experience an increase of 4.5 percent under this final rule in CY 2023 relative to total spending in CY 2022. This projected increase (shown in Column 7) of Table 110 of this final rule with comment period reflects the 3.8 percent OPD fee schedule increase factor, the change to except rural sole community hospitals from the clinic visit policy when provided at excepted off-campus provider-based departments, and the adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators, minus the difference in estimated outlier payments between CY 2022 (1.26

percent) and CY 2023 (1.0 percent). We estimate that the combined effect of all changes for CY 2023 will increase payments to urban hospitals by 4.9 percent. Overall, we estimate that rural hospitals will experience a 2.9 percent increase as a result of the combined effects of all the changes for CY 2023.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 6.8 percent for major teaching hospitals and an increase of 3.1 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 4.2 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 4.9 percent, proprietary hospitals will experience an increase of 1.3 percent, and governmental hospitals will experience an increase of 5.9 percent.

TABLE 110: ESTIMATED IMPACT OF THE CY 2023 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**Removal of 340b Drug Payment Policy**	**All Budget Neutral Changes (combined cols 2, 3, and 4) with Market Basket Update**	**Rural SCH Exception to Off Campus Provider Based Department Visits Policy**	**All Changes**
ALL PROVIDERS *		3,508	0.0	0.1	0.8	4.8	0.1	4.5
ALL HOSPITALS		3,414	0.0	0.2	0.9	5.0	0.1	4.7
	(excludes hospitals held harmless and CMHCs)							
URBAN HOSPITALS		2,707	0.1	0.2	1.2	5.3	0.0	4.9
	LARGE URBAN	1,388	0.1	0.1	1.3	5.4	0.0	5.0
	(GT 1 MILL.)							
	OTHER URBAN	1,319	0.0	0.3	1.0	5.2	0.1	4.8
	(LE 1 MILL.)							
RURAL HOSPITALS		707	-0.1	0.0	-1.0	2.7	0.7	2.9
	SOLE COMMUNITY	375	-0.2	0.0	-1.8	1.7	1.1	2.3
	OTHER RURAL	332	0.0	-0.1	0.6	4.3	0.0	4.0
BEDS (URBAN)								
	0 - 99 BEDS	907	0.5	0.1	-1.3	3.1	0.0	2.7
	100-199 BEDS	764	0.3	0.2	-0.6	3.7	0.0	3.4
	200-299 BEDS	417	0.1	0.2	0.2	4.4	0.1	4.0
	300-499 BEDS	391	0.1	0.2	1.0	5.1	0.0	4.6
	500 + BEDS	228	-0.2	0.2	3.4	7.3	0.0	6.9
BEDS (RURAL)								
	0 - 49 BEDS	327	0.2	0.0	-1.3	2.5	0.2	2.3
	50- 100 BEDS	222	-0.1	0.3	-1.3	2.6	0.6	2.5
	101- 149 BEDS	81	-0.2	0.1	-0.3	3.3	0.8	3.6
	150- 199 BEDS	40	-0.2	-0.6	-0.4	2.6	1.3	3.9
	200 + BEDS	37	-0.4	-0.2	-0.9	2.3	0.9	2.8

REGION (URBAN)								
	NEW ENGLAND	129	-0.1	0.0	1.2	5.0	0.0	4.9
	MIDDLE ATLANTIC	314	-0.1	-0.1	1.5	5.2	0.0	4.8
	SOUTH ATLANTIC	451	0.2	-0.1	1.1	5.1	0.0	4.8
	EAST NORTH CENT.	420	-0.1	-0.1	1.2	4.9	0.0	4.7
	EAST SOUTH CENT.	161	0.2	-0.2	2.3	6.2	0.0	5.9
	WEST NORTH CENT.	182	-0.1	1.2	1.4	6.3	0.1	5.2
	WEST SOUTH CENT.	446	0.2	0.1	0.1	4.1	0.0	3.9
	MOUNTAIN	202	0.4	1.3	0.6	6.2	0.1	5.6
	PACIFIC	354	0.2	0.2	1.3	5.6	0.0	5.1
	PUERTO RICO	48	1.1	-0.2	-2.6	2.0	0.0	2.0
REGION (RURAL)								
	NEW ENGLAND	19	-0.4	-0.7	-1.3	1.3	1.9	2.9
	MIDDLE ATLANTIC	47	-0.2	-0.4	-0.7	2.4	1.7	4.1
	SOUTH ATLANTIC	107	0.0	0.0	-0.4	3.4	0.1	3.4
	EAST NORTH CENT.	112	-0.2	-0.4	-1.2	2.0	0.3	2.1
	EAST SOUTH CENT.	136	0.0	-0.2	0.5	4.1	0.4	4.4
	WEST NORTH CENT.	86	-0.3	0.7	-2.2	1.9	1.1	1.7
	WEST SOUTH CENT.	132	0.3	-0.5	-2.0	1.5	0.6	2.0
	MOUNTAIN	45	0.1	2.1	-0.9	5.0	0.3	3.1
	PACIFIC	23	-0.2	-0.7	0.1	3.0	0.9	3.6
TEACHING STATUS								
	NON-TEACHING	2,180	0.3	0.1	-0.8	3.4	0.1	3.1
	MINOR	825	0.1	0.1	0.5	4.6	0.1	4.2
	MAJOR	409	-0.3	0.2	3.3	7.2	0.1	6.8
DSH PATIENT PERCENT								
	0	3	0.8	-0.4	-3.1	1.0	0.0	0.8
	GT 0 - 0.10	224	0.5	0.5	-2.6	2.1	0.0	1.7
	0.10 - 0.16	240	0.3	0.1	-2.5	1.6	0.0	1.1
	0.16 - 0.23	562	0.2	0.0	-2.5	1.5	0.1	1.3
	0.23 - 0.35	1,107	0.0	0.2	1.1	5.1	0.2	4.8
	GE 0.35	864	-0.1	0.1	3.9	8.0	0.1	7.6
	DSH NOT AVAILABLE **	414	-1.1	0.1	-2.6	0.1	0.0	-0.4
URBAN TEACHING/ DSH								

	TEACHING & DSH	1,092	-0.1	0.2	2.0	6.0	0.0	5.6
	NO TEACHING/DSH	1,198	0.4	0.1	-0.7	3.6	0.0	3.3
	NO TEACHING/NO DSH	3	0.8	-0.4	-3.1	1.0	0.0	0.8
	DSH NOT AVAILABLE2	414	-1.1	0.1	-2.6	0.1	0.0	-0.4
TYPE OF OWNERSHIP								
	VOLUNTARY	1,935	0.0	0.1	1.2	5.2	0.1	4.9
	PROPRIETARY	1,042	0.5	0.1	-2.7	1.6	0.0	1.3
	GOVERNMENT	437	-0.1	0.3	2.2	6.3	0.0	5.9
CMHCs		27	-9.1	0.0	-3.1	-8.6	0.0	0.0

	Column (1) shows total hospitals and/or CMHCs.
	Column (2) includes all final CY 2023 OPPS policies and compares those to the CY 2022 OPPS.
	Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2023 hospital inpatient wage index. The final rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the final CY 2023 target payment-to-cost ratio is the same as the CY 2022 PCR target (0.89)
	Column (4) shows the impact of paying for 340B-acquired drugs at ASP+6 percent and making the adjustment to remove the 3.19 percent CY 2018 OPPS budget neutrality adjustment from payment for non-drug services.
	Column (5) shows the impact of all budget neutrality adjustments and the addition of the 3.8 percent OPD fee schedule update factor (4.1 percent reduced by 0.3 percentage points for the productivity adjustment).
	Column (6) shows the differential impact of the proposed exception for rural sole community hospitals from the clinic visits policy when furnished at off campus provider based departments.
	Column (7) shows the additional adjustments to the conversion factor, including the change to except rural sole community hospitals from the clinic visit policy when provided at excepted off campus provider-based departments and estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.
	These 3,508 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
	** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

e. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 110 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2022, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2021 claims used for ratesetting in the final rule. We excluded days with one or two services because our policy only pays a per diem rate for partial hospitalization when three or more qualifying services are provided to the beneficiary. We note that under our final policy, in order to pay appropriately and protect access to PHP services in CMHCs, for CY 2023 but not for subsequent years, we are applying an equitable adjustment, under the authority set forth in section 1833(t)(2)(E) of the Act, to the CY 2023 CMHC APC payment rate by maintaining the CY 2022 CMHC APC payment rate. As a result, we estimate that CMHCs will experience no change in CY 2023 payments relative to their CY 2022 payments.(shown in Column 7). For a detailed discussion of our final PHP policies, please see section VIII of this final rule with comment period.

Column 3 shows the estimated impact of adopting the final FY 2023 wage index values which result in an increase of 0.0 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the final changes in APC policy for CY 2023 and the final FY 2023 wage index updates, will result in an estimated decrease of – 3.1 percent. Column 7 reflects no change, per our final policy to maintain the CY 2022 CMHC APC payment rates in CY 2023.

f. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will

rise and will decrease for services for which the OPPS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18.1 percent for all services paid under the OPPS in CY 2023. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the Final CY 2023 comprehensive APC payment policy discussed in section II.A.2.b of this final rule with comment period. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

g. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of this final rule with comment period. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the changes in this final rule with comment period.

h. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $2.53 billion in program payments for OPPS services furnished in CY 2023. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this final rule

with comment period will increase these Medicaid beneficiary payments by approximately $150 million in CY 2023. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately 30 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $150 million Medicaid increase, approximately $85 million will be from the Federal Government and $65 million will be from State governments.

i. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

- Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.B of this final rule with comment period for a discussion of our final policy of using cost report data prior to the PHE. We note, in that section we discuss the alternative proposal we considered regarding applying the standard ratesetting process, in particular the selection of cost report data used, which would include claims and cost report data including the timeframe of the PHE. We note that there are potential issues related to that data, including the effect of the PHE on the provider departmental CCRs that would be used to estimate cost. In this final rule with comment period, as discussed in section X.D, we are finalizing a policy of using updated CY 2021 claims data in CY 2023 OPPS ratesetting, while using cost report CCRs with reporting periods prior to the PHE.

We note that these policy considerations also have ASC implications since the relative

weights for certain surgical procedures performed in the ASC setting are developed based on the OPPS relative weights and claims data.

2. Estimated Effects of CY 2023 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII of this final rule with comment period, we are setting the CY 2023 ASC relative payment weights by scaling the final CY 2023 OPPS relative payment weights by the final ASC scalar of 0.8594. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 111 and 112.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket update for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2023 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which would be the hospital market basket update for CY 2023. We calculated the CY 2023 ASC conversion factor by adjusting the CY 2022 ASC conversion factor by 1.0008 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2022 and CY 2023 and by applying the CY 2023 productivity-adjusted hospital market basket update factor of 3.8 percent (which is equal to the projected

hospital market basket update of 4.1 percent reduced by a productivity adjustment of 0.3 percentage point). The CY 2023 ASC conversion factor is $51.854 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the final changes for CY 2023 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2021 and CY 2023 with precision. We believe the net effect on Medicare expenditures resulting from the final CY 2023 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the final update to the CY 2023 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the final CY 2023 updates to the ASC payment system on Medicare payments to

ASCs, assuming the same mix of services, as reflected in our CY 2021 claims data. Table 111 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2022 payments to estimated CY 2023 payments, and Table 112 shows a comparison of estimated CY 2022 payments to estimated CY 2023 payments for procedures that we estimate would receive the most Medicare payment in CY 2022.

In Table 111, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 111.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

- Column 2—Estimated CY 2022 ASC Payments were calculated using CY 2021 ASC utilization data (the most recent full year of ASC utilization) and CY 2022 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2022 ASC payments.

- Column 3—Estimated CY 2023 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items

and services group that is attributable to proposed updates to ASC payment rates for CY 2023 compared to CY 2022.

As shown in Table 111, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the final update to ASC payment rates for CY 2023 will result in a 3 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 4 percent increase in aggregate payment amounts for nervous system procedures, 7 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 5 percent increase in aggregate payment amounts for digestive system procedures, a 2 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 4 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 3.8 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 3.8 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 7 percent increase in aggregate musculoskeletal procedure payments. The increase in payment rates for musculoskeletal procedures as a result of increased OPPS relative weights and device portions is further increased by the 3.8 percent ASC rate update for these procedures. Conversely, we estimate only a 3 percent increase in aggregate eye and ocular adnexa procedures related to a decrease in OPPS relative weights partially offsetting the 3.8 percent ASC rate

update. For estimated changes for selected procedures, we refer readers to Table 111 provided later in this section.

TABLE 111: ESTIMATED IMPACT OF THE CY 2023 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2022 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2022 ASC Payments (in Millions) (2)	Estimated CY 2023 Percent Change (3)
Total	$5,859	4
Eye	$1,789	3
Nervous System	$1,200	4
Musculoskeletal	$999	7
Gastrointestinal	$896	5
Cardiovascular	$287	2
Genitourinary	$215	4

Table 111 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2023. The table displays 30 of the procedures receiving the greatest estimated CY 2022 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2022 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2022 ASC Payments were calculated using CY 2021 ASC utilization (the most recent full year of ASC utilization) and the CY 2022 ASC payment rates. The estimated CY 2022 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2023 Percent Change reflects the percent differences between the estimated ASC payment for CY 2022 and the estimated payment for CY 2023 based on the final update.

TABLE 112: ESTIMATED IMPACT OF THE FINAL CY 2023 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2022 ASC Payment (in millions) (3)	Estimated CY 2023 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,196	4
63685	Insrt/redo spine n generator	$300	1
45380	Colonoscopy and biopsy	$235	5
45385	Colonoscopy w/lesion removal	$191	5
27447	Total knee arthroplasty	$182	4
63650	Implant neuroelectrodes	$174	8
43239	Egd biopsy single/multiple	$160	3
64483	Njx aa&/strd tfrm epi l/s 1	$106	4
66991	Xcapsl ctrc rmvl insj 1+	$98	1
64590	Insrt/redo pn/gastr stimul	$95	5
66982	Xcapsl ctrc rmvl cplx wo ecp	$91	4
27130	Total hip arthroplasty	$81	5
64635	Destroy lumb/sac facet jnt	$77	4
29827	Sho arthrs srg rt8tr cuf rpr	$72	5
J1097	Phenylep ketorolac opth soln	$71	-6
64493	Inj paravert f jnt l/s 1 lev	$66	4
36902	Intro cath dialysis circuit	$65	6
G0105	Colorectal scrn; hi risk ind	$60	5
66821	After cataract laser surgery	$60	6
C9740	Cysto impl 4 or more	$51	0
62323	Njx interlaminar lmbr/sac	$45	2
22869	Insj stablj dev w/o dcmprn	$43	5
27279	Arthrodesis sacroiliac joint	$42	27
45378	Diagnostic colonoscopy	$37	5
G0121	Colon ca scrn not hi rsk ind	$36	5
64561	Implant neuroelectrodes	$35	7
15823	Revision of upper eyelid	$35	1
64721	Carpal tunnel surgery	$34	3
65820	Relieve inner eye pressure	$32	3
J1096	Dexametha opth insert 0.1 mg	$32	-2

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2023 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures to be designated as office-based for CY 2023. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with

procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we proposed to designate as office-based in CY 2023, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPPS and ASC Payment System

As required by OMB Circular A-4 (available on the Office of Management and Budget website at: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this final rule with comment period. The first accounting statement, Table 113, illustrates the classification of expenditures for the CY 2023 estimated hospital OPPS incurred benefit impacts associated with the final CY 2023 OPD fee schedule increase. The second accounting statement, Table 114, illustrates the classification of expenditures associated with the 3.8 percent CY 2023 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. Table 115 includes the annual estimated impact of hospital OQR and ASCQR programs, and the prior authorization process.

TABLE 113: ACCOUNTING STATEMENT: CY 2023 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2022 TO CY 2023 ASSOCIATED WITH THE CY 2023 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$2,530 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 114: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2022 TO CY 2023 AS A RESULT OF THE FINALCY 2023 UPDATED TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$150 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$150 million

TABLE 115: ESTIMATED COSTS IN CY 2023

CATEGORY	Costs
Burden	$-11,688,943 million*
Regulatory Familiarization	$17.204 million**

*The annual estimate includes the impact of Hospital OQR and ASCQR Programs, and the Prior Authorization Process.
** Regulatory familiarization costs occur upfront only.

4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59492 through 59494) for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2021 payment determinations. Of the 3,356 hospitals that met eligibility requirements for the CY 2022 payment determination, we determined that 88 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2023 OPPS/ASC Finalized Rule Policies

We do not anticipate that the CY 2023 Hospital OQR Program policies will impact the number of facilities that will receive payment reductions. In this final rule with comment period, we are finalizing to: (1) add an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period; (2) align the patient encounter quarters with the calendar year beginning with the CY 2024 reporting period; and (3) change reporting for the OP-31 measure from mandatory to voluntary beginning with the CY 2025 payment determination.

As shown in Table 104 in section XXIII.B.4 (Collection of Information) of this final rule with comment period, we estimate a total information collection burden decrease for 3,350 OPPS hospitals of -325,847 hours at a cost of -$15,138,852 annually associated with our finalized policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection

burden estimates. We refer readers to section XXIII.B of this final rule with comment period (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program. We do not believe the finalized policies will have any further economic impact beyond information collection burden.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV of this final rule with comment period, we discuss our finalized policies affecting the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. For the CY 2022 payment determination, of the 5,386 ASCs that met eligibility requirements, we determined that 290 ASCs did not meet the requirements to receive the full annual payment update under the ASC fee schedule.

b. Impact of CY 2023 OPPS/ASC Finalized Policies

In section XVI of this final rule with comment period, we are finalizing to change the reporting for the ASC-11 measure from mandatory to voluntary beginning with the CY 2023 reporting period. As shown in Table 105 in section XXIII.C.3.e (Collection of Information) of this final rule with comment period, we estimate a total information collection burden decrease for 4,646 ACSs of -72,107 hours at a cost of -$3,350,091 annually associated with our finalized policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.C of this final rule with comment period (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program. We do

not believe the finalized policy will have any further economic impact beyond information collection burden.

6. Effects of Requirements for the Rural Emergency Hospitals (REH) Program

a. Background

In section XVIII.A of this final rule with comment period, we discuss our finalized policies to provide payment to REHs, including the following finalized proposals: (1) the payment rate for an REH service would be calculated using the OPPS prospective payment rate for the equivalent covered OPD service increased by 5 percent; (2) the additional 5 percent payment for REH services, above the amount that would be paid for covered OPD services, would not be subject to a copayment; (3) for CY 2023, the monthly facility payment that each REH will receive would be determined by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in CY 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in CY 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during CY 2019. The difference is divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual amount of this additional facility payment per individual REH. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive.

b. Impact of CY 2023 OPPS/ASC Final Rule With Comment Period REH Policies

For CY 2023, we have determined there are 1,716 CAHs and rural subsection (d) hospitals with 50 or fewer beds that are eligible to convert to become an REH in the nation. A study[359] estimated that 68 eligible providers or approximately 4 percent of all eligible providers

[359] "How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?" July 2021. Pink, GH et. al. *Findings Brief – NC Rural Health Research Program.*

would become a REH in CY 2023, and we use this number of REHs for our impact analyses. We acknowledge that the number of conversions could be less than or significantly greater than this estimate.

We developed a percentile analysis estimating how much revenue from rendering medical services a provider would lose or gain during CY 2023 if it decided to convert to a REH. We estimated that a provider in the 95th percentile of total annual REH medical service payment would receive an additional $2,089,700 in Medicare payments. We estimated that a provider in the 100th percentile of total annual REH medical service payment would receive an additional $3,362,560 in Medicare payments. Since a REH provider conversion rate of 4 percent falls between the 95th percentile and the 100th percentile of total annual REH medical service payment spending, we took the average of the additional spending for the 95th and 100th percentiles to determine the additional medical service spending for each provider converting to a REH in CY 2023 would be $2,726,130. Since we do not have any information on individual providers that may convert, nor do we have any information on characteristics of regions where REH conversions may be more likely, our best assumption regarding the impact of the REH policy is that providers who anticipate the most financial benefit from converting to an REH would be the most likely providers to convert.

Next, we determined the annual facility payment amount for a provider that converts to an REH in CY 2023. The finalized monthly facility payment for CY 2023 is $272,866. When this amount is multiplied by 12 months, the total annual facility payment is equal to $3,274,392. To determine the total impacts of the REH policy, we need to multiply the additional medical service spending amount of $2,726,130 by 68 providers which equals $185,376,820. Next, we multiply the total annual facility payment amount of $3,274,392 by 68 providers which equals

$222, 658, 656. Finally, we combine the two amounts together, and we obtain a final estimate of the impacts of the REH provider policy of an additional $408,035,476 in Medicare payments.

7. Effects of Rural Emergency Hospitals (REH) Physician Self-Referral Law Updates

The discussion of the physician self-referral law provisions related to REHs appears in section XVIII.E of this final rule with comment period. As discussed in section XVIII.A.4 of this final rule with comment period, we are finalizing our proposal to revise certain existing exceptions to the physician self-referral law applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party. Specifically, we are revising the exceptions for physician recruitment at § 411.357(e), obstetrical malpractice insurance subsidies at § 411.357(r), retention payments in underserved areas at § 411.357(t), electronic prescribing items and services at § 411.357(v), assistance to compensate a nonphysician practitioner at § 411.357(x), and timeshare arrangements at § 411.357(y) to also permit an REH to provide remuneration to a physician (or an immediate family member of a physician) if all requirements of the applicable exception are satisfied. All the revisions will ensure that exceptions applicable to compensation arrangements that may already be used by existing CAHs and small rural hospitals eligible to undergo conversion to an REH remain available to REHs. We believe that the continued availability of these exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH.

8. REH Provider Enrollment

The only impacts of our finalized REH enrollment policies are the information collection requirements associated with the facility's completion and submission of a Form CMS-855A change of information application to convert from a CAH or hospital (as defined in section

1886(d)(1)(B) of the Act) to an REH. These are addressed in detail in section XXIII.G of this final rule with comment period. As explained in that section, we estimate a Year 1 burden of 68 hours (68 applications x 1 hour per application) at a cost of $2,784 (based on an hourly wage estimate of $40.94).

9. Effects of Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services" (84 FR 61142, November 12, 2019).[360] As part of the CY 2021 OPPS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, December 29, 2020). The regulations governing the prior authorization process are located in 42 CFR part 419, subpart I, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we are finalizing our proposal to require prior authorization for a new service category: Facet joint interventions. We are adding the service category to § 419.83(a)(3). We are also requiring that the prior authorization process for the additional service category will be effective for dates of services on or after July 1, 2023. The addition of the service category is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

[360] See also Correction Notice issued January 3, 2020 (85 FR 224).

The overall economic impact on the health care sector to require prior authorization for the additional service category is dependent on the number of claims affected. Table 116, Overall Economic Impact on the Health Sector, lists an estimate of the overall economic impact on the health sector for the new service category. The values populating this table were obtained from the cost reflected in Table 117, Annual Private Sector Costs, and Table 118, Estimated Annual Administrative Costs to CMS. Together, Tables 117 and 118 combine to convey the overall economic cost impact to the health sector for the new service category, which is illustrated in Table 116. It should be noted that due to the July start date for prior authorization for the new service category, year one includes only 6 months of prior authorization requests.

Based on the estimate, the overall economic cost impact is approximately $13.3 million in the first year based on 6 months for the new service category. The 5-year impact is approximately $118.7 million, and the 10-year impact is approximately $250.4 million. The 5- and 10-year impacts account for year one, including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $65.3 million. We believe there are likely to be other benefits that result from the prior authorization requirement for the new service category, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We solicited public comments on the potential increased costs and benefits associated with this proposed provision for the new service category.

TABLE 116: OVERALL ECONOMIC COST IMPACT ON THE HEALTH SECTOR

Economic Impact Costs	Year 1	5 Years	10 Years
Private Sector Costs	$3,694,954	$32,232,056	$67,903,435
Medicare Costs	$9,625,364	$86,488,072	$182,566,457
Total Economic Impact to Health Sector	$13,320,318	$118,720,128	$250,469,892

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the final rule with comment period will change the billing practices of those providers. We believe that the purpose of the statute and this rule is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the additional OPD service category subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect will be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding the new service category will offer additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

1. Private Sector Costs

We do not believe that this rule will significantly affect the number of legitimate claims submitted for the new service category. However, we do expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the additional service category will be equivalent to that of submitting documentation and clerical activities associated with prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 117: YEAR 1 (6 MONTH) PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests- Initial Submissions	97,301	0.5	48,651	$1,666,773

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests- Resubmissions	31,928	0.5	15,964	$546,922
Mailed in Requests- Initial Submissions	41,701	0.5	20,850	$714,331
Mailed in Requests- Resubmissions	13,683	0.5	6,842	$234,395
Mailing Costs	55,384	5		$276,920
Provider Demonstration- Education	2,487	3	7,461	$255,614
Total			99,768	$3,694,954

2. Administrative Costs to CMS

CMS will incur additional costs associated with processing the prior authorization requests for the new service category. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education, outreach, and system changes.

TABLE 118: YEAR 1 (6 MONTH) ESTIMATED ADMINISTRATIVE COSTS TO CMS

Service Category	Estimated Year One Administrative Cost (6 Months)
Facet Joint Interventions- 10 Codes	$9,625,364

3. Estimated Beneficiary Costs

We expect a reduction in the utilization of the new Medicare OPD service category when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision; we are unable to quantify that burden. Although the rule permits utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There will be quantifiable benefits for this rule because we expect a reduction in the unnecessary utilization of the new Medicare OPD service category subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on a 25 percent savings percentage, we estimate that for the first 6 months, there will be savings of $32.6 million overall. Annually, we estimate an overall gross savings of $65.3 million. These savings represent a Medicare benefit from more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits will also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the additional OPD services category will ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner

recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements will likely be reduced by the requirement that a provider submits clinical documentation created as part of its prior authorization request.

10. Rural Emergency Hospitals CoPs

This final rule with comment period addresses the CoPs required for REH designation, which in accordance with the statute, may be sought by CAHs and small rural hospitals. It also finalizes several new CAH requirements that we believe are appropriate under the existing program as well as to REHs. However, note that the costs of these CAH requirements are not attributable to the new REH program (except where such costs are experienced by entities that remain open due to the REH option but would have closed otherwise). The baseline for the estimates of REH costs is the status quo had the new program had not been created. The final CoPs for the new REH provider type are similar to those already met by the facilities that will potentially convert to REH status, and for collection of information purposes we did not subtract offsetting savings from providers who would already meet these standards and who decide to make little change when updating their status.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other healthcare providers and suppliers are small entities,

either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We estimate that almost all of the new REH facilities, and the great majority of CAHs, are or would be small entities on the basis of legal status, revenues, or both. The North American Industry Classification System Code for the converting hospitals is 622110 (General Medical and Surgical Hospitals), and for the REHs to which they convert the closest Code is 621493 (Freestanding Ambulatory Surgical and Emergency Centers). HHS uses an increase in costs or decrease in revenues of more than 3 percent as its threshold for ‘‘significant economic impact’’. Our collection of information estimates are that the 68 facilities converting to REH status (as estimated by the NC RHRP study referenced in the COI section) would face average annual costs of about $22,600 each (68 × $22,600 = $1,537,000 (COI burden estimate)). The North Carolina Rural Health Research Program estimated that the 68 hospitals it thought most likely to convert to REH status had average patient revenues of $7.3 million. For these facilities, the 3 percent threshold would be about $219,000, almost ten times our estimated cost of information collection. The CLA study does not present average facility revenues. However, we note that while it reaches a broad range of conversion estimates, we do not believe that it would have reached different conclusions had it presented such calculations. These relationships between revenues and costs would not be substantially different if the number of conversions was substantially fewer or substantially greater in number. More importantly, these facilities would be converting voluntarily to the new program. We expect that the costs any facility faces would be less than the anticipated gains of conversion, or it would not convert. This positive relationship of expected gains from conversion compared to current costs and revenues is explicit in the CLA modeling. The effects of the final policy changes on CAHs are even smaller.

The average annual cost per CAH for the new Conditions of Participation would be about $2,755 each (1,360 facilities × $2,755 = the $3,747,000 COI estimate), a tiny fraction of 1 percent of annual patient revenues estimated in the NC RHRP study at about $24 million a year. Moreover, the final change in the definition of primary roads could prevent the loss of the CAH designation for 3 to 4 CAHs. We note that we proposed no change in rural hospital standards, so they are not directly regulated by this final rule with comment period. For these reasons, an Initial Regulatory Flexibility Analysis is not required for the REH CoP provisions. Furthermore, as described provision by provision earlier in this preamble, we carefully sought to keep regulatory burdens on REH providers to a reasonable minimum, taking into account our obligation to reduce health care inequities, their small size, and the statutory and practical limitations on their status as providers. For example, we proposed to allow systems composed of multiple and separately certified hospitals, CAHs, and/or REHs to have unified or integrated governing bodies, unified infection prevention and control and antibiotic stewardship programs, and unified and integrated medical staff.

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the number of commenters on this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers choose not to comment on the

proposed rule. For these reasons, we thought that the number of commenters on the CY 2023 OPPS/ASC proposed rule would be a fair estimate of the number of reviewers of this final rule.

We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimated that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $921.76 (8 hours x $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $1,473,89 4($921.76 x 1,599 reviewers on the CY 2023 OPPS/ASC proposed rule).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's "Table of Size Standards" at http://www.sba.gov/content/table-small-business-size-standards. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule with comment period. As

a result, the Secretary has determined that this rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period will increase payments to small rural hospitals by approximately 2.5 percent. Therefore, it should not have a significant impact on the approximately 549 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies established in this rule apply more broadly to OPPS providers and do not specifically focus on small rural hospitals. As a result, the impact on those providers may depend more significantly on their case mix of services provided, since the broader impact on the hospital category is more dependent on the OPD update factor, as indicated in the impact table.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022,

that threshold level is currently approximately $165 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Conclusion

The changes we are finalizing in this final rule with comment period will affect all classes of hospitals paid under the OPPS as well as affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2023. Table 110 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 4.5 percent increase in payments for all services paid under the OPPS in CY 2023, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, changes to the pass-through payment estimate, exception for rural SCHs from the clinic visit policy for services furnished at off campus PBDs, and adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators. However, some classes of providers that are paid under the OPPS will experience more significant gains or losses in OPPS payments in CY 2023.

The updates we are making to the ASC payment system for CY 2023 will affect each of the approximately 5,900 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASCs patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year than in previous years. Table 111

demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.7 percent for CY 2023.

H. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 110 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 5.9 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXIII of this final rule with comment period, this rule should not have a significant effect on small rural hospitals.

I. Congressional Review

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on XXXXX XX, 20XX.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping

requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.1801 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 405.1801 Introduction.

* * * * *

(b) * * *

(2) * * *

(ii) Some of these nonprovider entities are required to file periodic cost reports and are paid on the basis of information furnished in these reports. Except as provided at § 413.420(g), these nonprovider entities may not obtain a contractor hearing or a Board hearing under section 1878 of the Act or this subpart.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

4. Section 410.27 is amended by:

a. Revising paragraphs (a)(1)(iii) and (a)(1)(iv)(A) and (B); and

b. Removing paragraph (a)(1)(iv)(D).

The revisions reads as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in § 413.65 of this subchapter, except for mental health services furnished to beneficiaries in their homes through the use of communication technology;

(iv) * * *

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this chapter, or through the use of communication technology for mental health services, general supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure.

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision.

(1) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2023, the presence of the physician for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only);

(2) Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure;

* * * * *

5. Section 410.28 is amended by revising paragraph (e) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under one of the three levels of supervision (as defined in paragraphs (e)(1) through (3) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and

applicable State law, by a nonphysician practitioner (physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).

(1) *General Supervision*. General supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure. Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

(2) *Direct supervision*. (i) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, "direct supervision" means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room where the procedure is performed.

(ii) For services furnished under arrangement in nonhospital locations, "direct supervision" means the physician or nonphysician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

(iii) Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (e)(2)(ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(3) *Personal Supervision*. Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

* * * * *

6. Section § 410.40 is amended by revising paragraphs (f)(1), (2), and (5) to read as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(f) * * *

(1) From any point of origin to the nearest hospital, CAH, REH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH or REH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, REH, or SNF to the beneficiary's home.

* * * * *

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with any applicable state or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital, REH (effective January 1, 2023), or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

7. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

8. Section 411.351 is amended by revising the definition "Rural area" and adding the definition "Rural emergency hospital" to read as follows:

§ 411.351 Definitions.

* * * * *

Rural area means an area that is not an urban area as defined at § 412.64(b) of this chapter.

Rural emergency hospital has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91 of this chapter.

* * * * *

9. Section 411.357 is amended by revising paragraphs (e)(6), (r)(2) introductory text, (r)(2)(ii) through (v), (t)(5), (v)(1)(i), (x)(7), and (x)(8) and adding paragraph (y)(10) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(e) * * *

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The "geographic area served" by a federally qualified health center, rural health clinic, or rural emergency hospital is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center, rural health clinic, or rural emergency hospital may include one or more zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients.

* * * * *

(r) * * *

(2) A payment from a hospital, federally qualified health center, rural health clinic, or rural emergency hospital that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

* * * * *

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, rural health clinic, or rural emergency hospital and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment.

(iv) The hospital, federally qualified health center, rural health clinic, or rural emergency hospital does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), rural health clinic(s), or rural emergency hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(t) * * *

(5) *Application to other entities.* This paragraph (t) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital. For purposes of paragraph (t), the geographic area served by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in section (e)(6)(ii) of this section.

* * * * *

(v) * * *

(1) * * *

(i) Hospital or rural emergency hospital to a physician who is a member of its medical staff;

* * * * *

(x) * * *

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The "geographic area served" by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) * * *

(10) This paragraph (y) applies to remuneration provided by a rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

10. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

11. Section 412.1 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) * * *

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, and for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators.

* * * * *

12. Section 412.2 is amended by adding paragraph (f)(10) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(f) * * *

(10) A payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as specified in § 412.113 of subpart H.

* * * * *

13. Section 412.100 is amended by revising paragraph (b) to read as follows:

§ 412.100 Special treatment: Kidney transplant programs.

* * * * *

(b) *Costs of kidney acquisition.* Kidney acquisition costs include allowable costs incurred in the acquisition of a kidney from a living or a deceased donor by the hospital, or from a deceased donor by an organ procurement organization. These costs are listed in § 413.402(b) of this chapter.

14. Section 412.113 is amended by adding paragraph (f) to read as follows:

§ 412.113 Other payments.

* * * * *

(f) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators*. (1) For cost reporting periods beginning on or after January 1, 2023, a payment adjustment to a hospital for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators is made as described in paragraph (f)(2) of this section.

(2) The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

15. Section 412.190 is amended by revising paragraph (c) to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

* * * * *

(c) *Frequency of publication and data used*. The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

16. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

17. Section 413.1 is amended by adding paragraph (a)(1)(ii)(L) and revising paragraph (a)(2)(i) to read as follows:

§ 413.1 Introduction.

(a) * * *

(1) * * *

(ii) * * *

(L) Section 1834(x) of the Act authorizes payment for services furnished by Rural Emergency Hospitals (REHs) and establishes the payment methodology.

(2) * * *

(i) Hospitals, critical access hospitals (CAHs), and rural emergency hospitals (REHs);

* * * * *

18. Section 413.13 is amended by adding paragraph (c)(2)(vii) to read as follows:

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

* * * * *

(c) * * *

(2) * * *

(vii) ***Services furnished by a rural emergency hospital (REH).*** Services furnished by a rural emergency hospital are subject to the payment methodology set forth in Part 419, subpart K.

* * * * *

19. Section 413.24 is amended by revising paragraphs (f)(4)(i) and (ii) and (f)(4)(iv)(A) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(4) * * *

(i) As used in this paragraph, "provider" means a hospital, rural emergency hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals; cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies; cost reporting periods ending on or after December 31, 2004 for

hospices, and end-stage renal disease facilities; cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers; and cost reporting periods beginning on or after January 1, 2023 for rural emergency hospitals, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

* * * * *

(iv) (A) Effective as specified in paragraphs (f)(4)(iv)(A)(*1*) through (*5*) and except as provided in paragraph (f)(4)(iv)(C) of this section, a provider must submit a hard copy of a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and the certification statement described in paragraph (f)(4)(iv)(B) of this section signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report.

(*1*) For hospitals, effective for cost reporting periods ending on or after September 30, 1994;

(2) For skilled nursing facilities and home health agencies, effective for cost reporting periods ending on or after February 1, 1997*;*

(*3*) For hospices and end-stage renal disease facilities, effective for cost reporting periods ending on or after December 31, 2004;

(*4*) For organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, effective for cost reporting periods ending on or after March 31, 2005; and

(*5*) For rural emergency hospitals, effective for cost reporting periods beginning on or after January 1, 2023.

* * * * *

20. Section 413.198 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

* * * * *

(b) * * *

(4) * * *

(ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;

* * * * *

21. Section 413.400 is amended by revising the definitions of "Hospital-based organ procurement organization (HOPO)", "Transplant hospital", "Transplant hospital/HOPO (TH/HOPO)", and "Transplant program" to read as follows:

§ 413.400 Definitions.

* * * * *

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report.

* * * * *

Transplant hospital (*TH)* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (TH/HOPO) refers to a TH, or a TH that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the TH's Medicare cost report.

Transplant program means an organ-specific transplant program within a TH (as defined in this section).

* * * * *

22. Section 413.402 is amended by revising paragraphs (a), (b)(3), (4), and (7), (b)(8)(i) and (ii), and (d)(2)(ii) to read as follows:

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition*. Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH.

(b) * * *

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.

(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.

* * * * *

(7) Surgeons' fees for excising deceased organs (currently limited to $1,250 for kidneys).

(8) * * *

(i) Excised organ to the TH; and

(ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

* * * * *

(d) * * *

(2) * * *

(ii) Transportation costs of the deceased donor after organ procurement for funeral services or for burial.

* * * * *

23. Section 413.404 is amended by revising paragraphs (a)(2), (b)(2), (b)(3) introductory text, (b)(3)(i) introductory text, (b)(3)(i)(A) through (C), (b)(3)(ii) introductory text, (b)(3)(ii)(A) and (B), (b)(3)(ii)(C) introductory text, (b)(3)(ii)(C)(*1*) through (*3*), (c)(1)(i) and (ii), (c)(2)(i) through (iv), and (c)(3) to read as follows:

§ 413.404 Standard acquisition charge.

(a) * * *

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either deceased donor organs or living donor organs, by organ type.

* * * * *

(b) * * *

(2) When a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A TH must establish SACs for living donor organs. A TH/HOPO must establish SACs for deceased donor organs.

(i) Living donor SAC for THs –

(A) *Definition.* The living donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC*—(*1*) *Initial living donor SAC.* A TH calculates its initial living donor SAC for each living donor organ type as follows:

(*i*) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(*1*)(*i*) of this section by the projected number of usable living donor organs to be procured by the TH during the TH's cost reporting period.

(*2*) *Subsequent living donor SAC.* A TH calculates its subsequent years' living donor SAC for each living donor organ type as follows:

(*i*) By using the TH's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) Dividing the costs in paragraph (b)(3)(i)(C)(*2*)(*i*) of this section by the actual number of usable living donor organs procured by the TH during that prior cost reporting period.

* * * * *

(ii) *Deceased donor SAC for TH/HOPOs*—(A) *Definition.* The deceased donor SAC is an average cost that a TH/HOPO incurs to procure a deceased donor organ.

(B) *Calculating the deceased donor SAC*—(*1*) *Initial deceased donor SAC.* A TH/HOPO calculates its initial deceased donor SAC for each deceased donor organ type as follows:

(*i*) By estimating the reasonable and necessary costs it expects to incur to procure deceased donor organs, combined with the expected costs of acquiring deceased donor organs from OPOs or other THs.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(*1*)(*i*) of this section by the projected number of usable deceased donor organs to be procured by the TH/HOPO within the TH's cost reporting period.

(*2*) *Subsequent deceased donor SAC.* A TH/HOPO calculates its subsequent years' deceased donor SAC for each deceased donor organ type as follows:

(*i*) By using the TH's actual organ acquisition costs for the deceased donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) By dividing the costs in paragraph (b)(3)(ii)(B)(*2*)(*i*) of this section by the actual number of usable deceased donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the deceased donor SAC.* Costs that may be used to develop the deceased donor SAC include, but are not limited to the following:

(*1*) Costs of organs acquired from other THs or OPOs.

(*2*) Costs of transportation as specified in § 413.402(b)(8).

(*3*) Surgeons' fees for excising deceased donor organs (currently limited to $1,250 for kidneys).

* * * * *

(c) * * *

(1) * * *

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of deceased donor non-renal organs the IOPO expects to procure within its cost reporting period.

* * * * *

(2) * * *

(i) *General.* An IOPO's contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure deceased donor kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable deceased donor kidneys the IOPO expects to procure.

(ii) *Initial year.* The contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years.* The contractor computes the kidney SAC for subsequent years using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor kidneys procured during

that cost reporting period. The kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in § 413.420(d)(1).

(iv) *SAC adjustments.* The IOPO's contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

* * * * *

(3) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type and not the procuring IOPO's SAC when billing the TH receiving the organ.

24. Section 413.412 is revised to read as follows:

§ 413.412 Intent to transplant, intent for research, counting en bloc, and unusable organs.

(a) *Principles for organs intended for transplant for organ acquisition payment purposes*.

(1) An organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type. These costs include the costs associated with an organ intended for transplant, but subsequently determined unsuitable for transplant and furnished for research.

(3) An organ intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs.

(4) Subject to paragraph (a)(4)(iii) of this section, OPOs and THs must reduce total organ acquisition costs, when the organ is intended for transplant but determined unsuitable for transplant and instead furnished for research, as follows:

(i) by deducting the costs to furnish organs for research from total organ acquisition costs, or

(ii) by offsetting the total organ acquisition costs by the revenue received for these organs.

(iii) In no event may the reduction in total organ acquisition costs as a result of application of paragraph (a)(4) of this section exceed the costs incurred to furnish organs for research.

(5) When the costs to furnish organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center, no offset is necessary.

(b) *Principles for organs intended for research for organ acquisition payment purposes*.

(1) An organ is intended for research when the OPO or TH designates it for research prior to the time the donor enters the hospital's operating room for surgical removal of the organ.

(2) Medicare does not share in the acquisition costs of an organ intended for research and costs to procure these organs must not be included in organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(3) An organ intended for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(c) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count -

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

(d) *Unusable organs.*

(1) An organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a physician determines,

upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable.

(2) OPOs and THs include the cost to procure unusable organs, as described in paragraph (d)(1) of this section, in total organ acquisition costs reported on their Medicare cost report.

25. Section 413.414 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(1) and (2), and (c)(3)(i) and (ii) to read as follows:

§ 413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle*. If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the TH that performs the transplant in certain instances. To determine whether Medicare has liability to the TH that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the TH that performs the transplant to review the TH's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire

cost, Medicare may have a secondary payer liability to the TH that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the TH must not count the organ as a Medicare usable organ.

(3) * * *

(i) The TH must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the TH that performs the transplant counts the organ as a Medicare usable organ.

* * * * *

26. Section 413.416 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(2) through (4), (d) introductory text, and (d)(1) to read as follows:

§ 413.416 Organ acquisition charges for kidney-paired exchanges.

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's TH procures and furnishes a kidney to a recipient's TH all of the following are applicable:

* * * * *

(2)(i) The donor's TH bills the recipient's TH.

(ii) The donor's TH bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's TH records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs.

(4) The recipient's TH records as part of its kidney acquisition costs -

(i) The amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's TH.

(d) *Donor's procurement occurs at recipient TH*. In a kidney-paired exchange—

(1) When a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's TH; and

* * * * *

27. Section 413.418 is revised to read as follows:

§ 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.

(a) *General.* A donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. These services must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team, must be authorized by the OPO, and are included as organ acquisition costs when:

(1) there is consent to donate, and

(2) declaration of death has been made, or if a declaration of death has not been made, death is imminent and it is necessary that the services be provided prior to declaration of death in order to avoid compromising the viability of the organs for transplant.

(b) *Amounts billed for organ acquisition costs*. When a donor community hospital or TH incurs costs for services furnished to a deceased donor, or a donor whose death is imminent as described in paragraph (a), as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

28. Section 413.420 is amended by revising paragraphs (a), (c)(1)(ii), (iv), and (v), (d), and (e)(2)(i) and (ii) to read as follows:

§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

(a) *Principle.* (1) Covered services furnished by IOPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by IOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

* * * * *

(c) * * *

(1) * * *

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or laboratory, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or laboratory.

* * *

(iv) To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

* * * * *

(d) *Interim reimbursement.* (1) THs with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by THs on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all THs and contractors.

(e) * * *

(2) * * *

(i) *Retroactive adjustment*. A retroactive adjustment in the amount paid under the interim rate is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to THs, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

29. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

30. Section 416.166 is amended by revising paragraph (d)(1) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(d) * * *

(1) *Pre-proposed rule CPL recommendation process*. On or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

* * * * *

31. Section 416.172 is amended by adding paragraph (h) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(h) *Special payment for certain code combinations*—(1) *Eligibility*. A code combination is eligible for the payment specified in paragraph (h)(2) of this section if the code combination is—

(i) Eligible for a C-APC complexity adjustment under the OPPS; and

(ii) Comprised of a separately payable surgical procedure, that is listed on the ASC Covered Procedures list (§ 416.166), and one or more packaged add-on codes that are listed on the ASC covered procedures or ancillary services lists (§ 416.164(b)).

(2) *Calculation of payment.* (i) Except as specified in paragraph (h)(2)(ii) of this section, CMS calculates the payment for code combinations that meet the eligibility requirements in paragraph (h)(1) of this section by applying the methodology specified in § 416.171(a) to the OPPS C-APC complexity-adjusted relative weights.

(ii) For primary procedures assigned device-intensive status that are a component of a code combination that is eligible for payment under paragraph (h)(2) of this section, the primary procedure of the code combination retains its device-intensive status, and—

(A) The device portion is equivalent to the device portion of the device-intensive APC under the OPPS (§ 419.44(b)); and

(B) The non-device portion is calculated in accordance with the methodology specified in § 416.171(a).

32. Section 416.174 is amended by revising paragraph (a) to read as follows:

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) Eligibility for separate payment for non-opioid pain management drugs and biologicals. Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological estimated by CMS for the year exceeds the OPPS drug packaging threshold set for such year through notice and comment rulemaking.

(3) The drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in paragraph (a) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The drug or biological is not already separately payable in the OPPS or ASC payment system under a policy other than the one specified in this section.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

33. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

34. Part 419 is amended by revising the heading to read as set forth above.

35. Section 419.43 is amended by adding paragraph (j) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(j) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators*—(1) *General rule*. For cost reporting periods beginning on or after January 1, 2023, CMS provides for a payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as described in paragraph (j)(2) of this section.

(2) *Amount of adjustment.* The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (j)(2) of this section in a budget neutral manner.

36. Section 419.46 is amended by revising paragraph (f)(3)(iv) and adding paragraph (f)(3)(v) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(3) * * *

(iv) Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or

(v) Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

* * * * *

37. Section 419.47 is added to read as follows:

§ 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE) Studies

(a) *Creation of a new HCPCS code for Category B IDE Studies.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under 42 CFR 405.201, when CMS determines that:

(1) The Medicare coverage IDE study criteria in 42 CFR 405.212 are met; and

(2) A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of the study.

(b) *Payment for Category B IDE Studies.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (a) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under 42 CFR 405.201; and

(2) Calculate the single packaged payment rate for the HCPCS code based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

38. Section 419.83 is amended by revising paragraphs (a)(3) and (b) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) * * *

(3) The Facet Joint Interventions service category requires prior authorization beginning for service dates on or after July 1, 2023.

(b) *Adoption of the list of services and technical updates.*

(1) CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.

(2) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

* * * * *

39. Subpart K is added to read as follows:

Subpart K - Payments to Rural Emergency Hospitals (REHs)

§ 419.90 Basis and scope of subpart.

§ 419.91 Definitions.

§ 419.92 Payment to rural emergency hospitals.

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

§ 419.94 Preclusion of administrative and judicial review.

Subpart K - Payments to Rural Emergency Hospitals (REHs)

§ 419.90 Basis and scope of subpart.

(a) *Basis.* This subpart implements sections 1861(kkk) and 1834(x) of the Act, which establish the rural emergency hospital Medicare provider type and the payment requirements applying to such entities.

(b) *Scope.* This subpart describes the methodologies used to determine payment for REH services and the monthly facility payment amount paid to REHs.

§ 419.91 Definitions.

As used in this subpart -

Rural Emergency Hospital or *REH* means an entity as defined in § 485.502 of this chapter.

Rural Emergency Hospital (REH) Services means all covered outpatient department (OPD) services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the OPPS when provided in a hospital paid under the OPPS for outpatient services, provided that such services are furnished consistent with the conditions of participation at 42 CFR §§ 485.510 through 485.544.

§ 419.92 Payment to rural emergency hospitals

(a) *Payment for REH services*

(1) *Medicare payment.* A rural emergency hospital that furnishes a REH service on or after January 1, 2023, is paid an amount equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service, increased by 5 percent.

(2) *Beneficiary copayment.* The beneficiary copayment for a REH service is the amount determined under section 1833(t)(8) of the Act for the equivalent covered OPD service, excluding the 5 percent payment increase described in paragraph (a)(1) of this section.

(b) *Monthly facility payment.* Effective January 1, 2023, REHs are paid a monthly facility payment equal to 1/12 of the annual additional facility payment amount described in paragraphs (b)(1) and (b)(2) of this section.

(1) *Calculation of monthly facility payment for 2023.* For calendar year 2023, the annual additional facility payment amount is:

(i) The total amount that the Secretary determines was paid by the Medicare program and from beneficiary copayments to all critical access hospitals in calendar year 2019; minus

(ii) The estimated total amount that the Secretary determines would have been paid by the Medicare program and from beneficiary copayments to critical access hospitals in calendar year 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during calendar year 2019; divided by

(iii) The total number of critical access hospitals enrolled in Medicare in calendar year 2019.

(2) *Calculation of monthly facility payment for 2024 and subsequent years.* For calendar year 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

(3) *Recording and Reporting the use of the monthly facility payment.* A rural emergency hospital receiving the monthly facility payment must maintain detailed information as specified by the Secretary as to how the facility has used the monthly facility payments and must make this information available to the Secretary upon request.

(c) *Payment for services furnished by an REH that do not meet the definition of REH services*. A service furnished by an REH that does not meet the definition of an REH service under § 419.91, including a hospital service that is excluded from payment under the OPPS as described in § 419.22, is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.

(1) *Payment for ambulance services*

Ambulance services furnished by an entity owned and operated by a rural emergency hospital are paid under the ambulance fee schedule as described at section 1834(l) of the Act.

(2) *Payment for post-hospital extended care services*

Post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility are paid under the skilled nursing facility prospective payment system described at section 1888(e) of the Act.

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) Items and services furnished by an off-campus provider-based department of an REH, as defined in paragraph (b) of this section, are not applicable items and services under sections 1833(t)(1)(B)(v) and (t)(21) of the Act and are paid as follows:

(1) REH services furnished by an off-campus provider-based department of an REH are paid as described in § 419.92(a)(1).

(2) Services that do not meet the definition of REH services that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c).

(b) For the purpose of this section, "off-campus provider-based department of an REH" means a "department of a provider" (as defined at § 413.65(a)(2) of this chapter) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a "remote location of a hospital" (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

§ 419.94 Preclusion of administrative and judicial review

(a) There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(1) The determination of whether a rural emergency hospital meets the requirements of this subpart.

(2) The determination of payment amounts under this subpart.

(3) The requirements established by this subpart.

PART 424-CONDITIONS FOR MEDICARE PAYMENT

40. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

41. Amend § 424.518 by revising paragraph (a)(1)(viii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

(a) * * *

(1) * * *

(viii) Hospitals, including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

* * * * *

42. Add § 424.575 to read as follows:

§ 424.575 Rural emergency hospitals.

(a) A rural emergency hospital (as defined in § 485.502 of this chapter) must comply with all applicable provisions in this subpart in order to enroll and maintain enrollment in Medicare.

(b) A provider that was enrolled in Medicare as of December 27, 2020 as a critical access hospital or a hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) with not

more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) (or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act) converts its existing enrollment to that of a rural emergency hospital (as defined in § 485.502 of this chapter) via a Form CMS-855A change of information application per § 424.516 rather than a Form CMS-855A initial enrollment application.

PART 485 - CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

43. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

44. Subpart E is added to read as follows:

Subpart E – Conditions of Participation: Rural Emergency Hospitals (REHs)

Sec.

485.500 Basis and scope.
485.502 Definitions.
485.504 Basic Requirements.
485.506 Designation and certification of REHs.
485.508 Condition of participation: Compliance with Federal, State, and local laws and regulations.
485.510 Condition of participation: Governing body and organizational structure of the REH.
485.512 Condition of participation: Medical staff.
485.514 Condition of participation: Provision of services.
485.516 Condition of participation: Emergency services.
485.518 Condition of participation: Laboratory services.
485.520 Condition of participation: Radiologic services.
485.522 Condition of participation: Pharmaceutical services.
485.524 Condition of participation: Additional outpatient medical and health services.
485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
485.528 Condition of participation: Staffing and Staff Responsibilities.
485.530 Condition of participation: Nursing services.
485.532 Condition of participation: Discharge planning.
485.534 Condition of participation: Patient's rights.

485.536 Condition of participation: Quality assessment and performance improvement program.
485.538 Condition of participation: Agreements.
485.540 Condition of participation: Medical records.
485.542 Condition of participation: Emergency preparedness.
485.544 Condition of participation: Physical environment.

Subpart E – Conditions of Participation: Rural Emergency Hospitals (REHs)

§ 485.500 Basis and scope.

Section 1861(kkk) of the Act requires the Secretary to establish the conditions REHs must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients receiving services at these entities.

§ 485.502 Definitions.

As used in this subpart:

Rural Emergency Hospital or *REH* means an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The time calculation for determining the length of stay of a patient receiving REH services begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH. The discharge occurs when the physician or other appropriate clinician has signed the discharge order, or at the time the outpatient service is completed and documented in the medical record.

The entity must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-hospital extended care services.

§ 485.504 Basic Requirements.

Participation as an REH is limited to facilities that –

(a) Meet the definition in § 485.502; and

(b) Have in effect a provider agreement as defined at § 489.3 of this chapter to provide services.

(c) Meet the conditions of participation set out in this subpart.

§ 485.506 Designation and certification of REHs.

Criteria for CMS certification. CMS certifies a facility as an REH if the facility was, as of December 27, 2020 –

(a) A critical access hospital; or

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1881(d)(2)(D) of the Act; or

(c) A hospital as defined in section 1881(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in section 42 CFR 412.103 as of December 27, 2020.

§ 485.508 Condition of participation: Compliance with Federal, State, and local laws and regulations.

(a) The REH must be in compliance with applicable federal laws related to the health and safety of patients.

(b) The REH must be located in a State that provides for the licensing of such hospitals under State or applicable local law; and is

(1) Licensed in the state as an REH; or

(2) approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.

(c) The REH must assure that personnel are licensed or meet other applicable standards that are required by state or local laws to provide services within the applicable scope of practice.

§ 485.510 Condition of participation: Governing body and organizational structure of the REH

There must be an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. If an REH does not have an organized governing body, the person or persons legally responsible for the conduct of the REH must carry out the functions specified in this part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Ensure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment;

(i) Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The REH grants privileges in accordance with recommendations from qualified medical personnel.

(ii) Medical staff privileges must be periodically reappraised by the REH. The scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.

(iii) If the REH assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the REH dependent solely upon certification, fellowship, or membership in a specialty body or society.

(8) Ensure that, when telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(9) Ensure that when telemedicine services are furnished to the REH’s patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the REH and as such, in accordance with § 485.510(b), furnishes the contracted services in a manner that permits the REH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services.

The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such REH's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the REH's medical staff, or their designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the REH. For a multi-facility system, including a multi-hospital or multi-REH system, using a single governing body, the single multi-facility or multi-REH system governing body must consult directly with the individual responsible for the organized medical staff (or their designee) of each hospital or REH within its system in addition to the other requirements of this paragraph (a).

(b) *Standard: Contracted services.* The governing body must be responsible for services furnished in the REH whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the REH to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The REH must maintain a list of all contracted services, including the scope and nature of the services provided.

§ 485.512 Condition of participation: Medical staff

The REH must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the REH.

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must be composed of doctors of medicine or osteopathy. In accordance with state law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at § 482.12(c)(1) of this chapter and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site

telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with paragraph (d) of this section, permit the REH to comply with all applicable conditions of participation for the contracted services. The REH's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 485.510(a)(1) through (7) and § 485.512(a)(1) and (2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the REH with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients, and all complaints the REH has received about the distant-site physician or practitioner.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by state law of the state in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by state law of the state in which the hospital is located.

(4) If an REH is part of a system consisting of multiple separately certified hospitals, critical access hospitals, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, critical access hospitals, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified REH must demonstrate that:

(i) The medical staff members of each separately certified REH in the system (that is, all medical staff members who hold specific privileges to practice at that REH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective REH;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified REH (that is, all medical staff members who hold specific privileges to practice at that REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their REH;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

(c) *Standard: Medical staff bylaws*. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (for example, active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the REH, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 485.510(a)(8) and (9), and § 485.512(a)(3) and (4).

§ 485.514 Condition of participation: Provision of services

(a) The REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law.

(b) The policies must be developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.528(b)(1) of this part.

(c) The policies must include the following:

(1) A description of the services the REH furnishes, including those furnished through agreement or arrangement.

(2) Policies and procedures for emergency medical services.

(3) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the REH.

(4) Policies and procedures that address the post-acute care needs of patients receiving services in the REH.

(d) The policies must be reviewed at least biennially by the group of professional personnel required under paragraph (b) of this section and updated as necessary by the REH.

§ 485.516 Condition of participation: Emergency services

The REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* The emergency services of the REH must be--

(1) Organized under the direction of a qualified member of the medical staff; and

(2) Integrated with other departments of the REH.

(b) *Standard: Personnel.* There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(c) *Standard: Compliance with CAH requirements.* The REH must meet the requirements specified in § 485.618 of this part, with respect to:

(1) 24-hour availability of emergency services (§ 485.618(a) of this part).

(2) Equipment, supplies, and medication (§ 485.618(b) of this part).

(3) Blood and blood products (§ 485.618(c) of this part).

(4) Personnel (§ 485.618(d) of this part).

(5) Coordination with emergency response systems (§ 485.618(e) of this part).

§ 485.518 Condition of participation: Laboratory services.

The REH must provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services, patient population, and services offered. The REH must ensure that —

(a) Laboratory services are available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(b) Emergency laboratory services are available 24 hours a day.

§ 485.520 Condition of participation: Radiologic services.

The REH must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services, as well as the diagnostic services, must be furnished by the REH and provided by personnel qualified under state law. The REH must ensure that REH patients or personnel are not exposed to radiation hazards.

(a) *Standard: Radiologic services*. The REH must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel*. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel*. (1) The REH must have a full-time, part-time, or consulting qualified radiologist, or other personnel qualified under State law, to interpret only those radiologic tests that are determined by the medical staff to require specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records*. Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of their interpretations.

(2) The REH must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

§ 485.522 Condition of participation: Pharmaceutical services.

The REH must have pharmaceutical services that meet the needs of its patients. The REH must have a pharmacy or a drug storage area that is directed by a registered pharmacist or other qualified individual in accordance with state scope of practice laws. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the REH's registered pharmacist or other qualified individual.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles and in accordance with state and federal laws.

(1) A pharmacist or competent individual in accordance with state scope of practice laws must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacist or competent individual in accordance with state law and scope of practice must be available for a sufficient time to provide oversight of the REH's pharmacy services based on the scope and complexity of the services offered at the REH.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services for the provision of all services provided by the REH.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* Drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state law, to ensure patient safety.

(1) All compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or competent individual in accordance with state law and scope of practice and performed consistent with state and federal laws.

(2) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(i) All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) must be kept locked within a secure area.

(ii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) Drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state law.

(c) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood transfusions, blood products and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

(4) There must be an REH procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 485.524 Condition of participation: Additional outpatient medical and health services

If the REH provides outpatient medical and health services in addition to providing emergency services and observation care, the medical and health services must be appropriately organized and meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Patient services.* The REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to,

radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. If the REH provides outpatient and medical health diagnostic and therapeutic items and services, those items and services must align with the health needs of the community served by the REH.

If the REH provides outpatient medical and health services in addition to providing emergency services, the REH must --

(1) Provide items and services based on nationally recognized guidelines and standards of practice;

(2) Have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate;

(3) Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences;

(4) Have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH.

(5) Have personnel providing these services who meet the requirements at § 485.524(b).

(b) *Standard: Personnel for additional outpatient and medical health services.* The REH must --

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) For any specialty services offered at the REH, have a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant providing services with experience and training in the specialty service area and in accordance with their scope of practice.

(c) *Standard: Orders for outpatient medical and health services.* Outpatient medical and health services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient.

(2) Is licensed in the state where they provide care to the patient.

(3) Is acting within their scope of practice under state law.

(4) Is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

(i) All practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the requirements of paragraph (c)(1) through (4) of this section for authorization by the medical staff and the REH for ordering the applicable outpatient services for their patients.

(d) *Standard: Surgical services.* If the REH provides outpatient surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the REH in accordance with the designation requirements under paragraph (a) of this section.

(1) *Designation of qualified practitioners.* The REH designates the practitioners who are allowed to perform surgery for REH patients, in accordance with its approved policies and procedures, and with state scope of practice laws. Surgery is performed only by --

(i) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(ii) A doctor of dental surgery or dental medicine; or

(iii) A doctor of podiatric medicine.

(2) *Anesthetic risk and evaluation.* (i) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(ii) A qualified practitioner, as specified in paragraph (d)(3) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(iii) Before discharge from the REH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (d)(3) of this section.

(3) *Administration of anesthesia.* The REH designates the person who is allowed to administer anesthesia to REH patients in accordance with its approved policies and procedures and with state scope-of-practice laws.

(i) Anesthesia must be administered by only --

(A) A qualified anesthesiologist;

(B) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(C) A doctor of dental surgery or dental medicine;

(D) A doctor of podiatric medicine;

(E) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(F) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(G) A supervised trainee in an approved educational program, as described in § 413.85 or §§ 413.76 through 413.83 of this chapter.

(ii) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(4) *Discharge*. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(5) *Standard: State exemption.* (i) An REH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (d)(3) of this section, if the state in which the REH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that they have consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the state and has concluded that it is in the best interests of the state's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with state law.

(ii) The request for exemption and recognition of state laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

§ 485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The REH must have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The REH must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings;

(3) The infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and

transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the services furnished by the REH.

(b) *Standard: Antibiotic stewardship program organization and policies.* The REH must demonstrate that --

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the REH; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the services furnished by an REH.

(c) *Standard: Leadership responsibilities.* (1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the REH's QAPI leadership.

(2) The infection prevention and control professional(s) are responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the REH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-facility systems.* If a REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member REH's unique

circumstances and any significant differences in patient populations and services offered in each REH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the REH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

(e) *COVID-19 and Seasonal Influenza reporting.* Beginning at the conclusion of the COVID-19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph, the REH must electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary.

(1) Related to COVID-19, to the extent as required by the Secretary, this report must include the following data elements:

(i) Suspected and confirmed COVID-19 infections among patients and staff.

(ii) Total COVID-19 deaths among patients and staff.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies

(v) Total patient census and capacity.

(vi) Staffing shortages.

(vii) COVID-19 vaccine administration data of patients and staff.

(viii) Relevant therapeutic inventories or usage, or both.

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients and staff.

(ii) Total influenza deaths among patients and staff.

(iii) Confirmed co-morbid influenza and COVID-19 infections among patients and staff.

(f) *Standard: Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential.* The REH must electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency, as defined in § 400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this

paragraph will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

(1) The REH must electronically report information about the infectious disease pathogen, relevant to the declared PHE, in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include, the following:

(i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.

(ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.

(iii) Personal protective equipment and other relevant supplies in the REH.

(iv) Capacity and supplies in the REH relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.

(v) Total patient census, capacity, and capability.

(vi) Staffing shortages.

(vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.

(viii) Relevant therapeutic inventories or usage, or both.

(ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors, or both, of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

(2) Unless the Secretary specifies an alternative format by which the REH must report these data elements, the REH must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or potentially individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

(3) The REH must provide the information specified in this paragraph on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

(g) *Standard: COVID-19 Vaccination of REH staff.* Until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph, the REH must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following REH staff, who provide any care, treatment, or other services for the REH and/or its patients:

(i) REH employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the REH and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following REH staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the REH that are performed exclusively outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the REH and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the REH has granted, an exemption from the staff COVID-19 vaccination requirements based on recognized clinical contraindications or applicable federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the REH's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

§ 485.528 Condition of participation: Staffing and Staff Responsibilities

(a) *Standard: Emergency Department Staffing.* The emergency department of the REH must be staffed 24 hours a day, 7 days a week by an individual or individuals competent in the skills needed to address emergency medical care. This individual(s) must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

(b) *Standard: Staffing.* (1) The REH must have a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the REH.

(4) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the REH has one or more patients receiving emergency care or observation care.

(c) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy must --

(i) Provide medical direction for the REH's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the REH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically review the REH's patient records, provide medical orders, and provide medical care services to the patients of the REH.

(iv) Periodically review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent where state law requires record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy must be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(d) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the REH's staff must --

(i) Participate in the development, execution and periodic review of the written policies governing the services the REH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the REH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the REH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is placed in observation care at the REH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the REH is notified of the patient's status.

(e) *Standard: Periodic review of clinical privileges and performance.* The REH requires that --

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the REH must be evaluated by a member of the REH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the REH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the REH must be evaluated by one of the following --

(i) One Quality Improvement Organization (QIO) or equivalent entity.

(ii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patient under an agreement between the REH and a distant-site hospital, the distant-site hospital; or

(iii) In the case of distant-site physicians and practitioners providing telemedicine

services to the REH's patients under a written agreement between the REH and a distant-site telemedicine entity, one Quality Improvement Organization (QIO) or equivalent entity.

(3) The REH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

§ 485.530 Condition of participation: Nursing services

The REH must have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. The nursing services must be furnished and supervised by a registered nurse. Nursing services must meet the needs of patients.

(a) *Standard: Organization and staffing*. Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice.

(b) *Standard: Nursing leadership.* The director of the nursing service must be a licensed registered nurse. The individual is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the REH.

§ 485.532 Condition of participation: Discharge planning.

An REH must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and their caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the REH to post-discharge care, and reduce the factors leading to preventable hospital admissions or readmissions.

(a) *Standard: Discharge planning process.* The REH's discharge planning process must identify, at an early stage of the provision of services, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-REH care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate services following those furnished by the REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the REH must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The REH's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(7) The REH must assess its discharge planning process on a regular basis. The assessment must include ongoing periodic review of a representative sample of discharge plans.

(8) The REH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The REH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.* The REH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

§ 485.534 Condition of participation: Patient's rights

An REH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) An REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The REH must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The REH's governing body or responsible individual must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The REH must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the REH.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* The patient has the right to --

(1) Participate in the development and implementation of their plan of care.

(2) Make informed decisions regarding their care, including being informed of their health status, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) Formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives, in accordance with § 489.100 of this part

(Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part.

(c) *Standard: Privacy and safety.* The patient has the right to --

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their medical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request.

(i) The records must be provided in the form and format requested by the individual, if it is readily producible in such form and format. This includes in an electronic form or format when such medical records are maintained electronically or if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual.

(ii) The records must be provided within a reasonable time frame. The REH must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Definitions. (i) A restraint is --

(A) Any manual method, physical or mechanical device, material, or equipment that

immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements*. The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The REH must provide patient-centered competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing

contracted services in the REH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements*: REHs must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the REH must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the REH staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such

restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* An REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

§ 485.536 Condition of participation: Quality assessment and performance improvement program

The REH must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The REH must measure, analyze, and track quality indicators, including adverse patient events, staffing, and other aspects of performance that assess processes of care including REH service and operations.

(b) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

(c) *Standard: Program activities.* (1) The REH must set priorities for its performance improvement activities that --

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the REH. An adverse patient event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. Medical error means an error that occurs in the delivery of health care services.

(3) The REH must take actions aimed at performance improvement and, after implementing those actions, the REH must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Executive responsibilities.* The REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the REH-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the REH's performance and reducing risk to patients.

(e) *Standard: Unified and integrated QAPI program for an REH in a multi-facility system.* If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that --

(1) The unified and integrated QAPI program is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed.

§ 485.538 Condition of participation: Agreements

Standard: Agreements with trauma centers. The REH must have in effect an agreement with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH that is--

(a) Licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the State; and

(b) Licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

§ 485.540 Condition of participation: Medical records.

(a) *Standard: Records system*. (1) The REH must maintain a medical records system in accordance with written policies and procedures.

(2) The records must be legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the REH must maintain a record that includes, as applicable --

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient,

and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information.* (1) The REH must maintain the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) The REH must have written policies and procedures that govern the use and removal of records from the REH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records must be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

(d) *Standard: Electronic notifications.* If the REH utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the REH must demonstrate that --

(1) The system's notification capacity is fully operational and the REH uses it in accordance with all state and federal statutes and regulations applicable to the REH's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of the patient's registration in the REH's emergency department.

(4) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time the patient's discharge or transfer from the REH's emergency department.

(5) The REH has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for their care.

§ 485.542 Condition of participation: Emergency preparedness.

The REH must comply with all applicable federal, state, and local emergency preparedness requirements. The REH must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The REH must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The REH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to --

(i) Food, water, medical, and pharmaceutical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the REH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the REH, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the REH.

(5) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency.

(7) The role of the REH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The REH must develop and maintain an emergency preparedness communication plan that complies with federal, state, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, state, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) REH's staff.

(ii) Federal, state, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the REH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The REH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The REH must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the REH must conduct training on the updated policies and procedures.

(2) *Testing.* The REH must conduct exercises to test the emergency plan at least annually. The REH must do the following:

(i) Participate in a full-scale exercise that is community-based every 2 years.

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

(B) If the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the REH's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and

NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) *Emergency generator fuel.* CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must --

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The material listed in this paragraph (g) is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, CMS must publish a document in the Federal Register and the material must be available to the public. All approved material is available for inspection at CMS and the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, email: scott.cooper@cms.hhs.gov or call (410) 786-9465. For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The material may be obtained from the following source(s) in this paragraph (g):

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

§ 485.544 Condition of participation: Physical environment.

The REH must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are ensured.

(1) There must be emergency power and lighting in at least the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(3) The REH must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(b) *Standard: Facilities.* The REH must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in patient care, pharmaceutical, food preparation, and other appropriate areas.

(c) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the REH must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

(2) In consideration of a recommendation by the state survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an REH, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients in an REH.

(4) An REH may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) When a sprinkler system is shut down for more than 10 hours, the REH must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(d) *Standard: Building Safety.* Except as otherwise provided in this section, the REH must meet the applicable provisions and must proceed in accordance with the 2012 edition of the

Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an REH.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the REH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

§ 485.546 Condition of participation: skilled nursing facility distinct part unit

If the REH provides skilled nursing facility services in a distinct part unit, the services furnished by the distinct part unit must be separately licensed and certified and comply with the requirements of participation for long-term care facilities specified in part 483, subpart B of this subchapter.

Subpart F – Conditions of Participation: Critical Access Hospitals (CAHs)

3. Section 485.610 is amended by revising paragraph (c) to read as follows:

§ 485.610 Condition of participation: Status and location.

* * * * *

(c) *Standard: Location relative to other facilities or necessary provider certification.*

(1) The CAH is located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a

necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(2) Primary roads of travel for determining the driving distance of a CAH and its proximity to other providers is defined as:

(i) A numbered federal highway, including interstates, intrastates, expressways or any other numbered federal highway with 2 or more lanes each way; or

(ii) A numbered State highway with 2 or more lanes each way.

* * * * *

45. Section 485.614 is added to subpart F to read as follows:

§ 485.614 Condition of participation: Patient's rights.

A CAH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of their plan of care.

(2) The patient or their representative (as allowed under State law) has the right to make informed decisions regarding their care. The patient's rights include being informed of their health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the

confidentiality of their clinical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) *Definitions.* (i) A *restraint* is --

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to

protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The CAH must provide patient-centered, trauma informed competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements:* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

* * * * *

46. Section 485.631 is amended by adding paragraph (e) to read as follows:

§ 485.631 Condition of participation: Staffing and staff responsibilities.

* * * * *

(e) *Standard: Unified and integrated medical staff for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that:

(1) The medical staff members of each separately certified CAH in the system (that is, all medical staff members who hold specific privileges to practice at that CAH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective CAH;

(2) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight,

as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH;

(3) The unified and integrated medical staff is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(4) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

§ 485.635 [Amended]

47. Section 485.635 is amended --

a. In paragraph (b)(2) introductory text by removing the reference "42 U.S.C. 236a" and adding in its place the reference "42 U.S.C. 263a"; and

b. By redesignating paragraph (f) as § 485.614(h).

48. Section 485.640 is amended by adding paragraph (g) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(g) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the CAH as responsible for

communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

49. Section 485.641 is amended by adding paragraph (f) to read as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(f) *Standard: Unified and integrated QAPI program for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

PART 489 - PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

50. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

51. Section 489.2 is amended by adding paragraph (b)(11) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) * * *

(11) Rural emergency hospitals (REHs).

* * * * *

52. Section 489.24(b) is amended by revising the definitions of "Hospital" and "Participating hospital" to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act and a rural emergency hospital as defined in section 1861(kkk)(2).

* * * * *

Participating hospital means

(1) a hospital;

(2) a critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act; or

(3) a rural emergency hospital as defined in section 1861(kkk)(2) of the Act.

* * * * *

Dated: _____.

_____

Xavier Becerra,

Secretary,

Department of Health and Human Services.