Small Entity Compliance Guide

Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy, and Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

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The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act (RFA).

The complete text of this final rule can be found on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1734-F.html.

Summary

This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program requirements for Eligible Professionals; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; Medicare enrollment of Opioid Treatment Programs; payment for office/outpatient evaluation and management services; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA-PD plan and Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy. This final rule also finalizes certain provisions of the interim final rules with comment period that CMS issued on March 31, 2020, May 8, 2020, and September 2, 2020 in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID-19). This rule also establishes coding and payment for virtual check-in services and for personal protective equipment (PPE) on an interim final basis.

Background

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. Per the statute, RVUs must be established for three categories of resources (work, practice expense (PE); and malpractice expense) and we must establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

Provisions of the Final Rule

CY 2021 PFS Ratesetting:
We finalized a series of standard technical proposals involving practice expense, including the implementation of the third year of the market-based supply and equipment pricing update, and standard rate-setting refinements to update premium data involving malpractice expense and geographic practice cost indices (GPCIs).

With the budget neutrality adjustment, as required by law, to account for changes in RVUs including significant increases for E/M visit codes, the final CY 2021 PFS conversion factor is $32.41, a decrease of $3.68 from the CY 2020 PFS conversion factor of $36.09. The PFS conversion factor reflects the statutory update of 0.00 percent and the adjustment necessary to account for changes in relative value units and expenditures that would result from finalized policies

Medicare Telehealth and Other Services involving Communications Technology:
For CY 2021, we finalized the additional services added to the Medicare telehealth list on a Category 1 basis that are similar to services already on the telehealth list.

Additionally, we finalized the creation of a third, temporary category of criteria for adding services to the list of Medicare telehealth services. Category 3 describes services added to the Medicare telehealth list during the public health emergency (PHE) for the COVID-19 pandemic (COVID-19 PHE) that will remain on the list through the calendar year in which the PHE ends.

We also clarified that licensed clinical social workers, clinical psychologists, physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs) can furnish the brief online assessment and management services as well as virtual check-ins and remote evaluation services. To facilitate billing by these practitioners for the remote evaluation of patient-submitted video or images and virtual check-ins (HCPCS codes G2010 and G2012), we are establishing two new HCPCS G codes (HCPCS codes G2550 and G2551).

In the March 31, 2020 COVID-19 interim final rule with comment (IFC), we established separate payment for audio-only telephone (E/M) services. While we did not propose to continue to recognize these codes for payment under the PFS in the absence of the COVID-19 PHE, we noted that the need for audio-only interactions could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office. Additionally, based on support from commenters, we are establishing payment on an interim final basis for a new HCPCS G code describing 11-20 minutes of medical discussion to determine the necessity of an in-person visit (HCPCS code G2252).

Remote Physiologic Monitoring (RPM) Services:
We clarified our payment policies related to the RPM services described by CPT codes 99453, 99454, 99091, 99457, and 99458. In addition, we finalized as permanent policy two modifications to RPM services that we finalized in response to the COVID-19 PHE.

Immunization Services:
We are maintaining payment rates for immunization administration services described by CPT codes 90460, 90461, 90471, 90472, 90473, and 90474, and HCPCS codes G0008, G0009, and G0010 at their CY 2019 payment levels in consideration of payment stability for stakeholders, public health concerns and the importance of these services for Medicare beneficiaries

Direct Supervision by Interactive Telecommunications Technology
We finalized a policy allowing direct supervision to include virtual presence of the supervising physician or practitioner using real-time, interactive audio and video technology through the end of the COVID-19 PHE or the end of 2021, whichever is later. We recognized that in some cases, the physical proximity of the physician or practitioner might present additional infection exposure risk to the patient and/or practitioner.

Payment for Office/Outpatient Evaluation and Management (E/M) and Analogous Visits:
We will be largely aligning our E/M visit coding and documentation policies with changes laid out by the CPT Editorial Panel for office/outpatient E/M visits, beginning January 1, 2021. We finalized revisions to the times used for ratesetting for the office/outpatient E/M visit code set.

We finalized revaluation of a number of code sets that include, rely upon, or are analogous to office/outpatient E/M visits commensurate with the increases in values we finalized for office/outpatient E/M visits for CY 2021.

We are also clarifying the definition of HCPCS add-on code G2211 (formerly referred to as GPC1X), previously finalized for office/outpatient E/M visit complexity, and refining our utilization assumptions for this code.

Policies Regarding Professional Scope of Practice and Related Issues:
- *Supervision of Diagnostic tests by Certain Nonphysician Practitioners (NPPs)*: we finalized our proposal to make permanent following the COVID-19 PHE, the same policy that was finalized under the May 1, 2020 COVID-19 IFC (85 FR 27550 through 27629) for the duration of the COVID-19 PHE to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests within their scope of practice and state law. We are also adding certified registered nurse anesthetists (CRNAs) to this list. These practitioners must maintain the required statutory relationships under Medicare with supervising or collaborating physicians.
- *Pharmacists Providing Services Incident to Physicians' Services*: we are reiterating the clarification provided in the May 1, 2020 COVID-19 IFC (85 FR 27550 through 27629), that pharmacists may fall within the regulatory definition of auxiliary personnel under our "incident to" regulations. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.
- *Therapy Assistants Furnishing Maintenance Therapy*: We finalized the Part B policy for maintenance therapy services that was adopted on an interim basis for the COVID-19 PHE in the May 1, 2020 COVID-19 IFC (85 FR 27556). This finalized policy allows physical therapists (PTs) and occupational therapists (OTs) to delegate the furnishing of maintenance therapy services, as

clinically appropriate, to a physical therapy assistant (PTA) or an occupational therapy assistant (OTA). This Part B policy allows PTs/OTs to use the same discretion to delegate maintenance therapy services to PTAs/OTAs that they utilize for rehabilitative services.

- *Medical Record Documentation*: We clarified that physicians and NPPs, including therapists, can review and verify documentation entered into the medical record by members of the medical team for their own services that are paid under the PFS. We also clarified that therapy students and students of other disciplines, working under a physician or practitioner who furnishes and bills directly for their professional services to the Medicare program, may document in the record so long as the documentation is reviewed and verified (signed and dated) by the billing physician, practitioner, or therapist.
- *PFS Payment for Services of Teaching Physicians and Resident "Moonlighting" Services*: For residency training sites of a teaching setting that are outside of a metropolitan statistical area (MSA), the CY 2021 PFS final rule established a policy to allow teaching physicians to use interactive, real-time audio/video to interact with the resident through virtual means to meet the requirement that they be present for the key portion of the service, including when the teaching physician involves the resident in furnishing Medicare telehealth services. In addition, for residency training sites of a teaching setting that are outside of an MSA, the CY 2021 PFS final rule allows teaching physicians involving residents in providing care at primary care centers to provide the necessary direction, management and review for the resident's services using interactive, real-time audio/video communications technology. For these sites, residents furnishing services at primary care centers may furnish an expanded set of services to beneficiaries, including communication technology-based services and inter-professional consults.

Finally, the CY 2021 PFS final rule permanently expanded the settings in which residents may moonlight to include the services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program. To prevent the potential duplication of payment with the Inpatient Prospective Payment System (IPPS) for GME, and regardless of whether the resident's services are performed in the outpatient department, emergency department or inpatient setting of a hospital in which they have their training program, the medical record must show that the resident furnished identifiable physician services that meet the conditions of payment of physician services to beneficiaries in providers in § 415.102(a); that the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the state in which the services are performed; and that the services are not performed as part of the approved GME program.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs):

We finalized our proposal to extend the definition of OUD treatment services to include opioid antagonist medications, specifically naloxone, that are approved by Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for emergency treatment of opioid overdose, as well as overdose education. We also finalized the proposed creation of a new add-on code to cover the cost of providing patients with nasal naloxone and pricing this code based upon the methodology under section 1847A of the Act, except that the payment amount shall be average sales price (ASP) + 0. Since auto-injector naloxone is no longer available in the marketplace, we are instead finalizing a second new add-on code to cover the cost of providing patients with injectable naloxone and we are contractor pricing this code for CY 2021. We finalized our proposal to apply a frequency limit on the codes describing naloxone, but we are allowing exceptions in the case where the beneficiary overdoses and uses the supply of naloxone given to them by the OTP, to the extent that the additional supply of naloxone is medically reasonable and necessary. Additionally, we finalized our proposal to allow periodic assessments to be furnished via two-way interactive audio-video communication technology.

Section 2002 of the Support Act:
Section 2002 of the SUPPORT Act required the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential substance use disorders (SUDs) and a review of any current opioid prescriptions. We are implementing section 2002 of the SUPPORT Act requirements, which complements existing requirements of the IPPE and AWV. The review of medical history, and therefore, current medications, includes a review of any current opioid prescriptions. Clinicians in the course of conducting the AWV and IPPE may also determine that a referral for further evaluation and management is appropriate for patients who are identified as high risk for SUD. Referral to treatment is a critical component of getting patients who have a possible SUD the necessary care. The new IPPE and AWV elements required by the SUPPORT Act, working in tandem with our existing relevant requirements, will promote the early detection of high-risk patients and help empower clinicians to offer appropriate referrals.

Section 2003 of the Support Act:
Section 2003 of the SUPPORT Act requires that, effective January 1, 2021, the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program, subject to any exceptions, which HHS may specify. To help inform CMS's implementation of section 2003, we issued a Request for Information entitled "Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information," as a separate document on July 30.

Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions:
We finalized conforming changes to the data reporting and payment requirements at 42 C.F.R. part 414, subpart G, to reflect the revisions to the data reporting period and phase-in of payment reductions enacted in the FCAA and the CARES Act for the Medicare Clinical Laboratory Fee Schedule (CLFS).

In summary, the revisions are as follows:
- The next data reporting period of January 1, 2022 through March 31, 2022, for CDLTs that are not ADLTs will be based on the data collection period of January 1, 2019 through June 30, 2019.
- After the data reporting period in 2022, there is a three-year data reporting cycle for CDLTs that are not ADLTs (that is 2025, 2028, and so on)
- Additionally, the statutory phase-in of payment reductions resulting from private payor rate implementation is extended through CY 2024. There is a 0.0 percent payment reduction for CY 2021 as compared to the amount established for CY 2020, and for CYs 2022 through 2024; payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

Principal Care Management Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs):
In the CY 2020 PFS final rule, separate payment was established for Principal Care Management (PCM) services paid under the PFS. For PCM services furnished on or after January 1, 2020, we established two new HCPCS codes, G2064 and G2065,that describe comprehensive care management services of a single high-risk disease. We finalized the revision of 42 CFR 405.2464 to reflect the current payment methodology that was finalized in the CY 2020 PFS final rule and added the 2 new HCPCS codes, G2064 and G2065, to the general care management HCPCS code, G0511, for PCM services furnished in RHCs and FQHCs beginning January 1, 2021.

RHCs and FQHCs that furnish PCM services will bill HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim. The current payment rate for HCPCS code G0511 is the average of the national non-facility PFS payment rate for the RHC/FQHC care

management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491). HCPCS G2064 and G2065 will be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 will be updated annually based on the PFS amounts for these codes.

Rebase and Revise the FQHC Market Basket:
We finalized rebasing and revising the FQHC market basket to reflect a 2017 base year. The 2017 based FQHC market basket update for CY 2021 is 2.4 percent. The multifactor productivity adjustment for CY 2021 is 0.7 percent. The final CY 2021 FQHC payment update is 1.7 percent.

Medicare Shared Savings Program:
We finalized changes to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and quality-reporting requirements for performance years beginning on January 1, 2021 to align with Meaningful Measures, reduce reporting burden and focus on patient outcomes. For performance year 2020, we finalized to provide automatic full credit for CAHPS® patient experience of care surveys.

In response to new telehealth code policies finalized in this rule and to update the definition of primary care services used for beneficiary assignment to reflect the codes for assessment and care planning services for patients with cognitive impairment and chronic care management services, we finalized the inclusion of new evaluation and management and care management CPT and HCPCS codes in the methodology used to assign beneficiaries to ACOs. In addition, we finalized our proposals to exclude certain services furnished in skilled nursing facilities from the assignment methodology when provided by clinicians billing through FQHCs and RHCs, and to modify the definition of primary care services to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed for services furnished in an inpatient care setting. We are also codifying our policy of adjusting an ACO's historical benchmark to reflect any regulatory changes to the beneficiary assignment methodology in the regulations governing the benchmarking methodology.

We finalized several policies that will further reduce burden associated with repayment mechanisms. Beginning with the application cycle for an agreement period starting on January 1, 2022 and annually thereafter, renewing ACOs and re-entering ACOs that are the same legal entities as ACOs that previously participated in the program, that wish to continue use of their existing repayment mechanism in a new agreement period may decrease their repayment mechanism amount if a higher amount is not needed for their new agreement period. The final rule includes a revised methodology for calculation of repayment mechanism amounts beginning with the application cycle for an agreement period starting on January 1, 2022, and annually thereafter. The final rule also offers a one-time opportunity for eligible ACOs that renewed their agreement periods beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of their repayment mechanisms if the ACO's recalculated repayment mechanism amount for performance year 2021 is less than their existing repayment mechanism amount.

The interim final rule with comment period (IFC) issued by CMS on March 31, 2020, and the IFC issued by CMS on May 8, 2020, included provisions modifying or clarifying Shared Savings Program policies to address the impact of the PHE for COVID-19 on ACOs. In the CY 2021 PFS final rule, in response to public comments received, we finalized the Shared Savings Program provisions in these IFCs, with several modifications. We revised the regulations specifying the adjustment to program calculations for episodes of care for treatment of COVID-19 to ensure greater consistency in the policies used to identify inpatient services provided by inpatient prospective payment system (IPPS) and non-IPPS providers that trigger an episode of care for treatment of COVID-19. We finalized the regulation specifying the expanded definition of primary care services for purposes of determining beneficiary assignment with modifications for greater

consistency with the existing beneficiary assignment methodology. Specifically, we are finalizing that the expanded definition, which includes telehealth codes for virtual check-ins, e-visits, and telephonic communication, will apply when the assignment window for a benchmark or performance year includes any months during the PHE for COVID-19 as defined in § 400.200. we added a provision specifying that the additional primary care service codes will be applied to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) of the COVID-19 PHE.

Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Food, Drug, and Cosmetic Act:

Some drugs approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act share similar labeling and uses with generic drugs that are assigned to multiple source drug codes. we proposed to continue assigning certain section 505(b)(2) drug products to existing multiple source drug codes when such drug products meet the definition of multiple source drug set forth at section 1847A(c)(6)(C) of the Act. This approach would apply to section 505(b)(2) drug products where a billing code descriptor for an existing multiple source code describes the product and other factors, such as the product's labeling and uses, are similar to products that are already assigned to the code.

The proposed approach is consistent with the concept of paying similar amounts for similar services and with efforts to curb drug prices. The proposal also would encourage competition among products that are described by one billing code and share similar labeling.

In response to comments asking for more detail about our proposed approach and requests to delay finalizing a decision, we are not finalizing the proposal or the corresponding regulation text for CY 2021.

Removal of Outdated National Coverage Determinations (NCDs):

We finalized the removal of six outdated or obsolete National Coverage Determinations (NCDs). Removing outdated NCDs means Medicare Administrative Contractors no longer are required to follow those outdated coverage policies when it comes to covering services for beneficiaries. The result will allow flexibility for these contractors to determine coverage for beneficiaries in their geographic areas based on more recent evidence and information.

Small Entities Affected

For purposes of the RFA, physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) are considered small businesses if they generate revenues of $10 million or less, according to the Small Business Administration size schedule. We estimate that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in section VIII. of the final rule (Regulatory Impact Analysis), as well as elsewhere in the final rule are intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. (See Table 106 (CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty) of the final rule, which show the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 106.)

For the Quality Payment Program, we estimate that between 210,000 and 270,000 clinicians will become Qualifying APM Participants (QPs) and the total lump sum APM Incentive Payments will

be approximately $535-685 million in the 2022 Quality Payment Program payment year. We estimate that approximately 880,000 clinicians will be MIPS eligible clinicians for the 2020 MIPS performance period. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments and positive MIPS payment adjustments ($433 million redistributed) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance.

Section 101(a) of the Medicare Access and CHIP Reauthorization Act of 2015 repealed the previous statutory update formula (known as the Sustainable Growth Rate) and specified the PFS update for CY 2015 and beyond. The PFS update for CY 2021 is 0.00 percent, which is reflected in the overall update. After applying the required budget neutrality adjustment, the conversion factor for January 1, 2021 through December 31, 2021 will be $32.41. Please refer to section VIII. of the final rule for the full regulatory impact analysis.

This rule imposes no direct federal compliance requirements with significant economic impacts on small entities. In order to assist physicians, NPPs, and suppliers including IDTFs in understanding and adapting to changes in Medicare billing and payment procedures, we have developed webpages that include additional material on the PFS at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html and https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.