

February 1, 2018

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Medicare Advantage and Part D have been successful in providing Medicare beneficiaries with options so that they can choose the healthcare that best fits their individual health needs. These programs demonstrate the value of private sector innovation and creativity and CMS is committed to continuing to make changes that promote greater innovation, transparency, flexibility, and program simplification.

Since January 2017, CMS has met with numerous stakeholders to discuss how to strengthen Medicare Advantage and Part D. As part of this outreach, we also released a Request for Information in the 2018 Rate Announcement and Call Letter. We appreciate the comments and ideas we received through these meetings and in response to the Request for Information. The suggestions provided by stakeholders have been thoughtful and creative and have provided valuable perspectives on changes that can continue to transform these important programs. We have used that input to develop a set of proposed policies and updates for 2019 that we believe will remove barriers to innovation and foster greater transparency, flexibility, and program simplification.

On December 27, 2017, we released for comment proposed changes to the Part C risk adjustment model used to pay for aged and disabled beneficiaries, and are continuing to solicit comment on those proposed changes until Monday, March 5, 2018. In accordance with section 1853(b)(2) of the Social Security Act, we are now notifying you of additional planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2019. Also included with this notice are proposed changes in the payment methodology for CY 2019 for Part D and annual adjustments for CY 2019 to the Medicare Part D benefit parameters for the defined standard benefit. For 2019, CMS will announce the MA capitation rates and final payment policies on Monday, April 2, 2018, in accordance with the timetable required by section 1853(b), as established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) and amended by the Securing Fairness in Regulatory Timing Act of 2015 (SFRTA) (Pub. L. 114-106). The Advance Notice of Methodological Changes is published no fewer than 60 days before the publication of the Rate Announcement and provides a minimum 30-day period for public comment.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage and the national Medicare fee-for-service growth percentage, which are key factors in

determining the MA capitation rates. Attachment II sets forth changes in the Part C payment methodology for CY 2019. Attachment III sets forth the changes in the Part D payment methodology for CY 2019. Attachment IV presents the annual adjustments for CY 2019 to the Medicare Part D benefit parameters for the defined standard benefit. Attachment V presents the preliminary risk adjustment factors.

Attachment VI provides the draft CY 2019 Call Letter for MA organizations; section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; Medicare-Medicaid Plan (MMP); and employer and union-sponsored MA or Part D group plans, including both employer/union-only group health plans and direct contract plans. The draft CY 2019 Call Letter contains proposals relating to the quality rating system and information these plan sponsor organizations will find useful as they prepare their bids for the new contract year. In addition, the draft CY 2019 Call Letter includes draft bid and operational guidance for plans.

To submit comments or questions electronically, go to <https://www.regulations.gov>, enter the docket number “CMS-2017-0163” in the “Search” field, and follow the instructions for “submitting a comment.”

Comments will be made public, so submitters should not include any confidential or personal information. In order to receive consideration prior to the April 2, 2018 release of the final Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern Standard Time on Monday, March 5, 2018.

/ s /

Demetrios Kouzoukas
Principal Deputy Administrator
and Director, Center for Medicare

I, Jennifer Wuggazer Lazio, am a Member of the American Academy of Actuaries. I meet the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained in this Advance Notice. My opinion is limited to the following sections of this Advance Notice: The growth percentages and United States per capita cost estimates provided in Attachment I; the qualifying county determination, calculation of Fee for Service cost, IME phase out, and ESRD rates discussed in Attachment II; Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2019 described in Attachment III and in Attachment IV.

/ s /

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Attachments

2019 ADVANCE NOTICE TABLE OF CONTENTS

Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2019	6
Section A. MA Growth Percentage	6
Section B. FFS Growth Percentage	6
Attachment II. Changes in the Part C Payment Methodology for CY 2019	9
Section A. MA Benchmark, Quality Bonus Payments and Rebate	9
Section B. Calculation of Fee for Service Cost	15
Section C. IME Phase Out.	22
Section D. ESRD Rates.	22
Section E. Clinical Trials	23
Section F. Location of Network Areas for PFFS Plans in Plan Year 2020	24
Section G. MA Employer Group Waiver Plans.	25
Section H. CMS-HCC Risk Adjustment Model for CY 2019	30
Section I. ESRD Risk Adjustment Model for CY 2019.	30
Section J. Frailty Adjustment for PACE organizations and FIDE SNPs	34
Section K. Medicare Advantage Coding Pattern Adjustment.	35
Section L. Normalization Factors	36
Section M. Medical Loss Ratio Credibility Adjustment	41
Section N. Encounter Data as a Diagnosis Source for 2019.	42
Section O. Quality Payment Program.	43
Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2019.	45
Section A. Update of the RxHCC Model	45
Section B. Encounter Data as a Diagnosis Source for 2019	46
Section C. Part D Risk Sharing	46
Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2019.	49
Section E. Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap.	54
Section F. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap	56
Section G. Part D Calendar Year Employer Group Waiver Plans Prospective Reinsurance Payment Amount.	56
Section H. Enhanced Medication Therapy Management (MTM) Model.	56
Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2019.	58
Section A. Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API).	58

Section B. Annual Percentage Increase in Consumer Price Index (CPI)	59
Section C. Calculation Methodology	60
Section D. Retiree Drug Subsidy Amounts.	63
Section E. Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries	63
Attachment V. RxHCC and ESRD Risk Adjustment Factors	65
Attachment VI. Draft CY 2019 Call Letter	97
How to Use This Call Letter.	99
Section I – Parts C and D	100
Section II – Part C	168
Section III – Part D	193
Section IV – Medicare-Medicaid Plans	222
Appendix 1: Methodology for Plan Finder (PF) Composite Price Accuracy Display Measure	227
Contract Selection	227
PF Composite Price Accuracy Score.	227

Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2019

For 2019, the MA county rates are based on the specified amount as defined in Section A2 below. Section 1853(n)(4) of the Social Security Act requires that the benchmark (increased by quality bonus percentages where applicable) be capped at the level of the 1853(k)(1) applicable amount. The 2019 FFS cost is calculated, in part, using the FFS growth percentage. CMS intends to rebase the county FFS rates for 2019 as part of the calculation of the rates for 2019.

Throughout this document, the Social Security Act will be referred to as “the Act.”

Section A. MA Growth Percentage

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2019 is 5.44 percent. This estimate reflects an underlying trend change for CY 2019 in per capita cost of 4.05 percent and, as required under section 1853(c)(6)(C) of the Act, adjustments to the estimates for prior years as indicated in the table below.

Table I-1 below summarizes the estimates for the change in the national per capita MA growth percentage for aged/disabled beneficiaries.

Table I-1. Increase in the National Per Capita MA Growth Percentages for 2019

	Prior Increases	Current Increases			NPCMAGP for 2019 With §1853(c)(6)(C) adjustment¹
	2003 to 2018	2003 to 2018	2018 to 2019	2003 to 2019	
Aged+Disabled	58.76%	60.88%	4.05%	67.40%	5.44%

¹Current increases for 2003-2019 divided by the prior increases for 2003-2018

Section B. FFS Growth Percentage

Section 1853(n)(2) of the Act requires that the specified amount for a county be calculated as a percentage of the county FFS costs. Table I-2 below provides the current estimate of the change in the Aged/Disabled FFS United States per capita cost (USPCC), which will be used as the basis for the county FFS rates. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2019 divided by the prior projected FFS USPCC for 2018.

Table I-2 also shows the change in the FFS USPCC for dialysis-only ESRD. Statewide dialysis-only ESRD rates are determined by applying a historical average geographic adjustment to a projected FFS dialysis-only ESRD USPCC. We will use a 5-year average of State data to

determine the average geographic adjustment, similar to the method used to determine the geographic adjustments for non-ESRD rates.

Table I-2. Increase in the USPCC Growth Percentage for CY 2019

	Total USPCC – Non-ESRD	FFS USPCC – Non-ESRD	Dialysis-only ESRD
Current projected 2019	\$910.38	\$882.33	\$7,495.03
Prior projected 2018	\$863.39	\$847.73	\$7,133.42
Percent increase	5.44%	4.08%	5.07%

Table I-3 compares last year's estimate of the total non-ESRD USPCC with current estimates for 2003 to 2021, and Table I-4 compares last year's FFS non-ESRD USPCC estimates with current estimates. The total USPCCs are the basis for the National Per Capita MA Growth Percentages. In addition, these tables show the current projections of the USPCCs through 2021. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide. None of the data presented here pertain to the Medicare prescription drug benefit.

In accordance with the CY 2017 Quality Payment Program (QPP) final rule with comment period (81 FR 77008), we expect that clinician payment adjustments will be made in CY 2019. Consistent with current policy, FFS incentives will continue to be included in the calculation of FFS costs for MA ratesetting purposes such that an estimate of the aggregate impact will be taken into account in the projected FFS USPCC for 2019. Attachment II Section B contains additional information regarding the calculation of FFS costs.

Table I-3.-Comparison of Current & Previous Estimates of the Total USPCC – Non-ESRD

	Part A		Part B		Part A & Part B		
Calendar Year	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Ratio
2003	\$296.18	\$296.18	\$247.66	\$247.66	\$543.84	\$543.84	1.000
2004	\$314.08	\$314.08	\$271.06	\$271.06	\$585.14	\$585.14	1.000
2005	\$334.83	\$334.83	\$292.86	\$292.86	\$627.69	\$627.69	1.000
2006	\$345.30	\$345.30	\$313.70	\$313.70	\$659.00	\$659.00	1.000
2007	\$355.44	\$355.44	\$330.68	\$330.68	\$686.12	\$686.12	1.000
2008	\$371.90	\$371.90	\$351.04	\$351.04	\$722.94	\$722.94	1.000
2009	\$383.91	\$383.91	\$367.93	\$367.93	\$751.84	\$751.84	1.000
2010	\$383.93	\$383.94	\$376.81	\$376.82	\$760.74	\$760.76	1.000
2011	\$387.95	\$386.94	\$386.23	\$386.24	\$774.18	\$773.18	1.001
2012	\$377.47	\$378.95	\$392.75	\$392.77	\$770.22	\$771.72	0.998
2013	\$381.19	\$381.19	\$399.46	\$399.56	\$780.65	\$780.75	1.000
2014	\$371.96	\$371.71	\$418.42	\$418.73	\$790.38	\$790.44	1.000
2015	\$375.48	\$374.40	\$435.69	\$436.25	\$811.17	\$810.65	1.001
2016	\$380.16	\$374.68	\$446.33	\$447.60	\$826.49	\$822.28	1.005
2017	\$386.19	\$378.11	\$464.62	\$462.05	\$850.81	\$840.16	1.013
2018	\$389.05	\$382.86	\$485.88	\$480.53	\$874.93	\$863.39	1.013
2019	\$400.71	\$396.50	\$509.67	\$511.10	\$910.38	\$907.60	1.003
2020	\$416.99	\$412.63	\$535.66	\$538.17	\$952.65	\$950.80	1.002
2021	\$437.08		\$566.33		\$1,003.41		

Table I-4. Comparison of Current & Previous Estimates of the FFS USPCC – Non-ESRD

	Part A		Part B		Part A & Part B		
Calendar Year	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Ratio
2010	\$371.17	\$371.17	\$374.91	\$374.91	\$746.08	\$746.08	1.000
2011	\$371.38	\$370.01	\$384.39	\$384.39	\$755.77	\$754.40	1.002
2012	\$357.17	\$359.17	\$391.94	\$391.94	\$749.11	\$751.11	0.997
2013	\$365.51	\$365.50	\$395.73	\$395.85	\$761.24	\$761.35	1.000
2014	\$366.25	\$365.80	\$408.81	\$409.16	\$775.06	\$774.96	1.000
2015	\$371.54	\$370.14	\$429.12	\$430.15	\$800.66	\$800.29	1.000
2016	\$375.00	\$367.52	\$436.56	\$439.16	\$811.56	\$806.68	1.006
2017	\$377.95	\$369.28	\$456.08	\$455.72	\$834.03	\$825.00	1.011
2018	\$379.90	\$377.28	\$470.02	\$470.45	\$849.92	\$847.73	1.003
2019	\$390.02	\$390.42	\$492.31	\$498.55	\$882.33	\$888.97	0.993
2020	\$404.71	\$405.85	\$515.98	\$524.10	\$920.69	\$929.95	0.990
2021	\$423.38		\$544.43		\$967.81		

These estimates are preliminary and could change when the final rates are announced no later than April 2, 2018 in the Announcement of CY 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Further details on the derivation of the national per capita MA growth percentage and the FFS growth percentage will also be presented in the April 2, 2018 Announcement.

Attachment II. Changes in the Part C Payment Methodology for CY 2019

Section A. MA Benchmark, Quality Bonus Payments and Rebate

Section 1853(c)(1)(D)(ii) of the Act requires CMS to rebase the county FFS rates, which form the basis of the specified amount described in Section A2 below, periodically but not less than once every three years. When the rates are rebased, CMS updates its estimate of each county's FFS costs using more current FFS claims information. CMS intends to rebase the county FFS rates for 2019. (Please note that throughout this document, the terms "benchmark" and "county rate" are used interchangeably, and the term "service area benchmark" indicates the bidding target for an MA plan based on its specific service area.)

The Programs of All-Inclusive Care for the Elderly (PACE) plans are exempt from the use of the specified amount, per section 1853(n)(5) of the Act.

A1. Applicable Amount

The applicable amount is the rate established under section 1853(k)(1) of the Act. As CMS intends to rebase the rates in 2019, the applicable amount for 2019 is the greater of: (1) the county's 2019 FFS cost or (2) the 2018 applicable amount increased by the CY 2019 National Per Capita Medicare Advantage Growth Percentage. As discussed in Section A5, section 1853(n)(4) of the Act requires that the benchmark (determined taking into account the quality bonus percentage increase) for each county must be capped at the county's applicable amount.

A2. Specified Amount

Under section 1853(n)(2)(A) of the Act, the specified amount is based upon the following formula:

$$(2019 \text{ FFS cost minus IME phase-out amount}) \times (\text{applicable percentage} + \text{applicable percentage quality increase})$$

Where:

IME phase-out amount is the indirect costs of medical education phase-out amount as specified at section 1853(k)(4) and sections 1853(n)(2)(E) and (F);

Applicable percentage is a statutory percentage applied to the county's base payment amount, as described at section 1853(n)(2)(B); and

Applicable percentage quality increase, referred to in this document as the quality bonus payment (QBP) percentage, is a percentage point increase to the applicable percentage for a county in a qualifying plan's service area.

Section 1853(n)(2)(C) of the Act requires CMS to determine applicable percentages for a year based on county FFS rate rankings for the most recent year that was a rebasing year. To determine the CY 2019 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2018 average per capita FFS rate, because 2018 is the most recent rebasing year prior to 2019. CMS will then place the rates into four quartiles. For the territories, CMS will assign an applicable percentage to each territory county based on where the territory county rate falls in the quartiles established for the 50 States and the District of Columbia.

CMS is publishing the 2019 applicable percentages by county with the Advance Notice at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>. Each county's applicable percentage is assigned based upon its quartile ranking, as follows:

Table II-1. FFS Quartile Assignment

Quartile	Applicable Percentage
4 th (highest)	95%
3 rd	100%
2 nd	107.5%
1 st (lowest)	115%

Section 1853(n)(2)(D) of the Act provides that, beginning in 2013, if there is a change in a county's quartile ranking for a payment year compared to the county's ranking in the previous year, the applicable percentage for the area for the year shall be the average of: (1) the applicable percentage for the previous year and (2) the applicable percentage for the current year. For both years, CMS will calculate the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision. For example, if a county's ranking changed from the second quartile to the third quartile, the applicable percentage would be 103.75 percent for the year of the change – the average of 107.5 percent and 100 percent.

A3. Quality Bonus Payment Percentage

The Act provides for CMS to make quality bonus payments to MA organizations that meet quality standards measured under a five-star quality rating system. In this document, we refer to this quality bonus as the *quality bonus payment (QBP) percentage* instead of using the statutory term *applicable percentage quality increase*. The QBP percentage is a percentage point increase to the applicable percentage for each county in a qualifying plan's service area, before multiplying the percentage by the FFS rate for the year to determine the specified amount.

Table II-2 shows the QBP percentage for each Star Rating for 2019 payments. For CY 2019 payments, plans with fewer than four stars will not receive a QBP percentage increase to the county rates, and plans with four or more stars will receive a QBP percentage increase to the county rates, as set forth in sections 1853(n) and 1853(o) of the Act. See Section A6 for rebate percentages for CY 2019.

**Table II-2 Percentage Add-on to Applicable Percentage
for Quality Bonus Payments**

Star Rating	2019 QBP Percentage
Fewer than 4 stars	0%
4 stars	5%
4.5 stars	5%
5 stars	5%

An MA plan's Star Rating is the rating assigned to its contract; the contract rating is applied to each plan under that contract. MA plans with a Star Rating of four or more stars will bid against their service area benchmarks that include the 5-percentage point QBP add-on to the applicable percentage for the benchmark in each county in the service area. For 2019, MA plans with a Star Rating of fewer than four stars will bid against service area benchmarks that do not include QBP add-ons to the county rates, with the exceptions of new MA plans and low enrollment plans. As discussed below, all benchmarks (determined after application of the QBP percentage) are capped at the section 1853(k)(1) applicable amount per section 1853(n)(4) of the Act.

New MA Plans

New MA plans are treated as qualifying plans that are eligible to receive a QBP percentage increase to the county rates, except that the QBP percentage will be 3.5 percentage points, per section 1853(o)(3)(A)(iii)(I)(cc) of the Act. That is, new MA plans will bid against a service area benchmark that reflects a 3.5 percentage point increase to the applicable percentage used to set the benchmark for each county in the plan's service area. Per section 1853(o)(3)(A)(iii)(II) of the Act, for the purpose of determining a QBP percentage, the term "new MA plan" refers to an MA plan offered by a parent organization that has not had another MA contract in the preceding three-year period. As discussed below, all rates are capped at the section 1853(k)(1) applicable amount (determined after application of the QBP percentage) – per section 1853(n)(4) of the Act.

For 2019, CMS intends to continue the policy finalized in the 2012 Rate Announcement (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>) that for a parent organization that has had a contract with CMS in the preceding three-year-period, any new MA contract under that parent organization will receive an enrollment-weighted average of the Star Ratings earned by the parent organization's existing

MA contracts. Such plans may qualify for a QBP increase based on the enrollment-weighted average rating of the parent organization.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) contained provisions to permit reasonable cost reimbursement contracts to transition into MA plans through CY 2019, and allowed Medicare Advantage Organizations (MAOs) to deem the enrollment of their cost enrollees into successor affiliated MA plans that meet specific conditions. MACRA amended section 1853(o)(4) of the Act such that, for its first three years as a converted MA plan receiving deemed enrollment, the converted plan shall not be treated as a new MA plan.

Low Enrollment Plans

Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at § 422.258(d)(7)(iv)(B),¹ provides that for 2013 and subsequent years, CMS shall develop a method for determining whether an MA plan with low enrollment is a qualifying plan for purposes of receiving an increase in payment under section 1853(o). We apply this determination at the contract level, and thus determine whether a contract (meaning all plans under that contract) is a qualifying contract. Pursuant to § 422.252, a low enrollment contract is one that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

Section 1853(o)(3)(A)(ii) of the Act does not address the amount of the increase for low enrollment contracts. For 2019 payments, we intend to continue the current policy that low enrollment contracts be included as qualifying contracts that receive the QBP percentage of 3.5 percentage points, similar to the QBP percentage increase applied to new MA plans. We discussed the basis of this policy in detail in the 2018 Rate Announcement (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>).

Contract Consolidations and QBP

CMS proposed in the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4182-P) (82 FR 56336) that when consolidations involve two or more contracts for health and/or drug services of the same plan type under the same legal entity combining into a single contract at the start of a contract year, the rating used to determine QBP status (“QBP rating”) for that first year following the consolidation would be the enrollment weighted average of what would have been the QBP ratings of the surviving and consumed contracts using the contract enrollment in November of the year the Star Ratings were released. For example, if two contracts consolidate starting in January 2020, the 2020 QBP rating would be based on the 2019 Star Ratings released

¹ All regulatory cites are to Title 42 of the Code of Federal Regulations unless otherwise noted.

in October 2018 using the November 2018 enrollment of the surviving and consumed contracts. The application of this policy for CY 2019 and future periods will be addressed in the pending rulemaking.

A4. Qualifying County Bonus Payment

Beginning with contract year 2012, section 1853(o)(2) of the Act extends a double QBP percentage to a qualifying plan located in a “qualifying county.” For 2019, a qualifying county is a county that meets the following three criteria:

- (1) has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000;
- (2) as of December 2009, had at least 25 percent of MA-eligible beneficiaries residing in the county enrolled in a MA plan; and
- (3) has per capita FFS County spending for 2019 that is less than the national monthly per capita cost for FFS for 2019.

See section 1853(o)(3)(B) of the Act.

As an example, a qualifying plan with a rating of 4.5 stars will have 5 QBP percentage points added to the applicable percentage of each county in its service area. For each qualifying county in that plan’s service area, an additional 5 percentage points will be added to that county’s applicable percentage for a total increase of 10 percentage points used to calculate the benchmark. If this qualifying county otherwise has an applicable percentage of 95 percent, this is increased to 105 percent to reflect the quality bonus payment percentage for that county. As discussed below, all benchmarks are capped at the section 1853(k)(1) applicable amount (determined after application of the QBP percentage) per section 1853(n)(4) of the Act.

CMS will publish a complete list of qualifying counties in the final 2019 Rate Announcement. The listing will contain all counties that meet all three criteria stated above. Two of the three elements for determining a qualifying county (2004 urban floors (Y/N) for each county, and 2009 Medicare Advantage penetration rates) can be found in the 2018 Rate Calculation Data file (columns Z and AA) on the CMS website at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html>. The 2019 FFS rates, which are necessary for the third criterion, are not available at the time this Advance Notice is published. The FFS rates and the national average FFS spending amount will be published in the final 2019 Rate Announcement.

A5. Cap on Benchmarks

Section 1853(n)(4) of the Act requires that the benchmark (determined taking into account application of the QBP percentage) for a county must be capped at the level of the county’s

applicable amount determined under section 1853(k)(1). We interpret this provision as requiring that the QBP increase must be included in the benchmark before the comparison is made to determine if the cap is applied. Thus, for all counties, post-QBP percentage rates are capped at the section 1853(k)(1) applicable amount.

CMS shares the concerns stakeholders have raised about any rate-setting mechanism that diminishes incentives for MA plans to continuously improve the care provided to Medicare beneficiaries, and agrees that a primary goal of the Star Rating system for MA is to encourage plans to continuously improve the quality of the care provided to their enrollees. However, while we appreciate the concerns stakeholders have raised in connection with the cap on benchmarks, CMS has not identified an approach under section 1853(n)(4) of the Act to eliminate application of the rate cap or exclude the bonus payment from the cap calculation.

A6. Rebate

Under section 1854(b)(1)(C) of the Act, except for MSA plans, the level of rebate for each plan is based on the plan's Star Rating. Rebates for each plan are calculated as a percentage of the amount by which the risk-adjusted service area benchmark exceeds the risk-adjusted bid. Under § 422.266(b), plans may use rebates to fund mandatory supplemental benefits and/or to buy down beneficiary premiums for Part B and/or prescription drug coverage. Section 1854(b)(1)(C) stipulates rebate percentages that apply based on a plan's Star Rating, as shown in Table II-3.

Table II-3. MA Rebate Percentages

Star Rating	2019
4.5+ Stars	70%
3.5 to < 4.5 stars	65%
< 3.5 stars	50%

Section 1854(b)(1)(C)(vi)(II) of the Act requires that, for purposes of determining the rebate percentage, a new MA contract under a new parent organization will be treated as having a Star Rating of 3.5 stars for 2012 and subsequent years. The statute is silent on the rebate percentage to assign to low enrollment plans in years after 2012. We view this as a gap in the statute, particularly in light of the direction in section 1853(o)(3)(A)(ii) to treat low enrollment plans as qualifying plans for purposes of the quality bonus payment percentage. As we have in prior years, CMS intends to treat low enrollment plans as having a Star Rating of 3.5 stars for purposes of determining the rebate percentage for 2019.

As mentioned above, MACRA amended section 1853(o)(4) of the Act such that, for the first three years that a former reasonable cost reimbursement contract is a converted MA plan receiving deemed enrollment, the converted plan shall not be treated as a new MA plan.

Section B. Calculation of Fee for Service Cost

The FFS cost for each county is a product of (1) the national FFS cost, or United States per-capita cost (USPCC), and (2) a county-level geographic index called the average geographic adjustment (AGA).

For 2019, we are proposing to continue to incorporate refinements developed in prior years to update the claims data used to calculate the AGAs and to continue the repricing of historical data in the AGA calculation. Specifically, we will incorporate updates and refinements to the AGA calculation methodology to reflect changes in FFS payment rules. Historical claims data will be repriced to reflect the most current wage and cost indices. CMS will re-price hospital inpatient, hospital outpatient, skilled nursing facility, and home health claims to reflect the most current wage indices, and re-tabulate physician claims with the most current Geographic Practice Cost Index. We will also reprice historical claims to account for legislative and regulatory changes made to payments to disproportionate share hospitals and reprice durable medical equipment claims to account for the change in prices associated with the competitive bidding program. Repricing historical claims, in conjunction with rebasing rates for 2019, ensures that the 2019 FFS rates for each county reflect the most current FFS fee schedules and payment rules.

With this Advance Notice, we are releasing the 2016 FFS cost data by county used in the development of the 2019 ratebook. This data is available on the CMS website at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Data.htmlhttps://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html>. This data will not reflect adjustments for ACO shared savings and losses and will not reflect adjustments for claim repricing for the most recent Medicare FFS payment rules and parameters.

B1. AGA Methodology for 2019

In the first step, CMS is proposing to add the 2016 cost and enrollment data to, and drop the 2011 cost and enrollment data from, the historical claims experience used to develop new geographic cost indices for each county. As a result, the five-year rolling average will be based on original Medicare claims data from 2012–2016. CMS will then perform a series of adjustments to the original Medicare data to estimate FFS rates per county, explained below as successive steps.

In the second step, CMS will exclude hospice expenditures and FFS claims paid on behalf of cost plan enrollees from the 2016 claims. Comparable adjustments were previously made to 2012–2015 claims data in the development of the FFS rates for prior years.

For Puerto Rico, CMS will continue to only include claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment for all five years (2012–2016). While most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in

Puerto Rico must take affirmative action to opt-in to Part B coverage. CMS continues to believe it is appropriate to adjust the FFS rate calculation in Puerto Rico used to determine MA rates so that it is based on beneficiaries who are enrolled in both Part A and Part B in order to produce a more accurate projection of FFS costs per capita in Puerto Rico.

In 2017 and 2018, the Secretary had directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the nationwide propensity of beneficiaries with zero claims. For the 2017 and 2018 Rate Announcements, the Office of the Actuary evaluated experience exclusively for beneficiaries who were enrolled in both Parts A and B and were not dually eligible for Veterans Affairs (VA) coverage. The 2018 study analyzed experience for calendar years 2011 through 2015 and only considered FFS beneficiaries enrolled mid-year. On average, 14.4 percent of A and B Puerto Rico FFS beneficiaries were found to have no Medicare claim reimbursements per year. This compares to a nationwide, non-territory, proportion of 6.0 percent of FFS beneficiaries without Medicare spending. These results were applied to the Puerto Rico FFS experience by adjusting the weighting of the enrollment and risk scores for the zero-claim cohort to reflect the nationwide proportion of zero-claim beneficiaries. The resulting impact was measured as an average increase in the standardized FFS costs in Puerto Rico of 4.4 percent for 2011 through 2015. Accordingly, a 4.4 percent adjustment was then applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2018 ratebook development.

We are considering whether a similar adjustment should be applied for 2019. The Office of the Actuary will perform an analysis that is similar to the analysis performed in 2017 and 2018, but with an updated five years of data: 2012–2016. We welcome comments regarding a similar update to Puerto Rico's experience in the development of the 2019 FFS rate. We will review the results of this study and any comments that we receive, and we will specify in the final Rate Announcement any adjustment that we determine may be necessary based on those results and comments.

We appreciate the concerns previously raised by stakeholders regarding FFS data and MA benchmarks in Puerto Rico, and continue to welcome public input and suggestions regarding methodological changes that may be appropriate.

In the third step, CMS will re-price the historical inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2012–2016 to reflect the most current (i.e., FY 2018) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2018) Geographic Practice Cost Indices. For 2019, CMS will also continue to adjust historical FFS claims to account for legislative changes to section 1886(d)(5)(F) of the Act, and the enactment of 1886(r). These changes reduced Medicare Disproportionate Share Hospital (DSH) Payments to inpatient hospitals by 75 percent, and created new uncompensated care payments (UCP), effective October 1, 2013. Consistent with the methodology implemented beginning in 2016, CMS will adjust claims for fiscal year (FY) 2012 and FY 2013 for each DSH hospital to reflect the

reduction in DSH payments and the allocation of the UCP by incorporating the corresponding requirements of the final FY 2018 Inpatient Prospective Payment System (IPPS) rule. Similarly, we are proposing to adjust the UCP represented in the FY 2014 through 1st quarter FY 2017 claims to reflect the requirements of the final FY 2018 IPPS rule. For 2019, repricing for Puerto Rico inpatient claims will continue to reflect the Consolidated Appropriations Act, 2016 (Pub. L. 114-113, Division O, section 601), which amended section 1886(d)(9)(E) of the Act.

We will continue re-pricing Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims from 2012–2016 to reflect the most current DMEPOS prices associated with the Competitive Bidding Program (CBP), and will continue using the latest Round 1 and Round 2 prices in making these adjustments. Section 1847(b)(5) of the Act requires that “single payment amounts” replace the current Medicare DMEPOS fee schedule amounts for selected DMEPOS items in specific competitive bidding areas (CBAs). Eight HCPCS codes for diabetic supplies were included in the National Mail Order (NMO) program. We will continue to include the latest single payment amounts for NMO DMEPOS items to reprice the historical payments for DMEPOS claims. Section 1834(a)(1)(F) of the Act requires CMS to adjust the fee schedule amounts for DMEPOS furnished on or after January 1, 2016 in non-CBAs based on information from the Competitive Bidding Program (CBP). We propose using the 2018 fully adjusted fees to reprice the non-CBA FFS claims for 2012–2016.

As done for 2018, we are proposing to make an additional adjustment to the 2012, 2013, 2014, and 2015 claims to account for shared savings payments and shared losses made to Medicare Shared Savings Program (SSP) ACOs and Pioneer ACOs for experience in the respective year. For 2019, the adjustments will also include 2016 shared savings, shared losses, and performance based payments under the following programs and models: SSP, Pioneer ACO model, Comprehensive Care for Joint Replacement (CJR) Model, Next Generation ACO (NGACO) and Oncology Care Model (OCM). The shared savings payments made under the Comprehensive Primary Care (CPC) Initiative will be reflected in the repricing of 2014, 2015, and 2016 claims.

The adjustment reflects an allocation of the shared payments and losses based on the distribution of the ACO’s enrollment by county. The adjustment includes the application of the two percent sequestration reduction on these ACO adjustments for claims incurred on or after April 1, 2013.

ACO experience for 2016 may be found at <https://innovation.cms.gov/initiatives/Pioneer-ACO-Model> for the Pioneer model; at <https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model> for the NGACO model; and at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram> for the SSP.

The key aspects of these adjustments are:

- Allocate ACO shared savings or shared loss amounts geographically, as applicable based on each ACO’s unique population and performance, according to the distribution of counties in which each ACO’s assigned beneficiaries reside.

- Represent such allocated shared savings payments and shared losses recoupment on a per-capita basis based on total FFS enrollment as of July 1 of the experience year.
- Exclude per-capita shared savings and losses attributed to beneficiaries in ESRD status as of July 1 of the experience year.
- Similar to last year, shared savings payments made to ACOs in SSP, Pioneer ACOs, NGACOs, and CPC practices, and reconciliation payments made under the Bundled Payment for Care Improvement (BPCI) model will be reflected as additional expenditures in the experience year (i.e., the year when the savings were generated rather than when they were paid). Shared losses will be included as negative expenditures in the experience year. The amounts will be represented in the county level Part A and Part B expenditures proportional to the Part A and Part B share of the FFS USPCC for the experience year.
- We are also proposing an adjustment for population-based payment models for a limited number of Pioneer ACO claims from 2014, 2015, and 2016 and NGACO claims for 2016. Under this optional feature of the model, certain participants receive a monthly fee that ultimately offsets a percentage reduction in marginal FFS payments over the same year. For each affected claim, the reduction amount represents the portion of the fee associated with that particular claim and is therefore added back to the reduced FFS amount so that the total reimbursement amount is represented.

A further adjustment is being proposed for Medicare shared savings payments made under the Medicare-Medicaid managed fee-for-service financial alignment model for 2013-2015 experience. The payment will be allocated by county based on the distribution of the program enrollment.

Consideration has been given to adjusting the FFS claims experience for care management fees, per-beneficiary-per-month fees, and/or advance payment of shared savings paid to providers for other innovation models conducted in 2012-2016 period.² We have determined that the fees paid under the Multi-Payer Advanced Primary Care Practice Demonstration are already reflected in historical FFS claims, and therefore, no adjustment is warranted.

We also intend to use for 2019, as the source of the county designation of beneficiaries used in the summarization of the risk scores, the county assignment used for the ratebook FFS claims and enrollment. For contract years 2016 and earlier, the county assignment for each FFS beneficiary was based on the ZIP code associated with the beneficiary's mailing address. Beginning with the 2017 ratebook, we used the county provided by the Social Security Administration, which is the same county assignment as the ratebook FFS claims and enrollment.

² Information about the various innovation models is available in the Report to Congress, available at: <https://innovation.cms.gov/Files/reports/rtc-2016.pdf>.

The statutory component of the Regional MA benchmarks will also be based on this proposed county designation of beneficiaries. Under our implementation of section 1858(f)(2) of the Act, the standardized PPO benchmark for each MA region includes a statutory component consisting of the weighted average of the county capitation rates across the region for each appropriate level of star rating. The enrollment weights for the statutory component will reflect the proposed county designation of beneficiaries.

As in prior years, (1) CMS will make additional adjustments to the FFS costs for the items detailed below, and (2) the average of the five year geographic indices, based on the adjusted claims data, will be divided by the county's average five-year risk score from the 2019 risk model in order to develop the AGA for that county.

Additional Adjustments

Note that incentive payments for adoption and meaningful use of electronic health record (EHR) technology are not included in the claims used to develop the FFS costs and therefore no explicit adjustment is needed to exclude these payments from the FFS costs to comply with section 1853(c)(1)(D).

These adjustments are made after the AGA is calculated:

- Direct Graduate Medical Education: removed from FFS county costs (section 1853(c)(1)(D)(i) of the Act)
- Indirect Medical Education: removed from FFS county costs (sections 1853(n)(2)(E) and (F) of the Act)
- Credibility: for counties with less than 1,000 members, blend county experience with that of others in the market area
- Department of Defense (DoD): apply a cost ratio (an increase to claim costs) to counties with significant Tricare enrollment in the Uniformed Services Family Health Plan (USFHP) (section 1853(c)(1)(D)(iii) of the Act).
- Veterans Affairs (VA): apply an adjustment for experience of Medicare beneficiaries who are also eligible to receive care through the Veterans Health Administration (VHA).

Some of these adjustments are described in more detail below.

B2. Adjustment to FFS per Capita Costs for VA and DoD Costs

Last year for CY2018 FFS per capita cost projections, we did not apply the VA and DoD adjustments concurrently because we were unable to obtain the necessary data in time; the CY2018 VA and DoD adjustments were the same as those used in the CY2017 ratebook development. For CY 2019, we propose two related changes to the adjustment to fee for service (FFS) per capita costs for beneficiaries dually enrolled in Veterans Affairs (VA) and/or the Department of Defense (DoD) health programs. First, we propose to adjust the FFS rates by the

VA ratios and the DoD ratios, using results from a study based on FFS data from calendar years 2011-2015. Second, to address potential “double counting” of the effect, we are proposing to replace the separate VA and DoD adjustments with a consolidated adjustment.

To approximate an adjustment to the county FFS payment rates for VA, we first analyzed the cost impact of removing Veterans Affairs (VA) dual-benefit eligibles from the Medicare claims and enrollment. Specifically, we calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding VA dual-benefit eligibles (that is, all non-veteran beneficiaries) to all Medicare beneficiaries (that is, all beneficiaries) for each county.

We then multiplied 2018 FFS rates by the ratios calculated and analyzed the resulting change in rates for each county. We looked at the rate changes between the 2018 FFS rates calculated for all beneficiaries based on the new ratio and the old ratio. The rate changes do not reflect the impact of any payment rate minimums. OACT found that the impact for adjusting total FFS costs using the new ratio is that approximately 74% of the counties would receive an increase, and 26% of the counties would receive a decrease. The average of the impact on 2018 FFS rate is \$3.78. Additionally, we have tabulated the impact of the VA adjustment on the CY 2018 QBP payment rates, which are presented in the below Table B2-1.

Similar analysis was done on Department of Defense (DoD) ratios. This analysis was performed separately for all DoD and Uniformed Services Family Health Plan (USFHP)-only enrollees to compare the average FFS costs to determine if there were significant differences between the DoD groups and the total Medicare population. To approximate an adjustment to the county FFS payment rates, we analyzed the cost impact of removing the dual-benefit eligibles from the Medicare claims and enrollment. For this analysis, dual-benefit eligibles were defined as those Medicare beneficiaries who are also eligible to receive care through the Department of Defense. We calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding dual-benefit eligibles (DoD) to all Medicare beneficiaries (or all beneficiaries) for each county.

We analyzed the ratios in counties with at least 10 members in the respective groups and found that there was no statistical significance of the DoD ratios, but did find that the USFHP-only ratios were significant. Accordingly, adjustments were made to counties with at least 10 USFHP members and CMS then adjusted the FFS rates by the ratios calculated.

Based on the analysis of Medicare claims for DoD dual enrollees for calendar years 2011-2015, we found that the impact for adjusting total FFS costs based on the new ratio and the old ratio is that approximately 5.3% of the counties would receive an increase, and 0.2% of the counties would receive a decrease. The average of the impact on 2018 FFS rate for DoD alone is \$3.21. Additionally, we have tabulated the impact of the DoD adjustment on the CY 2018 QBP payment rates, which are presented in the below Table B2-2.

In the 2018 FFS rates, the majority of counties had an adjustment for VA, whereas less than 6 percent, or 179 of 3,247, of the county FFS rates reflected an additional adjustment for DoD

dual-benefit eligibles. Further, the average absolute value of the adjustment for the counties with a DoD adjustment averaged only 0.4 percent in 2018. Despite the relatively small impact of the DoD adjustment, there could be interaction between the VA and DoD adjustment that was not accounted for in the methodology used in the CY 2018 rate development.

Therefore, we are proposing to apply the DoD and VA adjustments concurrently for CY 2019 instead of the independent application of the adjustments for CY 2018. We believe that concurrent calculation of the adjustment will have minimal impact versus independent application of the adjustments, and will eliminate the double-counting impact of DoD and VA dual-benefit eligibles. The corresponding impact of the proposed consolidated VA-DoD adjustment on the CY 2018 QBP payment rates are presented in the below Table B2-3. Additionally, the impact by county of the new methodology can be found on the CMS website at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>.

**Table B2-1 Impact of VA Adjustment on 2018 QBP
Payment Rates**

	0.0% QBP Rate	3.5% QBP Rate	5.0% QBP Rate
% of counties with rate increase	62.3%	56.9%	53.4%
% of counties with rate decrease	37.7%	43.1%	46.6%
Average impact	\$2.87	\$2.48	\$2.23

**Table B2-2 Impact of DoD Adjustment on 2018 QBP
Payment Rates**

	0.0% QBP Rate	3.5% QBP Rate	5.0% QBP Rate
% of counties with rate increase	4.7%	4.4%	4.0%
% of counties with rate decrease	0.8%	1.1%	1.5%
Average impact on counties with change	\$2.60	\$2.35	\$2.01

**Table B2-3 Impact of Proposed Combined VA-DoD
Adjustment on 2018 QBP Payment Rates**

	0.0% QBP Rate	3.5% QBP Rate	5.0% QBP Rate
% of counties with rate increase	62.5%	57.1%	53.5%
% of counties with rate decrease	37.5%	42.9%	46.5%
Average impact	\$2.97	\$2.57	\$2.31

Section C. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) amended section 1853(k)(4) of the Act to require CMS to phase out indirect medical education (IME) amounts from MA capitation rates. Sections 1853(n)(2)(E) and (F) apply the same phase-out to FFS costs in the calculation of the specified amount in setting MA rates. Pursuant to section 1894(d)(3) of the Act, PACE programs are excluded from the IME payment phase-out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under fee-for-service Medicare.

For purposes of making this adjustment for 2019, we will first calculate the 2019 FFS rates including the IME amount. This initial amount will serve as the basis for calculating the IME reduction that we will carve out of the 2019 rates. The absolute effect of the IME phase-out on each county will be determined by the amount of IME included in the initial FFS rate. Under section 1853(k)(4)(B)(ii) of the Act, the maximum reduction for any specific county in 2019 is 6.0 percent of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2019 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section D. ESRD Rates

In developing the 2019 ESRD Medicare Advantage benchmarks, we obtain the FFS dialysis reimbursement and enrollment data for each state for the years 2012–2016. For each year, we compute the per capita costs by state. The geographic indices for each year are calculated by dividing the state per capita cost by the total per capita cost of the nation. The average geographic adjustment (AGA) by state is then determined by calculating a 5-year weighted average of the geographic indices, which is standardized by dividing by the 5-year average risk scores. We calculated the 2016 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2016 data above, and using trend factors, develop the prospective 2019 FFS ESRD dialysis USPCC.

We have recently incorporated enhancements to the ESRD data system and projection methodology, and will now be able to apply repricing adjustments to the CY2019 ESRD rates. Similar to the non-ESRD rate methodology, we are proposing to reprice the ESRD historical inpatient, hospital outpatient, and skilled nursing facility claims from 2012-2016 to reflect the most current (i.e., FY 2018) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2018) Geographic Practice Cost Indices. We are proposing to reprice the ESRD PPS dialysis claims for the years 2014-2016, given that 2014 was the first year that the dialysis PPS system was fully phased in. We are also proposing to adjust historical FFS claims for ESRD beneficiaries to account for legislative and regulatory changes to the provisions under section 1886(d)(5)(F) of the Act, and the establishment of 1886(r). These changes replaced 75 percent of hospital Medicare Disproportionate Share Hospital (DSH) payments with uncompensated care

payments (UCP) beginning on October 1, 2013. CMS would adjust claims for fiscal year (FY) 2012 and FY 2013 for each DSH hospital to reflect the reduction in DSH payments and the allocation of the UCP by incorporating the corresponding requirements of the final FY 2018 Inpatient Prospective Payment System (IPPS) rule. Similarly, we are proposing to adjust the UCP represented in the FY 2014 through 1st quarter FY 2017 claims to reflect the requirements of the final FY 2018 IPPS rule. For 2019, the adjustments will also include 2016 shared savings, and shared losses performance based payments made under the Comprehensive ESRD Care model.

The 2019 ESRD dialysis rates by state are determined by multiplying the 2019 FFS ESRD dialysis USPPC by the state AGA. The 2019 ESRD dialysis rate is adjusted by removing the direct graduate medical education (GME) expenses and the gradual phase-out of indirect medical education (IME) expenses.

Section E. Clinical Trials

In 2019, CMS intends to continue to pay on a fee-for-service basis for qualified clinical trial items and services provided to MA enrollees in clinical trials that are covered under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (Medicare NCD Manual, Pub. 100-3, Part 4, Section 310.1). The payment and coverage standards applicable to NCDs under 42 CFR 422.109 apply to NCD 310.1, which provides coverage under original Medicare for clinical trials that meet its criteria and are not addressed by a separate NCD. CMS has previously made the determination that all clinical trials covered under NCD 310.1 trigger the significant cost threshold such that coverage and payment are controlled by § 422.109(c).

As detailed in the 2017 Rate Announcement, MA enrollees are able to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. CMS does not require MA enrollees to relinquish their MA coverage if they wish to participate in a clinical trial.

CMS requires MAOs, in accordance with § 422.109(c)(2), to provide coverage for: (1) services to diagnose conditions covered by clinical trial services, (2) most services furnished as follow-up care to clinical trial services, and (3) services already covered by the MAO. Should an MA enrollee choose to participate in a clinical trial, he or she may remain in his or her MA plan while paying FFS costs for a qualifying clinical trial. As finalized in the CY 2011 Rate Announcement, effective for CY 2011 and subsequent years, MAOs must reimburse enrollees for cost sharing incurred for clinical trial services that exceed the MA plans' in-network cost sharing for the same category of service. The MAO owes this difference even if the enrollee has not yet paid the clinical trial provider. The enrollee's clinical trial cost sharing must also count towards the in-network out-of-pocket maximum. This cost-sharing requirement applies to all qualifying clinical trials; MAOs cannot choose the clinical trials or clinical trial items and services for which this policy applies. The policy of requiring MAOs to pay the difference

between original Medicare cost sharing and in-network cost sharing for clinical trial services is unchanged from 2011.

By requiring MAOs to provide in-network cost sharing for clinical trial services, CMS is requiring MAOs to provide MA enrollees with coverage for clinical trial services consistent with the coverage they have for all other similar services. These policies ensure that MA enrollees do not have unexpected cost sharing liability for clinical trials, as those cost sharing amounts will not be different from the cost sharing amounts applicable to in-network services of a similar kind.

If an MAO conducts its own clinical trial, the MAO may explain to its enrollees the benefits of participating in its clinical trial; however, the MAO may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the MAO, nor may it create impediments to an enrollee's participation in a non-MAO-sponsored clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. However, an MAO may request, but not require, that enrollees notify the MAO when they choose to participate in Medicare-qualified clinical trials.

In addition, clinical trial sponsors/providers are permitted to submit original Medicare "paid" clinical trial claims to MAOs on behalf of MA enrollees in order to obtain reimbursement for the difference between original Medicare cost sharing liabilities and in-network MA cost sharing liabilities. A trial sponsor/provider need only collect cost sharing from such an enrollee once both Medicare and the MAO have paid.

MAOs are responsible for coverage and payment of items and services furnished in certain clinical studies that are *not* covered under NCD 310.1. These include investigational device exemption (IDE) trials and studies conducted under NCDs (separate from NCD 310.1) that require coverage with evidence development (CED). MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service as per § 422.109. Approved CED studies are posted on the CMS Coverage with Evidence Development webpage at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. Billing instructions are issued for each NCD.

For more information on these policies, please refer to the Medicare Managed Care Manual, Pub. 100-16, Chapter 4 (Benefits and Beneficiary Protections), section 10.7 (Clinical Trials).

Section F. Location of Network Areas for PFFS Plans in Plan Year 2020

Section 1852(d)(4) of the Act requires MAOs offering certain non-employer MA PFFS plans in network areas to enter into signed contracts with a sufficient number of providers to meet the access standards applicable to coordinated care plans. Specifically, non-employer MA PFFS plans that are offered in a network area (as defined in section 1852(d)(5)(B) of the Act) must

meet the access standards described in section 1852(d)(4)(B) through written contracts with providers. These PFFS plans may not meet access standards by establishing payment rates that are at least the rates that apply under original Medicare and having providers deemed to be contracted as described in § 422.216(f).

Network area is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as an area that the Secretary identifies (in the announcement of the proposed payment rates for the previous plan year under section 1853(b)(1)(B)) as having at least 2 network-based plans (as defined in section 1852(d)(5)(C)) with enrollment as of the first day of the year in which the Announcement is made. We will include a list of network areas for plan year 2020 in the final Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. We will also make the list available on the CMS website at <https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html>. We will use January 1, 2018 enrollment data to identify the location of network areas for plan year 2020.

Section G. MA Employer Group Waiver Plans

We intend to continue to waive the Bid Pricing Tool bidding requirements for all MA employer/union-only group waiver plans (EGWPs) for 2019. CMS proposes, as a condition of the waiver of the bidding requirements and the waivers otherwise provided to EGWPs, to establish payment amounts as described herein. As in 2017 and 2018, for 2019, Part C entities offering employer/union-only group waiver plans would not be required to submit Part C bid pricing information in the Part C bid pricing tool. CMS has authority under section 1857(i) of the Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. CMS believes that waiving the requirement to submit 2019 Part C bid pricing information will facilitate the offering of Part C plans for employers and unions seeking to establish high quality coverage for their Medicare eligible retirees by avoiding the cost and administrative burden of submitting the complex bids required from non-EGWPs. We refer the reader to the detailed discussion of our rationale and responses to commenters' questions in the CY 2017 Rate Announcement, Attachment III, Section F (pages 27-44) for additional information, and to responses to questions received by the Office of the Actuary, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/ActuarialBidQuestions.html>.

In connection with the continuation of this waiver, for 2019 CMS is proposing to fully transition in 2019 to using only individual market plan bids to calculate the bid-to-benchmark (B2B) ratios to set EGWP payments, as initially discussed in the 2017 Advance Notice and Rate Announcement. The completion of this transition was initially contemplated for implementation in 2018, but was delayed for the reasons articulated in the 2018 Rate Announcement. We are now proposing to complete this transition for 2019. The payment policy described in more detail

below for EGWPs is being proposed for implementation for 2019 in connection with the waiver of submission of bid pricing information.

First, for 2019, we will use the average B2B ratio for individual market plan bids, including RPPOs, from the prior payment year (2018) to calculate the 2019 Part C base payment amounts for EGWPs by quartile³.

The calculations for the ratios will therefore be as follows:

First: [(weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2018 individual market plan bids by February 2018 actual enrollment)/(weighted average of the county standardized benchmarks for 2018 individual market plan bids by February 2018 actual enrollment)] = 2018 individual market B2B ratios (percentage by quartile).

The bid-to-benchmark ratios used for 2019 payment will be announced in the 2019 Rate Announcement, calculated using February 2018 enrollment.

Second, as in 2017 and 2018:

- The B2B ratios are applied to each of the published 5%, 3.5%, and 0% bonus county ratebook rates for the payment year to establish Part C base payment amounts for EGWPs based on their star rating for each county.
- In order to calculate a county rebate payment, each county level EGWP Part C base payment amount is compared to the corresponding published 5%, 3.5% and 0% bonus county benchmarks for the payment year (2019), which include adjustments for qualifying counties, to determine the amount of savings. The savings amount is multiplied by the corresponding rebate percentage to determine the Part C EGWP county level rebate amount.
- The EGWP Part C base payment amount is added to the Part C EGWP rebate amount to establish the county level local EGWP total payment amount.
- The total payment amount will be risk adjusted in payment using beneficiary-specific risk scores. Therefore, the formula applied for local EGWP payment on a per beneficiary basis will be: (base county payment rate + county rebate) × beneficiary level risk score.

³ Territories will not be included in the weighted average B2B ratio, but will be assigned the weighted average of the quartile within which their counties fall. To determine the CY 2019 applicable percentages, CMS ranks counties from highest to lowest based upon their 2018 average per capita FFS costs and places the rates into four quartiles. When calculating the 2018 B2B ratios, CMS would group counties by the 2018 unblended quartiles and these B2B ratios would then be applied to the 2019 unblended quartiles.

For RPPO EGWPs, the weighted average B2B ratios will be calculated as described above. To establish the Part C base RPPO EGWP payment amount, we will then also apply the same methodology as described above.

In order to calculate the RPPO EGWP rebate amounts, these percentages will be applied for each county within a region to the published payment year regional benchmarks to establish the savings amount and rebate amounts by star rating and quartile.

The RPPO EGWP Payment Formula is $(\text{Base County Payment Rate} + \text{Regional Rebate}) \times \text{beneficiary level risk score}$ where each is calculated as follows:

- Base County Payment Rate = Bid to Benchmark Ratio \times 2019 MA Monthly Capitation Rate
- Regional Rebate = $(1 - \text{Bid to Benchmark Ratio}) \times 2019 \text{ Regional Rate} \times \text{Rebate percentage}$
- The 2019 Regional rate is based on a blend of the statutory and bid component. As with non-EGWPs, if there is no bid component of the 2019 Regional rate (i.e., no individual bids in a region), then the EGWP rate will be based solely on the statutory component.

As was the case in 2017 and 2018, for 2019 there will be no Part C Regional PPO EGWP bids to include in the calculation of the MA regional benchmarks. The statutory components of the regional standardized A/B benchmarks will continue to be published each year as part of the Announcement of Medicare Advantage Payment Rates. CMS will also continue to publish the final MA regional standardized A/B benchmarks in late summer, which will reflect the average bid component of the regional benchmark based on non-EGWP bid submissions.

As a result of this proposal, each 3-star local EGWP in a given county would receive the same payment amount that includes the same rebate amount, multiplied by their beneficiaries' risk scores. MA EGWPs would not be able to distinguish between the amount they are paid for basic benefits and the amount they are paid for supplemental benefits. In light of this, CMS proposes to continue to waive the requirement for MA EGWPs to allocate rebate dollars to any specific purpose for 2019; further, MA EGWPs would also not be permitted to buy down Part B premiums for their enrollees from the Part C payment as part of these waivers.

Under current rules, when a non-EGWP MAO uses rebates to buy-down a portion of the Part B premiums for their beneficiaries, CMS retains the rebate amount identified by the MAO and coordinates directly with the Social Security Administration to ensure that each beneficiary's Part B premiums is appropriately calculated and withheld from the beneficiary's Social Security check or billed to the beneficiary. However, under this payment methodology for MA EGWPs, plan specific rebate amounts would not be identifiable; therefore, this process would continue to be unavailable to MA EGWPs in 2019. MA EGWPs would also continue to be prohibited from separately refunding Part B premiums for their enrollees.

Moreover, in 2019, the following rules will continue to apply as they did in 2017 and 2018 under this proposed payment methodology:

- MA EGWPs will not receive payment for members that elect Hospice given that plan specific rebate amounts are not identifiable under the proposed payment methodology.
- MA-EGWPs will continue to be paid using the ESRD ratebook for their ESRD beneficiaries in Transplant and Dialysis status and the MA ratebook for those beneficiaries in Functioning Graft status, in keeping with the current payment policy for non-EGWP MAOs.
- Consistent with how CMS pays capitation for Part B-only enrollees in the non-EGWP context, Part B-only MA EGWPs will continue to receive only the Part B portion of the EGWP payment amount, which is determined by multiplying it by the Part B percentage of the rate.
- MA EGWP MSA plans will not submit Bid Pricing Tools for 2019, but the 2019 local EGWP payment rates will not be applied to EGWP MSA plans. The monthly prospective payments for EGWP MSAs will be based on the following formula: 2019 MA Monthly Capitation County Rate x beneficiary risk score – 1/12 of the Annual MSA Deposit Amount. The 2019 Annual MSA Deposit Amount must be submitted in the appropriate Plan Benefit Package field.

Notwithstanding the proposed payment policies as described above, entities offering MA EGWPs must continue to meet all of the CMS requirements that are not otherwise specifically waived or modified, including, but not limited to, submitting information related to plan service areas, plan benefit packages and formularies in accordance with the rules for 2019.

Organizations must make a good faith effort in projecting CY 2019 member months for each plan and place the amount in the appropriate section of the 2019 Plan Benefit Package (PBP) submissions to CMS.

Notwithstanding the foregoing, we are also considering the inclusion of an additional step in calculating the B2B ratios as described above whereby an adjustment would be made to the calculation used to determine the B2B ratios to account for the difference in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) vs Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans

Under this alternative, for 2019, the 2018 individual market B2B ratios would be adjusted to account for the difference in the proportion of beneficiaries enrolled in HMO vs PPO between EGWPs and individual market plans. Specifically, to determine the weighted individual market B2B ratios, the individual market ratios would be calculated separately by plan type. HMO and HMOPOS plans would be combined into an “HMO plan type” and LPPO and RPPO plans

would be combined into a “PPO plan type.”⁴ Then the plan type individual market B2B ratios by quartile would each be weighted by the total proportion of 2018 EGWP enrollment in the plan type across all quartiles. The calculations for the ratios would therefore be as follows:

First: $[(\text{weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2018 individual market plan bids by February 2018 actual enrollment}) / (\text{weighted average of the county standardized benchmarks for 2018 individual market plan bids by February 2018 actual enrollment})] = 2018 \text{ individual market B2B ratios by quartile.}^5$

Second: The 2018 individual market B2B ratios would be calculated separately for HMO plan types and PPO plan types by quartiles. The PPO B2Bs by quartile would be weighted by the total proportion of EGWP PPO plan type enrollment, and the HMO B2Bs by quartile would be weighted by the total proportion of EGWP HMO plan type enrollment to result in the final B2B ratios for 2019 by quartile.

Alternatively, we are also seeking comment as to whether we should maintain the payment methodology that was applied in calculating the 2017 and 2018 MA EGWP payment rates for 2019. The bid-to-benchmark ratios used in 2017 and 2018 payment were calculated using a blend of all individual market plan bids and all EGWP bids from 2016, each weighted by 50 percent to determine the B2B ratios by quartile.

In addition, if we maintain the payment methodology that was applied in calculating the 2017 and 2018 MA EGWP payment rates, we are seeking comment on whether to include an additional step whereby an adjustment would be made to the calculation used to determine the B2B ratios to account for the difference in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) vs Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans.

Under this approach, the 2016 individual plan bid-to-benchmark ratios would be re-weighted, using February 2016 enrollment, based on the proportion of EGWP enrollment in PPOs vs. HMOs to determine the individual market portion of the blended bid-to-benchmark ratios.⁶

⁴ “HMO” Health Maintenance Organization, “HMOPOS” Health Maintenance Organization Point of Service, “PPO” Preferred Provider Organization, “LPPO” Local Preferred Provider Organization “RPPO” Regional Preferred Provider Organization.

⁵ These calculations will use the same exclusions and methods outlined in the footnote to the First step in the proposed methodology, except “PFFS” Private Fee For Service individual market plans would be excluded from these calculations.

⁶ For purposes of this calculation, HMO and HMOPOS 2016 bids are combined for the HMO plan type portion of the weighting methodology, and LPPO, RPPO and PFFS 2016 bids are combined for the PPO plan type portion of the weighting methodology.

Then, as in 2017 and 2018, the individual market plan bids would be weighted by 50 percent and EGWP bids would be weighted by 50 percent to determine the B2B ratios by quartile.

The calculation under this alternative would therefore be:

$$\frac{[(\text{weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2016 individual market final bids by February 2016 actual enrollment by HMO/PPO plan type})/(\text{weighted average of the county standardized benchmarks for individual market plan 2016 final bids by February 2016 actual enrollment by HMO/PPO plan type}) \times \text{percentage of EGWP HMO plan type enrollment and percentage EGWP PPO plan type enrollment}]}{50\%}$$

plus

$$\frac{[(\text{weighted average of the 2016 intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2016 EGWP final bids by February 2016 actual enrollment})/(\text{weighted average of the county standardized benchmarks for EGWP 2016 final bids by February 2016 actual enrollment})]}{50\%} = \text{percentage by quartile.}$$

We welcome comments on these and other approaches, and seek comment on whether an adjustment for HMO/PPO plan type as described above would be appropriate to implement and why.

Section H. CMS-HCC Risk Adjustment Model for CY 2019

On December 27, 2017, CMS published for public comment the proposed Part C risk adjustment model. As noted in that notice, all comments must be submitted to <https://www.regulations.gov/>, enter the docket number “CMS-2017-0163” in the “Search” field, and follow the instructions for “submitting a comment” no later than 6pm EST on Monday, March 5, 2018, so that they may be addressed in the 2019 Rate Announcement that will be released no later than April 2, 2018.

Section I. ESRD Risk Adjustment Model for CY 2019

CMS uses a separate model to pay for the Part A and Part B benefits provided to beneficiaries in ESRD status when enrolled in Medicare Advantage (MA) plans, PACE organizations, and certain demonstrations. For 2019, CMS proposes implementing an updated version of this ESRD risk adjustment model. The ESRD model currently used in payment was implemented in 2012 and has not been recalibrated since then. Therefore, for 2019, we propose to update the ESRD model. Furthermore, the 21st Century Cures Act allows all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, in addition to those already enrolled in Medicare Advantage (MA) plans when they enter ESRD status or able to enroll in MA plans under 42 CFR § 422.50. Since plan sponsors may experience an increase in the MA ESRD population in future years, we believe that it would be preferable to update the ESRD model prior to that time and are proposing the implementation of an ESRD model calibrated on data that are more recent. The

updated version of the model will result in payment that is more accurate and provides MAOs time to adjust to payments based on this new model prior to experiencing potential increases in enrollment.

While the HCCs used in the ESRD model are similar to those used in other Part C risk adjustment models, we calibrate the ESRD model using the FFS ESRD population and, therefore, the resulting coefficients reflect cost and disease patterns for this subgroup of beneficiaries.

Updates for 2019:

While the basic structure of the model and the HCCs will remain the same, CMS proposes the following two updates to the ESRD model for 2019:

- Update the data years underlying the model, and;
- Update the Medicaid factors to be concurrent with the payment year.

Model Recalibration

CMS recalibrated all of the components of the ESRD risk adjustment model for 2019 using data from FFS claims: we used 2014 diagnoses to predict 2015 expenditures. We estimated the coefficients for the condition categories by regressing the total expenditure for A/B benefits for each FFS ESRD beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (e.g., age/sex group, Medicaid status, disability status).

For all applicable model components, Medicaid designation in the recalibrated 2019 model is based on payment year status. Specifically, CMS will use the following data to indicate Medicaid status during any month in the payment year:

- One of the following dual status codes for beneficiaries who are entitled to Medicare:
 - 01 (Qualified Medicare Beneficiary (QMB) only)
 - 02 (QMB AND Medicaid coverage)
 - 03 (Specified Low-Income Medicare Beneficiary (SLMB) only)
 - 04 (SLMB AND Medicaid coverage)
 - 05 (Qualified Disabled and Working individuals (QDWI))
 - 06 (Qualifying individuals)
 - 08 (Other Dual Eligibles (Non QMB, SLMB, QDWI or QI) with Medicaid coverage)
 - 10 (Other Full Dual) (This category comprises dual eligible beneficiaries in the Territories, including those reported on the monthly report from the Commonwealth of Puerto Rico.)

- To operationally align with the Part C model, we will only use the following sources of Medicaid data:
 - State-reported Medicaid data (MMA State files)
 - Puerto Rico monthly Medicaid file
 - Point of Sale data

Structure of ESRD Model

The ESRD risk adjustment model that we are proposing for 2019 is structurally the same ESRD model that we have used since 2005 in that it retains separate coefficients for dialysis, transplant, and post-graft beneficiaries. Further, it is the same clinical version of the ESRD model that is currently being used in payment (i.e., we have not made any changes to the HCCs from the 2012 model, which are being used to calibrate the new ESRD model).

The components of the ESRD model are used to pay for populations with different ESRD statuses:

1. **Dialysis:** The ESRD dialysis component of the ESRD model is used to pay for beneficiaries who are in dialysis status.
2. **Transplant:** Transplant factors are used to pay for beneficiaries who have a kidney transplant. Factors are used in conjunction with the ESRD dialysis state ratebook to pay for the month in which a transplant occurred and the following two months.
3. **Post-graft:** The post-graft component of the ESRD model is used to pay for beneficiaries starting with the fourth month after a kidney transplant, for as long as they have a functioning graft (i.e., do not return to dialysis status).

The components of the ESRD model are described in more detail below.

Dialysis component

The dialysis component of the ESRD risk adjustment model comprises the following characteristics:

- A single set of coefficients for both community and institutional enrollees in dialysis status. The dialysis component of the ESRD model is calibrated using diagnoses and expenditure data for all beneficiaries in FFS who are in dialysis status. We constrain to zero the relative factors for kidney-related HCCs and interaction terms, because all of the beneficiaries in this model are in dialysis status.
- For new enrollees in dialysis status, the average projected spending is based on demographic factors. The demographic-only new enrollee factors are applied to beneficiaries in dialysis status who do not have 12 months of Part B in the data collection year. The dialysis new enrollee factors are estimated using data from:

- New enrollees with dialysis months in the payment year;
- Continuing enrollees with dialysis months in the payment year with up to three years of dialysis.
- Disease and Disabled-Disease Interactions: There are five Disease Interactions and seven Disabled-Disease Interactions in the dialysis component of the ESRD model.
 - Disease Interactions:
 - SEPSIS_CARD_RESP_FAIL
 - CANCER_IMMUNE
 - DIABETES_CHF
 - CHF_COPD
 - COPD_CARD_RESP_FAIL
 - Disabled-Disease Interactions:
 - NONAGED_HCC6
 - NONAGED_HCC34
 - NONAGED_HCC46
 - NONAGED_HCC54
 - NONAGED_HCC55
 - NONAGED_HCC110
 - NONAGED_HCC176

Transplant factors:

Transplant factors are estimated for the first three months following a transplant. To accommodate the high one-time cost of a transplant, CMS makes payments over three months to cover the transplant and immediate subsequent services. The first month's factor is the largest, as that is the month within which the transplant takes place, while the factors for months 2 and 3 are smaller for post-transplant recovery. CMS calibrated the payments by using fee-for-service hospital stay payments for the transplant, and physician and other services rendered for the hospital stay and the two months after discharge. The national average was converted to a relative factor by dividing by the predicted national average expenditures for dialysis patients. This allows CMS to use the State ESRD dialysis rates to make payments for beneficiaries who have a kidney transplant.

Most of the costs of a transplant accrue in the month of the transplant and the ESRD transplant factors account for this fact. By paying the majority of the cost in the month of transplant, CMS is ensuring that plans are not disadvantaged if the enrollee dies in the month of transplant.

Post-graft component:

To estimate the coefficients for the post-graft component of the ESRD model, CMS starts by calibrating both a single community and a single institutional model segment for the general FFS population, using the FFS aged/disabled, non-ESRD, model sample. Taking the resulting coefficients and holding them constant, we then use the post-graft population (the population of beneficiaries who are in the fourth or later month after kidney transplant) to calibrate coefficients for additional variables, as described below. In this second calibration step, the following adjustments are made:

- Kidney-related conditions are constrained to zero. The HCC for dialysis status (HCC134) is constrained to zero, because this is a population defined by having a functioning kidney and not in dialysis status. We have also constrained nephritis (HCC141) and acute and chronic kidney conditions (HCC134 through HCC 140) to be zero, because the post-graft population is expected to have functioning kidneys and reports of kidney disease may be reflections of inconsistent coding, rather than changes in health status.
- The following HCCs were not estimated using the aged/disabled population, but were instead estimated specifically using the post-graft population because the predicted expenditures for these HCCs are systematically different for the post-graft population:
 - HCC176: Complications of Specified Implanted Device or Graft
 - HCC186: Major Organ Transplant or Replacement Status
- There is a set of post-graft “add on” factors, which vary depending on the amount of time that has elapsed since kidney transplant. These “add on” factors take into account the additional cost of immunosuppressant drugs, as well as health status differences between the post-graft population and the non-ESRD population. There are separate factors for beneficiaries during the 4-9 months after a transplant and 10+ months after a transplant. Note that payment for the post-graft population is dependent on when a kidney transplant occurred, and not on Medicare entitlement due to ESRD status. Therefore, risk adjusted payments for a beneficiary who has had a kidney transplant and remains in post-graft status will be calculated based on the post-graft model.

Updating the handling of Medicaid and recalibrating a model with more recent data can change the marginal cost attributed to specific HCCs. Because of changes in the coefficient estimates and relative factors, risk scores for individuals and plan risk scores may change, depending on each individual’s contribution of diagnoses.

Section J. Frailty Adjustment for PACE organizations and FIDE SNPs

Section 1894(d)(2) of the Act requires CMS to take into account the frailty of the PACE population when making payments to PACE organizations. Section 1853(a)(1)(B)(iv) allows CMS to make an additional payment adjustment that takes into account the frailty of Fully

Integrated Dual Eligible (FIDE) Special Needs Plans (SNPs), if the FIDE SNP has similar average levels of frailty to the PACE program.

CMS estimates frailty factors to explain additional cost not explained by diagnoses in the CMS-HCC model. The factors are updated whenever the CMS-HCC model is updated. Since CMS is proposing to implement the “Payment Condition Count” model in 2019, we are also proposing updated frailty factors based on this model. These frailty factors are included in the calculation that determines frailty scores for FIDE SNPs. There is no change proposed to the frailty factors included in the frailty score calculation for PACE organizations in PY 2019.

Consistent with CMS’ proposal to blend risk scores, for FIDE SNP’s a blended frailty score will be compared with PACE frailty in the same manner as for PY 2018 to determine whether that FIDE SNP has a similar average level of frailty as PACE. The frailty factors for the CMS-HCC model used in payment years 2017 and 2018 can be found in the Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.

MAOs that are planning to sponsor a FIDE SNP, and that wish to receive frailty payments in 2019, must contract with a certified vendor to field the 2018 Health Outcomes Survey (HOS), or the 2018 Modified Health Outcomes Survey (HOS-M) at the PBP level. CMS uses activities of daily living (ADLs) obtained from the HOS survey or HOS-M survey, to calculate frailty scores. Table II-4 presents the preliminary recalibrated frailty factors for CY 2019 using the “Payment Condition Count” model proposed in Part I of the Advance Notice, published December 27, 2017.

Table II-4. FIDE SNP Frailty Factors for CY 2019

ADL	Non-Medicaid	Medicaid
0	-0.078	-0.141
1-2	0.161	0.021
3-4	0.303	0.151
5-6	0.303	0.371

Section K. Medicare Advantage Coding Pattern Adjustment

For 2019, CMS proposes to apply the statutory minimum MA coding pattern adjustment of 5.90 percent.

We are considering multiple methodologies to inform our final decision regarding the factor for PY 2019. Three methodologies that have been publicly discussed include:

- The methodology discussed in the Payment Year 2010 Advance Notice and Rate Announcement, found here: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>
- The methodology discussed in the Payment Year 2016 Advance Notice and Rate Announcement, also found at the same Web page.
- The methodology discussed in MedPAC’s March 2017 Report to Congress: Medicare Payment Policy. The report can be found here: http://medpac.gov/docs/default-source/reports/mar17_medpac_ch13.pdf?sfvrsn=0

We are considering these methodologies and seeking comments on them and alternative methodologies for finalizing the MA coding adjustment factor in the 2019 Rate Announcement.

Section L. Normalization Factors

The Part C risk adjustment model is calibrated with diagnosis and cost information for beneficiaries enrolled in Original Medicare (who are entitled to Part A, enrolled in Part B, and not in End Stage Renal Disease (ESRD) or hospice status). For a historical period (“calibration year”), the model estimates incremental cost for a variety of beneficiary characteristics (e.g., age and gender) and health conditions. Each incremental cost, known as a dollar coefficient, is divided by the predicted average per capita expenditure for beneficiaries in Original Medicare in a given year to create relative factors. Risk scores are the sum of relative factors assigned to each beneficiary based on their demographic characteristics and health status. For beneficiaries in Original Medicare, the average risk score is 1.0 in the denominator year.

When a risk adjustment model predicts expenditures in future years, the average risk score for Original Medicare beneficiaries may no longer be 1.0 due to changes in coding and population characteristics. CMS applies a normalization factor to each year’s risk scores to account for the trend in risk scores – encompassing these coding and population changes – that CMS projects to occur between the denominator year and the payment year.⁷ Effectively, the normalization factor keeps the average risk score at 1.0 in the payment year for beneficiaries in Original Medicare.

Part C normalization factors are the predicted average risk scores of beneficiaries in Original Medicare for a model in the payment year. RxHCC normalization factors are the predicted average risk scores of beneficiaries enrolled in Part D plans, including MA-PD plans and PDP plans. CMS calculates each normalization factor annually with historical risk score data and the payment year risk adjustment model. This annual update serves two purposes.

⁷ See the Social Security Act at §1853(a)(1)(C)(ii)(I).

First, it is important to keep the average risk score at 1.0 for beneficiaries in Original Medicare so that risk scores in the payment year align with the rates. A risk score accounts for the degree to which a beneficiary's health status results in expected cost that are more or less than the expected cost of the average beneficiary in Original Medicare. The rates, which are the benchmarks for Part C bidding, are standardized to represent the cost of an average beneficiary in Original Medicare in the payment year. Normalization helps to ensure that risk adjustment results in payments for individual beneficiaries that are adjusted for relative differences in expected costs but, on average, would not change the expected per capita cost if Medicare Advantage enrolls beneficiaries with the same risk profile as Original Medicare.

Second, updating the normalization factor annually stabilizes payments between model calibrations. Periodically, CMS updates the risk adjustment model with more current data, which resets the year that the average risk score is 1.0 (i.e., the denominator year). Applying a normalization factor to risk scores to account for trend between the denominator year and the payment year provides year-over-year stability and avoids the volatility that would otherwise occur in risk scores in years when the model is updated.

In payment year 2018, CMS returned to using a linear slope method of projecting normalization factors that we used prior to payment year 2015, after using a quadratic functional form for several years. Using this method, we projected the slope of the observed trend over five years of historical risk scores, from the denominator year to the payment year. We propose to maintain this methodology for all models in payment year 2019.

In Part I of the Advance Notice published December 27, 2017, CMS proposed to blend 75 percent of the risk score calculated with the CMS-HCC model used for payment in 2017 and 2018 with 25 percent of the risk score calculated with the proposed "Payment Condition Count" model. Consistent with that proposal, for payment year 2019, CMS proposes to calculate two normalization factors for Part C, one for the CMS-HCC model used in payment year 2017 and 2018, and one for the proposed "Payment Condition Count" model, that would be blended with their respective risk scores in payment.

The proposed Part C normalization factor for the CMS-HCC model used in payment years 2017 and 2018 is 1.041 and the proposed Part C normalization factor for the "Payment Condition Count" model is 1.038. The trend includes 2013 through 2017 risk scores to calculate the normalization factor for the CMS-HCC model, PACE model, ESRD Dialysis model, and ESRD Post-Graft model. The preliminary normalization factors and annual trends for each of these models are in L1 through L4.

We propose to use 2012 through 2016 risk scores to calculate the normalization factor for the RxHCC model; these factors and annual trends are shown in L5. The normalization factors for payment year 2019 will be finalized in the 2019 Announcement, to be released no later than April 2, 2018.

L1. Normalization for the CMS-HCC Model

The proposed 2019 normalization factor for Part C is 1.041 for the CMS-HCC model used for payment in 2017 and 2018, and 1.038 for the proposed “Payment Condition Count” model.

Both the proposed “Payment Condition Count” model and the CMS-HCC model used for payment in 2017 and 2018 have a 2015 denominator. Between 2013 and 2017, the average annual trend estimated from the population of FFS beneficiaries, excluding ESRD and hospice, is 0.0100 for the CMS-HCC model used in payment year 2017 and 2018 and 0.0093 for the proposed “Payment Condition Count” model. There are four years of trend between the denominator year and the payment year for both models.

The Part C normalization factor for the CMS-HCC risk adjustment models is applied to the community non-dual aged, community non-dual disabled, community full benefit dual aged, community full benefit dual disabled, community partial benefit dual aged, community partial benefit dual disabled, institutional, new enrollee, and C-SNP new enrollee risk scores.

The risk scores used to calculate the proposed 2019 normalization factor for the CMS-HCC model used in 2017 and 2018 and the proposed “Payment Condition Count” model are included in Table II-5. Part C Normalization Factor Trend.

Table II-5. Part C Normalization Factor Trend

Year	CMS-HCC Model used in Payment Year 2017 and 2018	Proposed “Payment Condition Count” model
2011	0.988	0.987
2012	0.996	0.996
2013	0.995	0.994
2014	0.998	0.998
2015	1.000	1.000
2016	1.020	1.019
2017	1.034	1.030

L2. Normalization Factor for the PACE Model

The proposed 2019 normalization factor for the CMS-HCC risk adjustment model used for the PACE program is 1.159.

The CMS-HCC model for PACE beneficiaries has a 2009 denominator. Between 2013 and 2017, the trend estimated from the population of FFS beneficiaries, excluding those with ESRD and hospice is 0.0149. There are ten years of trend between the denominator year and the payment year.

We are soliciting input on whether to apply a different approach to determining the normalization factor for the model used for the PACE program. We welcome thoughts on criteria to use to determine any different approach.

The normalization factor for the CMS-HCC model used for PACE is applied to the community, institutional, and new enrollee risk scores.

The risk scores used to calculate the proposed 2019 normalization factor for the PACE CMS-HCC risk adjustment model are included in Table II-6 PACE Normalization Factor Trend.

Table II-6. PACE Normalization Factor Trend

Year	CMS-HCC Model used for PACE
2011	1.030
2012	1.042
2013	1.042
2014	1.048
2015	1.052
2016	1.079
2017	1.101

L3. Normalization Factor for the ESRD Dialysis Model

The proposed 2019 normalization factor for the ESRD dialysis model is 1.033.

The ESRD Dialysis model has a 2015 denominator. Between 2013 and 2017, the trend estimated from the population of FFS beneficiaries with ESRD is 0.0082. There are four years of trend between the denominator year and the payment year.

The normalization factor for the ESRD Dialysis model is applied to dialysis, dialysis new enrollee, and transplant risk scores.

The risk scores used to calculate the proposed normalization factor for the proposed 2019 ESRD Dialysis model are included in Table II-7 ESRD Dialysis Normalization Factor Trend.

Table II-7. ESRD Dialysis Normalization Factor Trend

Year	ESRD Dialysis Model
2011	0.984
2012	0.996
2013	0.994
2014	0.997
2015	1.000
2016	1.015
2017	1.026

1A. Normalization Factor for ESRD Post-Graft Model

The proposed 2019 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.048.

The Post-Graft segment of the ESRD model has a 2015 denominator. Between 2013 and 2017, the trend estimated from the population of FFS with ESRD is 0.0117. There are four years of trend between the denominator year and the payment year.

The normalization factor for the CMS-HCC functioning graft model is applied to the functioning graft community, functioning graft institutional, and functioning graft new enrollee risk scores. The risk scores used to calculate the proposed normalization factor for the Post-Graft segment of the ESRD model are included below in Table II-8 ESRD Post-Graft Segment Normalization Factor Trend.

Table II-8. ESRD Post-Graft Segment Normalization Factor Trend

Year	ESRD Post-Graft Model
2011	0.985
2012	0.995
2013	0.993
2014	0.998
2015	1.000
2016	1.023
2017	1.039

L5. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The proposed 2019 normalization factor for the RxHCC model is 1.020.

The revised RxHCC model has a 2015 denominator. Between 2013 and 2016, the trend estimated from the population of beneficiaries enrolled in a PDP or an MA-PD is 0.0049. The normalization factor for the RxHCC model is applied to all Part D risk scores for beneficiaries enrolled in an MA-PD or PDP plan. There are four years of trend between the denominator year and the payment year.

The risk scores used to calculate the proposed 2019 normalization factor for the RxHCC model are included in Table II-9 RxHCC Normalization Factor Trend.

Table II-9. RxHCC Normalization Factor Trend

Year	RxHCC Model
2010	0.980
2011	0.989
2012	0.996
2013	0.989
2014	0.995
2015	1.000
2016	1.015

Section M. Medical Loss Ratio Credibility Adjustment

In the May 23, 2013 Medicare Medical Loss Ratio (MLR) final rule (CMS-4173-F) (78 FR 31284), CMS finalized the requirements for calculating the Medicare MLR at 42 CFR §§ 422.2400 through 422.2480 and 42 CFR §§ 423.2400 through 423.2480, including application of credibility adjustments at §§ 422.2440 and 423.2440, which provide that CMS will define and publish definitions of partial credibility, full credibility, and non-credibility and the credibility factors through the annual notice and comment process of publishing the Advance Notice and Final Rate Announcement.

In the Medicare MLR final rule at 78 FR 31295, we published two sets of credibility adjustments: one for MA-PD contracts and one for Part D stand-alone contracts. For CY 2019, we are not proposing any changes to the credibility adjustments for MA-PD and Part D stand-alone contracts published in the final rule. The applicable credibility adjustments would remain as provided below in Table II-10 and Table II-11.

**Table II-10. MLR Credibility Adjustments
for MA-PD Contracts**

Member months	Credibility adjustment
< 2,400	Non-credible
2,400	8.4%
6,000	5.3%
12,000	3.7%
24,000	2.6%
60,000	1.7%
120,000	1.2%
180,000	1.0%
> 180,000	Fully credible

**Table II-11. MLR Credibility Adjustments
for Part D Stand-Alone Contracts**

Member months	Credibility adjustment
< 4,800	Non-credible
4,800	8.4%
12,000	5.3%
24,000	3.7%
48,000	2.6%
120,000	1.7%
240,000	1.2%
360,000	1.0%
> 360,000	Fully credible

Section N. Encounter Data as a Diagnosis Source for 2019

On December 27, 2017, CMS published for public comment the proposed Part C risk adjustment model. Information regarding the use of encounter data as a diagnosis source for 2019 for payments for aged and disabled beneficiaries based on the CMS-HCC model and PACE model were also included in the Part C notice. As noted in that notice, all comments must be submitted to www.regulations.gov, enter the docket number “CMS-2017-0163” in the “Search” field, and follow the instructions for “submitting a comment” no later than 6:00 pm EST on Monday, March 5, 2018, so that they may be addressed in the 2019 Rate Announcement that will be released no later than April 2, 2018.

For PY 2019, CMS is also proposing to blend risk scores calculated using the ESRD risk adjustment model by adding 25% of the risk score calculated with diagnoses from encounter data

(supplemented with RAPS inpatient data) and FFS with 75% of the risk score calculated with diagnoses from RAPS and FFS.

Section O. Quality Payment Program

The purpose of the Quality Payment Program, enacted by the MACRA statute, is to promote greater value in Part B payments to clinicians in the Medicare program. Clinicians have two paths to choose from: the Merit-Based Incentive System (MIPS); or Advanced Alternative Payment Models (Advanced APMs). APMs are defined under section 1833(z)(3)(D) of the Act as a model under section 1115A of the Act (excluding a health care innovation award), the Medicare Shared Savings Program under section 1899 of the Act, a demonstration under section 1866C of the Act, or a demonstration required by federal law. Advanced APMs are a subset of APMs that meet certain criteria including requiring participants to use certified EHR technology, providing for payment for covered professional services based on MIPS-comparable quality measures, and either requiring participants to bear greater than nominal financial risk for monetary losses or being a Medical Home Model expanded under CMS Innovation Center authority (414.1415). Examples of Advanced APMs include certain tracks of the Medicare Shared Savings Program and Comprehensive Primary Care Plus (CPC+) Model. By meeting threshold levels of participation in Advanced APMs (in terms of Part B payments or patient counts), eligible clinicians can become qualifying APM participants (QPs) for a year. Eligible clinicians who are QPs for a year earn a lump sum 5% APM incentive payment and are excluded from the MIPS reporting requirements and payment adjustment.

For 2019, CMS will begin implementing an additional way for eligible clinicians to become QPs that considers their participation not only in Advanced APMs, but also in innovative alternative payment arrangements through other payers such as Medicaid, Medicare Advantage and commercial payers (Other Payer Advanced APMs). Beginning in 2019, eligible clinicians who participate in Advanced APMs but do not meet the thresholds to become QPs on that basis will have the opportunity to qualify as QPs through the All-Payer Combination Option. The All-Payer Combination Option takes into account eligible clinician participation in both Advanced APMs and in Other Payer Advanced APMs, which are non-Medicare payment arrangements that meet criteria similar to Advanced APMs (§ 414.1420).

CMS will need to obtain information from outside sources on payment arrangements with other payers in order to determine whether they are Other Payer Advanced APMs. Unlike Advanced APMs, CMS does not currently possess this information.

We will do this using both a payer-initiated process and a clinician-initiated process. The payer-initiated process will be carried out in 2018 prior to the 2019 performance period. On a voluntary basis, payers will submit information on payment arrangement they believe are Other Payer Advanced APMs. CMS is implementing the payer-initiated process prior to 2019 so that we can publicly announce which payment arrangements are Other Payer Advanced APMs prior

to the 2019 performance period. We believe this will benefit participating APM Entity and eligible clinicians. The clinician-initiated process for determining Other Payer Advanced APMs will generally occur after the 2019 performance period. APM Entities and eligible clinicians will be allowed to submit information on payment arrangements they are participating in that they believe are Other Payer Advanced APMs, but were not identified through the payer-initiated process.

As part of the 2019 bid submission, Medicare Health Plans (including MA plans, cost plans, and MMPs) may submit applications to determine if their payment arrangements are Other Payer Advanced APMs. Guidance and submission forms will be part of a Quality Payment Program module of the bid submission package released in April 2018. Payment arrangements must meet certain criteria to qualify as Other Payer Advanced APMs that are similar to the Advanced APM criteria. These criteria include requiring providers to use Certified EHR Technology (CEHRT), tying quality measurement to payment, and requiring providers to assume a certain level of financial risk (414.1420). More information about Other Payer Advanced APMs and the Quality Payment Program is available at <https://qpp.cms.gov/>.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2019

Section A. Update of the RxHCC Model

For 2019, we are proposing to implement an updated version of the RxHCC risk adjustment model used to adjust direct subsidy payments for Part D benefits offered by stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs).

The RxHCC model that is being used for PY 2018 was updated to reflect 2019 benefit structure.

A1. Update to reflect the 2019 benefit structure

CMS recalibrated the RxHCC risk adjustment model to reflect the 2019 benefit structure. This update involved adjustments to the Prescription Drug Event (PDE) data from the prediction year to approximate the 2019 benefit structure. The adjustments to the PDE data are similar to those made in previous years' model calibrations in that we incorporated the payment year 2019 plan liability in the coverage gap into the prediction year (2015) expenditure data. For 2019, plan liability for non-LIS beneficiaries in the coverage gap will be 63 percent for non-applicable (generic) drugs and 20 percent plan liability for applicable (brand) drugs in the coverage gap. In addition, we mapped all PDEs to the defined standard benefit across all phases of the Part D benefit. All other things being equal, the increase in plan liability due to the reduction in beneficiary cost sharing for non-applicable drugs and applicable drugs will differentially affect the risk scores of LIS and non-LIS beneficiaries. This is because plan liability for non-LIS populations, relative to LIS populations, will increase.

A2. Recalibration

The model being used for PY 2018 is calibrated on 2014 diagnoses and 2015 expenditure data from the PDE records. For this recalibration for 2019, we maintained the use of diagnosis data from 2014 fee-for-service (FFS) claims and MA-PD RAPS files, along with expenditure data from 2015 PDE records. The use of 2015 diagnoses and 2016 expenditures would have included a mix of ICD-9 diagnoses (January 2015 – September 2015) and ICD-10 diagnoses (October 2015 – December 2015). In order to maintain stability and reflect a year of diagnoses submitted under a single classification system we continued to use the 2014/2015 modeling sample for the 2019 recalibration. Beneficiaries in the model sample had to be: (1) FFS or Medicare Advantage (MA-PD or MA-only) for all 12 months of the base year (2014); and (2) enrolled in a PDP or an MA-PD for at least one month in the prediction year (2015).

Consistent with existing methodology, coefficients for condition categories were estimated by regressing the plan liability, adjusted as discussed in A1, for the Part D basic benefit for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. We imposed hierarchies on the condition categories, ensuring that more advanced and costly forms of a condition are reflected with a coefficient at least as high as related

conditions with lower severity. The resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (for example, age/sex group, low-income subsidy status, and disability status).

In order to calculate risk scores for payment, the dollar coefficients must be denominated to create relative factors. For the PY 2019 model calibration, we divided the dollar coefficient for each demographic factor and RxHCC in the model by the average predicted per capita expenditure in 2015. Consistent with the decision to continue to use the 2014/2015 modeling sample for the recalibration, CMS will continue to use a 2015 denominator to create the relative factors. These relative factors are then used to calculate risk scores for individual beneficiaries in the payment year. We developed the denominator for the revised RxHCC risk adjustment model using data from Medicare beneficiaries enrolled in both MA-PDs and PDPs, which results in an average risk score for the enrolled Part D population in the denominator year of 1.0. The denominator used to create relative factors for all segments of the model, is \$1,062.31.

When the RxHCC model is recalibrated to reflect an updated benefit structure, it can result in changes in condition category coefficients. Changes in the relative (denominated) factors can occur when the marginal cost attributable to an RxHCC changes differently than the average beneficiary cost. Recalibration of the RxHCC model can result in changes in risk scores for individual beneficiaries and for plan average risk scores, depending on each individual beneficiary's combination of diagnoses.

In Attachment V of this Notice, we provide draft factors for each RxHCC for each segment of the model.

Section B. Encounter Data as a Diagnosis Source for 2019

For PY 2018, CMS calculated risk scores by adding 15% of the risk score calculated using encounter data and FFS diagnoses with 85% of the risk score calculated using RAPS and FFS diagnoses.

For PY 2019, CMS proposes to calculate risk scores by adding 25% of the risk score calculated with diagnoses from encounter data (supplemented with RAPS inpatient data) and FFS with 75% of the risk score calculated from RAPS data and FFS diagnoses.

For PACE organizations for PY 2019, we propose to continue the same method of calculating risk scores that we have been using since PY 2015, which is to pool risk adjustment-eligible diagnoses from the following sources to calculate a single risk score (with no weighting): (1) encounter data, (2) RAPS, and (3) FFS claims.

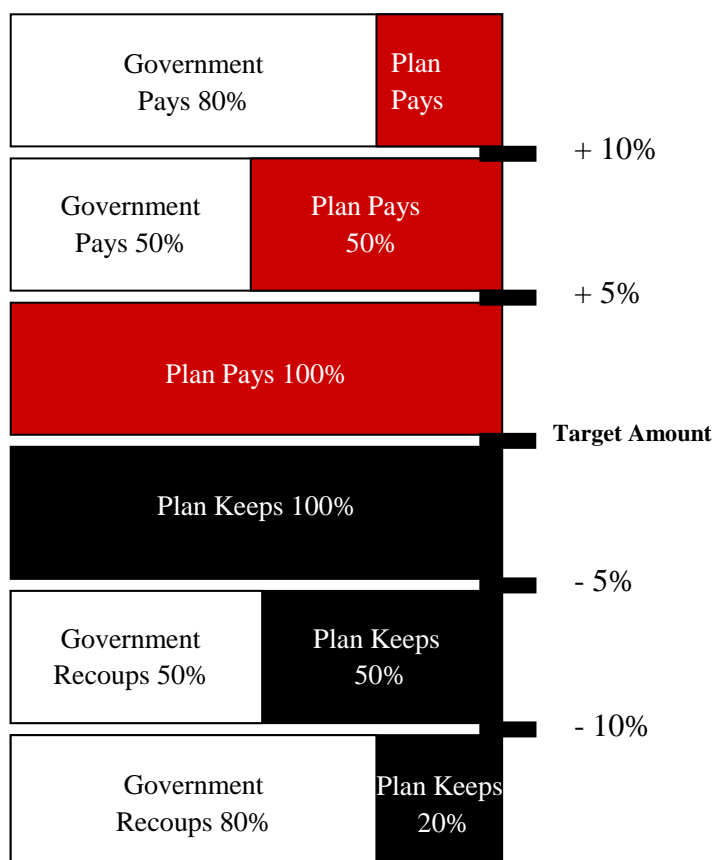
Section C. Part D Risk Sharing

The risk sharing payments provided by CMS limit Part D sponsors' exposure to unexpected drug expenses. Pursuant to section 1860D-15(e)(3)(C) of the Act and § 423.336(a)(2)(ii) of our

regulations, CMS may establish a risk corridor with higher threshold risk percentages for Part D risk sharing beginning in contract year 2012. Widening the risk corridor would increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS. While CMS may widen the risk corridors, the statute does not permit CMS to narrow the corridors relative to the 2011 thresholds.

CMS has evaluated the risk sharing amounts for 2008 – 2016 to assess whether they have decreased or stabilized. A steady decline or stabilization in the Part D risk sharing amounts would suggest that Part D sponsors have significantly improved their ability to predict Part D expenditures. However, CMS has found that risk sharing amounts continue to vary significantly in aggregate from year to year and among Part D sponsors in any given year. Therefore, we do not believe it is appropriate to adjust the parameters at this time, and we will apply no changes to the current threshold risk percentages for contract year 2019. We will continue to evaluate the risk sharing amounts each year to determine if wider corridors should be applied for Part D risk sharing.

Thus, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2018. The risk percentages for the first and second thresholds remain at +/- 5 percent and +/- 10 percent of the target amount, respectively, for 2019. The payment adjustments for the first and second corridors are 50 percent and 80 percent, respectively. Figure 1 below illustrates the risk corridors for 2019.

Figure 1. Part D Risk Corridors for 2019

C1. Risk sharing when a plan's adjusted allowable risk corridor costs (AARCC) exceed the target amount

For the portion of a plan's adjusted allowable risk corridor costs (AARCC) that is between the target amount and the first threshold upper limit (105 percent of the target amount), the Part D sponsor pays 100 percent of this amount. For the portion of the plan's AARCC that is between the first threshold upper limit and the second threshold upper limit (110 percent of the target amount), the government pays 50 percent and the plan pays 50 percent. For the portion of the plan's AARCC that exceeds the second threshold upper limit, the government pays 80 percent and the plan pays 20 percent.

Example: If a plan's AARCC is \$120 and its target amount is \$100, the Part D sponsor and the government cover \$9.50 and \$10.50, respectively, of the \$20 in unanticipated costs. The sponsor's responsibility is calculated as follows:

$$100\% \text{ of } (\$105 - \$100) + 50\% \text{ of } (\$110 - \$105) + 20\% \text{ of } (\$120 - \$110).$$

C2. Risk sharing when a plan’s adjusted allowable risk corridor costs (AARCC) are below the target amount

If a plan’s AARCC is between the target amount and the first threshold lower limit (95 percent of the target amount), the plan keeps 100 percent of the difference between the target amount and the plan’s AARCC. If a plan’s AARCC is between the first threshold lower limit and the second threshold lower limit (90 percent of the target amount), the government recoups 50 percent of the difference between the first threshold lower limit and the plan’s AARCC. The plan would keep 50 percent of the difference between the first threshold lower limit and the plan’s AARCC, as well as 100 percent of the difference between the target amount and first threshold lower limit. If a plan’s AARCC is less than the second threshold lower limit, the government recoups 80 percent of the difference between the plan’s AARCC and the second threshold lower limit, as well as 50 percent of the difference between the first and second threshold lower limits. In this case, the plan would keep 20 percent of the difference between the plan’s AARCC and the second threshold lower limit, 50 percent of the difference between the first and second threshold lower limits, and 100 percent of the difference between the target amount and the first threshold lower limit.

Example: If a plan’s AARCC is \$80 and its target amount is \$100, the Part D sponsor keeps \$9.50 while the government recoups \$10.50 of the \$20 in unexpected savings generated. The sponsor’s share is calculated as follows:

$$100\% \text{ of } (\$100 - \$95) + 50\% \text{ of } (\$95 - \$90) + 20\% \text{ of } (\$90 - \$80).$$

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2019

In accordance with section 1860D-2(b) of the Act, CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. As required by statute, the following Part D benefit parameters are updated using the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary (“Annual Percentage Increase” or API):

- the deductible, initial coverage limit, and out-of-pocket threshold⁸ for the defined standard benefit;
- minimum copayments for costs above the annual out-of-pocket threshold;
- maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
- the deductible for partial low-income subsidy (LIS) eligible enrollees; and

⁸ According to section 1860D-2(b)(4)(B)(i)(IV), for years 2016 through 2019, the out-of-pocket threshold is updated from the previous year by the lesser of (a) the API or (b) two percentage points plus the annual percentage increase in the consumer price index.

- maximum copayments above the out-of-pocket threshold for partial LIS-eligible enrollees.

The remaining parameters are indexed to the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average). Accordingly, the actuarial value of the drug benefit changes along with any change in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year.

D1. Annual Percentage Increase in Average Expenditures for Part D Drugs

The benefit parameters indexed to the API will be increased by 1.94 percent for 2019, as summarized by Table III-1 below. This increase reflects the 2018 annual percentage trend of 3.96 percent as well as a multiplicative update of -1.95 percent for prior year revisions. See Attachment IV for additional information on the calculation of the annual percentage increase.

Per § 423.886(b)(3) of our regulations, the cost threshold and cost limit for qualified retiree prescription drug plans are also indexed to the API. Thus, the cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 1.94 percent from their 2018 values.

D2. Annual Percentage Increase in Consumer Price Index

Section 1860D-14(a)(4) of the Act requires CMS to use the annual percentage increase in the CPI for the 12 month period ending in September 2018 to update the maximum copayments up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal Poverty Level for 2019. These maximum copayments will be increased by 1.78 percent for 2019 as summarized in Table III-1 below.

This increase reflects the 2018 annual percentage trend in CPI of 1.95 percent as well as a multiplicative update of -0.17 percent for prior year revisions.

Additionally, section 1860D-2(b)(4) of the Act requires that the out-of-pocket threshold for contract years 2016 through 2019 be updated from the previous year by the lesser of (1) the API or (2) two percentage points plus the annual percentage increase in CPI. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The cumulative annual percentage increase in CPI for 2018 as of July 2018 is 1.83 percent. This figure reflects the 2018 annual percentage increase in the July CPI of 2.58 percent, as well as a multiplicative update of -0.73 percent for prior year revisions. The cumulative annual percentage increase in the July CPI for 2018 plus two percentage points is greater than the 1.94 percent cumulative API described above. Thus, the out-of-pocket threshold will be increased by 1.94 percent for 2019.

See Attachment IV for additional information on the calculation of the annual percentage increase in the CPI.

D3. Determining Total Covered Part D Spending at Out-of-Pocket Threshold

Each year, CMS releases the Total Covered Part D Spending at the Out-of-Pocket Threshold, which is the amount of total drug spending, regardless of payer, required to reach the out-of-pocket threshold in the defined standard benefit. Due to reductions in beneficiary cost-sharing for drugs in the coverage gap phase for applicable (i.e., non-LIS) beneficiaries per section 1860D-2 of the Act, the total covered Part D spending may be different for applicable and non-applicable (i.e., LIS) beneficiaries. Therefore, CMS is releasing the two values described below:

- Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries. This is the amount of total drug spending for a non-applicable (i.e., LIS) beneficiary to reach the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program, or similar third party arrangement, this amount may be higher. This amount is calculated based on 100 percent cost-sharing in the deductible and coverage gap phases and 25 percent cost-sharing in the initial coverage phase.
- Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries. This is an *estimate* of the average amount of total drug spending for an applicable (i.e., non-LIS) beneficiary to reach the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement, this amount may be higher. This amount is estimated based on 100 percent beneficiary cost-sharing in the deductible phase, 25 percent cost-sharing in the initial coverage phase, and in the coverage gap, 37 percent cost sharing for “non-applicable” drugs and 80 percent cost-sharing – consisting of 30 percent beneficiary coinsurance and 50 percent Coverage Gap Discount Program discount – for “applicable” drugs. Please see Attachment IV for additional information on the calculation of the estimated total covered Part D spending for applicable beneficiaries.

The values can be found in Table III-1 below.

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2018	Prior year revisions	Annual percentage increase for 2019
API: Applied to all parameters but (1) and (2)	3.96%	−1.95%	1.94%
July CPI (all items, U.S. city average): Applied to (1)	2.58%	−0.73%	1.83%
September CPI (all items, U.S. city average): Applied to (2)	1.95%	−0.17%	1.78%

Part D Benefit Parameters

	2018	2019
Standard Benefit		
Deductible	\$405	\$415
Initial Coverage Limit	\$3,750	\$3,820
Out-of-Pocket Threshold (1)	\$5,000	\$5,100
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	\$7,508.75	\$7,653.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	\$8,417.60	\$8,906.55
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	\$3.35	\$3.40
Other	\$8.35	\$8.50
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	\$0.00	\$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	\$0.00	\$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services] [category code 3] (5)	\$0.00	\$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug (6)	\$1.25	\$1.25
Other (6)	\$3.70	\$3.80
Above Out-of-Pocket Threshold	\$0.00	\$0.00
Over 100% FPL [category code 1]		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	\$3.35	\$3.40
Other	\$8.35	\$8.50
Above Out-of-Pocket Threshold	\$0.00	\$0.00

	2018	2019
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI, income at or below 135% FPL and resources ≤ \$9,060 (individuals, 2018) or ≤ \$14,340 (couples, 2018) [category code 1] (7)		
Deductible	\$0.00	\$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	\$3.35	\$3.40
Other	\$8.35	\$8.50
Maximum Copayments above Out-of-Pocket Threshold	\$0.00	\$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below \$14,100 (individual, 2018) or \$ 28,150 (couples, 2018) [category code 4] (7)		
Deductible (6)	\$83.00	\$85.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	\$3.35	\$3.40
Other	\$8.35	\$8.50
Retiree Drug Subsidy Amounts		
Cost Threshold	\$405	\$415
Cost Limit	\$8,350	\$8,500

(1) Pursuant to section 1860D-2(b)(4)(B)(i)(IV) of the Act, for each of years 2016 through 2019, the out-of-pocket threshold increase is the lesser of the annual percentage increase or the July CPI plus two percentage points.

(2) September CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(3) For a beneficiary who is not considered an “applicable beneficiary,” as defined at section 1860D-14A(g)(1), and is not eligible for the Coverage Gap Discount Program, this is the amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.

(4) For a beneficiary who is considered an “applicable beneficiary,” as defined at section 1860D-14A(g)(1), and is eligible for the Coverage Gap Discount Program, this is the estimated average amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit.

(5) Per section 1860D-14(a)(1)(D)(i) of the Act, full-benefit dual eligible beneficiaries qualify for zero cost-sharing if they would be institutionalized individuals (or couple) if the individuals (couple) were not receiving home and community-based services.

(6) The partial LIS deductible is increased from the unrounded 2018 value of \$83.46, and the maximum copayments for non-institutionalized FBDE individuals with incomes no greater than 100 percent of the FPL are increased from the unrounded 2018 values of \$1.24 for generic/preferred multi-source drugs and \$3.73 for all other drugs.

(7) These resource limit figures will be updated for contract year 2019. Additionally, these amounts include \$1,500 per person for burial expenses. See the HPMS memorandum titled, “2018 Resource and Cost-Sharing Limits for Low-Income Subsidy (LIS)” for additional details.

Section E. Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap

The law requires phased reduction in applicable beneficiary cost-sharing for drugs in the coverage gap phase of the Medicare Part D benefit. This gradual reduction in cost-sharing began in CY 2011 and continues through CY 2020, ultimately resulting in 75 percent cost-sharing for applicable drugs, prior to the application of the 50 percent manufacturer discounts required by statute, and 25 percent cost-sharing for other covered Part D drugs (non-applicable drugs). An applicable drug is defined in section 1860D-14A(g)(2) of the Act to generally include covered Part D brand drugs that are either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic, licensed under section 351 of the Public Health Service Act (PHSA) (other than a product licensed under subsection (k) of such section 351) using a Biologics License Application (BLA). Non-applicable drugs generally are covered Part D drugs that do not meet the definition of an applicable drug, such as generic drugs. Note that non-applicable drugs also include any biosimilar products, or biologics licensed under section 351(k) of the PHSA using a BLA, per section 1860D-14A(g)(2)(A) of the Act. The reductions in cost-sharing, in conjunction with the Coverage Gap Discount Program, will effectively serve to close the Medicare Part D coverage gap for non-LIS beneficiaries by CY 2020.

In 2019, the coinsurance for applicable beneficiaries under basic prescription drug coverage is reduced to 37 percent for *non-applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After applying the 50 percent manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage is reduced to 30 percent for *applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2019.

Table III-2. Cost-Sharing for Applicable Drugs in the Coverage Gap

	Beneficiary Coinsurance	Plan Liability	Manufacturer Discount
2010	100% minus \$250 rebate ⁹	0%	0%
2011	50%	0%	50%
2012	50%	0%	50%
2013	47.5%	2.5%	50%
2014	47.5%	2.5%	50%
2015	45%	5%	50%
2016	45%	5%	50%
2017	40%	10%	50%
2018	35%	15%	50%
2019	30%	20%	50%
2020	25%	25%	50%

Table III-3. Cost-Sharing for Non-Applicable Drugs in the Coverage Gap

	Beneficiary Coinsurance	Plan Liability
2010	100%	0%
2011	93%	7%
2012	86%	14%
2013	79%	21%
2014	72%	28%
2015	65%	35%
2016	58%	42%
2017	51%	49%
2018	44%	56%
2019	37%	63%
2020	25%	75%

To be eligible for reduced cost-sharing, a Part D enrollee must have incurred gross covered drug costs above the initial coverage limit but true out-of-pocket costs (TrOOP) below the out-of-

⁹ The law authorized a coverage gap rebate payment of \$250 to any Part D beneficiary who reached the initial coverage phase in 2010. The rebate was not required to be spent on drugs.

pocket threshold. Moreover, Medicare beneficiaries enrolled in a qualified retiree prescription drug plan or those entitled to the low-income subsidy are not eligible for this reduced cost-sharing.

As beneficiary liability for covered Part D drug costs in the coverage gap decreases, plan liability increases. The increased plan liability amounts do not count toward TrOOP. Part D sponsors must account for the reductions in cost-sharing and increased plan liability when developing their Part D bids for payment year 2019.

Section F. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap

As described in the previous section, the law phases in a reduction in beneficiary cost-sharing for drugs in the coverage gap phase of the Medicare Part D benefit. Consistent with our policy on liability for dispensing and vaccine administration fees, as described in the Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, applicable beneficiaries will pay a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance in the coverage gap, after the application of the coverage gap discount program discount when applicable. The Part D sponsor will pay the remainder of the dispensing fee and vaccine administration fee, if any.

In 2019, applicable beneficiaries will pay 30 percent and plans will pay 70 percent of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap.

Section G. Part D Calendar Year Employer Group Waiver Plans Prospective Reinsurance Payment Amount

CMS makes prospective reinsurance payments to all Part D Calendar Year EGWP (CY EGWP) sponsors based on the average per member-per month (PMPM) actual (final) reinsurance amounts paid to Part D CY EGWP sponsors for the most recently reconciled payment year, which for PY 2019 is PY 2016. The average PMPM actual reinsurance amount paid to Part D CY EGWPs for 2016 was \$36.10.

Section H. Enhanced Medication Therapy Management (MTM) Model

CMS released an HPMS memo on September 28, 2015 announcing information pertaining to the Part D Enhanced Medication Therapy Management (MTM) Model. The memo stated that CMS would “offer a performance-based incentive payment in return for a minimum reduction [2%] in Medicare costs of care and successful data and quality reporting. The incentive will be set at a fixed \$2.00 per-member amount, which is equal to the level of recent LIS benchmark de minimis amounts. This performance-based payment will be in the form of an increase in government contribution to the plan premium, i.e., as an increase in the direct subsidy component of Part D

payment or an equivalent payment. The plan would still be receiving the total payment specified in its bid, not an additional add-on payment. However, the government-funded portion of the monthly bid would increase, and the beneficiary portion (premium) would correspondingly decrease for all plan enrollees. Thus, plan sponsors will submit standardized bids as usual based on their cost requirements, and then any additional premium subsidy earned will be subsequently applied to the plan premium prior to its inclusion in CMS low-income-premium-subsidy calculations. In other words, the premium reduction will be considered in determining the low-income premium benchmark.” Also, the memo indicated that, “Performance results in model Year One (2017) will translate into a performance-based payment in Year 3 (2019).”

Since this memo release, CMS has continued to implement and operationalize the Enhanced MTM model. Given timing and operational considerations, CMS is currently determining whether it will be possible for the model’s premium reductions to be considered when determining the 2019 low-income premium benchmarks.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2019

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is required by statute to update the parameters for the low-income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy each year. Included in this notice are (1) the methodologies for updating these parameters, (2) the updated parameters for the Part D defined standard benefit and the low-income subsidy benefit for 2019, and (3) the updated cost threshold and cost limit for qualified retiree prescription drug plans in 2019.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute:

- (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary (API); or
- (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

Section A. Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API)

Section 1860D-2(b)(6) of the Act defines the API as “the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.” The following parameters are updated using the “annual percentage increase”:

Deductible: From \$405 in 2018 and rounded to the nearest multiple of \$5.

Initial Coverage Limit: From \$3,750 in 2018 and rounded to the nearest multiple of \$10.

Out-of-Pocket Threshold: From \$5,000 in 2018 and rounded to the nearest multiple of \$50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From \$3.35 per generic or preferred drug that is a multi-source drug and \$8.35 for all other drugs in 2018, rounded to the nearest multiple of \$0.05.

Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low-Income Full Subsidy Eligible Enrollees: From \$3.35 per generic or preferred drug that is a multi-source drug and \$8.35 for all other drugs in 2018, rounded to the nearest multiple of \$0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From \$83¹⁰ in 2018 and rounded to the nearest \$1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From \$3.35 per generic or preferred drug that is a multi-source drug and \$8.35 for all other drugs in 2018, rounded to the nearest multiple of \$0.05.

Section B. Annual Percentage Increase in Consumer Price Index (CPI)

Annual Percentage Increase in Consumer Price Index, September (September CPI)

Section 1860D-14(a)(4) of the Act specifies that CMS use the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year to update the maximum copayment amounts up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal Poverty Level. These copayments are increased from \$ 1.25 per generic or preferred drug that is a multi-source drug and from \$3.70 for all other drugs in 2018 and rounded to the nearest multiple of \$0.05 and \$0.10 respectively.¹¹

Annual Percentage Increase in Consumer Price Index, July (July CPI)

Additionally, section 1860D-2(b)(4) of the Act requires that the “annual percentage increase” applied to the out-of-pocket threshold in 2019 be the lesser of the API or CPI+2%. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The API over the 12-month period ending in July of 2018 is lower than the change in CPI+2% during that period, and, therefore, the API will apply to the out-of-pocket threshold. The threshold is increased from \$5,000 in 2018 and rounded to the nearest multiple of \$50.

¹⁰ Per section 1860D-14(a)(4)(B) of the Act, the update for the deductible for partial low income subsidy eligible enrollees is applied to the unrounded 2018 value of \$83.46.

¹¹ Per section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2018 values of \$1.24 for multi-source generic or preferred drugs, and \$3.73 for all other drugs.

Section C. Calculation Methodology

Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API)

For contract years 2007 and 2008, the APIs, as defined in section 1860D-2(b)(6) of the Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with contract year 2009, the APIs are based on Part D program data. For the contract year 2019 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\text{August 2017–July 2018}}{\text{August 2016–July 2017}} = \frac{\$3,730.80}{\$3,588.60} = 1.0396$$

In the formula, the average per capita cost for August 2016 – July 2017 (\$3,588.60) is calculated from actual Part D PDE data, and the average per capita cost for August 2017 – July 2018 (\$3,730.80) is calculated based on actual Part D PDE data incurred from August 2017 – December 2017 and projected through July 2018.

The 2019 benefit parameters reflect the 2018 annual percentage trend, as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table IV-1.

Table IV-1. Revised Prior Years' Annual Percentage Increases

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	7.30%	7.30%
2008	5.92%	5.92%
2009	4.69%	4.69%
2010	3.14%	3.14%
2011	2.36%	2.36%
2012	2.16%	2.15%
2013	2.53%	2.53%
2014	–3.14%	–3.14%
2015	10.09%	10.12%
2016	9.90%	9.92%
2017	4.14%	4.00%
2018	3.94%	2.02%

Accordingly, the 2019 benefit parameters reflect a multiplicative update of -1.95 percent for prior year revisions. In summary, the 2018 parameters outlined in Section A are updated by 1.94 percent for 2019, as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2018	3.96%
Prior year revisions	-1.95%
Annual percentage increase for 2019	1.94%

Note: Percentages are multiplicative, not additive.
Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, September (September CPI)

To ensure that plan sponsors and CMS have sufficient time to incorporate cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, CMS includes in its methodology to calculate the annual percentage increase in the CPI for the 12-month period ending in September 2018, an estimate of the September 2018 CPI based on projections from the President's FY2019 Budget.

The September 2017 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2019 is calculated as follows:

$$\frac{\text{Projected September 2018 CPI}}{\text{Actual September 2017 CPI}} \text{ or } \frac{251.6}{246.8} = 1.0195$$

(Source: President's FY2019 Budget and Bureau of Labor Statistics, Department of Labor)

The 2019 benefit parameters reflect the 2018 annual percentage trend in the September CPI of 1.95 percent, as well as a revision to the prior estimate for the 2017 CPI increase over the 12-month period ending in September 2017. Based on the actual reported CPI for September 2017, the September 2017 CPI increase is now estimated to be 2.23 percent. Accordingly, the 2019 update reflects a -0.17 percent multiplicative correction for the revision to last year's estimate. In summary, the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal Poverty Level are updated by 1.78 percent for 2019, as summarized by Table IV-3.

Table IV-3. Cumulative Annual Percentage Increase in September CPI

Annual percentage trend for September 2018	1.95%
Prior year revisions	-0.17%
Annual percentage increase for 2019	1.78%

Note: Percentages are multiplicative, not additive.

Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, July (July CPI)

As is the case when calculating the annual CPI trend as of September 2018, the methodology to calculate the annual percentage increase in the CPI for the 12-month period ending in July 2018 includes an estimate of the July 2018 CPI based on projections from the President's FY2019 Budget.

The July 2017 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2019 is calculated as follows:

$$\frac{\text{Projected July 2018 CPI}}{\text{Actual July 2017 CPI}} \text{ or } \frac{251.1}{244.8} = 1.0258$$

(Source: President's FY2019 Budget and Bureau of Labor Statistics, Department of Labor)

The 2019 benefit parameters reflect the 2018 annual percentage trend in the July CPI of 2.58 percent as well as a revision to the prior estimate for the 2017 CPI increase. Based on the actual reported CPI for July 2017, the CPI increase over the 12-month period ending in July 2017 is estimated to be 1.73 percent. The prior year revision here reflects the difference between this actual 1.73 percent increase in CPI observed in July 2017 and the 2017 CPI increase estimate from the CY 2018 Rate Announcement.

In summary, the cumulative annual percentage increase in July CPI for 2019 is 1.83 percent, as summarized by Table IV-4. This value plus two percentage points is greater than the 1.94 percent cumulative API for 2019 described above. Thus, the out-of-pocket threshold will be increased by 1.94 percent for 2019.

Table IV-4. Cumulative Annual Percentage Increase in July CPI

Annual percentage trend for July 2018	2.58%
Prior year revisions	-0.73%
Annual percentage increase for 2019	1.83%

Note: Percentages are multiplicative, not additive.

Values are carried to additional decimal places and may not agree to the rounded values presented above.

Section D. Retiree Drug Subsidy Amounts

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are also updated using the API, as defined previously in this document. The updated cost threshold is rounded to the nearest multiple of \$5 and the updated cost limit is rounded to the nearest multiple of \$50. The cost threshold and cost limit are defined as \$400 and \$8,250, respectively, for plans that end in 2017, and as \$405 and \$8,350 for plans that end in 2018. For 2019, the cost threshold is \$415 and the cost limit is \$8,500.

Section E. Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries

For 2019, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is \$8,906.55. The figure is calculated given the following basic assumptions:

- 100 percent beneficiary cost-sharing in the deductible phase.
- 25 percent beneficiary cost-sharing in the initial coverage phase.
- 37 percent beneficiary cost-sharing for non-applicable drugs purchased in the coverage gap phase of the benefit.
- 80 percent cost-sharing for the ingredient cost and sales tax for applicable drugs purchased in the coverage gap phase of the benefit—comprised of 30 percent beneficiary coinsurance and 50 percent Coverage Gap Discount Program discount.
- 30 percent cost-sharing for the dispensing and vaccine administration fees for applicable drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.072 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 70 percent reduction in cost-sharing for dispensing and vaccine administration fees results in an overall reduction of 0.04 percent to 79.96 percent in cost-sharing for applicable (brand) drugs in the coverage gap.

The estimated total covered Part D spending at out-of-pocket (OOP) threshold for applicable beneficiaries is calculated as follows:

$$ICL + \frac{100\% \text{ beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \text{ or } \$3,820 + \frac{\$3,833.75}{75.3704\%} = \$8,906.55$$

- *ICL* is the Initial Coverage Limit equal to \$3,820
- *100 percent beneficiary cost-sharing in the gap* is the estimated total drug spending in the gap assuming 100 percent coinsurance and is equivalent to:

$$(\text{OOP threshold}) - (\text{OOP costs up to the ICL}) \text{ or } \$5,100 - \$1,266.25 = \$3,833.75$$

- *Weighted gap coinsurance factor* is calculated as follows:

(Brand Gross Drug Cost Below Catastrophic [GDCB] % for non-LIS \times 79.96% gap cost-sharing for applicable drugs) + (Generic GDCB % for non-LIS \times 37% gap cost-sharing for non-applicable drugs)

or

$$(89.31\% \times 79.96\%) + (10.69\% \times 37\%) = 75.3704\%$$

- *Brand GDCB % for non-LIS* is the percentage of gross covered drug costs below the OOP threshold for applicable beneficiaries (i.e., non-LIS) attributable to applicable drugs, as reported on the 2017 PDEs.
- *Gap cost-sharing for applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for applicable drugs in the coverage gap, where:

- *Coinsurance for applicable drugs* = is calculated as follows:

[(percentage of gross covered brand drug costs attributable to ingredient cost and sales tax) \times (cost-sharing percentage)] + [(percentage of gross covered brand drug costs attributable to dispensing and vaccine administration fees) \times (cost-sharing coinsurance percentage)]

or

$$79.96\% = [(99.928\% \times 80\%) + (0.072\% \times 30\%)]$$

- *Generic GDCB % for non-LIS* is the percentage of gross covered drug costs below the OOP threshold for applicable beneficiaries (i.e., non-LIS) attributable to non-applicable drugs as reported on the 2017 PDEs.
- *Gap cost-sharing for non-applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for non-applicable drugs in the coverage gap.

Attachment V. RxHCC and ESRD Risk Adjustment Factors

Table V-1. RxHCC Model Relative Factors for Continuing Enrollees	66
Table V-2. RxHCC Model Relative Factors for New Enrollees, Non-Low Income	72
Table V-3. RxHCC Model Relative Factors for New Enrollees, Low Income	73
Table V-4. RxHCC Model Relative Factors for New Enrollees, Institutional	74
Table V-5. List of Disease Hierarchies for RxHCC Model	75
Table V-6. ESRD Model Continuing Enrollee Dialysis Relative Factors	76
Table V-7. ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status	80
Table V-8. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries	81
Table V-9. ESRD Model Functioning Graft Relative Factors for Community Population	82
Table V-10. ESRD Model Functioning Graft Relative Factors for Institutionalized Population	87
Table V-11. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months	93
Table V-12. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More	94
Table V-13. List of Disease Hierarchies for the ESRD Model	95

Table V-1. RxHCC Model Relative Factors for Continuing Enrollees

Continuing Enrollees (CE) RxHCC Model Segments						
Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.306	-	0.429	1.765
35-44 Years		-	0.452	-	0.617	2.005
45-54 Years		-	0.555	-	0.716	1.691
55-59 Years		-	0.525	-	0.694	1.542
60-64 Years		-	0.487	-	0.630	1.404
65-69 Years		0.237	-	0.384	-	1.474
70-74 Years		0.237	-	0.360	-	1.350
75-79 Years		0.222	-	0.350	-	1.243
80-84 Years		0.202	-	0.311	-	1.151
85-89 Years		0.178	-	0.278	-	1.061
90-94 Years		0.130	-	0.225	-	0.944
95 Years or Over		0.064	-	0.140	-	0.752
Male						
0-34 Years		-	0.272	-	0.468	1.800
35-44 Years		-	0.390	-	0.592	1.792
45-54 Years		-	0.491	-	0.658	1.654
55-59 Years		-	0.526	-	0.665	1.472
60-64 Years		-	0.504	-	0.613	1.348
65-69 Years		0.263	-	0.362	-	1.307
70-74 Years		0.269	-	0.338	-	1.260
75-79 Years		0.242	-	0.337	-	1.190
80-84 Years		0.181	-	0.300	-	1.143
85-89 Years		0.134	-	0.283	-	1.075
90-94 Years		0.076	-	0.237	-	0.985
95 Years or Over		0.039	-	0.221	-	0.865
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.103	-	0.196	-	0.065
Originally Disabled_Male		-	-	0.133	-	0.065
Disease Coefficients	Description Label					
RXHCC1	HIV/AIDS	3.287	3.969	3.732	4.071	2.538
RXHCC5	Opportunistic Infections	0.274	0.115	0.173	0.160	0.180

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC15	Chronic Myeloid Leukemia	7.391	7.515	8.032	9.772	4.846
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	3.955	4.178	3.184	3.614	1.081
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.791	1.723	1.579	1.566	0.575
RXHCC18	Lung, Kidney, and Other Cancers	0.299	0.264	0.320	0.311	0.069
RXHCC19	Breast and Other Cancers and Tumors	0.098	0.088	0.078	0.113	0.069
RXHCC30	Diabetes with Complications	0.442	0.477	0.495	0.685	0.469
RXHCC31	Diabetes without Complication	0.289	0.269	0.312	0.384	0.318
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.988	10.419	3.071	10.310	0.465
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.104	0.207	0.059	0.225	0.087
RXHCC42	Thyroid Disorders	0.103	0.182	0.098	0.163	0.077
RXHCC43	Morbid Obesity	0.060	-	0.073	0.067	0.170
RXHCC45	Disorders of Lipoid Metabolism	0.037	-	0.068	0.087	0.055
RXHCC54	Chronic Viral Hepatitis C	3.198	3.675	2.882	2.907	0.929
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.561	0.363	0.847	0.526	0.361
RXHCC65	Chronic Pancreatitis	0.279	0.194	0.156	0.201	0.171
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.109	0.194	0.114	0.201	0.119
RXHCC67	Inflammatory Bowel Disease	0.547	0.472	0.451	0.819	0.213

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.077	0.061	0.140	0.167	0.075
RXHCC80	Aseptic Necrosis of Bone	0.179	0.252	0.108	0.143	0.114
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.780	0.751	1.277	2.037	0.653
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.382	0.415	0.477	0.794	0.185
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.216	0.339	0.236	0.349	0.173
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.053	0.159	0.119	0.201	-
RXHCC95	Sickle Cell Anemia	0.087	0.293	0.047	0.778	0.333
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.966	1.144	0.761	0.700	0.544
RXHCC97	Immune Disorders	0.565	0.521	0.481	0.448	0.347
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.087	0.160	0.047	0.217	0.044
RXHCC111	Alzheimer's Disease	0.496	0.255	0.175	0.034	-
RXHCC112	Dementia, Except Alzheimer's Disease	0.205	0.111	0.040	-	-
RXHCC130	Schizophrenia	0.275	0.305	0.399	0.691	0.193
RXHCC131	Bipolar Disorders	0.264	0.285	0.280	0.438	0.193
RXHCC132	Major Depression	0.130	0.213	0.142	0.306	0.163
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.130	0.175	0.142	0.306	0.107
RXHCC134	Depression	0.130	0.175	0.136	0.203	0.107
RXHCC135	Anxiety Disorders	0.050	0.114	0.084	0.169	0.107
RXHCC145	Autism	0.130	0.175	0.363	0.369	0.107

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	-	0.175	0.363	0.330	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	-	-	0.237	0.156	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.094	0.032	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.370	0.574	0.383	0.566	0.183
RXHCC157	Spinal Cord Disorders	0.118	0.093	0.093	0.056	0.056
RXHCC159	Inflammatory and Toxic Neuropathy	0.172	0.386	0.167	0.326	0.079
RXHCC160	Multiple Sclerosis	2.371	3.986	1.985	4.012	0.960
RXHCC161	Parkinson's and Huntington's Diseases	0.524	0.720	0.312	0.430	0.226
RXHCC163	Intractable Epilepsy	0.310	0.570	0.307	1.017	0.093
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.124	0.078	0.047	0.146	-
RXHCC165	Convulsions	0.054	0.026	0.029	0.067	-
RXHCC166	Migraine Headaches	0.141	0.213	0.126	0.139	0.109
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.136	0.302	0.155	0.209	0.194
RXHCC185	Primary Pulmonary Hypertension	0.746	2.210	0.624	1.775	0.252
RXHCC186	Congestive Heart Failure	0.168	0.147	0.221	0.141	0.136
RXHCC187	Hypertension	0.123	0.071	0.187	0.106	0.058
RXHCC188	Coronary Artery Disease	0.127	0.013	0.140	-	0.010
RXHCC193	Atrial Arrhythmias	0.296	0.104	0.138	0.010	0.090

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.046	-	0.039	-	-
RXHCC207	Spastic Hemiplegia	0.197	0.154	0.032	0.158	-
RXHCC215	Venous Thromboembolism	0.149	0.195	0.093	0.105	0.049
RXHCC216	Peripheral Vascular Disease	-	-	0.021	-	-
RXHCC225	Cystic Fibrosis	0.756	5.483	0.360	5.191	1.143
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.342	0.143	0.360	0.253	0.199
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.342	0.143	0.172	0.253	0.041
RXHCC241	Diabetic Retinopathy	0.321	0.240	0.223	0.148	0.159
RXHCC243	Open-Angle Glaucoma	0.284	0.239	0.330	0.267	0.227
RXHCC260	Kidney Transplant Status	0.354	0.181	0.375	0.413	0.188
RXHCC261	Dialysis Status	0.262	0.542	0.478	0.916	0.401
RXHCC262	Chronic Kidney Disease Stage 5	0.097	0.125	0.083	0.042	0.056
RXHCC263	Chronic Kidney Disease Stage 4	0.097	0.125	0.083	0.042	0.056
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.168	0.175	0.101	0.097	0.056
RXHCC314	Pemphigus	0.360	0.647	0.193	0.121	0.041
RXHCC316	Psoriasis, Except with Arthropathy	0.209	0.255	0.403	0.711	0.276
RXHCC355	Narcolepsy and Cataplexy	0.829	1.355	0.640	1.332	0.250
RXHCC395	Lung Transplant Status	1.298	0.814	0.971	0.849	0.879
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.059	0.814	0.971	0.849	0.188
RXHCC397	Pancreas Transplant Status	0.354	0.181	0.375	0.229	0.188

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Non-Aged Disease Interactions						
NonAged_RXHC C1	NonAged * HIV/AIDS	-	-	-	-	0.897
NonAged_RXHC C130	NonAged * Schizophrenia	-	-	-	-	0.275
NonAged_RXHC C131	NonAged * Bipolar Disorders	-	-	-	-	0.274
NonAged_RXHC C132	NonAged * Major Depression	-	-	-	-	0.181
NonAged_RXHC C133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.221
NonAged_RXHC C134	NonAged * Depression	-	-	-	-	0.111
NonAged_RXHC C135	NonAged * Anxiety Disorders	-	-	-	-	0.189
NonAged_RXHC C160	NonAged * Multiple Sclerosis	-	-	-	-	1.308
NonAged_RXHC C163	NonAged * Intractable Epilepsy	-	-	-	-	0.243

NOTE: The Part D Denominator used to calculate relative factors is \$1,062.31. This Part D Denominator is based on the combined PDP and MA-PD populations.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table V-2. RxHCC Model Relative Factors for New Enrollees, Non-Low Income

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.708	0.979	-	-
35-44 Years	1.223	1.233	-	-
45-54 Years	1.326	1.624	-	-
55-59 Years	1.268	1.790	-	-
60-64 Years	1.259	1.978	-	-
65 Years	0.534	1.983	1.158	1.983
66 Years	0.585	1.983	1.185	1.983
67 Years	0.599	1.983	1.185	1.983
68 Years	0.616	1.983	1.185	1.983
69 Years	0.642	1.983	1.185	1.983
70-74 Years	0.671	1.983	1.074	1.983
75-79 Years	0.690	1.983	0.821	1.983
80-84 Years	0.627	1.983	0.627	1.983
85-89 Years	0.623	1.983	0.623	1.983
90-94 Years	0.354	1.983	0.354	1.983
95 Years or Over	0.354	1.983	0.354	1.983
Male				
0-34 Years	0.469	0.857	-	-
35-44 Years	0.865	1.284	-	-
45-54 Years	1.163	1.619	-	-
55-59 Years	1.235	1.832	-	-
60-64 Years	1.207	2.146	-	-
65 Years	0.599	2.005	1.042	2.005
66 Years	0.645	2.005	1.037	2.005
67 Years	0.663	2.005	1.037	2.005
68 Years	0.693	2.005	1.037	2.005
69 Years	0.713	2.005	1.037	2.005
70-74 Years	0.759	2.005	0.964	2.005
75-79 Years	0.787	2.005	0.787	2.005
80-84 Years	0.714	2.005	0.714	2.005
85-89 Years	0.667	2.005	0.667	2.005
90-94 Years	0.317	2.005	0.317	2.005
95 Years or Over	0.317	2.005	0.317	2.005

NOTES:

1. The Part D Denominator used to calculate relative factors is \$1,062.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table V-3. RxHCC Model Relative Factors for New Enrollees, Low Income

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	1.010	2.122	-	-
35-44 Years	1.510	2.168	-	-
45-54 Years	1.562	2.254	-	-
55-59 Years	1.446	2.368	-	-
60-64 Years	1.357	2.204	-	-
65 Years	0.889	2.156	1.232	2.156
66 Years	0.593	2.156	0.825	2.156
67 Years	0.593	2.156	0.825	2.156
68 Years	0.593	2.156	0.825	2.156
69 Years	0.593	2.156	0.825	2.156
70-74 Years	0.598	2.156	0.776	2.156
75-79 Years	0.655	2.156	0.655	2.156
80-84 Years	0.655	2.156	0.655	2.156
85-89 Years	0.655	2.156	0.655	2.156
90-94 Years	0.556	2.156	0.556	2.156
95 Years or Over	0.556	2.156	0.556	2.156
Male				
0-34 Years	0.871	2.217	-	-
35-44 Years	1.246	2.221	-	-
45-54 Years	1.442	2.299	-	-
55-59 Years	1.358	2.159	-	-
60-64 Years	1.271	2.112	-	-
65 Years	0.884	2.006	1.129	2.006
66 Years	0.571	2.006	0.732	2.006
67 Years	0.546	2.006	0.732	2.006
68 Years	0.494	2.006	0.732	2.006
69 Years	0.514	2.006	0.732	2.006
70-74 Years	0.520	2.006	0.583	2.006
75-79 Years	0.541	2.006	0.541	2.006
80-84 Years	0.541	2.006	0.541	2.006
85-89 Years	0.521	2.006	0.521	2.006
90-94 Years	0.406	2.006	0.406	2.006
95 Years or Over	0.406	2.006	0.406	2.006

NOTES:

1. The Part D Denominator used to calculate relative factors is \$1,062.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table V-4. RxHCC Model Relative Factors for New Enrollees, Institutional

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.747	2.761
35-44 Years	2.747	2.761
45-54 Years	2.440	2.761
55-59 Years	2.440	2.761
60-64 Years	2.092	2.761
65 Years	2.177	2.761
66 Years	1.907	2.761
67 Years	1.907	2.761
68 Years	1.907	2.761
69 Years	1.907	2.761
70-74 Years	1.780	2.761
75-79 Years	1.550	2.761
80-84 Years	1.415	2.761
85-89 Years	1.351	2.761
90-94 Years	1.078	2.761
95 Years or Over	1.078	2.761
Male		
0-34 Years	2.386	2.776
35-44 Years	2.568	2.776
45-54 Years	2.342	2.776
55-59 Years	2.140	2.776
60-64 Years	2.084	2.776
65 Years	2.038	2.776
66 Years	1.775	2.776
67 Years	1.775	2.776
68 Years	1.775	2.776
69 Years	1.775	2.776
70-74 Years	1.679	2.776
75-79 Years	1.679	2.776
80-84 Years	1.490	2.776
85-89 Years	1.327	2.776
90-94 Years	1.327	2.776
95 Years or Over	1.327	2.776

NOTES:

1. The Part D Denominator used to calculate relative factors is \$1,062.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

SOURCE: RTI Analysis of 100% 2015 PDE, 2014 Carrier NCH, 2014 Inpatient SAF, 2014 Outpatient SAF, 2015 HPMS, 2015 CME, 2014-2015 Denominator, Part D Intermediate File, and 2014 Medicare Advantage Diagnoses File.

Table V-5. List of Disease Hierarchies for RxHCC Model

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is listed in this column...	...Then drop the RxHCC(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
15	Chronic Myeloid Leukemia	16, 17, 18, 19, 96, 98
16	Multiple Myeloma and Other Neoplastic Disorders	17, 18, 19, 96, 98
17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	18, 19
18	Lung, Kidney, and Other Cancers	19
30	Diabetes with Complications	31
54	Chronic Viral Hepatitis C	55
65	Chronic Pancreatitis	66
82	Psoriatic Arthropathy and Systemic Sclerosis	83, 84, 316
83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	84
95	Sickle Cell Anemia	98
96	Myelodysplastic Syndromes and Myelofibrosis	98
111	Alzheimer's Disease	112
130	Schizophrenia	131, 132, 133, 134, 135, 145, 146, 147, 148
131	Bipolar Disorders	132, 133, 134, 135
132	Major Depression	133, 134, 135
133	Specified Anxiety, Personality, and Behavior Disorders	134, 135
134	Depression	135
145	Autism	133, 134, 135, 146, 147, 148
146	Profound or Severe Intellectual Disability/Developmental Disorder	147, 148
147	Moderate Intellectual Disability/Developmental Disorder	148
163	Intractable Epilepsy	164, 165
164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	165
185	Primary Pulmonary Hypertension	186, 187
186	Congestive Heart Failure	187
225	Cystic Fibrosis	226, 227
226	Chronic Obstructive Pulmonary Disease and Asthma	227
260	Kidney Transplant Status	261, 262, 263, 397
261	Dialysis Status	262, 263
262	Chronic Kidney Disease Stage 5	263
395	Lung Transplant Status	396, 397
396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	397

How Payments are Made with a Disease Hierarchy: If a beneficiary triggers Disease Groups 163 (Intractable Epilepsy) and 164 (Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy), then DG 164 will be dropped. In other words, payment will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on DG 163 rather than DG 164.

SOURCE: RTI International.

Table V-6. ESRD Model Continuing Enrollee Dialysis Relative Factors

Variable	Description Label	Relative Factors
Female		
0-34 Years		0.618
35-44 Years		0.567
45-54 Years		0.522
55-59 Years		0.535
60-64 Years		0.553
65-69 Years		0.635
70-74 Years		0.653
75-79 Years		0.658
80-84 Years		0.671
85-89 Years		0.671
90-94 Years		0.671
95 Years or Over		0.671
Male		
0-34 Years		0.527
35-44 Years		0.502
45-54 Years		0.478
55-59 Years		0.495
60-64 Years		0.498
65-69 Years		0.562
70-74 Years		0.611
75-79 Years		0.634
80-84 Years		0.652
85-89 Years		0.663
90-94 Years		0.663
95 Years or Over		0.663
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex		
Medicaid_Female_Aged		0.067
Medicaid_Female_NonAged (Age <65)		0.065
Medicaid_Male_Aged		0.122
Medicaid_Male_NonAged (Age <65)		0.090
Originally Disabled_Female ²		-
Originally Disabled_Male ²		-
Originally ESRD_Female ³		-0.078
Originally ESRD_Male ³		-0.049
Disease Coefficients		
HCC1	HIV/AIDS	0.154

Variable	Description Label	Relative Factors
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.081
HCC6	Opportunistic Infections	0.052
HCC8	Metastatic Cancer and Acute Leukemia	0.295
HCC9	Lung and Other Severe Cancers	0.169
HCC10	Lymphoma and Other Cancers	0.136
HCC11	Colorectal, Bladder, and Other Cancers	0.076
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.046
HCC17	Diabetes with Acute Complications	0.244
HCC18	Diabetes with Chronic Complications	0.091
HCC19	Diabetes without Complication	0.066
HCC21	Protein-Calorie Malnutrition	0.055
HCC22	Morbid Obesity	0.073
HCC23	Other Significant Endocrine and Metabolic Disorders	0.013
HCC27	End-Stage Liver Disease	0.204
HCC28	Cirrhosis of Liver	0.086
HCC29	Chronic Hepatitis	0.069
HCC33	Intestinal Obstruction/Perforation	0.072
HCC34	Chronic Pancreatitis	0.073
HCC35	Inflammatory Bowel Disease	0.053
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.061
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.072
HCC46	Severe Hematological Disorders	0.180
HCC47	Disorders of Immunity	0.097
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.059
HCC51	Dementia With Complications	0.097
HCC52	Dementia Without Complication	0.045
HCC54	Drug/Alcohol Psychosis	0.048
HCC55	Drug/Alcohol Dependence	0.048
HCC57	Schizophrenia	0.142
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.091
HCC70	Quadriplegia	0.274
HCC71	Paraplegia	0.200
HCC72	Spinal Cord Disorders/Injuries	0.102
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.117
HCC74	Cerebral Palsy	0.036

Variable	Description Label	Relative Factors
HCC75	Polyneuropathy	0.059
HCC76	Muscular Dystrophy	0.062
HCC77	Multiple Sclerosis	0.069
HCC78	Parkinson's and Huntington's Diseases	0.065
HCC79	Seizure Disorders and Convulsions	0.066
HCC80	Coma, Brain Compression/Anoxic Damage	0.043
HCC82	Respirator Dependence/Tracheostomy Status	0.242
HCC83	Respiratory Arrest	0.114
HCC84	Cardio-Respiratory Failure and Shock	0.044
HCC85	Congestive Heart Failure	0.082
HCC86	Acute Myocardial Infarction	0.131
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.116
HCC88	Angina Pectoris	0.048
HCC96	Specified Heart Arrhythmias	0.093
HCC99	Cerebral Hemorrhage	0.078
HCC100	Ischemic or Unspecified Stroke	0.078
HCC103	Hemiplegia/Hemiparesis	0.086
HCC104	Monoplegia, Other Paralytic Syndromes	0.077
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.321
HCC107	Vascular Disease with Complications	0.126
HCC108	Vascular Disease	0.065
HCC110	Cystic Fibrosis	0.072
HCC111	Chronic Obstructive Pulmonary Disease	0.072
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.066
HCC114	Aspiration and Specified Bacterial Pneumonias	0.063
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.013
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	-
HCC124	Exudative Macular Degeneration	0.055
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.277
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.161
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.147
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.147
HCC161	Chronic Ulcer of Skin, Except Pressure	0.119
HCC162	Severe Skin Burn or Condition	0.042
HCC166	Severe Head Injury	0.043
HCC167	Major Head Injury	0.017

Variable	Description Label	Relative Factors
HCC169	Vertebral Fractures without Spinal Cord Injury	0.065
HCC170	Hip Fracture/Dislocation	0.050
HCC173	Traumatic Amputations and Complications	0.042
HCC176	Complications of Specified Implanted Device or Graft	-
HCC186	Major Organ Transplant or Replacement Status	0.154
HCC188	Artificial Openings for Feeding or Elimination	0.078
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.090
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.038
CANCER_IMMUNE	Cancer*Immune Disorders	0.025
DIABETES_CHF	Diabetes*Congestive Heart Failure	-
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.022
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.024
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.073
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.113
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.157
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.133
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.122
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.298
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.040

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is \$82,113.76.
2. Originally Disabled indicates beneficiary originally entitled to Medicare for reasons of disability other than ESRD.
3. Originally ESRD indicates beneficiary originally entitled to Medicare due to ESRD. Beneficiaries who are Originally ESRD cannot be Originally Disabled.
4. In the “disease interactions,” the variables are defined as follows:
 - Sepsis = HCC 2.
 - Cardiorespiratory Failure = HCCs 82-84.
 - Cancer = HCCs 8-12.
 - Immune Disorders = HCC 47.
 - Diabetes = HCCs 17, 18, 19.
 - Congestive Heart Failure = HCC 85.
 - Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table V-7. ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non- Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.793	1.066	1.120	1.328
35-44 Years	0.793	1.028	1.120	1.328
45-54 Years	0.877	1.029	1.120	1.368
55-59 Years	0.917	1.049	1.120	1.368
60-64 Years	0.975	1.112	1.181	1.387
65-69 Years	1.121	1.295	1.236	1.409
70-74 Years	1.191	1.397	1.331	1.444
75-79 Years	1.191	1.397	1.380	1.488
80-84 Years	1.221	1.397	1.380	1.488
85 Years or Over	1.164	1.454	1.380	1.488
Male				
0-34 Years	0.700	0.897	1.001	1.246
35-44 Years	0.700	0.922	1.001	1.246
45-54 Years	0.759	0.950	1.001	1.271
55-59 Years	0.865	1.015	1.033	1.292
60-64 Years	0.905	1.064	1.033	1.361
65-69 Years	1.025	1.249	1.033	1.361
70-74 Years	1.127	1.382	1.220	1.474
75-79 Years	1.181	1.382	1.253	1.474
80-84 Years	1.175	1.382	1.253	1.474
85 Years or Over	1.161	1.485	1.253	1.474

NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is \$82,113.76.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data.

Table V-8. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	Kidney Transplant <i>Actual</i> Dollars	Kidney Transplant Relative Risk Factor
Month 1	9,606	\$41,260.76	6.030
Months 2 and 3	18,651	6,126.29	0.895
Total (Actual Months 1-3)		\$53,493.60	

NOTES:

1. Kidney transplant is identified by MS-DRG 652.
2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.
3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator) \times 12. The CMS ESRD Dialysis Denominator value used was \$82,113.76.

SOURCE: RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data

Table V-9. ESRD Model Functioning Graft Relative Factors for Community Population

Variable	Description Label	Relative Factors
Functioning Graft Factors		
Aged 65+, with duration since transplant of 4-9 months		2.562
Aged <65, with duration since transplant of 4-9 months		2.174
Aged 65+, with duration since transplant of 10 months or more		1.121
Aged <65, with duration since transplant of 10 months or more		0.840
Female		
0-34 Years		0.196
35-44 Years		0.219
45-54 Years		0.256
55-59 Years		0.306
60-64 Years		0.360
65-69 Years		0.291
70-74 Years		0.350
75-79 Years		0.406
80-84 Years		0.480
85-89 Years		0.590
90-94 Years		0.724
95 Years or Over		0.737
Male		
0-34 Years		0.067
35-44 Years		0.076
45-54 Years		0.149
55-59 Years		0.226
60-64 Years		0.297
65-69 Years		0.274
70-74 Years		0.353
75-79 Years		0.425
80-84 Years		0.499
85-89 Years		0.625
90-94 Years		0.775
95 Years or Over		0.914
Medicaid and Originally Disabled Interactions with Age and Sex		
Medicaid_Female_Aged		0.275
Medicaid_Female_NonAged (Age <65)		0.137
Medicaid_Male_Aged		0.367
Medicaid_Male_NonAged (Age <65)		0.190
Originally Disabled_Female_Age ≥65		0.184
Originally Disabled_Male_Age ≥65		0.115

Variable	Description Label	Relative Factors
Disease Coefficients		
HCC1	HIV/AIDS	0.350
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.428
HCC6	Opportunistic Infections	0.426
HCC8	Metastatic Cancer and Acute Leukemia	2.627
HCC9	Lung and Other Severe Cancers	0.975
HCC10	Lymphoma and Other Cancers	0.668
HCC11	Colorectal, Bladder, and Other Cancers	0.298
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.156
HCC17	Diabetes with Acute Complications	0.243
HCC18	Diabetes with Chronic Complications	0.243
HCC19	Diabetes without Complication	0.094
HCC21	Protein-Calorie Malnutrition	0.593
HCC22	Morbid Obesity	0.278
HCC23	Other Significant Endocrine and Metabolic Disorders	0.234
HCC27	End-Stage Liver Disease	1.028
HCC28	Cirrhosis of Liver	0.384
HCC29	Chronic Hepatitis	0.243
HCC33	Intestinal Obstruction/Perforation	0.285
HCC34	Chronic Pancreatitis	0.282
HCC35	Inflammatory Bowel Disease	0.362
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.468
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.398
HCC46	Severe Hematological Disorders	1.325
HCC47	Disorders of Immunity	0.688
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.234
HCC51	Dementia With Complications	0.643
HCC52	Dementia Without Complication	0.328
HCC54	Drug/Alcohol Psychosis	0.352
HCC55	Drug/Alcohol Dependence	0.352
HCC57	Schizophrenia	0.442
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.260
HCC70	Quadriplegia	1.112
HCC71	Paraplegia	0.943
HCC72	Spinal Cord Disorders/Injuries	0.456

Variable	Description Label	Relative Factors
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.030
HCC74	Cerebral Palsy	-
HCC75	Polyneuropathy	0.284
HCC76	Muscular Dystrophy	0.544
HCC77	Multiple Sclerosis	0.546
HCC78	Parkinson's and Huntington's Diseases	0.583
HCC79	Seizure Disorders and Convulsions	0.221
HCC80	Coma, Brain Compression/Anoxic Damage	0.184
HCC82	Respirator Dependence/Tracheostomy Status	1.231
HCC83	Respiratory Arrest	0.540
HCC84	Cardio-Respiratory Failure and Shock	0.345
HCC85	Congestive Heart Failure	0.336
HCC86	Acute Myocardial Infarction	0.258
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.258
HCC88	Angina Pectoris	0.129
HCC96	Specified Heart Arrhythmias	0.303
HCC99	Cerebral Hemorrhage	0.252
HCC100	Ischemic or Unspecified Stroke	0.252
HCC103	Hemiplegia/Hemiparesis	0.467
HCC104	Monoplegia, Other Paralytic Syndromes	0.307
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.385
HCC107	Vascular Disease with Complications	0.431
HCC108	Vascular Disease	0.271
HCC110	Cystic Fibrosis	0.494
HCC111	Chronic Obstructive Pulmonary Disease	0.313
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.281
HCC114	Aspiration and Specified Bacterial Pneumonias	0.596
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.155
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.248
HCC124	Exudative Macular Degeneration	0.512
HCC134	Dialysis Status	–
HCC135	Acute Renal Failure	–
HCC136	Chronic Kidney Disease, Stage 5	–
HCC137	Chronic Kidney Disease, Severe (Stage 4)	–

Variable	Description Label	Relative Factors
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	–
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	–
HCC140	Unspecified Renal Failure	–
HCC141	Nephritis	–
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.492
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.285
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.955
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.799
HCC161	Chronic Ulcer of Skin, Except Pressure	0.503
HCC162	Severe Skin Burn or Condition	0.370
HCC166	Severe Head Injury	0.184
HCC167	Major Head Injury	0.184
HCC169	Vertebral Fractures without Spinal Cord Injury	0.456
HCC170	Hip Fracture/Dislocation	0.350
HCC173	Traumatic Amputations and Complications	0.290
HCC176	Complications of Specified Implanted Device or Graft	0.599
HCC186	Major Organ Transplant or Replacement Status	0.075
HCC188	Artificial Openings for Feeding or Elimination	0.643
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.654
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.133
CANCER_IMMUNE	Cancer*Immune Disorders	0.773
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.160
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.227
CHF_RENAL	Congestive Heart Failure*Renal Disease	–
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.453
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.561
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.534
NONAGED_HCC46	NonAged, Severe Hematological Disorders	2.791
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.549

Variable	Description Label	Relative Factors
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.066
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.746
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	—

NOTES:

1. The Denominator used to calculate the relative factors is \$9,366.89.
2. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
3. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.
4. In the “disease interactions,” the variables are defined as follows:
 Sepsis = HCC 2.
 Cardiorespiratory Failure = HCCs 82-84.
 Cancer = HCCs 8-12.
 Immune Disorders = HCC 47.
 Diabetes = HCCs 17, 18, 19.
 Congestive Heart Failure = HCC 85.
 Chronic Obstructive Pulmonary Disease = HCCs 110-111.
 Renal Disease = HCCs 134-141.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table V-10. ESRD Model Functioning Graft Relative Factors for Institutionalized Population

Variable	Description Label	Relative Factors
Functioning Graft Factors		
Aged 65+, with duration since transplant of 4-9 months		2.562
Aged <65, with duration since transplant of 4-9 months		2.174
Aged 65+, with duration since transplant of 10 months or more		1.121
Aged <65, with duration since transplant of 10 months or more		0.840
Female		
0-34 Years		0.848
35-44 Years		1.061
45-54 Years		0.992
55-59 Years		1.014
60-64 Years		1.017
65-69 Years		1.212
70-74 Years		1.120
75-79 Years		0.988
80-84 Years		0.861
85-89 Years		0.780
90-94 Years		0.651
95 Years or Over		0.484
Male		
0-34 Years		1.055
35-44 Years		0.956
45-54 Years		0.924
55-59 Years		0.971
60-64 Years		1.013
65-69 Years		1.267
70-74 Years		1.306
75-79 Years		1.295
80-84 Years		1.188
85-89 Years		1.101
90-94 Years		0.969
95 Years or Over		0.799
Medicaid and Originally Disabled		
Medicaid		0.074
Originally Disabled_Age ≥65		-
Disease Coefficients		
HCC1	HIV/AIDS	1.708

Variable	Description Label	Relative Factors
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.274
HCC6	Opportunistic Infections	0.568
HCC8	Metastatic Cancer and Acute Leukemia	1.289
HCC9	Lung and Other Severe Cancers	0.604
HCC10	Lymphoma and Other Cancers	0.451
HCC11	Colorectal, Bladder, and Other Cancers	0.284
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.194
HCC17	Diabetes with Acute Complications	0.373
HCC18	Diabetes with Chronic Complications	0.373
HCC19	Diabetes without Complication	0.165
HCC21	Protein-Calorie Malnutrition	0.252
HCC22	Morbid Obesity	0.429
HCC23	Other Significant Endocrine and Metabolic Disorders	0.359
HCC27	End-Stage Liver Disease	0.863
HCC28	Cirrhosis of Liver	0.479
HCC29	Chronic Hepatitis	0.479
HCC33	Intestinal Obstruction/Perforation	0.346
HCC34	Chronic Pancreatitis	0.422
HCC35	Inflammatory Bowel Disease	0.341
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.375
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.274
HCC46	Severe Hematological Disorders	0.766
HCC47	Disorders of Immunity	0.549
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.173
HCC51	Dementia With Complications	-
HCC52	Dementia Without Complication	-
HCC54	Drug/Alcohol Psychosis	0.112
HCC55	Drug/Alcohol Dependence	0.112
HCC57	Schizophrenia	0.217
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.217
HCC70	Quadriplegia	0.512
HCC71	Paraplegia	0.435
HCC72	Spinal Cord Disorders/Injuries	0.256

Variable	Description Label	Relative Factors
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.446
HCC74	Cerebral Palsy	-
HCC75	Polyneuropathy	0.323
HCC76	Muscular Dystrophy	0.296
HCC77	Multiple Sclerosis	-
HCC78	Parkinson's and Huntington's Diseases	0.141
HCC79	Seizure Disorders and Convulsions	0.065
HCC80	Coma, Brain Compression/Anoxic Damage	-
HCC82	Respirator Dependence/Tracheostomy Status	1.602
HCC83	Respiratory Arrest	0.466
HCC84	Cardio-Respiratory Failure and Shock	0.311
HCC85	Congestive Heart Failure	0.186
HCC86	Acute Myocardial Infarction	0.392
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.392
HCC88	Angina Pectoris	0.392
HCC96	Specified Heart Arrhythmias	0.247
HCC99	Cerebral Hemorrhage	0.105
HCC100	Ischemic or Unspecified Stroke	0.105
HCC103	Hemiplegia/Hemiparesis	-
HCC104	Monoplegia, Other Paralytic Syndromes	-
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.754
HCC107	Vascular Disease with Complications	0.300
HCC108	Vascular Disease	0.086
HCC110	Cystic Fibrosis	0.435
HCC111	Chronic Obstructive Pulmonary Disease	0.299
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.299
HCC114	Aspiration and Specified Bacterial Pneumonias	0.143
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.143
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.388
HCC124	Exudative Macular Degeneration	0.209
HCC134	Dialysis Status	—
HCC135	Acute Renal Failure	—

Variable	Description Label	Relative Factors
HCC136	Chronic Kidney Disease, Stage 5	–
HCC137	Chronic Kidney Disease, Severe (Stage 4)	–
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	–
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	–
HCC140	Unspecified Renal Failure	–
HCC141	Nephritis	–
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.968
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.378
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.225
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.225
HCC161	Chronic Ulcer of Skin, Except Pressure	0.225
HCC162	Severe Skin Burn or Condition	-
HCC166	Severe Head Injury	-
HCC167	Major Head Injury	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.237
HCC170	Hip Fracture/Dislocation	-
HCC173	Traumatic Amputations and Complications	0.061
HCC176	Complications of Specified Implanted Device or Graft	0.599
HCC186	Major Organ Transplant or Replacement Status	0.075
HCC188	Artificial Openings for Feeding or Elimination	0.482
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.339
Disease Interactions		
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.190
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.416
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.226
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.452

Variable	Description Label	Relative Factors
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.295
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.159
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.220
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.252
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.347
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.402
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.122
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.541
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.263
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.528
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.469
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.447
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.448
NONAGED_HCC6	NonAged, Opportunistic Infections	0.314

NOTES:

- The Denominator used to calculate the relative factors is \$9,366.89.
- The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.
- Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD.
- In the “Disease interactions” and “Non-Aged interactions,” the variables are defined as follows:
 - Sepsis = HCC 2.
 - Cardiorespiratory Failure = HCCs 82-84.
 - Diabetes = HCCs 17, 18, 19.
 - Congestive Heart Failure = HCC 85.
 - Chronic Obstructive Pulmonary Disease = HCCs 110-111.
 - Pressure Ulcer = HCCs 157-160.
 - Artificial Openings for Feeding or Elimination = HCC 188.
 - Aspiration and Specified Bacterial Pneumonias = HCC 114.
 - Schizophrenia = HCC 57.
 - Seizure Disorders and Convulsions = HCC 79.
 - Chronic Ulcer of Skin, except Pressure = HCC 161.
 - Bone/Joint/Muscle Infections/Necrosis = HCC 39.
 - Multiple Sclerosis = HCC 77.
 - Opportunistic Infections = HCC 6.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% institutional sample.

Table V-11. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 4-9 Months

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non- Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	2.978	3.143	—	—
35-44 Years	3.121	3.376	—	—
45-54 Years	3.189	3.479	—	—
55-59 Years	3.190	3.481	—	—
60-64 Years	3.307	3.582	—	—
65 Years	3.082	3.555	3.629	4.019
66 Years	3.077	3.459	3.629	4.019
67 Years	3.106	3.481	3.629	4.565
68 Years	3.159	3.512	3.846	4.565
69 Years	3.162	3.512	3.846	4.565
70-74 Years	3.252	3.547	3.846	4.565
75-79 Years	3.422	3.695	3.846	4.565
80-84 Years	3.576	3.914	3.846	4.565
85-89 Years	3.856	4.097	3.846	4.565
90-94 Years	3.856	4.263	3.846	4.565
95 Years or Over	3.856	4.263	3.846	4.565
Male				
0-34 Years	2.616	2.908	—	—
35-44 Years	2.831	3.233	—	—
45-54 Years	3.038	3.527	—	—
55-59 Years	3.077	3.592	—	—
60-64 Years	3.122	3.724	—	—
65 Years	3.079	3.706	3.388	4.373
66 Years	3.095	3.656	3.633	4.760
67 Years	3.144	3.713	3.685	4.760
68 Years	3.188	3.764	3.685	4.760
69 Years	3.252	3.764	3.961	4.760
70-74 Years	3.347	3.860	3.961	4.760
75-79 Years	3.621	3.969	3.961	4.760
80-84 Years	3.808	4.117	3.961	4.760
85-89 Years	4.038	4.339	3.961	4.760
90-94 Years	4.038	4.339	3.961	4.760
95 Years or Over	4.038	4.339	3.961	4.760

NOTES:

1. The relative factors are derived from the Graft New Enrollee model. The Denominator used to calculate the relative factors is \$9,366.89.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table V-12. ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration Since Transplant of 10 Months or More

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non- Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.644	1.809	—	—
35-44 Years	1.787	2.042	—	—
45-54 Years	1.855	2.145	—	—
55-59 Years	1.856	2.147	—	—
60-64 Years	1.973	2.248	—	—
65 Years	1.641	2.114	2.188	2.578
66 Years	1.636	2.018	2.188	2.578
67 Years	1.665	2.040	2.188	3.124
68 Years	1.718	2.071	2.405	3.124
69 Years	1.721	2.071	2.405	3.124
70-74 Years	1.811	2.106	2.405	3.124
75-79 Years	1.981	2.254	2.405	3.124
80-84 Years	2.135	2.473	2.405	3.124
85-89 Years	2.415	2.656	2.405	3.124
90-94 Years	2.415	2.822	2.405	3.124
95 Years or Over	2.415	2.822	2.405	3.124
Male				
0-34 Years	1.282	1.574	—	—
35-44 Years	1.497	1.899	—	—
45-54 Years	1.704	2.193	—	—
55-59 Years	1.743	2.258	—	—
60-64 Years	1.788	2.390	—	—
65 Years	1.638	2.265	1.947	2.932
66 Years	1.654	2.215	2.192	3.319
67 Years	1.703	2.272	2.244	3.319
68 Years	1.747	2.323	2.244	3.319
69 Years	1.811	2.323	2.520	3.319
70-74 Years	1.906	2.419	2.520	3.319
75-79 Years	2.180	2.528	2.520	3.319
80-84 Years	2.367	2.676	2.520	3.319
85-89 Years	2.597	2.898	2.520	3.319
90-94 Years	2.597	2.898	2.520	3.319
95 Years or Over	2.597	2.898	2.520	3.319

NOTES:

1. The relative factors are derived from the Graft New Enrollee model. The Denominator used to calculate the relative factors is \$9,366.89.
2. Originally Disabled terms refer to beneficiaries originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

SOURCE: RTI International analysis of 2014/2015 100% ESRD sample claims and enrollment data and 2014/2015 Medicare 100% sample.

Table V-13. List of Disease Hierarchies for the ESRD Model

DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column...	...Then drop the HCC(s) listed in this column
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9, 10, 11, 12
9	Lung and Other Severe Cancers	10, 11, 12
10	Lymphoma and Other Cancers	11, 12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28, 29, 80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71, 72, 103, 104, 169
71	Paraplegia	72, 104, 169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83, 84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87, 88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or Gangrene	107, 108, 161, 189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111, 112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135, 136, 137, 138, 139, 140, 141
135	Acute Renal Failure	136, 137, 138, 139, 140, 141
136	Chronic Kidney Disease, Stage 5	137, 138, 139, 140, 141
137	Chronic Kidney Disease, Severe (Stage 4)	138, 139, 140, 141
138	Chronic Kidney Disease, Moderate (Stage 3)	139, 140, 141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	140, 141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	158, 159, 160, 161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159, 160, 161

DISEASE HIERARCHIES		
Hierarchical Condition Category (HCC)	If the Disease Group is Listed in this column...	...Then drop the HCC(s) listed in this column
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160, 161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80, 167

How Payments are Made with a Disease Hierarchy: EXAMPLE: If a beneficiary triggers Disease Groups 8 (Metastatic Cancer and Acute Leukemia) and 9 (Lung and Other Severe Cancers), then DG 9 will be dropped. In other words, payment will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on DG 8 rather than DG 9. **SOURCE:** RTI International.

Attachment VI. Draft CY 2019 Call Letter

Draft CY 2019 Call Letter

Table of Contents

Attachment VI. Draft CY 2019 Call Letter	97
How to Use This Call Letter	99
Section I – Parts C and D	100
Annual Calendar	100
Enhancements to the 2019 Star Ratings and Future Measurement Concepts	106
Incomplete and Inaccurate Bid Submissions	157
Plan Corrections	159
Validation Audits	159
Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice	164
Enforcement Actions for Provider Directories	165
Audit of the Sponsoring Organization’s Compliance Program Effectiveness	165
Innovations in Health Plan Design	166
New Medicare Card Project (formerly the Social Security Number Removal Initiative, SSNRI)	167
Section II – Part C	168
Special Needs Plan (SNP) Legislative Sunset Provision	168
Overview of CY 2019 Benefits and Bid Review	168
Plans with Low Enrollment	170
Meaningful Difference (Substantially Duplicative Plan Offerings)	170
Total Beneficiary Cost (TBC)	171
Maximum Out-of-Pocket (MOOP) Limits	174
Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost Sharing Limits	175
Part C Cost Sharing Standards	176
Part C Optional Supplemental Benefits	180
Employer Group Waiver Plans	181
Tiered Cost Sharing of Medical Benefits	181
Outpatient Observation Services	182
Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)	182
Health Related Supplemental Benefits	182
Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs)	183
Medicare Advantage (MA) Uniformity Flexibility	184
Medicare Advantage (MA) Segmented Service Area Options	185
Medicare Diabetes Prevention Program (MDPP) Services Clarification	185
Special Needs Plan (SNP)-Specific Networks Research and Development	185

Rewards and Incentives for Completion of a Health Risk Assessment (HRA)	186
Cost Plan Transition to MA under MACRA	186
Cost Plan Competition Requirements	187
Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs	187
Parts A and B Cost-sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program	190
Encounter Data Listening Forums, Monitoring and Compliance Activities	191
Transparency & Timeliness with Prior Authorization Processes	193
Section III – Part D	193
Formulary Submissions	193
Expanding the Part D OTC Program	196
Medication Therapy Management (MTM) Annual Cost Threshold	197
Part D Benefit Parameters for Non-Defined Standard Plans	197
Benefit Review	198
Tier Composition	198
Improving Access to Part D Vaccines	199
Specialty Tiers	201
Low Enrollment Plans (Stand-alone PDPs only)	202
Improving Drug Utilization Review Controls in Medicare Part D	202
Coordination of Benefits (COB) User Fee	217
LIS Enrollee Cost-sharing for Out-of-Network Part D Drugs	217
Timely Updates to LIS Status Based on Best Available Evidence	218
Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs	218
Part D Mail-Order Refill Consent Policy– Solicitation for Comments	220
Section IV – Medicare-Medicaid Plans	222
Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2019	222
Appendix 1: Methodology for Plan Finder (PF) Composite Price Accuracy Display Measure	227
Contract Selection	227
PF Composite Price Accuracy Score	227

How to Use This Call Letter

The draft CY 2019 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs), Part D sponsors, and Medicare-Medicaid Plans (MMPs) need to take into consideration in preparing their 2019 bids.

CMS has designed the policies contained in this draft Call Letter to improve the overall management of the Medicare Advantage and Prescription Drug programs. CMS aims to expand flexibilities so that plans and providers are empowered to meet the needs of Medicare beneficiaries at the local level, while increasing beneficiary choice and improving the patient/physician relationship. The policies in the draft Call Letter also reflect CMS efforts to increase transparency in our decision-making and promote innovation.

If you have questions concerning this Call Letter, please contact: Kim Levin at Kimberlee.Levin@cms.hhs.gov (Part C issues), Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues), or mmcocapsmodel@cms.hhs.gov (MMP issues).

Section I – Parts C and D

Annual Calendar

Below is a combined calendar listing of key dates and timelines for operational activities that pertain to Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Prescription Drug Plan (PDP), Medicare-Medicaid Plan (MMP), and cost-based plans. The calendar provides important operational dates for all organizations such as the date bids are due to CMS, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings.

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
January 1 – February 14, 2018	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓			
January 9, 2018	Release of Contract Year CY 2019 Initial and Service Area Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansions.	✓	✓	✓	✓
January 10, 2018	MOC Renewal Submission period begins for SNP MOCs with approvals ending 12/31/2018.	✓			
January 2018	Industry Training and Technical Assistance for CY 2019 Model of Care (MOC) Submissions.	✓			
January 2018	Industry training on 2019 Applications.	✓	✓	✓	✓
February 14, 2018	CY 2019 Initial and Service Area Expansion Application for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion are due in the Health Plan Management System (HPMS) by 8pm EST.	✓	✓	✓	✓
February 14, 2018	MOC Renewals Submissions for SNP MOCs with approvals ending as of 12/31/2018 are due in HPMS by 8pm EST.	✓			
Late February, 2018	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓			
February, 2018	CMS releases instructional memo concerning updates to Parent Organization designations in HPMS.	✓	✓	✓	✓
February, 2018	Release of draft CY 2019 Formulary Reference File (FRF).	✓	✓	✓	✓
March 16, 2018	Parent Organization Update requests from MAOs and sponsors due to CMS (instructional memo released in February 2018).	✓	✓	✓	✓
Mid-Late March, 2018	Release of CY 2019 Formulary Reference File (FRF).	✓	✓	✓	✓
March 30, 2018	Release of the Fiscal Soundness Module in HPMS.	✓	✓	✓	✓
March/April, 2018	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2019.	✓	✓	✓	

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
Early April, 2018	CY 2019 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs, 1876 cost plans submitting MA conversion bids, and Part D sponsors for download from the CMS website. Information will assist plans in satisfying MA and Part D requirements, such as meeting meaningful difference (if applicable) and Total Beneficiary Cost (TBC) requirements prior to bid submission.	✓	✓	✓	
Early April, 2018	Information about renewal options for CY 2019 (including HPMS crosswalk charts) provided to plans.	✓	✓		
April 2, 2018	Release of the 2019 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released, including the CY 2018 Call Letter.	✓	✓	✓	✓
April 2018	Conference call with industry to discuss the Rate Announcement and CY 2018 Call Letter.	✓	✓	✓	✓
April 6, 2018	Release of the CY 2019 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓	✓
April 10, 2018	Deadline for MAOs and cost plans to submit requests for full contract consolidations for CY 2018.	✓		✓	
Mid-April, 2018	Release of HPMS Memo: Contract Year 2019 Medicare Advantage Bid Review and Operations Guidance.	✓		✓	
April 16, 2018	Release of the CY 2019 Medication Therapy Management (MTM) Program Submission in HPMS (11:59 p.m. PDT).		✓		✓
April 18, 2018	Industry training on CY 2019 Part D Formulary and Benefit Submission/Compliance Training.	✓	✓	✓	✓
Late April, 2018	Total Beneficiary Cost data for CY 2019 Bid Preparation Release.	✓			
April 30, 2018	Deadline for submission of CY 2019 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (except those participating in the Enhanced MTM Model test) (11:59 p.m. PDT).		✓		✓
May, 2018	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, pharmacy directory, and MMP models for CY 2019 available for all organizations.	✓	✓	✓	✓
Early May 2017	MA, MA-PD and PDP plans to notify CMS of intention to non-renew, as applicable, a county (ies) or region(s) for individuals, but continue the county (ies) or region(s) for “800 series” EGWP members, convert to offering employer-only contracts, or reduce its service area at the contract level. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓	
May, 2018	2018 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast.	✓	✓	✓	✓
May 4, 2018	Release of the CY 2019 Bid Upload Functionality in HPMS.	✓	✓	✓	✓
May 14, 2018	Deadline for submission of CY 2019 MTM Program attestations in HPMS (11:59pm PDT).		✓		✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
May 14, 2018	Release of CY 2019 Formulary Submission Module in HPMS.	✓	✓	✓	✓
May 18, 2018	Release of CY 2019 Actuarial Certification Module in HPMS.	✓	✓	✓	
Mid-Late May, 2018	Release of CY 2019 Formulary Reference File Update.	✓	✓	✓	✓
May 25, 2018	Plans/Part D sponsors begin to upload agent/broker compensation information in HPMS.	✓	✓	✓	✓
June 1, 2018	Release of the CY 2019 Marketing Module in HPMS. Plans/Part D sponsors begin to submit 2019 marketing materials.	✓	✓	✓	✓
Mid to late June, 2018	Release of the CY 2019 Medicare Marketing Guidelines in HPMS.	✓	✓	✓	✓
Late May, 2018	CMS sends qualification determinations to applicants based on review of the CY 2019 applications for new contracts or service area expansions.	✓	✓	✓	✓
June 2018	Release of state-specific marketing guidance for MMPs.				✓
May 31, 2018	Release of the 2017 DIR Submission Module in HPMS.	✓	✓	✓	✓
June 4, 2018	Deadline for submission of CY 2019 bids (including Service Area Verification) for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), “800 series” EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2019 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2019 Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Deadline for submission of a CY 2019 contract non-renewal, service area reduction via HPMS from MA plans, MA-PD plans, MMPs, PDPs and Medicare cost-based contractors and cost-based sponsors to Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PD plan benefit package (i.e., Plan 01, Plan 02) for CY 2019.	✓	✓	✓	✓ <i>Non-bid related items only</i>
Early June to Late August, 2018	CMS completes review and approval of CY 2019 bid data, to include pricing, plan benefit packages, and formularies. Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications.	✓	✓	✓	✓
June, 2018	Window for submitting first round of crosswalk exception requests through HPMS.	✓	✓	✓	
June 8, 2018	Deadline for submission of CY 2019 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS (11:59 a.m. EDT).		✓		✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
June 8, 2018	Deadline for submission of Medicare Advantage Value Based Insurance Design (VBID) file (Only applicable to Medicare Advantage Plans that have been preapproved for Part D VBID benefits) (11:59 a.m. EDT).	✓			
June 8, 2018	Deadline for submission of Additional Demonstration Drug (ADD) file (MMPs only) (11:59 a.m. EDT).				✓
June, 2018	2018 MA and PDP Audit and Enforcement Conference and Webcast.	✓	✓	✓	✓
Late June, 2018	CMS sends an acknowledgement letter to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓	✓
Early July, 2018	2019 Plan Finder pricing test submissions begin.	✓	✓	✓	✓
Early July, 2018	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS.	✓			
Early July, 2018	Deadline for D-SNPs requesting to be reviewed as Fully Integrated Dual-Eligible (FIDE) SNPs to submit their FIDE SNP Matrix to HPMS.	✓			
July 5, 2017	Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓			
Mid July, 2018	Release of CY 2019 FRF Update in advance of the Limited Formulary Update Window.	✓	✓	✓	✓
Mid-Late July, 2018	CY 2019 Limited Formulary Update Window.	✓	✓	✓	✓
Late July, 2018	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓	✓
July 2018	Second window for submitting HPMS crosswalk exceptions.	✓	✓	✓	
Late July / Early August, 2018	CMS releases the 2019 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, the Medicare Advantage regional PPO benchmarks, and the de minimis amount.	✓	✓	✓	✓
Late July / Early August, 2018	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓	
No Later Than July 29, 2018	CMS informs currently contracted organizations of its decision to not renew a contract for 2019.	✓	✓	✓	
August 1, 2018	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓	
August 17, 2018	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 16-20, 2018	CY 2019 preview of the 2018 Medicare & You plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓	✓
August 22-24, 2018	First CY 2019 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ MPF only

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
August 31, 2018	CY 2019 MTM Program Annual Review completed.		✓		✓
Late August, 2018	Contracting Materials submitted to CMS.	✓	✓	✓	
End of August/Early September, 2018	Plan preview periods of Part C & D Star Ratings in HPMS.	✓	✓	✓	
Early September, 2018	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
Mid-September, 2018	All 2018 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓	
September 4-7, 2018	Second CY 2019 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ <i>MPF only</i>
September 16 - 30, 2018	CMS mails the 2019 Medicare & You handbook to Medicare beneficiaries.	✓	✓	✓	✓
Late September, 2018	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications.	✓			
Late September, 2018	Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS.	✓	✓	✓	
September 30, 2018	<p>Deadline for plans to provide the following documents to current enrollees:</p> <p>Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D).</p> <p>The multi-language insert should be sent with the ANOC/EOC and the SB.</p> <p>Standardized ANOC with the Summary of Benefits for D-SNPs and MMPs that choose to separate the ANOC from the EOC.</p> <p>Abridged or comprehensive formularies</p> <p>LIS rider</p> <p>Pharmacy/Provider directories</p> <p>The documents identified above are the only CY 2019 documents permitted to be sent prior to October 1, 2018.</p>	✓	✓	✓	✓
October 1, 2018	<p>Organizations may begin marketing their CY 2019 plan benefits.</p> <p>Note: Once an organization begins marketing CY 2019 plans, the organization must cease marketing CY 2018 plans to anyone other than beneficiaries who are eligible for valid enrollment (e.g. age-ins and special enrollment periods (SEP)). Organizations may still provide CY 2018 materials upon request, conduct one-on-one sales appointments, and process enrollment applications.</p>	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
October 1, 2018	Tentative date for CY 2019 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓	✓
October 2, 2018	The final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, MMP and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, MMPs and cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2018.	✓	✓	✓	✓
October 11, 2018	Part C & D Star Ratings go live on medicare.gov on or around October 11, 2018.	✓	✓	✓	
October 15, 2018	Part D sponsors must post prior authorization and step therapy criteria on their websites for CY 2019.		✓		✓
October 15, 2018	2019 Annual Election Period begins All organizations/sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓		✓
Mid October, 2018	Release of the online CY 2020 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and “800 series” EGWPs and Direct Contract EGWPs).	✓	✓	✓	✓
November 12, 2018	Notices of Intent to Apply (NOIA) for CY 2020 due for MA and MA-PD plans, MMP, PDPs, and “800 series” EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November, 2018	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval.	✓	✓	✓	✓
Late November, 2018	Part C & D display measures data are posted in HPMS for plan preview.	✓	✓	✓	
December 1, 2018	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	
December 7, 2018	End of the Annual Election Period.	✓	✓		✓
Mid December, 2018	Part C & D display measures data on cms.gov updated.	✓	✓	✓	
December 31, 2018	Deadline for MMPs that separated the ANOC from the EOC to provide the EOC to enrollees.				✓
2019					
January 1, 2019	Plan Benefit Period Begins.	✓	✓	✓	✓
January 1 – March 31, 2019	Annual Medicare Advantage Open Enrollment Period (MA OEP).	✓			
January 2019	Release of CY 2020 MAO/MA-PD/MMP/PDP/SAE/EGWP applications.	✓	✓		✓
January, 2019	Industry training on CY 2020 applications.	✓	✓	✓	✓
February 2019	Applications due for CY 2020.	✓	✓	✓	✓
June 3, 2019	CY 2020 Deadline for bid and formulary submission.	✓	✓	✓	✓ <i>Non-bid related items only</i>

Enhancements to the 2019 Star Ratings and Future Measurement Concepts

CMS publishes the Part C and D Star Ratings each year to measure the quality of and reflect the experiences of beneficiaries in Medicare Advantage (MA) and Prescription Drug Plans (PDPs or Part D plans), assist beneficiaries in finding the best plan, and determine MA Quality Bonus Payments. Further, the Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by physicians, hospitals, and other providers.

CMS regularly reviews the measures and the methodology (used to generate the ratings) to incentivize plans and provide information that is a true reflection of plan performance and enrollee experience. We remain cognizant of the unique challenges of serving traditionally underserved subsets of the population. In addition to conducting our own research, CMS stays abreast of the related research and listens carefully to concerns about the Star Ratings. CMS works in collaboration with beneficiaries, stakeholders, measure developers, researchers, and other HHS collaborators to improve the Star Ratings.

As a result, we propose the enhancements described below to the 2019 Star Ratings and solicit comment in response to this draft Call Letter. In this document, we also describe possible enhancements for the 2020 Star Ratings and other future measurement concepts. Except as noted below, the methodology and measures used to calculate the ratings will remain the same as the 2018 Star Ratings.

For reference, the list of measures and a description of the methodology for the 2018 Star Ratings are included in the Technical Notes available on the CMS webpage:

<http://go.cms.gov/partcanddstarratings>.

After the 2019 Call Letter is finalized, CMS' current Part C & D Star Ratings contractor, RAND Corporation, will establish a Technical Expert Panel (TEP) in 2018 comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures. The TEP may also provide suggestions regarding the data integrity review process and how the Star Ratings should relate to audits and enforcement actions. RAND will analyze the suggestions from the TEP to provide feedback to CMS on potential future enhancements.

Reminders for 2019 Star Ratings

CMS assigns stars for each numeric measure score by applying one of two methods: clustering or relative distribution with significance testing. Each method is described in detail in the Technical Notes. Relative distribution with significance testing is applied to determine valid star cut points for Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. Clustering is applied to other Star Ratings measures. The cut points to determine star assignments for all measures and case-mix coefficients for the CAHPS survey and Health

Outcomes Survey (HOS) will be updated for 2019 Star Ratings using the most current data available.

As announced in previous years, we will review data quality across all measures, variation among organizations and sponsors, and measures' accuracy and validity before making a final determination about inclusion of measures in the Star Ratings.

We provide various datasets and reports to plan sponsors throughout the year. Part C and D sponsors should regularly review their underlying measure data that are the basis for the Part C and D Star Ratings and immediately alert CMS if errors or anomalies are identified so any issues can be resolved prior to the first plan preview period. For example, any necessary changes to the Independent Review Entity (IRE) data must be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (e.g., changes to 2017 IRE data must be made by June 30, 2018 for the 2019 Star Ratings).

New Measures for 2019 Star Ratings

- **Statin Use in Persons with Diabetes (SUPD) (Part D).** This Pharmacy Quality Alliance (PQA) measure is the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice according to the Medicare Enrollment Database (EDB) are excluded from the denominator of the SUPD measure for the entire year. Beneficiaries with end-stage renal disease (ESRD) at any time in the measurement year are also excluded. For the 2017 measurement year, CMS proposes to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs to use along with the EDB ESRD indicator that is currently used. We propose to add the SUPD measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year. In subsequent years, we propose a weight of 3 as an intermediate outcome measure, as prescription fills are a proxy for patients taking their prescribed medications, and adherence is necessary to reach clinical/therapeutic goals.
- **Statin Therapy for Patients with Cardiovascular Disease (Part C).** This measure was developed by the National Committee for Quality Assurance (NCQA) as part of HEDIS and is currently included as a display measure. It focuses on the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year. NCQA allows for the exclusion of certain conditions and symptoms that may indicate statin intolerance (e.g., myalgia, myositis, myopathy, or rhabdomyolysis). Please refer to the NCQA HEDIS 2018 Technical Specifications for Health Plans Volume 2 for measure

construction and technical specifications. We propose to include this measure in the 2019 Star Ratings as a process measure with a weight of 1, as it is based on medical records review if medications were prescribed.

Changes to Measures for 2019

- **Improvement measures (Part C & D).** The measures proposed to calculate the 2019 improvement measures are:

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Breast Cancer Screening	Process Measure	1	Yes
C	Colorectal Cancer Screening	Process Measure	1	Yes
C	Annual Flu Vaccine	Process Measure	1	Yes
C	Improving or Maintaining Physical Health	Outcome Measure	3	No
C	Improving or Maintaining Mental Health	Outcome Measure	3	No
C	Monitoring Physical Activity	Process Measure	1	Yes
C	Adult BMI Assessment	Process Measure	1	Yes
C	Special Needs Plan (SNP) Care Management	Process Measure	1	Yes
C	Care for Older Adults – Medication Review	Process Measure	1	Yes
C	Care for Older Adults – Functional Status Assessment	Process Measure	1	Yes
C	Care for Older Adults – Pain Assessment	Process Measure	1	Yes
C	Osteoporosis Management in Women who had a Fracture	Process Measure	1	Yes
C	Diabetes Care – Eye Exam	Process Measure	1	Yes
C	Diabetes Care – Kidney Disease Monitoring	Process Measure	1	Yes
C	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	Yes
C	Controlling Blood Pressure	Intermediate Outcome Measure	3	Yes
C	Rheumatoid Arthritis Management	Process Measure	1	Yes
C	Improving Bladder Control	Process Measure	1	Yes
C	Medication Reconciliation Post-Discharge	Process Measure	1	Yes
C	Plan All-Cause Readmissions	Outcome Measure	3	Yes
C	Getting Needed Care	Patients' Experience and Complaints Measure	1.5	Yes
C	Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	Yes
C	Customer Service	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Care Coordination	Patients' Experience and Complaints Measure	1.5	Yes
C	Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Health Plan Quality Improvement	Improvement Measure	5	No
C	Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5	Yes
C	Reviewing Appeals Decisions	Measures Capturing Access	1.5	Yes

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
C	Statin Therapy for Patients with Cardiovascular Disease	Process Measure	1	No
D	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
D	Appeals Auto-Forward	Measures Capturing Access	1.5	Yes
D	Appeals Upheld	Measures Capturing Access	1.5	Yes
D	Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Drug Plan Quality Improvement	Improvement Measure	5	No
D	Rating of Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1.5	Yes
D	MPF Price Accuracy	Process Measure	1	No
D	Medication Adherence for Diabetes Medications	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	Yes
D	MTM Program Completion Rate for CMR	Process Measure	1	Yes
D	Statin Use in Persons with Diabetes	Intermediate Outcome Measure	1	No

- Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D).** Beneficiaries with ESRD are excluded from the measure per the PQA measure specifications. For the 2017 measurement year, CMS proposes to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs along with the EDB ESRD indicator (currently used).
- Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D).** The Proportion of Days Covered (PDC) is adjusted for inpatient (IP) stays and hospice enrollment for MA-PDs and PDPs, and skilled nursing facility (SNF) stays for PDPs. In applying the adjustment, first we identify the start and end dates of relevant types of stays for beneficiaries included in the adherence measures. The start date is currently the admission date, and the end date is one day before the discharge date. The discharge date is not included in the PDC adjustment. The days of the relevant stays that occur during the beneficiary's measurement period are removed from the numerator and denominator of the PDC calculation. In addition, we shift the days' supply from Part D prescription fills that overlap with the stay to uncovered days after the end of the relevant stay, if applicable. This assumes the

beneficiary receives the relevant medication from a different source during the stay and “stockpiles” the Part D prescription fills for later use.

We found that in cases where the beneficiary has consecutive stays where the admission date of the second stay is one day after the discharge date, one day would not be removed from the PDC calculation. Therefore, we propose to concatenate consecutive stays to create a single admission and discharge date for the PDC adjustment.

- **MPF Price Accuracy (Part D).** CMS is proposing enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract’s MPF advertised prices. We propose the following changes (please see Appendix 1 for a more detailed methodology):
 1. Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract’s measure score as the mean of the contract’s Price Accuracy and Claim Percentage scores, based on the below indexes:
 - The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE’s date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as:

$$(\text{Total amount that PDE is higher than MPF} + \text{Total PDE cost}) / (\text{Total PDE cost}).$$
 - The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as:

$$(\text{Total number of claims where PDE is higher than MPF}) / (\text{Total number of claims})$$
 - The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.
 - A contract’s measure score is computed as:
 - $\text{Price Accuracy Score} = 100 - ((\text{Price Accuracy Index} - 1) \times 100)$
 - $\text{Claim Percentage Score} = (1 - \text{Claim Percentage Index}) \times 100$
 - $\text{Measure Score} = (0.5 \times \text{Price Accuracy Score}) + (0.5 \times \text{Claim Percentage Score})$
 2. Increase the claims included in the measure:
 - Expand the days’ supply of claims included from 30 days to 28-34, 60-62, or 90-100 days.

- Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.
3. Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. The PDE cost must exceed the PF cost by at least a cent (\$0.01) in order to be counted towards the accuracy score. A contract may submit an MPF unit cost up to 5 digits, where PDE cost is always specified to 2 decimal places. Previously, a PDE cost which exceeded the PF cost by \$0.005 would be counted.

In this measure, a contract's score is not lowered if PDEs are priced lower than MPF displayed pricing. Only price increases are counted in the numerator for this measure.

The proposed enhancements are largely those which had been previously finalized in the 2018 Call Letter. The proposal to round a drug's MPF cost will resolve the identified measurement error that resulted in CMS not implementing these changes for 2018 Star Ratings.¹² Simulations of these changes using 2016 MPF and PDE data found MA-PD and PDP performance to be similarly high, where the mean measure score is 91. The bottom 10th percentile of MA-PDs scored 81, and PDPs scored 85. We will continue providing contracts their preliminary as well as final MPF Price Accuracy reports, which contain claim level information.

Additionally, in response to the industry's requests for information about the broad impact of these changes to future Star Ratings, we propose to first publish the modified measure as a display measure for 2020 and 2021; we intend to then consider adding this measure for the 2022 Star Ratings. Pending such a change, we propose to continue to include the current MPF measure in the Star Ratings using the same methodology used for the 2018 Star Ratings, until the modified measure is incorporated. It is important to continue evaluation of sponsors' pricing data used by beneficiaries. Also, removing this measure from the Star Ratings until 2022 would potentially lower sponsors' overall Star Ratings given most contracts receive high ratings in this measure. We welcome stakeholder feedback about these changes, and the timing of implementing them into the display/Star Ratings measures.

- **Members Choosing to Leave the Plan (Part C & D).** We propose to expand the exclusions for this existing measure to include plan benefit package (PBP) service area reductions (SARs) that result in the unavailability of PBPs that the enrollee is

¹² Please see the HPMS memo released on August 9, 2017, "First Plan Preview of 2018 Star Ratings Data" <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Preview-2018-Star-Ratings-Data.pdf>

eligible to move to within the contract. The exclusions meeting the following specific scenarios would be added:

- The area reduced is part of non-Special Need Plan (SNP) PBPs and the only PBPs remaining in the contract that cover the area are SNP PBPs.
- The area reduced is part of a SNP PBP and there are no non-SNP PBPs or another SNP PBP within the contract of the same SNP type that cover the area.

Removal of Measures from Star Ratings

Beneficiary Access and Performance Problems (BAPP) (Part C & D). The BAPP measure is based on CMS' sanctions, civil money penalties (CMP) as well as Compliance Activity Module (CAM) data (this includes: notices of non-compliance, warning letters [with or without business plan], and ad-hoc corrective action plans (CAP) and the CAP severity). After several solicitations for public comment on the BAPP measure and considering comments from MA plans, advocates, and other stakeholders,¹³ CMS proposed in the CY2018 Advance Notice/draft Call Letter a number of revisions to the BAPP measure. In response to that proposal commenters expressed overwhelming support to implement a revision to the measure decoupling audits and enforcement actions from Star Ratings. The commenters cited reasons for recommending such revisions that included: the differences in methodologies and goals, the subjective nature of audits, and the absence of audit information for each plan each year. Advocates, however, submitted strong concerns about the proposal, including decoupling the BAPP measure from audit results. Based on the feedback, the strong support for a change to the measure specification, and concerns for providing additional notice and time to prepare for the significant changes, CMS decided to retain the current BAPP measure in the 2018 Star Ratings and signaled, in the 2018 Call Letter, an intention for 2019 Star Ratings: to remove from the BAPP measure all enforcement actions and reductions for plans under sanction due to audit findings; to propose to retire the current BAPP measure; and to introduce a new measure for the display page.

For the 2019 Star Ratings, CMS proposes to retire the current BAPP measure. We propose to modify the BAPP measure to only include Compliance Activity Module (CAM) data. The revised BAPP measure would be on the display page for the 2019 Star Ratings. We solicit stakeholders' input on the utility of this measure focused only on notices of non-compliance, warning letters, and ad-hoc corrective action plans and their severity.

¹³ Please refer to the CY2018 Advance Notice and CY2018 Rate Announcement for a summary of the history and comments received before the CY2018 Advance Notice proposal.

Temporary Removal of Measure from Star Ratings

Reducing the Risk of Falling (Part C). This current measure, collected through the Medicare HOS, assesses the percentage of beneficiaries who discussed falls, balance concerns, or walking with their healthcare provider and received fall risk intervention(s) from the provider. NCQA made two changes to this measure. First, NCQA changed the denominator of both indicators to include all beneficiaries age 65 and older, as opposed to limiting the denominator to those age 75 and older or age 65-74 with a balance problem, walking problem, or fall in the past year. This action removes a potential bias toward sampling only patients who were treated unsuccessfully. Second, NCQA updated the list of example interventions by removing the phrase “Check your blood pressure lying down or standing”. This aligns the list of interventions with current United States Preventive Services Task Force (USPSTF) recommendations. This change required revising the underlying survey questions in HOS. The revised questions will be first collected in 2018. As a result of this, there will be no data for this measure for the 2019 Star Ratings. We propose to add it to the 2020 display page and intend to add it for the 2021 Star Ratings.

Data Integrity

Data used for the Part C and D Star Ratings must be accurate and reliable. CMS’ longstanding policy has been to reduce a contract’s measure rating to one star if we determine that a contract’s measure data are incomplete, biased, or erroneous. As discussed in previous Call Letters, these reductions may result if CMS identifies mishandling of data or inappropriate processing, or if implementation of incorrect practices impacted specific measure(s). Examples would include, but are not limited to: a contract’s failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract’s failure to adhere to Plan Finder or PDE data requirements; a contract’s errors in processing coverage determinations/exceptions or organization determinations; compliance actions due to errors in operational areas that would directly impact the data reported or processed for specific measures; or a contract’s failure to pass Part C and D Reporting Requirements Data Validation related to organization/sponsor-reported data for specific measures. CMS’ modifications to measure-specific ratings due to data integrity issues are separate from any CMS compliance or enforcement actions related to a sponsor’s deficiencies. This policy is necessary to avoid assigning falsely high stars, especially when deficiencies have been identified that show CMS cannot objectively evaluate a sponsor’s performance in an area.

Sponsors should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications are posted on:

<http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx>. Information about Data Validation of Reporting Requirements data is posted on <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDDataValidation.html>.

Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from attempts to inflate performance or mask deficiencies. CMS has taken several steps in the past years to protect the integrity of the data we use to calculate Star Ratings; however, we continue to identify new vulnerabilities where inaccurate or biased data could result from sponsors' practices. Therefore, CMS will continue to conduct reviews to identify incomplete or biased Star Ratings measure data.

The Part C and D Reporting Requirements measures (SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) (Part D)) are calculated using data reported by plan sponsors and validated via an independent data validation using CMS standards. Per the Star Ratings Technical Notes, contracts that did not score at least 95% on data validation for these reporting sections and/or were not compliant with data validation standards/sub-standards for at least one of the data elements used to calculate the measures are not rated in this measure, and the contract's measure score is reduced to 1 star. We propose to define a contract as being non-compliant if it either receives a "No" or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation.

Proposed Scaled Reductions for Appeals IRE Data Completeness Issues

At present, there are four Star Ratings appeal measures that rely on data submitted to the IRE. Two of the measures are Part C measures (Plan Makes Timely Decisions about Appeals and Reviewing Appeals Decisions), and two are Part D measures (Appeals Auto-Forward and Appeals Upheld). The completeness of the IRE data is critical to allow accurate measurement of the appeals measures. All plans are responsible and held accountable for ensuring high quality and complete data to maintain the validity and reliability of the measures.

For verification and validation of the Part C and D appeals measures, CMS has relied primarily on the use of audit findings and targeted reviews. Contracts identified during an audit review to have systematic issues with the completeness of the IRE data have had their appeals measures reduced to one star. Plans and sponsors have expressed concern with the use of the audit findings for the sole source of information because of the perceived inequity of the application of the reductions that only audited contracts may face. Each year, a subset of contracts, not all contracts, are audited. Further, if a reduction due to IRE data integrity was applied, it resulted in a measure-level Star Rating of one star for the appeals measures.

In response to stakeholder concerns about both CMS' prior practice of reducing measure ratings to one star based on any finding of data inaccuracy, incompleteness, or bias, and the potential inequity in application of the data integrity policy related to audit findings (because not all plans

are audited every year), CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017.¹⁴ All contracts submitted data during the first year of the project. The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment size of the contract with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period.¹⁵ CMS reviewed and examined the data from the first collection of TMP data, but did not use it in the determination of appeals-related reductions for the 2018 Star Ratings.

CMS is proposing statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP data or audit. The reduction would be applied to the measure-level Star Rating for the applicable appeals measures. We are cognizant that there are varying degrees of data issues and as such, we have developed a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size-fits-all approach. The methodology would employ scaled reductions (one-star, two-star, three-star, or four-star reduction) based on the degree of missing IRE data. Contracts with the highest IRE data quality issues (i.e., largest percentage of missing or compromised data) would receive the largest reductions, while contracts with a lower degree of missing IRE data would receive a smaller reduction. The most severe reduction for IRE data completeness issues would be a four-star reduction, thus resulting in a measure-level Star Ratings of one star for the associated appeals measures. If a contract receives a reduction due to missing Part C IRE data, the reduction would be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction would be applied to both of the contract's Part D appeals measures. Further, we propose to use multiple data sources whenever possible to determine whether the IRE data are complete and if not, the severity of the missingness and/or data issues.

CMS' proposed scaled reduction methodology would be a three-stage process using the TMP data or audit for the means to determine: first, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, as the basis for the determination of

¹⁴ This project was discussed in the November 28, 2016 HPMS memo, "Industry-wide Appeals Timeliness Monitoring" as well as the December 02, 2016 follow-up email. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf>
<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf>.

¹⁵ Contracts with a mean annual enrollment of less than 50,000 are required to submit data for a three-month time period. Contracts with a mean enrollment of at least 50,000 but, at most 250,000 are required to submit data for a two-month time period. Contracts with a mean enrollment greater than 250,000 are required to submit data for a one-month period.

the estimated error rate; and finally, whether the estimated value is statistically greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.

Once the scaled reduction for a contract is identified using the methodology, the reduction would be applied to the contract's associated appeals measure-level Star Ratings. Since the minimum measure-level Star Rating is one star, if the difference between the associated appeals measure-level Star Rating (before the application of the reduction) and the identified scaled reduction is less than one, the contract would receive a measure-level Star Rating of one star for the appeals measure.

The error rate for the Part C and Part D appeals measures - using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period - would be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate is proposed to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP or audit data is dependent on the enrollment size of the contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria proposed.

The calculated error rate formula (Equation 1) for the Part C measures is proposed to be determined by the quotient of number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during the TMP or audit data collection period and the number of cases not forwarded to the IRE during the same period.

$$\text{Part C Calculated Error Rate} = \frac{\text{Number of cases not forwarded to the IRE}}{\text{Total number of cases that should have been forwarded to IRE}} \quad \text{Equation (1)}$$

The calculated error rate formula (Equation 2) for the Part D measures is proposed to be determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

$$\text{Part D Calculated Error Rate} = \frac{\text{Number of untimely cases not auto-forwarded to the IRE}}{\text{Total number of untimely cases}} \quad \text{Equation (2)}$$

Given the different lengths of TMP or audit data collected and evaluated (based on contract size), the number of non-forwarded cases in a three-month period per contract is projected. The projected number of cases not forwarded to the IRE in a three-month period would be calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data, by a constant determined by the associated time period. Contracts with mean annual

enrollments greater than 250,000 that submitted data from one-month, would have a constant of 3.0. Contracts with mean enrollments between 50,000 and 250,000 that submitted data from a two-month period, would have their number of cases found not to be forwarded to the IRE (based on the TMP or audit data) multiplied by the constant 1.5. Small contracts with mean enrollments less than 50,000 that submitted data for a three-month period would have their number of cases found not to be forwarded to the IRE multiplied by the constant 1.0. We propose that contracts would be subject to a possible reduction due to lack of data completeness if both conditions are met:

1. The calculated error rate is 20% or more.
2. The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions, the contract would not be subject to reductions for IRE data completeness issues. If a contract would be subject to a possible reduction based on the aforementioned conditions, a confidence interval estimate for the true error rate for the contract would be calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95%. The midpoint of the score interval would be determined using Equation 3.

$$\text{Midpoint} = \text{Calculated Error Rate} \times \left(\frac{\text{Total Number of Cases}}{\text{Total Number of Cases} + z^2} \right) + \frac{1}{2} \left(\frac{z^2}{\text{Total Number of Cases} + z^2} \right) \quad \text{Equation (3)}$$

The z score that corresponds to a level of statistical significance of 0.05, commonly denoted as $z_{\alpha/2}$ but for ease of presentation represented here as z. (The z value that will be used for the purpose of the calculation of the interval is 1.959964.).

For the Part C appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP or audit data, which is determined by Equation 1. The total number of cases in Equation 3 is the number of cases that should have been in the IRE for the Part C TMP or audit data.

For the Part D appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP or audit data, which is determined by Equation 2. The total number of cases in Equation 3 is the total number of untimely cases for the Part D appeals measures.

Letting the calculated error rate be represented by \hat{p} and the total number of cases represented as n, Equation 3 can be streamlined as follows (Equation 4):

$$\text{Midpoint} = \hat{p} \left(\frac{n}{n + z^2} \right) + \frac{1}{2} \left(\frac{z^2}{n + z^2} \right) \quad \text{Equation (4)}$$

The lower bound of the confidence interval estimate for the error rate is calculated using Equation 5 below:

$$\text{Lower Bound} = \text{Midpoint} - z \times \sqrt{\frac{1}{n+z^2} \left[\hat{p}(1 - \hat{p}) \left(\frac{n}{n+z^2} \right) + \frac{1}{4} \left(\frac{z^2}{n+z^2} \right) \right]} \quad \text{Equation (5)}$$

For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate would be compared to each of the thresholds in Table 1. If the contract's calculated lower bound is higher than the threshold, the contract would receive the reduction that corresponds to the highest threshold that is less than the lower bound. In other words, the contract's lower bound is being employed to determine whether the contract's error rate is significantly greater than the thresholds of 20%, 40%, 60%, and 80% to determine the scaled reduction. The proposed scaled reductions are in Table 1. The reductions due to IRE data completeness issues would be applied after the calculation of the measure-level Star Rating for the appeals measures. The reduction would apply to the Part C appeals measures or the Part D appeals measures.

It is important to note that a contract's lower bound could be statistically significantly higher than more than one threshold. The reduction would be determined by the highest threshold that the contract's lower bound exceeds. For example, if the lower bound for a contract is 64.560000%, the contract's estimated value is significantly greater than the thresholds of 20%, 40%, and 60% because the lower bound value 64.560000% is greater than each of these thresholds. The lower bound for the contract's confidence interval is not greater than 80%. The contract would be subject to the reduction that corresponds to the 60% threshold which is 3 stars.

Table 1: Proposed Thresholds and Associated Reductions

Proposed Thresholds Using the Lower Bound of Confidence Interval Estimate of the Error Rate	Reduction for Incomplete IRE Data (Stars)
20%	1
40%	2
60%	3
80%	4

Table 2: Part C Appeals Examples

Contract	Enrollment	Number of Cases not Sent to IRE	Number of Cases Forwarded to IRE	Number of Cases that should be in the IRE (n)	Projected Number of Cases not Forwarded	Calculated Error Rate (%)
A	10,000	6	2	8	6	75.000000
B	75,000	7	1	8	10.5	87.500000

Contract A has a mean annual enrollment of 10,000. The contract submitted TMP data using a three-month time period. The TMP data revealed that 6 cases were not forwarded to the IRE and 2 cases were sent to the IRE in the time period.

The contract's calculated error rate is found by dividing the number of cases not forwarded to the IRE by the total number of cases that should have been in the IRE. This results in a numerator of 6 and a denominator of 8 (2 cases in the IRE plus the 6 cases that were not forwarded to the IRE) or a calculated error rate of $6/8 = 0.75000000$ or 75%.

The number of cases not forwarded in the TMP time period of 3 months is 6. Since the contract's enrollment was under 50,000, the projected number of cases not forwarded is found by multiplying the number of cases not forwarded by a factor of 1.0. In other words, if a contract has an enrollment less than 50,000, the projected number of cases not submitted to the IRE is the same as the number of cases not submitted to the IRE in the TMP data. For Contract A, the projected number of cases not submitted to the IRE is 6.

The contract is not subject to a possible reduction because the projected number of cases not forwarded in a 3-month period to the IRE is less than 10. The contract receives the calculated measure-level Star Rating as detailed in the 2019 Star Ratings Technical Notes without a reduction for IRE data completeness issues.

Contract B has a mean annual enrollment of 75,000. The contract submitted TMP data using a two-month time period. The TMP data revealed that 7 cases were not forwarded to the IRE and 1 case was sent to the IRE in the time period.

The contract's calculated error rate is found by dividing the number of cases not forwarded to the IRE by the total number of cases that should have been sent to the IRE. This results in a numerator of 7 and a denominator of 8 (1 case in the IRE plus the 7 cases that were not forwarded to the IRE) or a calculated error rate of $7/8 = 0.87500000$ or 87.5%.

The projected number of cases not forwarded to the IRE in a 3-month period for Contract B is found by multiplying the number of cases not forwarded to the IRE in the TMP data (7) and the

constant 1.5, since the contract had a mean annual enrollment between 50,000 and 250,000 beneficiaries. Thus, for Contract B, the projected number of cases not submitted to the IRE is 7 times the constant 1.5 or 10.5 cases.

Contract B is subject to possible reductions for IRE data completeness issues because the calculated error rate is 20% or greater and the projected number of cases not submitted to the IRE exceeds 10.

Next, the midpoint of the score interval is calculated using Equation 4 substituting the calculated error rate of 0.87500000 (87.500000%) for \hat{p} , the total number of cases of 8 for n , and a z score of 1.959964.

$$\text{Midpoint} = \hat{p} \left(\frac{n}{n + z^2} \right) + \frac{1}{2} \left(\frac{z^2}{n + z^2} \right)$$

$$\text{Midpoint} = (0.87500000) \left(\frac{8}{8 + (1.959964)^2} \right) + \frac{1}{2} \left(\frac{(1.959964)^2}{8 + (1.959964)^2} \right)$$

This results in a midpoint of 0.75334716 (75.334716%).

The lower bound of the confidence interval is determined using Equation 5. The values substituted in the Equation 5 are consistent with the values used above.

$$\text{Lower Bound} = \text{Midpoint} - z \times \sqrt{\frac{1}{n + z^2} \left[\hat{p}(1 - \hat{p}) \left(\frac{n}{n + z^2} \right) + \frac{1}{4} \left(\frac{z^2}{n + z^2} \right) \right]}$$

$$\text{Lower Bound} = 0.75334716 - 1.959964 \times \sqrt{\frac{1}{8 + (1.959964)^2} \left[0.87500000(1 - 0.87500000) \left(\frac{8}{8 + (1.959964)^2} \right) + \frac{1}{4} \left(\frac{(1.959964)^2}{8 + (1.959964)^2} \right) \right]}$$

$$\text{Lower Bound} = 0.75334716 - 0.22423535 = 0.52911182 \text{ (52.911182\%).}$$

The value of the lower bound of the confidence interval for the error rate is then compared to the thresholds in Table 1. The thresholds associated with the scaled reductions are values of 20%, 40%, 60% and 80%. Since the lower bound (52.911182%) is greater than 40%, but less than 60%, the contract's two Part C appeals measure would be reduced by 2 stars due to IRE data completeness issues. The reduction would be applied after the measure-level Star Ratings are calculated as detailed in the 2019 Technical Notes. The maximum measure-level Star Rating Contract B could receive for the two Part C appeals measures is 3 stars. If the application of the

2-star reduction to the associated Part C appeals measure-level stars results in a measure-level Star Rating less than 1 star, the contract's Part C appeals measure would be rated 1 star.

Table 3: Part D Appeals Example

Contract	Enrollment	Number of Untimely Cases Not Auto- Forwarded	Number of Untimely Cases	Projected Number of Untimely Cases Not Auto- Forwarded	Calculated Error Rate (%)
D	350,000	25	28	75	89.285714

Contract D has a mean annual enrollment of 350,000. The contract submitted TMP data using a one-month time period. The TMP data revealed that 25 untimely cases were not forwarded to the IRE and 28 cases were untimely in the time period.

The contract's calculated error rate is found by dividing the number of untimely cases not auto-forwarded to the IRE by the total number of untimely cases. This results in a numerator of 25 and a denominator of 28 or a calculated error rate of $25/28 = 0.89285714$ or 89.285714%.

The projected number of untimely cases not auto-forwarded to the IRE for Contract D is found by multiplying the number of untimely cases not auto-forwarded to the IRE in the TMP data (25) and the factor 3.0 since the contract had a mean annual enrollment greater than 250,000 beneficiaries. For Contract D, the projected number of untimely cases not auto-forwarded to the IRE is 25 times the constant 3.0, which is 25×3.0 or 75 cases.

Contract D is subject to possible reductions for IRE data completeness issues because the calculated error rate is 20% or greater and the projected number of untimely cases not forwarded to the IRE exceeds 10.

Next, the midpoint of the score interval is calculated using Equation 4 substituting the calculated error rate of 0.89285714 (89.285714%) for \hat{p} , the total number of untimely cases of 28 for n , and a z score of 1.959964.

$$\text{Midpoint} = \hat{p} \left(\frac{n}{n + z^2} \right) + \frac{1}{2} \left(\frac{z^2}{n + z^2} \right)$$

$$\text{Midpoint} = (0.89285714) \left(\frac{28}{28 + (1.959964)^2} \right) + \frac{1}{2} \left(\frac{(1.959964)^2}{28 + (1.959964)^2} \right)$$

This results in a midpoint of 0.84546156 (84.546156%).

The lower bound of the confidence interval is determined using Equation 5. The values substituted in the Equation 5 are consistent with the values used above.

$$\text{Lower Bound} = \text{Midpoint} - z \times \sqrt{\frac{1}{n + z^2} \left[\hat{p}(1 - \hat{p}) \left(\frac{n}{n + z^2} \right) + \frac{1}{4} \left(\frac{z^2}{n + z^2} \right) \right]}$$

$$\text{Lower Bound} = 0.845456156 - 1.959964 \times \sqrt{\frac{1}{28 + (1.959964)^2} \left[0.87500000(1 - 0.87500000) \left(\frac{28}{28 + (1.959964)^2} \right) + \frac{1}{4} \left(\frac{(1.959964)^2}{28 + (1.959964)^2} \right) \right]}$$

$$\text{Lower Bound} = 0.84546156 - 0.11742007 = 0.72804148$$

The value of the lower bound of the confidence interval for the error rate is then compared to the thresholds in Table 1. The thresholds associated with the scaled reductions are 20%, 40%, 60%, and 80%. Since the lower bound (72.804148%) is greater than 60%, but less than 80%, the contract's two Part D appeals measure would be reduced by 3 stars due to IRE data completeness issues. The reduction would be applied after the measure-level Star Ratings are calculated as detailed in the 2019 Technical Notes. The maximum measure-level Star Rating Contract D could receive for the two Part D appeals measures is 2 stars. If the application of the 3-star reduction to the associated Part D appeals measure-level stars results in a measure-level Star Rating less than 1 star, the contract's Part D appeals measure would be rated 1 star.

2019 Star Ratings Program and the Categorical Adjustment Index

CMS' interim response to address the within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and dual eligible (LIS/DE) and disability status revealed in our comprehensive research conducted over multiple years culminated in the creation of the Categorical Adjustment Index (CAI). The CAI was first implemented in the 2017 Star Ratings Program. The values and abridged details of the methodology are provided in the annual Medicare Part C & D Star Rating Technical Notes available on the CMS webpage at <https://go.cms.gov/partcanddstarratings>. Additional details of the CAI methodology can be found in the CAI Methodology Supplement available at the same link.

There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best address the impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries in contracts. The final report of the findings of the two-year trial period by National Quality Forum (NQF) that temporarily lifted the restriction and allowed risk-adjustment of performance measures for socioeconomic status (SES) and other

demographic factors was released in July 2017.¹⁶ NQF has recommended a three-year initiative to further examine and consider social risk adjustment to allow evidence as to whether a change in their longstanding policy prohibiting risk adjustment for SES and other demographic factors should be revised.

We continue to engage the NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether case-mix adjustment of individual measures would be appropriate. The PQA examined their medication adherence measures, which are currently used in the Star Ratings Program, for potential risk adjustment¹⁷. Beginning in 2018, the PQA will include draft recommendations on risk adjustment of the three medication adherence measures: Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol. The draft recommendations are as follows:

- All three adherence measures should be risk adjusted for sociodemographic status (SDS) characteristics to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/LIS status, and disability status.
- The three adherence measures should be stratified by the beneficiary-level SDS characteristics listed above to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA has indicated that these draft recommendations will be included in the 2018 PQA Measure Manual, and will be finalized in 2019 once PQA completes the NQF measure endorsement maintenance of the three measures (NQF Endorsed # 0541). If finalized, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures.

NCQA has also completed their examination of a subset of the HEDIS measures used in the Star Ratings Program. NCQA has received approval from the Committee on Performance Measurement (CPM) to implement stratified reporting of four of the measures used in the Star Ratings Program: Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions.¹⁸ The measures would be stratified using the following subgroups: both LIS/DE and disabled, not LIS/DE and not disabled; LIS/DE and not disabled; not LIS/DE and disabled; and other.

¹⁶ NQF's Final Report can be assessed using the following link:

http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx

¹⁷ The PQA summary can be accessed at: [SDS Risk Adjustment PQA PDC CMS Part D Stars](#)

¹⁸ A summary of the NCQA analysis and recommendations can be accessed using the link that follows: <http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act>

An overall (i.e., non-stratified) result would also be required to be reported for this measure. The change to the specification would be applicable to the MA program reporting requirements. At present, NCQA is designing the reporting requirements and anticipate the change in its specification in the 2019 HEDIS Volume 2. CMS is considering how to best incorporate the information provided by the stratified reporting in future years of the Star Ratings.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), as required in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185), released the first in a two-part series of Reports to Congress (RTC) in December 2016.¹⁹ In it, ASPE analyzed the effect of social risk factors on health outcomes of Medicare beneficiaries. ASPE reviewed a number of CMS programs, including MA. CMS has carefully reviewed the report and is considering the feasibility of the considerations presented in ASPE's RTC for MA contracts and sponsors, as well as the impact on the use of the ratings for beneficiaries. ASPE's second report is due in the fall of 2019. In the meantime, CMS continues to be in dialogue with ASPE to discuss potential options for future MA Star Ratings.

CMS remains firmly committed to building the foundation for a long-term solution that appropriately addresses the issue at hand and aligns with our policy goals. CMS remains steadfast that any policy response must delineate the two distinct aspects of the issue - quality and payment. The Star Ratings are a reflection of the quality of a contract and thus, the response to address the LIS/DE/disabled effect revealed in our research must not distort the meaning and value of the quality ratings. Further, the long-term solution must recognize the unique challenges of serving vulnerable populations. While the measure stewards continue their work, CMS will continue to consider all feasible options that exist for a long-term response.

Since its inception, the application of the CAI has resulted in a modest movement of the Star Ratings. In 2017, nineteen MA-PDs had their overall Star Rating increase a half-star after the overall CAI was applied to their unadjusted overall Star Rating. Nine contracts had their overall rating change from 3.5 to 4.0 stars after the overall CAI was applied. For MA-only and MA-PDs, seven contracts increased a half-star after the Part C summary CAI was applied to their unadjusted Part C summary rating. Sixteen MA-PDs contracts increased a half-star after Part D CAI was applied to their unadjusted Part D summary rating. In 2017, the movement for stand-alone PDPs was bidirectional. Nine PDPs decreased a half-star and three increased a half-star after the PDP-specific CAI values were applied to their unadjusted Part D summary rating.

¹⁹ ASPE's first Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs can be accessed using the link that follows: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>.

For the 2018 Star Ratings, the impact of the CAI resulted in primarily positive movement of the ratings. A total of eleven MA-PDs saw their overall Star Rating increase by a half-star and one MA-PD's overall rating decreased by a half-star after the overall CAI was applied to their unadjusted overall Star Rating. Six contracts had their overall rating change from 3.5 to 4.0 after the CAI was applied. For MA-only and MA-PDs, eleven contracts increased a half-star and 4 decreased a half-star after the Part C summary CAI values were applied. A total of 4 MA-PD contracts increased a half-star after the Part D MA-PD summary CAI was applied to their unadjusted Part D summary rating. The movement for stand-alone PDPs was directional only. Six PDPs decreased a half-star after the PDP-specific CAI values were applied to their unadjusted Part D summary rating.

For the 2019 Star Ratings Program, CMS is proposing to continue the use of the interim analytical adjustment, the CAI. The overall methodology would remain unchanged for 2019.

As stated in the CY 2017 Call Letter (CY 2017 Rate Announcement, Attachment VII, pages 131-133), the CAI values will be updated annually and published in the final Call Letter. The CAI values will be determined using the previous Star Ratings year's measurement period, which allows the release of the CAI values well in advance of the first Star Ratings preview period. Thus, the 2019 CAI values are determined using data from the 2018 Star Ratings.

LIS/DE status for the categorization of the contracts for the 2019 Star Ratings will be based on the Medicare enrollment data from CY 2017. The disability status of an enrollee will be determined using information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems for CY 2017. Disability status is based on the original reason for entitlement code (OREC).

For the 2019 Star Ratings Program, the analysis and criteria used to select measures for adjustment were the same as those used for the 2017 Star Ratings Program. CMS updated its analyses of the measures using the 2016 measurement period data and evaluated the variability of within-contract differences in performance for a similar subset of Star Ratings measures examined last year.²⁰ A summary of the updated analysis conducted to select the measures including the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences is posted at <http://go.cms.gov/partcanddstarratings>. The decision criteria used to select measures for adjustment was (1) a median absolute difference

²⁰ The 18 clinical quality measures that comprised the subset of the Star Ratings measures examined for the 2019 CAI included: adult BMI assessment, annual flu vaccine, breast cancer screening, colorectal cancer screening, controlling blood pressure, diabetes care – blood sugar controlled, diabetes care – eye exam, diabetes care – kidney disease monitoring, improving bladder control, medication reconciliation post-discharge, MTM Program Completion Rate for CMR, osteoporosis management in women who had a fracture, plan all-cause readmissions, monitoring physical activity, rheumatoid arthritis management, medication adherence for diabetes medications, medication adherence for hypertension, medication adherence for cholesterol.

between LIS/DE and non-LIS/DE beneficiaries of 5 percentage points or more and/or (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

The measures selected for adjustment for the 2019 Star Ratings include six Part C measures and two Part D measures. For MA (MA-only, MA-PD) and 1876 contracts, the Part C measures selected for adjustment for the 2019 Star Ratings include: Annual Flu Vaccine, Breast Cancer Screening, Diabetes Care – Blood Sugar Controlled, Medication Reconciliation Post-Discharge, Osteoporosis Management in Women who had a Fracture, Plan All-Cause Readmissions²¹. For MA-PDs and PDPs, the two Part D measures selected for adjustment for the 2019 Star Ratings include: Part D Medication Adherence for Hypertension and MTM Program Completion Rate for CMR.

2019 Categorical Adjustment Index (CAI) Values

MA contracts have up to three mutually exclusive and independent adjustments – one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). PDPs have one adjustment for the Part D summary rating. Tables 4 – 15 provide the rating-specific categories for classification of contracts based on the percentage of LIS/DE and disabled beneficiaries along with the final adjustment categories.

Table 4 provides the range for the percentages that correspond to the LIS/DE categories determined by dividing the distribution of MA contracts' LIS/DE percentages into ten equal-sized groups. Table 5 provides the range of the percentages that correspond to the disability quintiles for the categorization of MA contracts for the CAI for the overall Star Rating.

The upper limit for each category is not included in that category, but rather the next higher category. For example, if a contract's percentage of LIS/DE beneficiaries is 9.486205%, the contract's LIS/DE initial category is L3. The exceptions for the upper limit exclusion for an initial group are the tenth initial category for LIS/DE and the fifth quintile for disability.

²¹ Using the adjusted measure selection criteria, plan all-cause readmissions was selected for adjustment for the 2019 Star Ratings. The adjustment of the plan all-cause readmissions measure scores for LIS/DE and disabled included case-mix weights that are part of the HEDIS measure specification and weighted effects coding to account for the different numbers of LIS/DE and non-LIS/DE beneficiaries per contract as well as, the unequal numbers of disabled and non-disabled beneficiaries in the data.

Table 4: Categorization of MA Contracts into Initial LIS/DE Groups for the Overall Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 6.147316
L2	6.147316 to less than 9.486205
L3	9.486205 to less than 11.709700
L4	11.709700 to less than 14.743797
L5	14.743797 to less than 19.979137
L6	19.979137 to less than 26.817676
L7	26.817676 to less than 39.929156
L8	39.929156 to less than 69.752170
L9	69.752170 to less than 100.000000
L10	100.000000

Table 5: Categorization of MA Contracts into Disability Quintiles for the Overall Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 15.059848
D2	15.059848 to less than 20.932235
D3	20.932235 to less than 27.405248
D4	27.405248 to less than 38.060705
D5	38.060705 to less than or equal to 100.000000

Table 6 provides the description of each of the final adjustment categories for the overall Star Rating for MA contracts and the associated values of the CAI for each final adjustment category.

Table 6: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1	D1 – D3	–0.041117
B	L2 - L4	D1 - D4	–0.011802
	L5	D1 - D2	
	L1	D4	
C	L6 - L7	D1 - D3	0.006484
	L8 - L9	D1	
	L5	D3 - D4	
	L6	D4	
	L1 - L5	D5	
D	L10	D1	0.041195
	L8	D2 - D5	
	L7	D4	
	L9 - L10	D2	
	L6 - L7	D5	
E	L9 - L10	D3 - D4	0.113869
	L9	D5	
F	L10	D5	0.142718

Tables 7 and 8 provide the range of the percentages that correspond to the initial LIS/DE groups and disability quintiles for the initial categories for the determination of the CAI values for the Part C summary rating.

Table 7: Categorization of MA Contracts into Initial LIS/DE Groups for the Part C Summary Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 5.992616
L2	5.992616 to less than 8.988495
L3	8.988495 to less than 11.438062
L4	11.438062 to less than 14.634338
L5	14.634338 to less than 19.378661
L6	19.378661 to less than 26.317568
L7	26.317568 to less than 39.614595
L8	39.614595 to less than 69.705289
L9	69.705289 to less than 100.000000
L10	100.000000

Table 8: Categorization of MA Contracts into Disability Quintiles for the Part C Summary Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 14.826108
D2	14.826108 to less than 20.812509
D3	20.812509 to less than 27.249755
D4	27.249755 to less than 38.009950
D5	38.009950 to less or equal to 100.000000

Table 9 provides the description of each of the final adjustment categories for the Part C summary rating and the associated value of the CAI for each final adjustment category.

Table 9: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L4 L1 - L2	D1 - D2 D3	-0.017642
B	L5 - L7 L8 - L9 L3 - L4 L1 - L2	D1 - D5 D1 D3 - D5 D4 - D5	0.006198
C	L8 - L10 L10 L8	D2 - D3 D1 D4 - D5	0.045454
D	L9 - L10 L9	D4 D5	0.076586
E	L10	D5	0.125909

Tables 10 and 11 provide the range of the percentages that correspond to the initial LIS/DE groups and the disability quintiles for the initial categories for the determination of the CAI values for the Part D summary rating for MA-PDs.

Table 10: Categorization of MA-PD Contracts into Initial LIS/DE Groups for the Part D Summary Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 6.086006
L2	6.086006 to less than 9.486205
L3	9.486205 to less than 11.818672
L4	11.818672 to less than 15.062762
L5	15.062762 to less than 20.400000
L6	20.400000 to less than 28.005752
L7	28.005752 to less than 41.258946
L8	41.258946 to less than 72.787572
L9	72.787572 to less than 100.000000
L10	100.000000

Table 11: Categorization of MA-PD Contracts into Disability Quintiles for the Part D Summary Rating

Disability Quintile	Percentage of Contract's Disabled
D1	0.000000 to less than 15.064161
D2	15.064161 to less than 21.113304
D3	21.113304 to less than 27.887822
D4	27.887822 to less than 39.190317
D5	39.190317 to less than 100.000000

Table 12 provides the description of each of the final adjustment categories for the Part D summary rating for MA-PDs and the associated values of the CAI for each final adjustment category.

Table 12: Final Adjustment Categories and CAI Values for the Part D Summary Rating for MA-PDs

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L3	D1	-0.031272
	L1	D2 - D3	
B	L4 - L8	D1 - D3	-0.007584
	L9	D1 - D2	
	L2 - L3	D2 - D3	
C	L1 - L6	D4 - D5	0.015478
	L7	D4	
D	L9 - L10	D3 - D4	0.086029
	L10	D1 - D2	
	L8	D4	
	L7 - L9	D5	
E	L10	D5	0.142243

Tables 13 and 14 provide the range of the percentages that correspond to the LIS/DE and disability quartiles for the initial categories for the determination of the CAI values for the Part D summary rating for PDPs. Quartiles are used for both dimensions (LIS/DE and disability) due to the limited number of PDPs as compared to MA contracts.

Table 13: Categorization of PDP Contracts into LIS/DE Quartiles for the Part D Summary Rating

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 1.669196
L2	1.669196 to less than 4.001965
L3	4.001965 to less than 15.204859
L4	15.204859 to less than or equal to 100.000000

Table 14: Categorization of PDP Contracts into Disability Quartiles for the Part D Summary Rating

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
D1	0.000000 to less than 7.415977
D2	7.415977 to less than 12.842575
D3	12.842575 to less than 19.147148
D4	19.147148 to less than or equal to 100.000000

Table 15 provides the description of each of the final adjustment categories for the Part D summary rating for PDPs and the associated value of the CAI per final adjustment category.

Please note that the CAI values for the Part D summary rating for PDPs are different from the CAI values for the Part D summary rating for MA contracts. Categories were chosen to enforce monotonicity and to yield a minimum of 10 contracts per final adjustment category. There are four final adjustment categories for PDPs for the Part D summary rating.

Table 15: Final Adjustment Categories and CAI Values for the Part D Summary Rating for PDPs

Final Adjustment Category	LIS/DE Quartile	Disability Quartile	CAI Value
A	L1	D1 - D3	-0.243619
B	L2 - L3	D1 - D4	-0.119773
	L1	D4	
C	L4	D1 - D4	0.047909

Additional Adjustment to Address Lack of an LIS Indicator for Enrollees in Puerto Rico

Puerto Rico has a unique healthcare market with a large percentage of low-income individuals in both Medicare and Medicaid and a complex legal history that affects its healthcare system in many ways. Puerto Rican beneficiaries are not eligible for LIS.

For the 2017 Star Ratings an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico (i.e., contracts with service areas entirely in Puerto Rico) to address the lack of LIS was applied to make the application of the CAI equitable for contracts in Puerto Rico. The additional adjustment resulted in a modified value for the percentage of LIS/DE for contracts operating solely in Puerto Rico. The adjustment resulted in a modified percentage of LIS/DE beneficiaries that was subsequently used to categorize contracts into the final adjustment category for the CAI. The model developed for the 2019 Star Ratings LIS/DE indicator will be available in Attachment O in the 2019 Medicare Part C & D Star Rating Technical Notes. The details of the LIS/DE indicator methodology are available in the CAI Methodology Supplement available at <http://go.cms.gov/partcanddstarratings>.

For the 2019 Star Ratings, CMS proposes to continue to employ the additional adjustment for contracts operating solely in Puerto Rico (using the most recent data available at the time of development of the model for the 2019 Star Ratings. The data sources include: the 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL); the ACS 5-year estimates for Puerto Rico and the 10 highest-poverty states of the percentage of people living below 150% of the FPL²²; and the CY 2017 Medicare Enrollment data. CMS continues to explore alternative data sources for Puerto Rico to provide both resource and income information for the determination of the additional adjustment.

CMS recognizes the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of LIS. For the 2019 Star Ratings, CMS proposes to continue to reduce the weights for the adherence measures to zero (0) for the summary and overall rating calculations and maintain the weight of three (3) for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico.

Disaster Implications

Natural disasters such as hurricanes and wildfires can directly affect our Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These disasters may negatively affect the

²² The data to develop the model is limited to the 10 states, drawn from the 50 states plus the District of Columbia, with the highest proportion of people living below the FPL as identified by the 1-year ACS estimates.

underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program. CMS is considering a variety of strategies to address Star Ratings issues related to contracts impacted by extreme and uncontrollable circumstances. We propose to adjust the 2019 and 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period, such as the disasters (Hurricanes Harvey, Irma, and Maria, and the wildfires in California) that occurred during the 2017 performance period. CMS is also concerned that certain natural disasters and emergencies that continue into early 2018 may interfere in plans' ability to conduct surveys needed for 2019 Star Ratings. Below we propose a policy to identify which contracts were impacted as well as rules to adjust the Star Ratings measures.

Identification of Affected Contracts

We are proposing a policy to identify MA and Part D contracts affected by extreme and uncontrollable circumstances that may impact their performance on Star Ratings measures and/or may impact their ability to collect the necessary measure-level data. These "affected contracts" would be the contracts eligible for the adjustments proposed below to take into account the effects of the extreme and uncontrollable circumstances.

We propose that affected contracts would be:

(1) Contracts operating solely in Puerto Rico (i.e., serving only residents of Puerto Rico);

OR

(2) Contracts that meet all of these criteria:

- a. The service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act.
- b. The service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act that served as a condition precedent for the Secretary's exercise of authority under Section 1135 of the Act.
- c. At least one enrollee under the contract resides in a FEMA-designated Individual Assistance area either at the time of the survey (for CAHPS and HOS adjustments to survey responses) or at the time of the disaster (for all other adjustments). For some adjustments, a certain percentage (25% or 60%) of the enrollees under the contract must reside in a FEMA-designated Individual Assistance area.

We propose that the policy should be tailored to the specific areas experiencing the extreme and uncontrollable circumstance. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as

hospitals or medical centers located in specific physical locations. For purposes of this policy, a narrower geographic scope than the full emergency area would ensure that the Star Ratings adjustments are focused on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects. We identify an area as having experienced extreme and uncontrollable circumstances if it is within an “emergency area” and “emergency period” as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act that served as a condition precedent for the Secretary’s exercise of the 1135 waiver authority (<https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx>). Major disaster areas are identified and can be located on Federal Emergency Management Agency (FEMA) Web site at <https://www.fema.gov/disasters>.

To further narrow the scope of this policy to ensure it is applied to those contracts most likely to have experienced the greatest adverse effects, we propose to limit this policy to Individual Assistance disaster declarations. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We focus on counties eligible for Individual Assistance as a result of a major disaster because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Therefore, adjustments to the Star Ratings are most appropriately targeted to areas where beneficiaries were eligible for individual and household assistance as a result of the disaster.

To determine whether a contract was impacted (such as that it would be an “affected contract” eligible for adjustments), we propose to compare the number of enrollees in the Individual Assistance area at the time of the disaster compared to the number of enrollees outside the Individual Assistance area. Using the Individual Assistance major disaster declaration as a requirement for the extreme and uncontrollable event policy ensures that the policy would apply only when the event is extreme, meriting the use of special adjustments to the Star Ratings, and targeting the specific area affected by the extreme and uncontrollable circumstance.

The Hurricanes Harvey, Irma, and Maria, and the recent California wildfires would trigger the extreme and uncontrollable circumstance policy as there were areas identified as “emergency areas” for “emergency periods” under Section 1135(g) as a result of these natural disasters; there were Stafford Act declarations of a major disaster applicable to them; the Secretary did exercise authority under Section 1135 of the Act as a result of these disasters; and there are enrollees residing in FEMA-designated Individual Assistance areas. During the measurement year for the 2019 Star Ratings, the effects of Hurricanes Harvey, Irma, and Maria, as well as the California wildfires were significant for Medicare beneficiaries, as well as for the Parts C and D organizations that provide important medical care and prescription drug coverage for them. We propose to limit relief to these major disasters since they affected large regions of the United States, leading to issues accessing medical care and prescription drug coverage. Further, plans

complete many preventive screenings at the end of the calendar year so disasters in this period may have an inordinate impact on 2019 Star Ratings. Finally, beneficiaries responding to CMS surveys early in 2018 will be reflecting predominately on events in late 2017 so these disasters may impact survey results.

We are also proposing that contracts operating solely in Puerto Rico (i.e., with service areas limited to Puerto Rico) be treated as affected contracts without further analysis because of the extent of damage in that area. Several areas remain without electricity in Puerto Rico and there are reports of significant population movement as a result of Hurricane Maria that are unique in scope to Puerto Rico compared to the other Individual Assistance areas designed by FEMA during 2017. Those contracts meet the other proposed criteria. As noted below, we also propose adjustments that are specific to contracts operating in Puerto Rico.

Contracts that do not meet the definition of an “affected contract” or the parameters discussed below would not be eligible for any adjustments under this policy.

CAHPS Adjustments:

For CAHPS, CMS is proposing to take into account the effects of these disasters in the following ways for affected contracts:

- (1) For contracts that operate solely in Puerto Rico, we propose to make the 2018 survey optional, given substantial ongoing issues contacting enrollees in Puerto Rico, the continuing loss of electricity in several areas, etc. If a contract in Puerto Rico chooses not to administer the 2018 survey, it would receive the contract’s 2018 CAHPS Star Ratings for the 2019 Star Ratings. If a contract in Puerto Rico chooses to administer the 2018 survey, it would receive the higher of the 2018 or 2019 Star Ratings (and corresponding measure ratings) for each CAHPS survey measure (including the annual flu vaccine measure). We are proposing this relief because of concerns that the adjustment to the 2018 survey results may not capture all possible impacts of the major disasters given the possibility of unusual response patterns due to the scope of the disasters, and we do not know what performance would have been observed in the absence of these disasters.
- (2) For other affected contracts, the MA organization would be required to administer the 2018 CAHPS survey unless the contract requested and we approved an exception because a substantial number of their enrollees have been displaced due to a FEMA-designated disaster in 2017 and it would be practically impossible to contact the required sample for the survey. Our proposed adjustment is two-fold: an adjustment for affected contracts and an additional adjustment for affected contracts with more than 25% of enrollees residing in FEMA-designated Individual Assistance areas.

The CAHPS scores for affected contracts would be adjusted to account for the impact of the disaster. A CAHPS respondent would be considered to reside in a FEMA-designated

disaster area if the respondent lives in a FEMA-designated Individual Assistance area at the time of the survey. This adjustment for non-Puerto Rico contracts would pool across contracts to develop separate estimates for each disaster. Unlike the usual procedures for case-mix adjustment, the coefficients would be estimated in a difference-in-differences manner (controlling for the previous year's scores in the same contracts). In particular, the estimated effect of a disaster would be the mean CAHPS score change from the previous year in affected counties minus the mean CAHPS score change from the previous year in unaffected counties, both estimated from only the contracts that have sample in both the affected counties and unaffected counties. This approach distinguishes changes that were specific to the affected areas from overall trends in CAHPS scores and only adjusts for the change in CAHPS scores that is specific to the affected areas. We propose to only adjust if the effects are in a consistent direction and adjustment is advantageous to contracts.

We further propose that affected contracts with more than 25% of beneficiaries residing in affected Individual Assistance areas at the time of the disaster would receive the higher of the 2018 or the adjusted 2019 Star Ratings (and corresponding measure ratings) for each CAHPS measure (including the annual flu vaccine measure). We chose the 25% cutoff based on analysis of the distribution of the data for the percent of enrollees per contract in the Individual Assistance areas at the time of the disasters. The 25% was chosen based on the distribution since no contracts were near this cut off and it would avoid including contracts with very few enrollees impacted. The measure-level scores for contracts with very few enrollees impacted should not be adversely affected by these disasters.

Further, contracts operating solely in Puerto Rico would be excluded from 2019 Star Ratings cut point calculations for CAHPS measures. Cut points for contracts operating solely in Puerto Rico would have their cut points calculated using only data collected in 2018.

HOS Adjustments:

For the HOS survey, we propose to follow similar procedures as CAHPS:

- (1) For contracts solely operating in Puerto Rico, we propose to make the 2018 HOS survey optional, given substantial ongoing issues contacting enrollees in Puerto Rico, the continuing loss of electricity in several areas, etc. If a contract in Puerto Rico chooses not to administer the 2018 HOS Cohort 21 Baseline and Cohort 19 Follow-up surveys, we propose that it would receive the previous year's Star Ratings (and corresponding measure ratings) for HOS and HEDIS-HOS measures in the 2020 Star Ratings. If a contract in Puerto Rico chooses to administer the 2018 HOS surveys, we propose to

assign it the higher of the current or previous year's Star Ratings (and corresponding measure ratings) for each HOS and HEDIS-HOS measure in the 2020 Star Ratings.

- (2) For affected contracts, the MA organization would be required to administer the 2018 HOS surveys unless the contract requests and CMS approves an exception because a substantial number of the contract enrollees have been displaced due to a FEMA-designated disaster in 2017 (i.e., Hurricanes Harvey, Irma, Maria, or the California wildfires) and it would be practically impossible to contact the required sample for the survey.

The HOS scores for affected contracts would be adjusted to account for the impact of the disaster. A HOS respondent would be considered to reside in a FEMA-designated disaster area if the respondent lives in a FEMA-designated Individual Assistance area at the time of the survey. The adjustment for non-Puerto Rico contracts would pool across contracts to develop separate estimates for each disaster. Unlike the usual procedures for case-mix adjustment, the coefficients would be estimated in a difference-in-differences manner (controlling for the previous year's scores in the same contracts). We propose to only adjust if the effects are in a consistent direction and adjustment is advantageous to contracts.

We further propose that affected contracts with more than 25% of beneficiaries residing in affected Individual Assistance areas at the time of the disaster would receive the higher of the current or previous year's Star Rating for each HOS and HEDIS-HOS measure (and corresponding measure rating) in the 2020 Star Ratings. We chose the 25% cutoff based on analysis of the distribution of the data for the percent of enrollees per contract in the Individual Assistance areas at the time of the disasters. Please see discussion above for more details.

Our proposal for cut points for non-CAHPS measures is addressed on page 48 below.

HEDIS Adjustments:

For HEDIS, contracts operating solely in Puerto Rico would have the option to report "NA" for all HEDIS measures; all other affected contracts would be required to report HEDIS data to CMS unless the MA organization of an affected contract requests and receives from CMS an exception given the inability to obtain both administrative and medical record data. All contracts in disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review. If a Puerto Rico contract reports an "NA" for any of the Star Ratings measures, the contract would receive the 2018 Star Ratings for that measure. If a Puerto Rico contract chooses to report any of the HEDIS measures, the contract would receive the higher of the 2018 or 2019 Star Rating (and corresponding measure rating) for each HEDIS measure reported. For affected contracts with more than 25% of beneficiaries in a FEMA-designated Individual Assistance area at the time of the disaster, we would take the higher of the

2018 or 2019 Star Ratings (and corresponding measure rating) for each HEDIS measure. Please see discussion above for the selection of the 25% cutoff.

Other Star Ratings Measure Adjustments:

We propose that for all other measures for affected contracts with at least 25% of beneficiaries in a FEMA-designated Individual Assistance area at the time of the disaster, we would take the higher of the 2018 or 2019 measure Star Rating (and corresponding measure rating).

We propose to exclude from this adjustment policy the following measures: Part C Call Center – Foreign Language Interpreter and TTY Availability; Part D Call Center – Foreign Language Interpreter and TTY Availability; Part C Plan Makes Timely Decisions about Appeals; Part C Reviewing Appeals Decisions; Part D Appeals Auto-Forward; and Part D Appeals Upheld. We propose to exclude these specific measures from the proposed adjustments for affected contracts because these measures and the underlying performance are completely in the plan’s control; we believe therefore that there should be no impact from the declaration of a disaster on plan performance in these areas.

Currently, contracts must have data for at least half of the attainment measures used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For contracts that revert back to the 2018 Star Rating for a particular measure, we propose that measure would be excluded in the measure count for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure for the 2019 and 2020 Star Ratings. That is, we would follow our usual rule where to receive a Star Rating in the improvement measures a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures.

Cut Points for Non-CAHPS Measures:

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to all the measures’ numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. We propose to exclude from this clustering algorithm the numeric values for affected contracts with 60% or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the disaster. We are proposing that these contracts be excluded to ensure that any impact of the disaster on their measure-level scores would not have an impact on the cut points for other contracts. However, these cut points calculated for all other contracts would be used to assess these contracts’ 2019 measure Star Ratings (which would be compared to the contracts’ 2018 measure Star Ratings to determine which is higher, and therefore used for the impacted contracts’ 2019 Star Ratings calculations, per above).

Similarly, we propose that affected contracts with 60% or more of their enrollees impacted would also be excluded from the determination of the performance summary and variance thresholds for the Reward Factor. However, these contracts would still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

For the measures using the 25% cutoff for reverting to last year's measure-level stars, if the affected contract did better for that measure in the prior year, we chose that cutoff based on analysis of the data. Contracts tend either to have very few enrollees impacted or most of their enrollees impacted. If one out of four enrollees were impacted during the period of the year when the disaster hit, there is a small chance that scores may have been impacted. If very few enrollees in a contract lived in impacted areas during the disaster period, the measure-level scores should not be impacted. The selection of the exclusion of numeric measures scores from contracts with 60% or more enrollees impacted from the determination of the cut points was chosen through an analysis of the distribution of the percent of enrollees impacted by contract across all contracts impacted. The 60% was chosen since there was a break in the distribution. Our approach in selecting 60% is conservative in case scores are impacted in contracts where a clear majority or all of the enrollees are impacted. We welcome comments on these policies to account for the potential impact on the 2019 Star Ratings from the widespread disasters in 2017.

2019 CMS Display Measures

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that are transitioned from inclusion in the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed solely for informational purposes. Organizations and sponsors will have the opportunity to preview the data for their display measures prior to release on CMS' website. Data for measures moved to the display page continue to be collected and monitored; poor scores on display measures may reveal underlying compliance and performance issues that are subject to enforcement actions by CMS. All 2018 display measures will continue to be shown as display measures on CMS.gov in 2019 unless noted below.

CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Other display measures may be provided as information only.

New 2019 Display Measure

- **Plan Makes Timely Decisions about Appeals (Part C).** We are proposing for display a new appeals measure which includes cases dismissed by the IRE because the plan has subsequently approved coverage/payment (using 2017 data). Currently, we exclude all cases dismissed/withdrawn by the IRE from this measure. However, plans' performance may be artificially improved as a result, especially if the dismissal were directly related to the plans' (untimely) approval. Inclusion of cases where the plan has subsequently

approved for coverage/payment that are dismissed or withdrawn at the IRE level could provide a more accurate assessment of plans' timeliness in their Part C appeals processing. We propose to include this modified measure on the 2019 and 2020 display pages; we intend also to add this revised measure to the 2021 Star Ratings. At that time the current "Plan Makes Timely Decisions about Appeals" measure would be retired.

Changes to Existing Display Measures

- Hospitalizations for Potentially Preventable Complications (Part C).** This measure is a risk-adjusted measure that assesses the rate of hospitalization for complications of chronic and acute ambulatory care-sensitive conditions. The measure is therefore an important indicator of care coordination, where hospitalizations represent a failure to prevent a serious complication. However, concerns raised by experts and stakeholders have led NCQA to consider updating the specifications to include hospital stays that are considered "observation stays" to improve completeness of the measure. That is, observation stays can also represent a failure to prevent serious complications. Therefore we propose to retain this measure as a 2019 display page measure. We will propose through rulemaking moving it to Star Ratings with a weight of 1 for the 2022 Star Ratings. In subsequent years, we intend to weight it 3 as an outcomes measure. Please refer to the NCQA HEDIS 2018 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications, as well as to more recent communications from NCQA as to updates in specifications.
- High Risk Medication (Part D).** The PQA High Risk Medication (HRM) measure calculates the percentage of Medicare Part D beneficiaries 65 years and older who received two or more prescription fills for the same HRM drug with a high risk of serious side effects in the elderly. This measure would remain on the display page for 2019 (based on 2017 data), and as noted in the 2018 Call Letter, we propose to use the updated PQA HRM drug list for that display. We also propose to adopt a specification change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.
- Drug-Drug Interactions (DDI) (Part D).** The PQA DDI measure is the percent of Part D beneficiaries who received a prescription for a target medication during the measurement period who were also dispensed a concurrent prescription for a contraindicated medication with or subsequent to the initial prescription. As discussed in the 2018 Call Letter, the PQA updated the DDI measure drug list. We propose to implement the revised list for the 2019 display measure using 2017 performance and PDE data.
- Antipsychotic Use in Persons with Dementia (APD) (Part D).** The PQA APD measure is the percentage of Part D beneficiaries 65 years or older with dementia who received prescription fills for antipsychotics without evidence of a psychotic disorder or related

condition. For the 2017 measurement year, the APD measure includes an overall measure rate and breakouts for community-only (COMM) residents and long-term nursing home (LTNH) residents. We propose to display the rates for the two population breakouts on the 2019 display page (in addition to the overall APD rate currently displayed). We will assess adding the APD measure to the Star Ratings in the future, which would be proposed through rulemaking.

- **Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D).** PQA's opioid measures examine multi-provider and/or high dosage opioid use among individuals 18 years and older without cancer and not in hospice care.

The PQA's Measure Update Panel and Quality Metrics Expert Panel approved non-substantial changes to the measures. First, each rate will have a separate title and the term "morphine equivalent dose" will be changed to "morphine milligram equivalents."

Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer.

Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

Additional changes made by the PQA to these measures include:

1. The opioid treatment period for Measures 1 and 3 must be 90 days or more.
2. ICD-9 and ICD-10 codes will be changed to align with the American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI) cancer value set.
3. All buprenorphine products indicated for medication-assisted treatment (MAT) will be excluded.

As mentioned in the 2018 Call Letter, we planned to implement these changes beginning with the 2017 Patient Safety reports. In response to the 2018 Call Letter, several commenters felt that Measure 3 mirrored the criteria used in the Overutilization Monitoring System (OMS), whereas the other two measures did not. Therefore, based on that feedback, we propose to add only the OHDMP measure to the 2019 Part D display page (using 2017 data). All three measures will continue to be reported to Part D plan sponsors through the Patient Safety reports.

In response to the 2018 Call Letter, some commenters suggested that the PQA lower the threshold in the opioid measures to align with the March 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain²³ and the revised OMS criteria thresholds. Due to the timing of their measure development and NQF endorsement process, the PQA has not yet revised their measures. It is our understanding that the PQA will discuss additional changes in 2018 along with a timeline for testing potential modifications. We will monitor updates to the measure specifications made by the PQA and consider for adoption after advance notice through a future Call Letter. CMS will re-assess including these measures in the Star Ratings once the PQA updates their measures to better align with the CDC Guideline and/or OMS.

Note, additional proposals to the Medicare Part D opioid overutilization policy are discussed within the Improving Drug Utilization Review Controls in Medicare Part D section.

- **Transition Monitoring (Part D).** Since 2015, CMS has produced two display measures using the results from the Transition Monitoring Program Analysis (TMPA). We propose to no longer display two separate contract-level measures, one for drugs within the classes for clinical concern and one for all other drugs. Instead, the results would be consolidated into one failure rate and display measure. This change aligns with the display measure for the Formulary Administration Analysis (FAA). Previously, the data was displayed as a percentage with one decimal place. In order to provide the most accurate results, beginning with the 2019 display measure, the data will be displayed as a percentage with two decimal places.
- **Formulary Administration Analysis measure (Part D).** This display measure, added in 2018, uses the results of the FAA used by CMS to evaluate whether Part D sponsors are appropriately adjudicating drug claims consistent with Part D requirements and sponsors' CMS-approved benefits.

Previously the data for this measure was displayed as a percentage with one decimal place. In order to provide the most accurate results, beginning with the 2019 display measure, the data will be displayed as a percentage with two decimal places.

- **Timely Effectuation of Appeals (Part D).** This measure is defined as the percent of appeals requiring effectuation that the plan effectuated in a timely manner (timely is defined as effectuation of the decision within one day for expedited appeals, and effectuation of the decision within three days for standard appeals). If the IRE does not receive a notice of effectuation before the report generation date, the IRE will count the effectuation as non-timely. Currently, this measure includes all data applicable to the time period being reported as of the date the report is generated by the IRE. Data may change

²³ See <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

based on the report date. Discrepancies may also result if the IRE received the effectuation notice late, even though the plan's effectuation was timely. Reopenings of appeals may extend into the following contract year which can impact effectuation data. In order to allow for these factors, we propose to modify this measure to be defined as all appeals received by the IRE in the defined timeframe. To account for reopenings and appeals that straddle the contract year, all decisions from this time period will be included up to May 1st of the following contract year. For example, the CY 2019 display measure's timeframe would be IRE cases received from 1/1/18 – 12/31/18 with decisions made before 5/1/19. Effectuations for appeals decided on or after May 1, 2019 that correspond to an appeal received 1/1/18 – 12/31/18 will not be reflected in these data and the timeliness of the reconsideration will be used. Additionally, we propose to exclude the results of appeals that occur beyond Level 2 (i.e., Administrative Law Judge or Medicare Appeals Council appeals) from this measure.

Display Measures being Retired

- **Enrollment Timeliness (Part C and D).** The measure assesses the timeliness of enrollment transactions using the number of plan generated enrollment transactions submitted to CMS within 7 calendar days of the application date and the total number of plan generated enrollment transactions submitted to CMS. Beginning in 2012, CMS has been displaying and monitoring the values of enrollment timeliness. Overall, contracts are receiving extremely high rates for this measure (96 percent on average). For the 2019 Star Ratings, we propose to discontinue the display of the measure. We encourage contracts to continue to track their enrollment timeliness.
- **Appropriate Monitoring of Patients Taking Long-term Medications and Asthma Medication Ratio (Part C).** NCQA removed the Medicare population from these measures. Therefore, we propose to discontinue display of these measures in 2019.

Forecasting to 2020 and Beyond

The following describes potential changes to existing measures and potential new measures. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings for 2020 or later. As we add new measures, CMS will consider which measures are topped out or have little variation across contracts to transition them to the display page.

As proposed in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P) proposed rule, which was published in the Federal Register on November 28, 2017 (82 FR 56336), we intend that changes to the measures for the 2021 Star Ratings and beyond would be governed by the regulations ultimately finalized pursuant to that proposed rule. We proposed there that new

measures or measures with substantial changes would be proposed through the Federal Register rulemaking process for the 2021 Star Ratings or beyond (82 FR 56378) while the Advance Notice/Call Letter process would continue to be used for the 2019 and 2020 Star Ratings.

Potential Changes to Existing Measures

- **Controlling High Blood Pressure (Part C).** Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association, NCQA is evaluating potential updates to the Controlling High Blood Pressure measure for HEDIS 2019. Additionally, NCQA is exploring modifications to the denominator criteria of the measure to improve feasibility and reduce burden, and potential administrative approaches for meeting numerator criteria.
- **Plan All-Cause Readmissions (Part C).** NCQA is exploring several revisions to the HEDIS Plan All-Cause Readmissions measure based on feedback they have received from the field and stakeholders. These revisions may impact the definition of the denominator, numerator, and risk adjustment model for data collected in 2018. The specific revisions they are exploring include: 1) Inclusion of observation stays in the denominator and numerator; 2) revising the measure denominator to be the overall plan population as opposed to index hospital admissions; and 3) adding death in the measurement year as a possible factor in the risk adjustment model for this measure. NCQA is also considering stratifying this measure to separate those individuals with high frequency of index hospital stays. These changes are pending NCQA's analyses. CMS is also proposing to combine the rates for ages 18-64 and ages 65+ for the revised PCR measure. The revised measure would use NCQA's new recommendation of 150 as the minimum denominator value for data to be used. The revised measure would be part of the display page for 2019 and 2020 before moving to the 2021 Star Ratings with a weight of 1 the first year and a weight of 3 thereafter. The current Plan All-Cause Readmissions measure would remain in the Star Ratings through 2020.

NCQA is also considering a possible stratification of the Plan All-Cause Readmissions measure to identify the percentage of hospital discharges that result in an unplanned hospital readmission during or after a skilled nursing facility stay for MA contracts. As noted below an alternate strategy would be to report readmissions from skilled nursing facilities as a new measure. CMS welcomes feedback on the value of stratified rates as well as the appropriateness of these revisions.

- **Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C).** NCQA modified this measure to include data on the use of MAT in the denominator and numerator components of the measure. This measure will continue to be included on the display page.

CMS would also welcome feedback to share with NCQA on the appropriateness of adding certain specific behavioral health diagnostic codes to this measure. Potential diagnostic codes might include self-harm, asphyxiation, overdose, and poisoning conditions.

- **Telehealth and Remote Access Technologies (Part C).** CMS solicited feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare-covered telehealth services and/or as provided by the MAO as an MA supplemental benefit, as eligible encounters in various Part C quality measures. For example, some HEDIS measures require a visit for the denominator, numerator, or exclusion, and we sought comment on whether telehealth and/or remote access technology encounters should be counted as eligible encounters for the relevant portion of the measure, that is whether for counting as part of a measure, such telehealth and/or remote access technology visits are equivalent to (reasonable replacements for) in-person visits for relevant clinical areas. CMS would welcome feedback to share with NCQA on feasibility of and strategies for addressing telehealth services especially regarding the following measures that are reported by Medicare contracts:
 - *Use of Spirometry Testing in the Assessment and Diagnosis of COPD*
 - *Adults' Access to Preventive/Ambulatory Health Services*
 - *Controlling High Blood Pressure*
 - *Comprehensive Diabetes Care*
- **Cross-Cutting Exclusions for Advanced Illness (Part C).** NCQA is evaluating the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected HEDIS measures. While HEDIS measures are designed to compare the quality of care provided to general populations or disease-specific care provided to individuals with a chronic condition, these measures may not be clinically appropriate for certain individuals with advanced illness and may overlook the quality issues that are specific to these patients. NCQA is therefore assessing the need for having exclusions for selected HEDIS measures for patients with advanced illness where providing certain treatments and services may not be appropriate. NCQA is exploring which specific illnesses and healthcare utilization may warrant an exclusion, and to which measures the exclusion should be applied. If approved, updates to HEDIS measures for any additional exclusions would be incorporated in HEDIS 2019.
- **Medication Adherence (ADH) for Cholesterol (Statins) (Part D).** The PQA updated this measure for 2018 to exclude beneficiaries with ESRD. We propose to apply this exclusion to the 2020 Star Ratings (based on 2018 data), in the same manner that the ESRD exclusion is currently applied to the Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Statin Use in Persons with Dementia measures.

- **Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D).** The PQA updated this measure for 2018 to include a new denominator exception as follows:
For patients eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program:
 - Exclude them from the denominator if they did not receive a CMR within this timeframe.
 - Include them in the denominator and the numerator if they received a CMR within this timeframe.

For example, if the patient was enrolled in the MTM program and eligible for CMR on November 2 of the measurement year, the patient would not be included in the denominator if the CMR were not received as of December 31, because there would have been fewer than 61 days of continuous eligibility. If the patient received a CMR by December 31, the patient would be included in the denominator and the numerator.

We plan to propose to apply this denominator exception to the 2020 Star Ratings (based on 2018 data).

- **Center for Medicare and Medicaid Innovation Model Tests.** The MA Value-Based Insurance Design (MA-VBID) model test is an opportunity for MAOs to offer supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. The Part D Enhanced MTM model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. We note that some stakeholders have expressed concern regarding the potential for the improvements in quality resulting from these tests to adversely influence the Star Ratings of contracts that are ineligible to participate (or that include some PBPs ineligible to participate). CMS' goal is to not penalize participants or non-participants in either model.

For the MA-VBID Model test, CMS is considering the option of excluding VBID-participants' data when calculating the cut points for relevant measures. CMS has waived the MTM requirements under Section 1860D-4(c)(2) and 42 CFR 423.153(d) and the Part D Reporting Requirements for MTM for Part D plans participating in the Part D Enhanced MTM Model. However, Part D sponsors with plans participating in this model must establish MTM programs in compliance with current requirements and reporting data for the remaining plans under each Part D contract. Therefore, the MTM Program CMR Completion Rates will be calculated using available plan-reported data from the remaining plans under the Part D contract. CMS plans to analyze if this approach significantly advantages or disadvantages Enhanced MTM model participants and evaluate potential adjustments as necessary, including the

establishment of different cut points for model participants or to case-mix adjust scores for the purpose of determining cut points.

Potential New Measures for 2020 and Beyond

- **Transitions of Care (Part C).** CMS appreciates feedback received about a new HEDIS Transitions of Care measure with four indicators:
 1. *Notification of Inpatient Admission:* Documentation of primary care practitioner notification of inpatient admission on the day of admission or the following day.
 2. *Receipt of Discharge Information:* Documentation of primary care practitioner receipt of specific discharge information on the day of discharge or the following day.
 3. *Patient Engagement After Inpatient Discharge:* Documentation of patient engagement (e.g., office visits, visits to the home, or telehealth) provided by primary care practitioner within 30 days after discharge.
 4. *Medication Reconciliation Post-Discharge* (which is currently a HEDIS measure): Documentation of medication reconciliation within 30 days of discharge.

The intent of the measure is to improve the quality of care transitions from an inpatient setting to home. We plan to propose to include this measure with the four indicators on the 2020 display measure for possible inclusion in the 2022 Star Ratings.
- **Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C).** CMS is considering use of a new HEDIS measure assessing follow-up care provided after an emergency department visit for patients with multiple chronic conditions. Patients with multiple chronic conditions are more likely to have complex care needs and follow-up after an acute event, like an emergency department visit, can help to prevent the development of more severe complications. The developer, NCQA, is evaluating what timeframe (e.g., 7, 14, or 30 days post-ED visit) and what types of follow-up (e.g., face-to-face office visits, telephone or web interactions, or visits to the home) are appropriate. We plan to propose to include this measure on the 2020 display page for possible inclusion in the 2022 Star Ratings.
- **Care Coordination Measures (Part C).** Effective care coordination, including care transition, contributes to improved health outcomes (http://www.qualityforum.org/200cNews_And_Resources/Press_Releases/2012/NQF_Endorses_Care_Coordination_Measures.aspx). CMS believes that 5-star MA contracts perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plan care coordination activities, however, is based largely on anecdotes and discussions with high performing plans, as well as on data from CAHPS surveys, which reflect enrollees' experiences with the care they receive.

CMS is working to expand efforts to better evaluate a plan's success at effective care coordination. We have identified potential new care coordination measures and are currently testing them for possible future implementation. We will provide more details at a later date.

- **Opioid Overuse (Part C).** For HEDIS 2018, NCQA is collecting data on Use of Opioids at High Doses and Use of Opioids from Multiple Providers. These measures are adapted from the PQA's opioid measures (discussed above). We welcome feedback from stakeholders about the value of including these Part C measures on the display page, given the similar Part D measures that constitute data for Patient Safety reports back to plans and which may also be reported on the display page.

For HEDIS 2019, NCQA will be testing a new measure concept that addresses members who were previously naïve to opioids who become long-term or “chronic” users. In addition to understanding the feasibility and utility of reporting this measure concept at the health plan level, testing of this concept will focus on exploring different definitions of “opioid naïve” and “chronic use,” as well as identifying populations that warrant exclusion from the measure. NCQA is also considering testing of a second measure concept that addresses the concurrent prescription of opioids and central nervous system (CNS) depressants. If this concept is pursued further, testing would focus on understanding the feasibility and utility of the measure, identifying populations to be excluded, and defining both the list of drugs included and the concurrent overlap period.

Since similar measures are being or have been developed as Part D measures, CMS is interested in feedback not only on the measure concepts, but also whether and how MA contracts have a unique role and responsibility, in contrast to stand-alone prescription drug plans, regarding opioid use, misuse, abuse and/or dependency, none of which would be captured by Part D measures. CMS would also be interested in feedback on the value of these measure concepts and how to weigh that value in contrast to any burden from measurement in this area.

- **Assessment of Care for People with Multiple High-Risk Chronic Conditions (Part C).** NCQA is considering a new measure concept that would adapt the current Care for Older Adults measure by expanding the number of indicators and broadening the populations covered by the set of measures. Care for Older Adults currently has four indicators and is reported by MA Special Needs Plans (SNPs) only. The new measure, Assessment of Care for People with Multiple High-Risk Chronic Conditions, would apply to all Medicare plans and would target the population of people with two or more high-risk chronic conditions. Using the same denominator introduced in the HEDIS 2018 first-year measure Follow-Up After Emergency Department Visit for People with Multiple High-Risk Chronic Conditions, the new measure would assess the percentage of members who had an expanded assessment during the measurement year. The following components may be included in the measure: physical function assessment, cognitive function assessment, pain assessment, fall risk

assessment, goals of care discussion, and advance care planning. The measure concept is currently undergoing testing to assess feasibility, alignment with current practice, and gaps in care. CMS welcomes feedback about this expansion of the number of indicators and broadening the product line beyond Medicare SNPs.

- **Depression Screening and Follow-Up for Adolescents and Adults (Part C).** NCQA developed a measure assessing the percentage of patients age 12 and older who were screened for depression using a standardized assessment tool, such as the PHQ-9, and if positive, received appropriate follow-up care within 30 days of the positive screen. This measure is part of NCQA's new effort to collect data using an Electronic Clinical Data System (ECDS). Depending on the results during the first year of implementation, CMS may consider this measure for the display page and Star Ratings in the future.
- **Unhealthy Alcohol Use Screening and Follow-Up (Part C).** NCQA adapted the provider-level NCQA measure, Unhealthy Alcohol Use: Screening & Brief Counseling (NQF 2152), for health plan reporting. The intent of this measure is to increase the use of alcohol screening and brief intervention, which is recommended by the USPSTF for adults 18 and older. A number of health plans have been helping to test and evaluate performance for the adapted measure and to gather information on feasibility of implementation at the health-plan level. This measure is part of NCQA's new effort to collect data using an ECDS. Depending on the results during the first year of implementation, CMS may consider this measure for the display page and Star Ratings in the future.
- **Readmissions from Post-Acute Care (Part C).** NCQA is pursuing opportunities to measure acute facility readmissions during or following a skilled nursing facility (SNF) stay for Medicare beneficiaries. Eleven percent of beneficiaries require skilled nursing following an acute facility stay. A readmission event during or after a SNF stay may be the result of inadequate provider communication during care transitions and poor discharge planning. NCQA is exploring the development of a new measure or, as noted above, the potential adaption of the Plan All-Cause Readmissions (PCR) measure to evaluate acute facility readmissions among Medicare beneficiaries during or after a SNF stay. If approved, the new measure or revisions to the current PCR measure would be included in HEDIS 2019. CMS welcomes feedback on the feasibility, utility, and burden of such a modification/stratification or new measure.
- **Adult Immunization Measure (Part C).** For HEDIS 2018, NCQA added the Pneumococcal Vaccination Coverage for Older Adults measure to the ECDS reporting domain. Measures in the HEDIS ECDS domain are calculated using electronic data from administrative claims, electronic medical records, case management systems and registries. For HEDIS 2019, NCQA will build off the pneumococcal measure and evaluate the relevance, scientific soundness, and feasibility of a composite measure for HEDIS that

assesses the receipt of routine adult vaccinations. The measure developer is focusing on four specific vaccines: influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccine; herpes zoster vaccine; and pneumococcal vaccine. If approved, the new measure would be included in HEDIS 2019. CMS would welcome feedback on the feasibility, value of, and burden/reduction in burden of this change in data source. Depending on results of implementation, CMS will determine the use of this new composite measure for the display page and Star Ratings for the future.

- **Anxiety (Part C).** NCQA is exploring the feasibility and acceptability of developing quality measures assessing care for those with anxiety disorders for inclusion in HEDIS. The approach is to conduct feasibility assessments and evidence reviews, which includes the consideration of clinical practice guidelines, evidence-based treatment, and symptom monitoring tools for all types of anxiety disorders. Recognizing the high prevalence of co-occurring anxiety and depression, NCQA is assessing the need for new anxiety quality measures or amended depression quality measures. Any new anxiety quality measures or changes for the depression measures would be included in HEDIS 2020 at the earliest. CMS welcomes feedback about the value and burden of measuring anxiety and of amending depression quality measures to address anxiety for inclusion in display and ratings measure in the future.
- **Polypharmacy Measures (Part D).** The PQA developed and endorsed three measures that identify potentially harmful concurrent drug use or polypharmacy. CMS reviewed these measures for potential inclusion in Patient Safety reporting, display page, or Star Ratings in the future.

Polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH): This measure assesses the percentage of individuals 65 years and older with concurrent²⁴ use of two or more unique ACH medications. To be included in the denominator, a beneficiary must have at least two fills of the same ACH medication with unique dates of service during the treatment period. Any beneficiary with a hospice indicator during the measurement year was excluded. Lower rates represent better performance. We tested the PQA specifications using 2016 PDE data as of May 6, 2017. We adjusted the measure for member-years and evaluated the number of contracts with greater than 30 member-years in the denominator. There were 743 active Part D contracts in 2016 (671 MA-PDs, 67 PDPs, and 5 employer direct contracts). Of the 743 active Part D contracts in 2016, eight contracts had no members eligible for the Poly-ACH measure (N=735). There were 621 MA-PD and PDP contracts that had greater than 30 member-years in the denominator, and about 16% of MA-PDs and 10% of PDP

²⁴The days of concurrent use is the sum of the number of days with overlapping days supply of the target medications. Concurrent use is defined as overlapping days for 30 or more (cumulative) days for both polypharmacy measures.

contracts did not meet the greater than 30 member-year denominator criterion. The table below provides the Part D contract distributions by contract type and member-year (M-Y) criterion.

Table 16: Distribution of the Poly-ACH Measure Rates, Part D, 2016

Part D Contracts			Percentiles							
Type	Group	Count	Min	10%	25%	50%	75%	90%	95%	Max
All		735	0.0%	4.3%	6.0%	7.3%	10.1%	13.9%	17.5%	51.3%
MA-PD	All	667	0.0%	4.1%	5.9%	7.3%	10.3%	14.4%	17.6%	51.3%
PDP	All	63	0.0%	5.8%	6.6%	7.6%	9.4%	11.3%	12.2%	20.0%
MA-PD	>30 M-Y	561	0.0%	5.0%	6.1%	7.3%	9.9%	13.0%	15.7%	30.8%
PDP	>30 M-Y	60	5.0%	5.8%	6.6%	7.6%	9.3%	11.1%	12.1%	12.7%

As the PQA measure manual notes, medication combinations in this measure are those for which serious adverse effects have been reported among older adults. It is generally accepted that a high burden of anticholinergic use is consistently associated with cognitive impairment and increased risk of dementia in older adults. The rate distributions show variability in use across both MA-PD and PDP contracts suggesting an opportunity for improvement to reduce the use of multiple concurrent ACH medications within Part D enrolled older adults. We propose to begin reporting the Poly-ACH measure in the Patient Safety reports for the 2018 measurement year. We plan to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). We will consider this measure for the 2023 Star Ratings (2021 data), which would be proposed through rulemaking.

Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS): This measure assesses the percentage of individuals 65 years and older with concurrent use of three or more unique CNS-active medications. To be included in the denominator, a beneficiary must have at least two fills of the same CNS-active medication with unique dates of service during the treatment period. Any beneficiary with a hospice indicator during the measurement year was excluded. Lower rates represent better performance.

We also tested the Poly-CNS PQA measure specifications using 2016 PDE data. We adjusted the measure for member-years and evaluated the number of contracts with greater than 30 member-years in the denominator. A total of 736 out of 743 Part D contracts in 2016 (668 MA-PDs, 63 PDPs, and 5 employer direct contracts) had a beneficiary who met the eligibility requirements for the Poly-CNS measure. When the greater than 30 member-year denominator criterion was applied, the total number of MA-PD and PDP contracts decreased to 698. Over 5% of MA-PD contracts and 9% PDP contracts were excluded. However, the distributions did not change, so those rates are not shown in the table below.

Table 17: Distribution of the Poly-CNS Measure Rates, Part D, 2016

Part D Contracts		Percentiles							
Type	Count	Min	10%	25%	50%	75%	90%	95%	Max
All	736	0.0%	4.8%	5.9%	7.7%	11.5%	16.9%	20.3%	44.4%
MA-PD	668	0.0%	4.7%	5.9%	7.7%	11.7%	17.0%	20.7%	44.4%
PDP	63	0.0%	5.4%	6.4%	7.8%	10.2%	14.3%	17.6%	28.5%

According to the American Geriatrics Society, there is moderate evidence to avoid concurrent use of three or more CNS agents in older adults due to an increased risk of falls and possible fractures. Based on the analysis, variability exists across Part D contracts on the use of multiple concurrent CNS medications. Again, CMS believes this measure represents an opportunity to identify and reduce concurrent use of multiple CNS medications and improve the health of Medicare Part D enrollees.

We propose to begin reporting the Poly-CNS measure in the Patient Safety reports for the 2018 measurement year. We plan to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). We will consider proposing this measure through rulemaking for the 2023 Star Ratings (2021 data).

We also plan to re-evaluate the utility of reporting the HRM Patient Safety reports and display measure since many of the same drugs are included in both the Poly-ACH and Poly-CNS measures.

Concurrent²⁵ Use of Opioids and Benzodiazepines: This measure assesses the percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.

We tested the measure specifications using 2016 PDE data. We adjusted the measure for member-years and evaluated the number of contracts with greater than 30 member-years in the denominator. A total of 680 Part D contracts met the eligibility requirements for the Concurrent Use of Opioids and Benzodiazepine measure. The rate associated with the top 5% of PDP contracts was 42.9% while MA-PD contracts had a higher rate of 51.4%.

²⁵ Concurrent use is defined as an overlapping supply for an opioid and a benzodiazepine for 30 or more cumulative days.

Table 18: Distribution of the Concurrent Use of Opioids and Benzodiazepines Measure Rates, Part D, 2016

Contracts		Percentiles							
Type	Count	Min	10%	25%	50%	75%	90%	95%	Max
All	680	4.1%	13.2%	16.5%	20.9%	25.3%	30.1%	33.7%	51.4%
PDP	61	9.6%	13.2%	15.7%	21.1%	25.6%	31.0%	35.5%	42.9%
MA-PD	614	4.1%	13.2%	16.5%	20.9%	25.2%	30.1%	33.7%	51.4%

We propose to begin reporting the Concurrent Use of Opioids and Benzodiazepines measure in the Patient Safety reports for the 2018 measurement year. We plan to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). We will consider this measure for the 2023 Star Ratings (2021 data) pending rulemaking. However, we seek feedback if there are concerns with adding this measure for the following reasons: (1) the Overutilization Monitoring System (OMS) identifies potential opioid overutilizers who are also receiving a benzodiazepine, and (2) a proportion of the concurrent opioid and benzodiazepines users will already be identified within the Poly-CNS measure.

Note: see additional proposals within the Improving Drug Utilization Review Controls in Medicare Part D section.

- **Additional PQA Medication Adherence Measures (Part D).** We evaluated two additional PQA endorsed medication adherence measures within the Medicare Part D population using 2016 PDE data. We adjusted the measure for member-years. There were 743 active Part D contracts in 2016 (671 MA-PDs, 67 PDPs, and 5 employer direct contracts).

Adherence to Non-Warfarin Oral Anticoagulants (ADH- NWOA): This measure is defined as the percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement period. The PQA measure manual states that adherence to all anticoagulants is important, and adherence to non-warfarin anticoagulants may be more critical to monitor since there is not a surrogate lab value such as the international normalized ratio (INR).

Individuals who filled at least two prescriptions for a NWOA on two unique dates of service at least 180 days apart during the treatment period and who received greater than 60 days' supply of the medication during the treatment period were included in the measure. The prescriptions can be for the same or different medications. Higher rates signify better performance.

Table 19: Distribution of the ADH-NWOA Measure Rates, Part D, 2016

Contracts		Percentiles							
Type	Count	Min	10%	25%	50%	75%	90%	95%	Max
All	714	0.0%	60.9%	69.4%	76.9%	85.0%	100.0%	100.0%	100.0%
MA-PD	647	0.0%	60.6%	68.6%	76.4%	85.1%	100.0%	100.0%	100.0%
PDP	62	50.0%	73.5%	75.9%	79.4%	85.3%	87.3%	89.9%	100.0%

The ADH-NWOA rates for all contracts ranged from 0.0% to 100% except for PDP contracts where the minimum rate was 50.0%. Over 50% of the MA-PD and PDP contracts had rates below 76% and 79%, respectively. Many of the low and high rates were associated with contracts with low denominator member-years. Overall, 462 or 37% of MA-PD and PDP contracts had 30 or fewer member-years in the denominator.

Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis

(ADH-MS): This measure assesses the percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80% during the measurement period. The denominator includes patients who filled at least two prescriptions for non-infused disease modifying agents for the treatment of multiple sclerosis on two unique dates and who received at least 56 days' supply of the medication during the treatment period. The prescriptions can be for the same or different medications. Higher rates signify better performance.

Of the 743 Part D contracts, 144 or 19% contracts had no members eligible for the ADH-MS measure in 2016. The table below reports the Part D contract rate distribution by contract type.

Table 20: Distribution of ADH-MS Measure Rates, Part D, 2016

Contracts		Percentile							
Types	Count	min	10%	25%	50%	75%	90%	95%	Max
All	599	0.0%	56.0%	68.5%	76.2%	85.2%	100.0%	100.0%	100.0%
MA-PD	535	0.0%	51.0%	67.9%	76.0%	85.5%	100.0%	100.0%	100.0%
PDP	59	0.0%	68.4%	72.5%	76.6%	80.5%	100.0%	100.0%	100.0%

The minimum and maximum rates for all contracts and contract types was 0.0% to 100%. Over half of the contracts had rates below 76% and the top 10% of contracts had rates at 100%. Similar to the ADH-NWOA rates, many of the high and low contract rates were associated with low denominator member-years (512 or 69% of MA-PD and PDP contracts had 30 or fewer member-years in the denominator).

Although we found some variability between the contract rates for both the ADH-NWOA and ADH-MS measures, many contracts had low member-year denominators. The low prevalence of

multiple sclerosis in many Part D contracts resulted in 19% of contracts having no members eligible for the ADH-MS measure and over 25% of contracts having a 100% adherence rate. Although the prevalence of NWOA use is much higher and only 4% of contracts had no members eligible for ADH-NWOA measure, many contracts had small denominators (less than 30 member-years). A total of 512 (69%) and 276 (37%) of MA-PD and PDP contracts had 30 or fewer member-years in the denominator for the ADH-MS and ADH-NWOA measures, respectively. Low denominators can affect the utility of a measure to assess contract performance. Currently, four adherence measures are already included in the Patient Safety reports (three are included in Star Ratings), so we are not considering adding these adherence measures to the Patient Safety reports, the display page, or Star Ratings at this time. However, given the high cost of these medications and the importance of adherence for achieving positive outcomes, we may consider including these measures within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future, along with the beneficiary-level data so contracts can focus adherence improvement efforts for these members.

Measurement and Methodological Enhancements

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. Feedback or recommendations can help CMS' continuing analyses, as well as our collaboration with measurement development entities such as NCQA and PQA. We will continue to analyze existing ratings measures to determine if measure scores are "topped out" or showing high performance across all contracts. In making decisions to transition such measures to the display page, CMS does not have a strict formula. Although some measures may show uniform high performance across contracts with little variation between them, we want to balance how critical the measures are to improving patient care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures. If plans have only recently achieved uniformly high performance, for example, or if no other measures capture a key focus in Star Ratings, a "topped out" measure may be retained in Star Ratings.

- CMS and measure developers are exploring additional measurement concepts for future work, such as functional status, and use of non-pharmacological or non-opioid pain management interventions, which will require use of non-claims data. CMS is interested in stakeholder feedback about how these "upstream" concepts can inform measurement of quality of care and how measurement of these concepts might help CMS assess MA contracts' role in and capacity to affect the quality of care. We are also interested in stakeholder feedback on how these concepts can be measured without adding undue burden on plans or providers. However, given the importance of addressing the opioid epidemic, we will consider adding measurement or reporting burden if less burdensome options are not available.

- Effective processing of Part C organization determinations and reconsiderations and Part D coverage determination and redeterminations by sponsors are critical areas of the MA and Part D program. CMS requirements for these processes provide key beneficiary protections for access to healthcare and prescription drugs. We have included appeals measures in the Star Ratings since 2007 because they are such important indicators of beneficiary access. We continue to be interested in developing new or enhanced measures of beneficiary access, especially with the industry-wide collection of data from sponsoring organizations as described earlier. In addition to the current measures of sponsoring organizations' timeliness and reliable decision-making, we remain interested in potentially evaluating sponsoring organizations' compliance with effectuating appeals and provider outreach requirements, as well as appropriate clinical-decision making and notification to beneficiaries.

Incomplete and Inaccurate Bid Submissions

Incomplete Submissions

Under Sections 1854(a)(1)(A) and 1860D-11(b) of the Social Security Act, initial bid submissions for all MA, MA-PD, and PDPs are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY 2019, the bid submission deadline is June 4, 2018 at 11:59 PM Pacific Daylight Time.

The following components are required, if applicable, to constitute a complete bid submission:

- Plan Benefit Package (PBP),
- Bid Pricing Tool (BPT) (if applicable),
- Service Area Verification (SAV),
- Plan Crosswalk (if applicable),
- Cost Sharing Justification (if applicable, as described in the "Part C Cost Sharing Standards" section of this Call Letter),
- Formulary Submission (if offering a Part D plan with a formulary),
- Formulary Crosswalk (if offering a Part D plan with a formulary); and
- Substantiation (supporting documentation for bid pricing tool).

All MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids are submitted by the June deadline. Employer Group Waiver Plans are subject to the submission requirements that have not been waived. Consistent with past years, CMS reminds organizations that all required components of an organization's bid must be submitted by the deadline in order for the bid to be considered complete. If any of the required components are not successfully submitted by the deadline, the bid submission will be considered incomplete and not accepted by CMS absent extraordinary circumstances. This policy is consistent with previous years (for example, please refer to the memo "Release of Contract Year (CY) 2018 Bid Upload Functionality in HPMS," dated May 5, 2017).

The Health Plan Management System (HPMS) Bid Upload functionality, which is made available to organizations in May, allows organizations to submit each required bid component well in advance of the deadline. The Bid Upload functionality includes reporting tools that track those components that were successfully submitted and those that are still outstanding. Organizations should take advantage of these resources and make certain that all components of their bid are submitted successfully and accurately by the submission deadline.

All organizations are expected to contact the HPMS Help Desk at hpms@cms.hhs.gov about any technical upload or validation errors well in advance of the bid submission deadline. All organizations should make sure that appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that might prevent the bid from proceeding to desk review.

Inaccurate Submissions

CMS reminds organizations that it will only approve a Part D bid under 42 C.F.R. §423.272(b) if the organization offering the plan's bid complies with all applicable Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations. In addition, all Part C bids under §422.254(a)(3) must be complete, timely, and accurate or CMS has the authority to impose sanctions or may choose not to renew the contract (see also §§422.256 and 423.265). Bids that contain inaccurate information and/or fail to meet established thresholds may, among other things, result in an unnecessary diversion of CMS and organizations' and sponsors' time and call into question an organization's or a sponsor's ability and intention to fully comply with Part C and D requirements. Examples of bids containing information that is clearly inaccurate under Part D requirements and established thresholds are:

- An MA-PD bid that does not offer required prescription drug coverage throughout its service area as required under §423.104(f)(2) (see also section 20.4.4 of Chapter 5 of the Prescription Drug Benefit Manual),
- A PDP bid for a non-defined standard plan that does not meet the Part D Benefit Parameters set forth in the applicable law and defined benefit thresholds specified in the CY 2019 Call Letter, or
- A Part D bid that includes an incorrect PBP-to-formulary crosswalk.

CMS will issue a compliance notice or request for a corrective action plan to organizations and sponsors that submit clearly inaccurate bids on June 4, 2018 or otherwise violate bidding procedures. Actions triggering such compliance action could include, but are not limited to, the resubmission of bids prior to CMS authorization for bid modification, failure to meet Part C and D requirements, or failure to meet established thresholds. In addition, organizations and sponsors that submit inaccurate bids may not be allowed to revise their bids to correct inaccuracies, and the bids may be denied. Organizations and sponsors should engage in sufficient due diligence to make certain their bids are accurate before submission.

Plan Corrections

As required by 42 C.F.R. §§422.254, 423.265(c)(3) and 423.505(k)(4), completion of the final actuarial certification serves as documentation that the final bid, as uploaded, has been verified and is complete and accurate at the time of submission. A request by an organization or sponsor for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's or sponsor's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. A plan correction provides plans with the opportunity to change information in the PBP and must be supported by the BPT. Typos or minor data input errors that do not affect benefits do not need to be submitted as a plan correction. MA organizations are encouraged to conduct a quality review prior to bid submission, and are permitted to make necessary changes during the bid review process to align information in the PBP with the submitted BPT.

After bids are approved, CMS will not reopen the submission gates to correct errors identified by the organization or sponsor until the plan correction window in September. The plan correction window will be open from early September to late September 2018 and the specific dates will be announced in future guidance. The only changes to the PBP that are allowed during the plan correction period are those that modify the PBP data to align with the BPT. No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide organizations and sponsors the guidance and tools necessary for a complete and accurate bid submission. These tools will include a Medicare Plan Finder (MPF) summary table report that will be released in HPMS in May. Organizations and sponsors can upload their bid multiple times in HPMS prior to bid submission and can use the HPMS bid reports to verify the accuracy of the submitted bids. Organizations and sponsors are encouraged to use this time prior to the submission deadline to verify their bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance action and will be suppressed in MPF until the first MPF update in November. In addition, CMS may issue more severe compliance actions such as warning letters and requests for corrective action plans to organizations and sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice relating to a plan correction for CY 2018.

Validation Audits

CMS conducts program audits of Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), and Medicare-Medicaid Plans (MMPs), here collectively referred to as "sponsoring organizations," that participate in these programs. These program audits measure a sponsoring organization's compliance with the terms of its contract with CMS, in particular the requirements associated with access to medical services, drugs, and other beneficiary protections

required by Medicare. CMS requires sponsoring organizations who have been audited and found to have deficiencies to undergo a validation audit to ensure correction.

Since 2016, pursuant to 42 CFR §§422.503(d)(2)(iv) and 423.504(d)(2)(iv), CMS has required that when an audit demonstrates that a sponsoring organization has failed to comply with program requirements, the sponsoring organization must hire an independent auditor to conduct a validation audit to demonstrate correction of conditions cited during the initial audit. CMS's current guidance titled "Program Audit Validation Close-Out" is available on CMS's Part C and Part D Compliance and Audits webpage, in the "Program Audits" section at the following link: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html>.

On July 18, 2017, CMS hosted a listening session to solicit industry input on ways in which the program audit validation process could be improved. Sponsors and independent auditing firms provided valuable feedback during that session and via email in the weeks following the event. Based the feedback, CMS is considering several process improvements and enhancements to the program audit validation process that are intended to promote consistency and decrease burden on Sponsors.

We welcome comments on the process changes summarized below. Any modifications to the validation audit process will be summarized in the final 2019 Call Letter and reflected in the Program Audit Validation Close-Out guidance available on the Compliance and Audits webpage.

Threshold for Requiring an Independent Validation Audit

CMS currently requires sponsoring organizations that have more than five program audit conditions in their final audit report to hire an independent auditing firm to conduct a validation audit. CMS conducts the validation audits of sponsoring organizations that fall below this threshold. We are seeking comments on whether this threshold should be increased or decreased, or limited to conditions that may cause adverse impacts to beneficiaries. Our proposal described below aims to exclude a category of conditions from consideration in the threshold because they do not directly and adversely impact beneficiaries.

During the validation listening session, sponsoring organizations requested flexibility regarding the threshold for requiring an independent audit, asserting that there were challenges with hiring an independent auditing firm when only a limited number of conditions required validation. In response to this comment, we propose to modify the threshold used to determine when a sponsoring organization must hire an independent auditing firm. Specifically, CMS intends to exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation. The identification of CPE conditions in a program audit indicate weakness(es) in a sponsoring organization's compliance program and its ability to prevent, detect and correct Medicare Parts C or D program non-compliance and fraud, waste and abuse (FWA) in a timely and well-

documented manner. As such, CPE conditions require a customized audit approach that specifically tests correction of the issue but usually requires a lower level of effort from auditors to determine if the non-compliance has been corrected. For this reason, we believe that it is appropriate to exclude these conditions from the threshold calculation. Sponsoring organizations with more than five non-CPE conditions cited in their final audit report will be required to hire an independent auditing firm. CMS will conduct the validation audits of sponsoring organizations that fall below this proposed threshold. As a result, we estimate that the number of sponsoring organizations that will be required to hire an independent auditing firm will decrease by approximately three percent.

We also clarify that although we intend to exclude CPE conditions from the threshold calculation used in determining whether a sponsoring organization would be required to hire an independent auditing firm, the requirement to validate correction of CPE conditions would not be eliminated. Once a sponsoring organization meets or exceeds the threshold, thus requiring an independent audit, all conditions, including CPE conditions, identified during the program audit must be validated by the independent auditor. Likewise, if the sponsoring organization audit results are below the threshold, CMS will conduct the validation of all conditions, including CPE.

Conflict of Interest Limitations on Independent Auditing Firms

Currently, when an independent validation audit is required, the sponsoring organization must ensure that the independent auditing firm is free of any conflicts of interest. Examples of conflicts of interest include consultants who provide management consulting to the sponsoring organization, assist the sponsoring organizations with audit-related operations, and/or assist with the correction of the sponsoring organization's audit conditions. However, consultants used by the sponsoring organization to conduct "mock audits", "pre-assessments" or prior independent audits, or those who have never provided consult or assistance with the correction of audit findings for the sponsoring organization are not considered to have a conflict of interest.

During the validation listening session, sponsoring organizations requested that CMS permit the use of the same auditing firm used for their annual external Compliance Program Effectiveness (CPE) audit for conducting the validation audit. We want to clarify that sponsoring organizations are not precluded from selecting the same independent auditing firm that is used for their annual external CPE audit, as long as the firm has not provided consulting services or assistance with the correction of audit findings. Sponsoring organizations with specific questions as to whether a potential conflict of interest exists should contact their CMS validation lead for individual guidance.

As outlined below, CMS also would begin to collect information from independent auditing firms in the validation work plan that will be helpful in assessing potential conflicts of interest.

Required use of CMS Validation Audit Work Plan Template

As outlined in CMS's current guidance, essential elements must be included in validation audit work plans and reports but the format and design are left to the discretion of the independent auditing firm.

Under the current process, CMS meets with the sponsoring organization and validation auditor after reviewing the validation work plan to request clarification and discuss any required modifications. Because independent validation audits were new in 2016, and given the individualized nature of each audit, CMS found these discussions valuable in defining sampling methods and universe periods and ensuring overall consistency across validation audits.

During the validation listening session, sponsoring organizations indicated that bids from independent auditing firms varied. Other commenters asserted that the reason for the price variance was that some independent auditing firms employ a minimum of two auditors per audit program area and include registered clinicians, but other firms do not. Several commenters expressed support for a standardized audit work plan template to promote consistency and efficiency.

Based on CMS's experience in reviewing validation audit work plans and industry input, we intend to create a validation work plan template that sponsoring organizations undergoing independent validation audits in 2019 would be required to submit. In accordance with the Paperwork Reduction Act of 1995 (the PRA), we intend to include the draft template in an upcoming Federal Register proposed information collection.

The template would include sections to capture the following information:

- A summary of the independent auditing firm's prior experience with Medicare Part C and Part D auditing, including examples of the experience.
- A summary of any Medicare-related work previously performed for the sponsoring organization by the independent auditing firm. This information is useful to CMS in assessing potential conflicts of interest.
- A listing of all staff (including credentials) that will complete the audit. CMS intends to clarify which sections of the audit require registered clinicians (physician, RN, pharmacist). A minimum of two auditors per program area would be required in order to satisfy the requirement that a complete and full independent review be performed.
- Expectations for the timeframe of universe periods. In general, the universe periods specified in the program audit protocols (i.e., Part D Formulary and Benefit Administration (FA), Part D Coverage Determinations, Appeals, and Grievances (CDAG), Part C Organization Determinations, Appeals, and Grievances (ODAG), Service Authorization Requests, Appeals and Grievances (SARAG)) will be maintained in the validation audit,

consistent with the initial audit. The universe periods for Special Needs Plans - Model of Care (SNP-MOC) and Medicare-Medicaid Plan Care Coordination and Quality Improvement Program Effectiveness (CCQIPE) would vary based on the applicable condition. For example, when assessing compliance with the annual Health Risk Assessment (HRA) requirement, samples would be selected only from the identified clean period by assessing whether only those members that were due for the HRA during the clean period received them timely. Similarly, the universe period for Compliance Program Effectiveness (CPE) would also vary based on condition; however, the review should examine operations in the timeframe after CPE conditions were remediated.

- Expectations for sampling cases for both universe integrity testing and to evaluate case compliance related to a specific condition; these expectations would be used to ensure the reliability of the independent audit findings. Consistent with CMS's program audit protocols, CMS would expect to see a minimum of 5 sampled cases to verify the accuracy and completeness of each CDAG, ODAG, and SARAG universe submitted for the audit. CMS would expect to see a minimum of 10 sample cases to test the compliance outcome of a sampled case selected to test remediation of a specific condition. CMS does not require case sampling to test compliance for outcomes related to timeliness and Independent Review Entity (IRE) forwarding because all cases in the applicable universes must be evaluated for compliance. In addition, CMS will identify in the work plan when "targeted" sampling is required, and the targeted criteria that should be applied.
- A requirement to attach the independent auditing firm's proposed audit report template. The validation report template should include, at a minimum, the auditing firm's identifying information, the validation audit's objective, scope, methodology, and summary of results. In addition, to ensure the independent auditor can attest to performing a complete and independent review, the report should include details of any new findings (i.e., those not included in the program audit report). For additional detail, please refer to CMS's current guidance document "Program Audit Validation Close-Out" that is located on the webpage referenced above. The report template must be submitted with the work plan template, for review and approval by CMS prior to submission of the final report.

We believe that a CMS specified standardized work plan template will facilitate consistency across all validation audits and may also help to standardize the cost of an independent audit and improve inter-rater reliability across independent auditors.

Timeframe to Complete Validation Audits

Currently, sponsoring organizations have 150 calendar days from the date that all of their program audit Corrective Action Plans (CAPs) are accepted by CMS to complete a validation audit and submit the independent audit report to CMS for review.

During the validation listening session, commenters suggested that the current timeframe does not allow sufficient time to first remediate issues, then accumulate a sufficient “clean period” to use as the basis for validation testing. Other commenters stated that smaller sponsoring organizations, with fewer cases from which to draw, find it hard to complete meaningful validation testing in the allotted timeframe. Based on 2016 validation audit experience, CMS agrees with the commenters and intends to extend the timeframe by 30 days. Sponsoring organizations would have 180 days from the date that CMS accepts their program audit CAPs to undergo a validation audit and submit the independent audit report to CMS for review.

Submitting Independent Audit Report to CMS

Following the validation listening session, we were asked to clarify the process for submitting validation audit reports to CMS. CMS currently requires the sponsoring organization to submit its independent auditing firm’s validation audit report to CMS along with any additional information they would like CMS to consider.

We clarify that the sponsoring organization would continue to submit its independent auditing firm’s validation report to CMS but would also be required to copy the independent auditor on the submission. The report should be submitted to CMS as received from the independent auditing firm (i.e., without modification by the sponsoring organization). CMS encourages sponsoring organizations to submit additional documentation addressing any concerns with, or rebuttals to, the auditor’s report.

Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice

While CMS currently makes Civil Money Penalty (CMP) information public, via the CMS website, beneficiaries typically do not go to this location when evaluating plans for enrollment. In an effort to remain transparent with enrollees when sponsoring organizations receive a CMP for violations of program requirements, starting with the 2019 Annual Election Period (AEP), CMS intends to display an icon or other type of notice on Plan Finder for sponsoring organizations that have received a CMP. CMS expects that the icon or notice would provide current enrollees and prospective enrollees with general information about a CMP, and may link to the CMP letter on the CMS website for that particular sponsoring organization. This would be consistent with how CMS currently displays a sanction icon on Plan Finder for sponsoring organizations that have been subject to intermediate sanctions (CMP icon, however, will not block enrollments into the plan). This action is consistent with CMS’s obligation under section 1851(d) of the Act to provide information to enable beneficiaries to make an informed enrollment decision and the requirements at 42 C.F.R. §§ 422.111(g) and 423.128(f), which allow CMS to require the disclosure of a sponsoring organization’s performance and contract compliance deficiencies to current and/or potential enrollees.

CMS proposes to begin displaying the CMP icon (or other type of notice) on Plan Finder for the 2019 AEP for any sponsoring organization that receives a CMP in 2018 (or receives a CMP for a 2017 Program Audit). Beginning in 2019, CMS proposes that regular updates would occur throughout the year.

Enforcement Actions for Provider Directories

In the 2017 Call Letter, CMS provided guidance on the future of provider directory requirements and best practices. CMS stated that inaccurate provider directories can impede access to care and bring into question the adequacy and validity of the Medicare Advantage Organization's (MAO's) network as a whole. In addition, CMS notified the industry that monitoring activities around provider directories could result in compliance and enforcement actions if non-compliance is detected. Since then, CMS has received several inquiries as to when CMS would impose enforcement actions for provider directory violations.

As in all instances of non-compliance, Civil Money Penalties (CMPs) and other enforcement actions may be imposed against MAOs that have received a compliance notice or notices for violations that have gone uncorrected. Also, CMS has the discretion to take enforcement actions when egregious instances of non-compliance are discovered. If CMPs are imposed for provider directory errors, penalty amounts would initially be calculated on a per determination basis.

Audit of the Sponsoring Organization's Compliance Program Effectiveness

Pursuant to 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), sponsoring organizations are required annually to audit the effectiveness of their compliance program and share results with their governing body. These audits require extensive sponsoring organization resources and entail conducting a review of processes and outcomes, discussions with employees and first-tier, downstream and related entities (FDRs), and preparing documentation and demonstrating compliance with program requirements. CMS performs program audits of 30-40 sponsoring organizations every year, and these audits include a review of compliance program effectiveness. This includes assessing whether they are compliant with establishing and maintaining compliance programs which include measures to prevent, detect, and correct Parts C or D program noncompliance and fraud, waste and abuse. When selected for a CMS program audit, sponsoring organizations are still required to perform an internal annual compliance program effectiveness (CPE) audit... CMS has received multiple inquiries from stakeholders expressing the burden on sponsoring organizations when they have to perform their own internal CPE audit while also being responsive to a CMS program audit in the same year. Many sponsoring organizations have adopted our CMS audit protocols to perform their own internal audits, which results in a duplication of effort. The industry has inquired if sponsoring organizations may consider a CMS program audit as satisfying the annual audit of their compliance program.

CMS is considering allowing sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit requirement in 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F) for one year from the date of the CMS program audit. CMS is seeking comment on this. The one year time frame would allow sponsoring organizations to complete their CMS CPE program audit process and remediation before a new CPE audit is initiated by the sponsor to evaluate compliance performance. CMS also requests comments on how this will impact burden for sponsoring organizations undergoing a program audit. CMS believes that it will reduce burden on sponsoring organizations already undergoing a CMS program audit and will eliminate the duplication of effort. Additionally, we believe it will allow time to implement appropriate corrective actions in response to the CMS audit and monitor implementation of those corrective actions to ensure that they are effective. It should be noted that nothing in this proposal would eliminate the more significant requirements in 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F), which require sponsoring organizations to conduct internal auditing and monitoring of their operations as well as the operations of their FDRs to ensure compliance with Medicare program requirements.

Innovations in Health Plan Design

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models intended to lower costs while preserving or enhancing quality of care for Medicare, Medicaid, and CHIP beneficiaries. In the 2016 Call Letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries.

In response to these efforts, the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) model tests began operations on January 1, 2017. Each of these model tests is described below.

Potential means of adjustment to account for the impact of these models on Star Ratings are discussed above under the section, Enhancements to the 2019 Star Ratings and Future Measurement Concepts.

Medicare Advantage Value-Based Insurance Design Model Test

The MA-VBID model test is an opportunity for MAOs to offer supplemental benefits or reduced cost sharing to enrollees with CMS approved chronic conditions, focused on the services that are of highest clinical value to them. Only those MAOs expressly authorized by CMS to participate in the model may do so, and only within PBPs accepted into the model test. The model is testing whether the additional flexibility provided to MAOs to develop and offer interventions can improve health outcomes and lower expenditures for Medicare Advantage enrollees.

In CY 2018, CMS is testing the model in Alabama, Arizona, Indiana, Iowa, Massachusetts, Michigan, Oregon, Pennsylvania, Tennessee, and Texas. Beginning in CY 2019, CMS will also

test the MA-VBID model in California, Colorado, Florida, Georgia, Hawaii, Maine, Minnesota, Montana, New Jersey, New Mexico, North Carolina, North Dakota, South Dakota, Virginia, and West Virginia.

CMS has authorized thirteen MAOs from ten parent organizations in Indiana, Massachusetts, Michigan, and Pennsylvania to participate in the model test in CY 2018, and released a Request for Applications for CY 2019 participation. The Request for Application process will be timed to allow applicants to choose to participate in the VBID model or in the Medicare Advantage uniform flexibility.

For more information, including a description of other changes to the model test's design for CY 2019, please visit: <https://innovation.cms.gov/initiatives/vbid/>.

Part D Enhanced MTM Model

The Part D Enhanced MTM model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. The model is an opportunity for stand-alone basic Part D plans to right-size their investments in MTM services, identify and implement innovative strategies to optimize medication use, improve coordination of care between plans and providers, and strengthen system linkages.

Six Part D Sponsors encompassing 22 PBPs are participating in CMS's Part D Enhanced MTM model for 2018. These plans will offer MTM programs subject to the terms and conditions of the model test in the selected regions. All other Part D plans, including any ineligible plans offered by the PDP sponsors of participating plans, will remain subject to the current regulatory requirements for MTM programs. For more information, please visit:

<https://innovation.cms.gov/initiatives/enhancedmtm/>.

New Medicare Card Project (formerly the Social Security Number Removal Initiative, SSNRI)

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (PL 114-10 s.501) included a mandate to remove the current Health Insurance Claim number (HICN) from Medicare cards by April 2019. This is a reminder that, beginning in April 2018, the current Social Security Number based HICN will be replaced with a new Medicare number, the Medicare Beneficiary Identifier (MBI). MBIs will be assigned to all Medicare recipients, and new Medicare cards will be mailed to beneficiaries beginning in April 2018.

During the transition period, (April 1, 2018 to December 31, 2019), Medicare plans can use either the HICN or the MBI to exchange data with CMS. CMS will continue to disseminate information related to this change to Medicare health and drug plans as it becomes available. More information can be found at (<https://www.cms.gov/Medicare/New-Medicare-Card/index.html>). Questions can be sent to NewMedicareCardSSNRemoval@cms.hhs.gov.

Section II – Part C

Special Needs Plan (SNP) Legislative Sunset Provision

Special Needs Plans (SNPs) were first authorized by Congress in 2003 for a certain period of years. The program has been extended several times through Congressional action since that time. Most recently, section 206 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) extended the SNP program through December 31, 2018. At this time, the SNP program has not been reauthorized by Congress for contract year (CY) 2019. CMS will continue to accept applications for SNPs, Models of Care (MOCs), and other SNP-related material for new and renewing SNPs, based on a belief that Congress will likely act in 2018 to extend the SNP program, and to be prepared in that event for SNPs to be offered without interruption. Please note, although CMS will accept bids and may sign contracts in anticipation of action by Congress this year, CMS does not have the authority to allow SNP offerings in CY 2019 absent Congressional action this year to reauthorize SNPs for CY 2019. If Congress does not extend the SNP program, any contracts for CY2019 SNPs will be void. We will provide updates to the industry as needed throughout the year.

Overview of CY 2019 Benefits and Bid Review

Portions of this guidance apply to cost-based plans and MA plans (including EGWPs, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs), and Institutional Special Needs Plans (I-SNPs)).

Medicare-Medicaid Plans in a capitated model under the Medicare-Medicaid Financial Alignment Initiative are not subject to the review criteria summarized in the table below and benefit review guidance for these plans will be provided separately.

CMS makes all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expects all MAOs to submit their best, accurate, and complete bid(s) on or before the Monday, June 4, 2018 deadline. Any organization whose bid fails the Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference (if applicable, see below), Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements at any time prior to final approval will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of error(s).

The following table displays key MA bid review criteria and identifies the criteria that are used to review the bids of the various plan types identified in the column headings.

Table 21: Plan Types and Applicable Bid Review Criteria

Bid Review Criteria	Applies to Non-Employer Plans (Excluding Dual Eligible SNPs)	Applies to Non-Employer Dual Eligible SNPs	Applies to 1876 Cost Plans	Applies to Employer Plans
Low Enrollment 42 C.F.R. § 422.506(b)(1)(iv) and (b)(2)	Yes	Yes	No	No
Meaningful Difference (if applicable) 42 C.F.R. § 422.254(a)(4) and §422.256(b)(4)	Yes	No	No	No
Total Beneficiary Cost section 1854(a)(5)(C)(ii) of the Act 42 C.F.R. § 422.254	Yes	No	No	No
Maximum Out-of-Pocket (MOOP) Limits 42 C.F.R. §422.100(f)(4) and (5) and §422.101(d)(2) and (3)	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing 42 C.F.R. § 422.254(b)(4)	Yes	Yes	No	Yes
Service Category Cost Sharing 42 C.F.R. §§417.454(e), 422.100(f) and 422.100(j)	Yes	Yes	Yes ¹	Yes
Part C Optional Supplemental Benefits 42 C.F.R. §422.100(f)	Yes	Yes	No	No

¹ Section 1876 Cost Plans and MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 C.F.R. §§417.454(e) and 422.100(j)).

CMS has interpreted and applied the regulatory standards for service category cost sharing standards and amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) requirements for CY 2019 and has provided guidance on these requirements in each applicable section below. Consistent with last year, MAOs also must address other requirements in their bids, such as the medical loss ratio and health insurance providers' fee, and are expected to do so

independently of our requirements for benefits or bid review. Therefore, CMS is not making specific adjustments or allowances for these changes in the benefits review requirements.

Plans with Low Enrollment

At the end of March, CMS will send affected MAOs a list of non-SNP plans that have fewer than 500 enrollees or of SNP plans that have fewer than 100 enrollees and that have been in existence for three or more years [as of March 2018 (three annual election periods)]. The notification represents CMS's decision not to renew these plans under 42 C.F.R. §422.506(b)(1)(iv) and (b)(2). Plans with low enrollment located in service areas that do not have a sufficient number of competing options of the same plan type (such that the low enrollment plan still represents a viable plan option for beneficiaries), as determined by CMS, will not receive this notification. Please note that 42 C.F.R. §422.514 is a minimum enrollment requirement that is applied at the contract level as part of the MA application process and is independent of this plan-level requirement.

Through return e-mail, MAOs must either (1) confirm each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2019, or (2) provide a justification for renewal. If CMS does not find a unique or compelling reason the low enrollment plan is a viable plan option for beneficiaries, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting justifications will be included with the list of low enrollment plans sent to the MAO. These requirements do not apply to Section 1876 cost plans, employer plans, or MA Medical Savings Account (MSA) plans.

CMS recognizes there may be certain factors, such as the specific populations served and geographic location of the plan that led to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because they focus on a subset of enrollees with certain medical conditions. CMS will consider this information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs should follow CMS renewal/non-renewal guidance (see HPMS memo: Information about Renewal Options for 2019, to be issued in early April 2018 and/or section 50 of Chapter 16B) to determine whether a low enrollment plan may be consolidated with another plan(s). CMS will continue to evaluate and implement low enrollment requirements on an annual basis.

Meaningful Difference (Substantially Duplicative Plan Offerings)

Pursuant to 42 C.F.R. §422.254(a)(4) and §422.256(b)(4), MAOs offering more than one plan in a given service area must ensure the plans are substantially different so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs. CMS proposed to eliminate the meaningful difference requirement beginning in CY 2019 as part of the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost

Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P) proposed rule, which was published in the Federal Register on November 28, 2017 (82 FR 56336) and is reviewing comments regarding this proposal. CMS will provide instructions in the final rule and the CY 2019 Final Call Letter or a HPMS memorandum regarding the meaningful difference requirement for CY 2019.

Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Act to deny MAO bids, on a case-by-case basis, if it determines the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next through the use of the TBC standard. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The methodology for developing the CY 2019 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 21, 2017 titled "Medicare Plan Finder (MPF) Plan Version of Out-of-Pocket Cost (OOPC) Model for CY 2019." Customary updates for utilization data, as well as PBP and formulary data used for CY 2019 bid submissions, are also included in the 2019 model.

The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. By limiting excessive increases in the TBC from one year to the next, CMS is able to make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases. As in past years, CMS will evaluate TBC for non-employer plans (excluding D-SNPs). MA plans offering Part C uniformity flexibility (discussed later in this section) and/or participating in the Value-Based Insurance Design (VBID) model test will be subject to the TBC evaluation for CY 2019; however, benefits and cost sharing reductions (entered in Section B-19 of the PBP) that are offered as part of Part C uniformity flexibility or the VBID model test will be excluded from the TBC calculation. This approach allows CMS to readily evaluate changes in cost sharing and benefits that are provided to all enrollees in a plan.

Under 42 C.F.R. §422.254, CMS reserves the right to further examine and request changes to a plan bid even if a plan's TBC is within the required amount. This approach not only protects enrollees from significant increases in cost sharing or decreases in benefits, but also confirms enrollees have access to viable and sustainable MA plan offerings.

CMS will continue to incorporate the technical and payment adjustments described below and expect organizations to address other factors, such as coding intensity changes, risk adjustment model changes, and payment of the health insurance providers fee independently of our TBC requirement. As such, plans are expected to anticipate and manage changes in payment and other factors to minimize changes in benefit and cost sharing over time. CMS also reminds MAOs that

the Office of the Actuary extends flexibility on margin requirements so MAOs can satisfy the TBC requirement.

In mid-April 2018, as in past years, CMS will provide plan specific CY 2019 TBC values and incorporate the following adjustments in the TBC calculation to account for changes from one year to the next:

- Technical Adjustments: (1) annual changes in OOPC model software and (2) maximum Part B premium buy-down amount change in the bid pricing tool (TBD for CY 2019).
- Payment Adjustments: (1) county benchmark, and (2) quality bonus payment and/or rebate percentages.

CMS is proposing to increase the TBC change threshold, for most plans, from \$34.00 PMPM to \$36.00 PMPM in CY 2019 to provide flexibility in addressing medical and pharmacy inflation and benefit design and formulary changes. Therefore, a plan experiencing a net increase in adjustments must have an effective TBC change amount below the \$36.00 PMPM threshold to avoid denial of the bid under section 1854(a)(5)(C)(ii). Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the \$36.00 PMPM threshold. In an effort to support plans that received increased quality compensation and experience large payment adjustments, along with holding plans accountable for lower quality, CMS will apply the TBC evaluation as follows. CMS requests comment on whether the \$36.00 PMPM threshold should be higher or lower for CY 2019.

For CY 2019, the TBC change evaluation will be treated differently for the following specific situations:

- Plans with an increase in quality bonus payment and/or rebate percentage, and an overall payment adjustment amount greater than \$36.00 PMPM will have a TBC change threshold of \$0.00 PMPM (i.e., -1 times the TBC change limit of \$36 PMPM) plus applicable technical adjustments.
- Plans with a decrease in quality bonus payments and/or rebate percentage, and an overall payment adjustment amount less than -\$36.00 PMPM will have a TBC change threshold of \$72.00 PMPM (i.e., 2 times TBC change limit of \$36.00 PMPM) plus applicable technical adjustments. That is, plans are not be allowed to make changes that result in greater than \$72.00 worth of decreased benefits or increased premiums.
- Plans with a star rating below 3.0 and an overall payment adjustment amount less than -\$36.00 PMPM will have a TBC change threshold of \$72.00 PMPM (i.e., 2 times TBC change limit of \$36.00) plus applicable technical adjustments.
- Plans not accounted for in the three specific situations above are evaluated at the \$36 PMPM limit, similar to CY 2018.

Consistent with last year, CMS will maintain the CY 2018 TBC evaluation for Special Needs Plans for End Stage Renal Disease (ESRD) but reflect the increase in the overall TBC change threshold:

- ESRD SNPs with an increase in the overall payment adjustment amount greater than \$36.00 PMPM will have a TBC change threshold of \$0.00 PMPM (i.e., –1 times the TBC change limit of \$36 PMPM) plus applicable technical adjustments.
- ESRD SNPs with a decrease in the overall payment adjustment amount less than -\$36.00 PMPM will have a TBC change threshold of \$72.00 PMPM (i.e., 2 times TBC change limit of \$36.00 PMPM) plus applicable technical adjustments. That is, plans are not allowed to make changes that result in greater than \$72.00 worth of decreased benefits or increased premiums.

If CMS provides an opportunity to correct CY 2019 TBC issues following the submission deadline, the MAO cannot change its formulary (e.g., adding drugs etc.) as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS identified formulary review concerns negatively affects the formulary and bid review process. For example, portions of the annual formulary review process are based on outlier analyses. If an MAO were permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely impacted. In addition, significant formulary changes will necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor's formulary and could affect approval of its contract. Detailed TBC information and examples will be provided in mid-April 2018 via the HPMS Memorandum titled "CY 2019 MA Bid Review and Operations Guidance."

CMS will maintain the TBC evaluation used during CY 2018 for consolidating or crosswalking plans. CMS will include the operational details of this process in the annual HPMS Memo titled "CY 2019 Medicare Advantage Bid Review and Operations Guidance," issued in mid-April.

CMS is considering the elimination of the current TBC evaluation in future years, subject to statutory and regulatory limitations or changes. CMS requests comment on this matter and suggestions on other approaches to determine whether plan bids propose too significant an increase in cost sharing or decrease in benefits from one plan year to the next; we interpret the statutory provision as one granting authority for us to deny bids on these grounds to protect beneficiaries from significant increases in cost or decreases in benefits. Our goal is to improve innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique healthcare needs and financial situation.

Maximum Out-of-Pocket (MOOP) Limits

As codified at 42 CFR §422.100(f)(4) and (5) and §422.101(d)(2) and (3), all MA plans, including employer group plans and SNPs, must establish limits on enrollee out-of-pocket spending that do not exceed the annual maximum amounts set by CMS. Although the MOOP requirement is for Parts A and B services, an MAO can include supplemental benefits as services that are subject to the MOOP. MA plans may establish as their MOOP any amount within the ranges shown in the table.

Table 22 below displays the CY 2019 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to Local PPOs and Regional PPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP (\$0 - \$3,400) results in greater flexibility for individual service category cost sharing. The possible ranges of the MOOP amount within each plan type are displayed in order to illustrate that MOOP limits may be lower than the CMS-established maximum amounts and what MOOP amounts qualify as mandatory and voluntary MOOP limits. As clarified in previous Call Letters, the in-network MOOP amount dictates the combined MOOP range for PPOs (i.e., PPOs are not permitted to offer a combined MOOP amount within the mandatory range, while having an in-network MOOP amount within the voluntary range).

Table 22: CY 2019 Voluntary and Mandatory MOOP Range Amounts by Plan Type

Plan Type	Voluntary	Mandatory
HMO	\$0 - \$3,400	\$3,401 - \$6,700
HMO POS	\$0 - \$3,400 In-network	\$3,401 - \$6,700 In-network
Local PPO	\$0 - \$3,400 In-network and \$0 - \$5,100 Combined	\$3,401 - \$6,700 In-network and \$3,401 - \$10,000 Combined
Regional PPO	\$0 - \$3,400 In-network and \$0 - \$5,100 Combined	\$3,401 - \$6,700 In-network and \$3,401 - \$10,000 Combined
PFFS (full network)	\$0 - \$3,400 Combined	\$3,401 - \$6,700 Combined
PFFS (partial network)	\$0 - \$3,400 Combined	\$3,401 - \$6,700 Combined
PFFS (non-network)	\$0 - \$3,400	\$3,401 - \$6,700

As explained in the CY 2012 Call Letter, MOOP limits are currently based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. Actual data for Parts A and B services are based on claims from the National Claims History files. The Office of the Actuary conducts an annual analysis to help CMS determine the proposed MOOP amounts by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and Original Medicare. The mandatory MOOP amount represents

approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, five percent of Original Medicare beneficiaries are expected to incur approximately \$6,700 or more in Parts A and B deductibles, copayments and coinsurance. The voluntary MOOP amount of \$3,400 represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs.

Since the MOOP requirement was finalized in 42 C.F.R. § 422.100(f)(4) and (5), a strict application of the 95th and 85th percentile would have resulted in MOOP limits fluctuating from year-to-year. CMS has exercised discretion to maintain stable MOOP limits from year-to-year, if the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages, and does not discourage the adoption of the lower voluntary MOOP amount if the limit increases one year and then decreases the next.

Although most dual-eligible enrollees are not responsible for paying cost sharing, certain D-SNPs (Medicare Non-Zero Dollar Cost Sharing Plans) enroll dual-eligible enrollees who do pay cost sharing. Also, any dual-eligible enrollee exempted from cost sharing who loses his/her Medicaid eligibility may be responsible for cost sharing for the period they have lost Medicaid coverage, and remain enrolled in the D-SNP. This also applies to Zero Dollar Cost Sharing Plans that apply cost sharing in their Medicare Part A and B benefit package but enroll only dual-eligible individuals who are exempt from cost sharing.

D-SNPs have the flexibility to establish \$0 as the MOOP limit, thereby guaranteeing there is no cost sharing for plan enrollees, including those who are liable for Medicare cost sharing. Otherwise, if the D-SNP does apply cost sharing for Medicare Part A and B covered benefits, then it must track enrollees' out-of-pocket spending, and it is up to the plan to develop the process and vehicle for doing so.

Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost Sharing Limits

Total MA cost sharing for Part A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis and must not be discriminatory. In order to ensure that cost sharing is consistent with both 42 C.F.R. § 422.254(b)(4) and §422.100(f)(2), CMS will evaluate actuarial equivalent cost sharing limits separately in the following service categories for CY 2019: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. Please note that factors for Inpatient in Column 4 of the table below (Part B Adjustment Factor to Incorporate Part B Cost Sharing) have been updated for CY 2019.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the BPT. Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to

Original Medicare Actuarially Equivalent Cost Sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

Once the comparison amounts have been determined, excess cost sharing can be identified. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1) and the comparison amount (column #5). The table below uses illustrative values to demonstrate the mechanics of this determination.

Table 23: Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	PMPM Plan Cost Sharing (Parts A&B) (BPT Col. l)	Original Medicare Allowed (BPT Col. m)	Original Medicare AE Cost sharing (BPT Col. n)¹	Part B Adjustment Factor to Incorporate Part B Cost Sharing (Based on FFS data)	Comparison Amount (#3 × #4)	Excess Cost Sharing (#1 – #5, min of \$0)	Pass/Fail
Inpatient	\$33.49	\$331.06	\$25.30	1.395	\$35.30	\$0.00	Pass
SNF	\$10.83	\$58.19	\$9.89	1.066	\$10.54	\$0.29	Fail
DME	\$3.00	\$11.37	\$2.65	1	\$2.65	\$0.35	Fail
Part B-Rx	\$0.06	\$1.42	\$0.33	1	\$0.33	\$0.00	Pass

¹ PMPM values in column 3 for Inpatient and Skilled Nursing Facility only reflect Part A fee-for-service actuarial equivalent cost sharing for that service category.

NOTE: Beginning in CY 2017, CMS waived the requirement for MA employer plans to submit a Bid Pricing Tool (BPT), which affects our ability to evaluate the PMPM Actuarial Equivalent Cost Sharing discussed in this section. MA employer plans continue to be subject to all unwaived MA regulatory requirements regardless of whether they are affirmatively evaluated as part of bid review or in connection with other oversight.

Part C Cost Sharing Standards

For CY 2019, CMS will continue the current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. Table 24 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for MA

plans that we will not consider discriminatory or in violation of other applicable standards. CY 2019 bids must reflect enrollee cost sharing for in-network services no greater than the amounts displayed below. These standards will be applied only to in-network Parts A and B services unless otherwise indicated in the table. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. Inpatient and Skilled Nursing Facility (Days 21 through 100) standards have been updated to reflect estimated changes in Original Medicare cost for CY 2019. Per our authority at 42 C.F.R. §422.113(b)(2)(v), the Emergency Care/Post Stabilization Care limit for plans has been increased for CY 2019 to better align cost sharing with actual costs and as an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services. The voluntary MOOP amount increased from \$100 to \$120, while the mandatory MOOP amount increased from \$80 to \$90. CMS expects having different limits based on the plan's MOOP amount will encourage organizations to offer benefit packages with a lower voluntary MOOP amount, while maintaining beneficiary protection.

Table 24: CY 2019 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	PBP Section B data entry field	Voluntary MOOP	Mandatory MOOP
Inpatient Hospital – Acute - 60 days	1a	N/A	\$4,314
Inpatient Hospital – Acute - 10 days	1a	\$2,552	\$2,042
Inpatient Hospital – Acute - 6 days	1a	\$2,325	\$1,860
Inpatient Hospital Psychiatric - 60 days	1b	\$2,737	\$2,190
Inpatient Hospital Psychiatric - 15 days	1b	\$2,075	\$1,660
Skilled Nursing Facility – First 20 Days ^{1,2}	2	\$20/day	\$0/day
Skilled Nursing Facility – Days 21 through 100 ^{1,2}	2	\$172/day	\$172/day
Emergency Care/Post Stabilization Care ³	4a	\$120	\$90
Urgently Needed Services ³	4b	\$65	\$65
Partial Hospitalization	5	\$55/day	\$55/day
Home Health	6a	20% or \$35	\$0
Primary Care Physician	7a	\$35	\$35
Chiropractic Care	7b	\$20	\$20
Occupational Therapy	7c	\$40	\$40
Physician Specialist	7d	\$50	\$50
Psychiatric and Mental Health Specialty Services	7e and 7h	\$40	\$40
Physical Therapy and Speech-language Pathology	7i	\$40	\$40
Therapeutic Radiological Services	8b	20% or \$60	20% or \$60
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or \$10
DME-Diabetic Shoes or Inserts	11c	N/A	20% or \$10
Dialysis Services ¹	12	20% or \$30	20% or \$30
Part B Drugs-Chemotherapy ^{1,4}	15	20% or \$75	20% or \$75
Part B Drugs-Other	15	20% or \$50	20% or \$50

¹ MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services (42 CFR §§417.454(e) and 422.100(j)).

² MA plans that establish a voluntary MOOP may have cost sharing for the first 20 days of a SNF stay. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).

³ Emergency Care and Urgently Needed Care benefits are not subject to plan level deductible amount and/or out-of-network providers. The dollar amount included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance).

⁴ Part B Drugs - Chemotherapy cost sharing displayed is for services provided on an outpatient basis and includes administration services.

MAOs have the option to charge either coinsurance or a copayment for most service category benefits. For example, based on the cost sharing requirements indicated above for Part B Drugs – Chemotherapy, a plan can choose to either assign up to a 20% coinsurance or \$75 copayment to that particular benefit. MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services (42 CFR §422.100(j)). Although CMS has not established a specific service category cost sharing limit for all possible services, CMS has a longstanding interpretation of the anti-discrimination provisions that payment of less than 50% of the contracted (or Medicare allowable) rate and use of cost sharing for services that exceeds 50% of the total MA plan financial liability for the benefit discriminates against enrollees who need those services. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Original Medicare service category cannot exceed 50% of the average contracted rate of that service (Medicare Managed Care Manual, Chapter 4, Section 50.1). For example, cardiac and pulmonary rehabilitation services are areas of concern that CMS continues to monitor and requires MA organizations provide justification for cost sharing above the following amounts for CY 2019: cardiac rehabilitation services (\$50), intensive cardiac rehabilitation services (\$100), and pulmonary rehabilitation services (\$30). CMS has determined that the cited amounts are non-discriminatory.

Copayments are expected to reflect specific benefits identified within the PBP service category or a reasonable group of benefits or services provided. Some PBP service categories may identify specific benefits for which a unique copayment would apply (e.g., category 3 includes specific benefits for cardiac rehabilitation, intensive cardiac rehabilitation and pulmonary rehabilitation services), while other categories include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (e.g., category 8b includes outpatient diagnostic radiological services). It is expected that organizations typically have much lower cost sharing for enrollees than our requirements due to effective managed care principles, effective negotiations between organizations and providers, and competition.

MAOs with benefit designs using a coinsurance or copayment amount for which CMS does not have an established threshold for non-discriminatory cost-sharing (e.g., coinsurance for inpatient or copayment for durable medical equipment) must submit documentation with their initial bid that clearly demonstrates how the coinsurance or copayment amount satisfies the regulatory requirements, as interpreted and implemented here, for each applicable plan. This documentation may include information for multiple plans and must be identified separately from other supporting documentation submitted as part of the BPT. The documentation must be submitted for each plan through the supporting documentation upload section titled "Cost-Sharing Justification" in HPMS. The upload will be available to all MA plan types (both employer and individual market), but not for stand-alone PDPs. The link for uploading cost sharing justification files will be located at Plan Bids > Bid Submission > CY 2019 > Upload > Cost-Sharing Justification.

CMS annually evaluates available Medicare data and other information to apply MA requirements in accordance with applicable law. Organizations are afforded the flexibility to design their benefits as they see fit so long as they satisfy Medicare coverage requirements.

For CY 2020 CMS is considering changes to its policies related to service category cost sharing limits. For example, inpatient limits are based on Original Medicare cost data and other limits are based on at least 50% of the total MA plan financial liability for the benefit. CMS is soliciting comments on whether CMS's interpretation of the cost sharing limits is impacting plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options. Our goal is to encourage plans' to be innovative and offer high value, affordable plan options tailored to beneficiaries' specific healthcare and financial needs.

Part C Optional Supplemental Benefits

As part of our evaluation whether the bid and benefits are not discriminatory against enrollees with specific (or high cost) health needs, CMS will continue to review non-employer bid submissions to verify enrollees electing optional supplemental benefits are receiving reasonable value. CMS will continue to consider a plan to be non-discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following thresholds: (a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15% and (b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by a percent of premium, is no greater than 30%.

CMS understands some supplemental benefits are based on a multi-year basis, but the plan bids submitted each year are evaluated based on that particular plan year.

Employer Group Waiver Plans

Beginning in CY 2017, CMS waived the requirement for MA employer plans to submit a MA or Part D Bid Pricing Tool (BPT), but employer plans must complete and submit the MA portion of the Plan Benefit Package (PBP) in accordance with CMS requirements. Organizations should make a good faith effort in projecting CY 2019 member months for each plan and place the amount in Section A-2 of the PBP. The following question must be completed for all MA and 1876 Cost Plan organizations: “Indicate CY 2019 total projected member months for this plan.”

Tiered Cost Sharing of Medical Benefits

MAOs may choose to tier cost sharing of medical benefits to encourage enrollees to seek care from providers the plan has identified based on efficiency and quality data as described in Chapter 4, §50.1 of the MMCM. The tiered cost sharing of medical benefits must be applied so all plan enrollees are charged the same cost sharing amount for any specific provider and all providers are available and accessible to all enrollees in the plan. CMS reminds organizations they may not exclude any members from being eligible to access tiered providers.

For CY 2019, CMS does not expect MAOs to submit a proposal summarizing their intent to tier cost sharing of medical benefits prior to bid submission. MAOs are expected to indicate they are tiering medical benefits and the applicable service categories in Section A-6 of the PBP. MAOs must use minimum/maximum data entry and notes fields to describe tiering in each applicable section of the PBP.

Tiered cost sharing of medical benefits must satisfy the following standards:

- The plan fully discloses tiered cost sharing amounts and requirements to enrollees and plan providers;
- The services at each tier of cost sharing are available to all enrollees;
- Enrollees may not be limited to obtaining services from providers/suppliers assigned to a particular tier;
- All enrollees are charged the same amount for the same service provided by the same provider; and
- Deductibles, MOOP, and out-of-network benefits are not to be tiered.

The following examples of “differential cost sharing” are allowable, and not considered to be tiering of medical benefits:

- Facility settings for furnishing some services, such as diagnostic imaging services; and
- In-network versus out-of-network services.

Outpatient Observation Services

The outpatient hospital services category in the PBP (B9a) includes a variety of services such as observation, outpatient palliative care, and outpatient surgical services (i.e., outpatient surgical services not provided in an Ambulatory Surgical Center as defined by Original Medicare). Observation care is a highly utilized, well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment to support plan of care decisions such as, whether a patient needs to be admitted as inpatient or may be discharged from the hospital. In an effort to make the cost sharing for observation services more transparent, CMS will distinguish the cost sharing for observation services from other outpatient hospital services by modifying PBP category B9a to include separate cost sharing data entries.

Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

CMS has determined that the National Coverage Determination (NCD) requiring coverage of supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD) is considered a significant cost under 42 C.F.R. § 422.109(a)(2). As a result, for CY 2018 only, original fee-for-service Medicare will pay for reasonable and necessary items and services obtained by beneficiaries enrolled in MA plans. (See HPMS email, Subject titled “MAO Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)” sent on August, 12, 2017). For CY 2019, MAOs should account for these items and services in their bids as a basic benefit, and should not include these Medicare-covered items and services as supplemental benefits.

Health Related Supplemental Benefits

CMS currently defines a supplemental health care benefit in the Medicare Managed Care Manual (section 30.1) as an item or service (1) not covered by Original Medicare, (2) that is primarily health related, and (3) for which the MA plan must incur a non-zero direct medical cost. An item or service that meets all three conditions may be proposed as a supplemental benefit in an MA plan’s bid and submitted plan benefit package. The final determination of benefit status is made by CMS during the annual benefit package review.

An item or service is primarily health related if the primary purpose of the item or service is to prevent, cure, or diminish an illness or injury. CMS has not previously allowed an item or service to be eligible as a supplemental benefit if the primary purpose is daily maintenance. However, medical and health care research has demonstrated the value of certain items and services that can diminish the impact of injuries or health conditions and reduce avoidable emergency and health care utilization. For example, fall prevention devices can be an effective means to assist enrollees at high risk of fall and protect against the likelihood of additional injury resulting from a fall; CMS believes provision of a fall prevention device – and similar items and

services that diminish the impact of injuries/health conditions and reduce avoidable utilization - could be provided as a supplemental benefit for a defined period of time and in certain situations.

CMS intends to expand the scope of the primarily health related supplemental benefit standard. Section 1852(a)(3) permits the offering of “healthcare benefits” as supplemental benefits but does not define the term. We therefore have authority to interpret the term more broadly than we have in the past, to permit MA plans to offer additional benefits as “supplemental benefits” so long as they are healthcare benefits. Under our new interpretation, in order for a service or item to be “primarily health related,” it must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. Any supplemental health benefit proposed by an MA organization must be reasonably and rationally encompassed by this standard. This will allow MA plans more flexibility in offering supplemental benefits that can enhance beneficiaries’ quality of life and improve health outcomes.

The primary purpose of an item or service will be determined by national typical usages of most people using the item or service and by community patterns of care. To be considered healthcare benefits, supplemental benefits must focus directly on an enrollee’s healthcare needs. Supplemental benefits under this broader interpretation must be medically appropriate and ordered by a licensed provider as part of a care plan if not directly provided by one; supplemental benefits do not include items or services solely to induce enrollment. Prior to bid submissions, CMS will issue detailed guidance for MAOs on this issue as they consider upcoming plan offerings. This guidance will be based on previous stakeholder feedback and comments in response to the draft Call Letter.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs)

Over the past several years, CMS has sought to improve care coordination and enhance the experience of care for beneficiaries, particularly those that are a part of the SNP population. We believe that specialized, targeted care through enhanced disease management programs is one way to achieve this goal. Beginning CY 2019, D-SNPs and I-SNPs may offer the EDM supplemental benefit that is currently available to Non-SNP MA plans.

As discussed in section 30.1 of the Medicare Managed Care Manual, services in a supplemental EDM benefit would include qualified case managers with specialized knowledge about the target disease(s)/condition(s), educational activities that are focused on the target disease(s)/condition(s), and routine monitoring applicable to the target disease(s)/condition(s). The benefit may be proposed as a supplemental benefit in an MA plan’s bid and submitted plan benefit package.

The EDM supplemental benefit will not be made available to Chronic Condition SNPs (C-SNPs) as it is not necessary. C-SNPs must already have comprehensive targeted disease management elements (beyond the EDM supplemental benefit requirements) in order to receive the special C-SNP designation and marketing and enrollment accommodations.

Medicare Advantage (MA) Uniformity Flexibility

CMS has determined that providing access to services (or specific cost sharing and/or deductibles for services or items) that is tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the MA regulations at §422.100(d). We have determined that the statutory provisions at sections 1852(d)(1) and 1854(c) and the regulation at § 422.100(d) mean that we have the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits. Targeted supplemental benefits can be offered through a benefit package that ensures equal treatment of enrollees with the same clinical conditions for whom such services and benefits are useful consistent with section 1852's equal access and anti-discrimination provisions, and is priced at a uniform premium consistent with the requirement for uniform bids and premiums in section 1854(c) of the Act. CMS believes this flexibility will help MA plans better manage healthcare services for particularly vulnerable enrollees. Such flexibility is not without limits, however, as section 1852(b)(1)(A) prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. MA regulations (e.g., §§422.100(f)(2) and 422.110(a)) reiterate and implement this non-discrimination requirement. In interpreting these obligations to protect against discrimination, CMS has historically indicated that the purpose of the requirements is to protect high-acuity beneficiaries from adverse treatment on the basis of their higher cost health conditions. (79 FR 29843; 76 FR 21432; and 74 FR 54634.) As MA plans consider implementation of flexibility in the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations. CMS will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other conditions, particularly higher-cost conditions. We will review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded from these targeted benefits in favor of healthier populations.

Under this proposal, for example, an MA plan could identify enrollees diagnosed with specific diseases, such as diabetes, chronic heart failure, and COPD, as medically vulnerable and in need of additional services. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable, and the enrollee must be diagnosed by a plan provider. If an MA plan wants to propose a targeted supplemental benefit offering but has questions as to

whether or not it is allowable, CMS will establish a special mailbox following issuance of the Final Call Letter.

Medicare Advantage (MA) Segmented Service Area Options

CMS reviewed section 1854(h) of the Social Security Act (the Act) and MA regulations governing plan segments and has determined that it has the authority to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. CMS is revising its interpretation of the regulations to allow MA plan segments to vary by supplemental benefits, premium, and cost sharing, consistent with the MA regulatory requirements defining segments at §422.262(c)(2). Segments are defined in the MA regulations at §422.262(c)(2). MA plans can segment Part C benefits however if an MA plan offers Part D it must offer the Part D benefit uniformly within the plans service area including any segments the MA plan may have.

Medicare Diabetes Prevention Program (MDPP) Services Clarification

In the CY 2017 Physician Fee Schedule (PFS), we finalized the nationwide expansion of the MDPP model and defined the parameters of MDPP services. The model was further defined in the CY 2018 PFS final rule. The MDPP expanded model is effective April 1, 2018. The services provided under this expanded model function as Medicare Part B covered services.

MDPP services consist of structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The goal of the MDPP expanded model is to prevent the onset of type 2 diabetes in individuals with an indication of prediabetes. Like preventive benefits and under §422.100(k), eligible Medicare beneficiaries must be covered at zero cost sharing, if in-network. We want to ensure that MA plans are aware that while they must cover MDPP services in accordance with the MDPP regulations, they may also offer additional MDPP-like services as a supplemental benefit. For example, although MDPP services cannot be provided only remotely or in a 100% virtual format under current regulations as a basic benefit under Part B, an MA plan may offer similar services in a virtual format as a supplemental benefit through the Remote Access Technology supplemental benefit. The similar supplemental benefit does not count as the Part B covered service, but may still be offered by the plan.

Special Needs Plan (SNP)-Specific Networks Research and Development

In the CY 2018 Final Call Letter, CMS announced plans to move forward on developing SNP-specific network adequacy evaluations. CMS believes that the current network adequacy criteria and exception request process account for the unique healthcare needs and delivery patterns for Medicare Advantage (MA) beneficiaries enrolled in SNPs, including chronic condition SNPs (C-

SNPs), dual eligible SNPs (D-SNPs), and institutional SNPs (I-SNPs). We continue to examine the need for SNP-specific network adequacy evaluations and welcome continued stakeholder feedback.

Rewards and Incentives for Completion of a Health Risk Assessment (HRA)

Regulations at §422.134 allow MA plans to create Rewards and Incentives (RI) Programs that provide rewards and incentives to enrollees for participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of healthcare resources. Under §422.112(b)(4)(i), all MA plans must make a best effort to conduct an initial assessment of each enrollee's healthcare needs within 90 days of the effective date of enrollment. Finally, regulations at §422.101(f)(1)(i) require all SNPs to perform a comprehensive initial HRA within the first 90 days of enrollment and conduct reassessments annually thereafter.

Completion of a federally mandated survey, though arguably a health-related activity, may not be included in an RI Program because of the potential for biased responses due to the influence of rewards and incentives. CMS has previously included HRAs in this exclusion because of §§422.112 and 422.101. However, CMS also believes a completed HRA is vital to proper care management, improved health, and promotes the efficient use of healthcare resources – so much so that, beginning in CY 2014, CMS included SNPs' HRA timeliness and completion rates as factors in the Star Ratings methodology. CMS now also recognizes that HRA tools must be designed to objectively assess and analyze the medical, functional, cognitive, psychosocial and mental health needs of each beneficiary, and therefore do not consist of material that is susceptible to bias like other enrollee satisfaction and outcome surveys.

Therefore, beginning CY 2019, MA plans may include the completion of an HRA as a permitted health-related activity in an RI Program. An RI Program is not a benefit but it must be included in the bid as a non-benefit expense. See section 100 of Chapter 4 of the Medicare Managed Care Manual for more information about rewards and incentives.

Cost Plan Transition to MA under MACRA

CMS wants to remind cost plan entities that they must complete the transition to MA by contract year 2019 in order to deem their cost enrollees into an affiliated MA plan offered by the organization under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) cost transition requirements. In connection with the transition of cost to MA, MACRA also delayed the implementation of the cost plan competition requirements through contract year 2018.

MACRA specifies notification, enrollment, and benefit requirements that transitioning cost plans must follow in order to be eligible for deeming enrollees, which are generally codified as amendments to section 1876(h) of the Act. In addition, the transitioning cost plan (if it is to receive the deemed enrollment instead of an existing affiliated MA plan) must meet all contracting requirements necessary to become an MA plan.

Any plan wishing to deem enrollees from its cost plan to one of its MA plans under the MACRA provisions must notify CMS of that intention via the HPMS crosswalk process. This may be completed as early as May of 2018 for enrollments in 2019, the final contract year for deeming enrollment from a non-renewing cost plan to an affiliated MA plan. All crosswalks must be completed by the time the bid is due, unless a plan qualifies to submit a crosswalk during the exceptions window. Plans are responsible for following all contracting, enrollment, and other transition guidance released by CMS.

CMS has released guidance on the requirements of the cost plan transition which is available at the following link: <https://www.cms.gov/Medicare/Health-Plans/MedicareCostPlans/index.html>

Cost Plan Competition Requirements

CMS wants to remind MAOs that the cost plan competition requirements will first be effective in 2019, that is, cost plans affected by these requirements will first be unable to offer a cost plan in a service area or portion of a service area in contract year 2019. Under amendments to section 1876(h)(5)(C) of the Act, implementation of the cost plan competition requirements was delayed until the end of contract year 2018 by MACRA.

CMS will non-renew any portion of a cost plan's service area if there are at least two competing MA local or two MA regional coordinated care plans with a minimum of 5,000 enrollees (urban areas) or 1,500 enrollees (non-urban areas) for the entire year prior to the non-renewal. We used 2017 enrollment data to determine the cost plans subject to non-renewal pursuant to section 1876(h)(5)(C). CMS provided the results of the competition analysis to each cost contract in December, 2017.

Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs

CMS continues to seek opportunities to maximize the potential for D-SNPs to align benefits and improve coordination for Medicare-Medicaid enrollees. In previous Call Letter cycles, we sought stakeholder input on a variety of opportunities for greater integration and coordination. Based on that feedback, CMS has identified certain priority areas for further integration for interested states and plans. We have begun to work on some of these priorities – including with regard to oversight, integrated model materials, non-renewals, and models of care – with certain states and welcome the opportunity to expand this work and to partner with additional states in which there are integrated D-SNP products available to Medicare-Medicaid enrollees. We have identified the following specific areas in which administrative alignment for integrated D-SNPs is currently feasible within existing statutory, regulatory, and operational constraints:

- **Oversight:** Improving CMS-state communication and information sharing as permitted by applicable law to improve oversight and administration of D-SNP contracts.

- **Integrated model materials:** Collaborating with states to develop a set of model materials with integrated benefit information for use by integrated D-SNPs. In response to previous stakeholder comments on this topic we have prioritized the following materials:
 - ***Summary of Benefits.*** The Summary of Benefits (SB) is a brief summary of plan benefits and cost-sharing which, as described in sections 30.6, 100.1, and 100.2.2 of the Medicare Marketing Guidelines (MMG) (interpreting §422.111), must be posted on MA plan websites by September 30 each year, provided with any enrollment form, and available upon request to members. Starting with the CY 2017 cycle, integrated D-SNPs have had flexibility to display integrated Medicare and Medicaid benefits, as applicable, in their SBs.²⁶ CMS worked with Minnesota to develop model SB language for integrated D-SNPs to use there in CY 2018 and, based on that work, is working with Massachusetts to develop similar model language for integrated D-SNPs to use in that state for CY 2019.
 - ***Annual Notice of Change (ANOC)/Evidence of Coverage (EOC).*** Plans must send an ANOC summarizing changes to plan benefits for the upcoming contract year to current enrollees for receipt by September 30 each year under §422.111. In addition, plans must provide – at the time of enrollment and annually thereafter – an EOC containing detailed plan and benefits information.. Starting with the CY 2018 cycle, the standardized ANOC and EOC models for D-SNPs include new opportunities for integrating Medicare and Medicaid benefit descriptions similar to those available in the SB guidance.
 - ***Provider and Pharmacy Directory.*** Plans must make network provider and pharmacy information available at the time of enrollment and annually thereafter (by posting on the plan website by September 30 and making hard copies available). Based on our work with Medicare-Medicaid Plans and with D-SNPs in the Minnesota Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience, we believe that inclusion of all available providers – including those offering services only covered through Medicaid – in one document will facilitate beneficiary understanding of both their Medicare and Medicaid provider choices and streamline health plan processes. For the last several contract years, CMS has worked with Minnesota to develop model language, based on MMP templates that would allow health plans to integrate this information into one document for use in that state that satisfies both Medicare and Medicaid regulatory

²⁶ Guidance for CY 2017 was issued in the April 15, 2016 HPMS memo, “Summary of Benefits Guidance for Contract Year 2017.” Guidance for CY 2018 was included in Appendix 4 of the Medicare Marketing Guidelines, issued July 20, 2017.

requirements. Based on that work, we are working with Massachusetts to develop similar model language for integrated D-SNPs to use in that state for CY 2019.

- **Formulary.** Plans must make a formulary available at the time of enrollment and annually thereafter (by posting on the plan website by September 30 and making hard copies available). Similar to directories, we believe integration of Part D and Medicaid-covered prescription and over-the-counter drug/product information in one document is beneficial to both plan enrollees and to health plans. As with the SB and directory, CMS has some experience developing model materials for integrated D-SNPs in Minnesota and is working with Massachusetts to develop integrated formulary model language for integrated D-SNPs to use in that state for CY 2019.
- **D-SNP Non-Renewals:** Coordinating state and CMS communications and processes for D-SNP non-renewals, including working with states and plans to develop state-specific integrated non-renewal notices that include information about changes in the delivery of Medicaid benefits that will accompany the non-renewal of an integrated D-SNP.
- **Model of Care:** Providing technical assistance to states on the implementation of more robust D-SNP model of care (MOC) submissions that incorporate information about the integration of Medicare and Medicaid Managed Long Term Services and Supports (MLTSS). States interested in requiring their contracted D-SNPs to include additional information in their Model of Care (MOC) submissions about the provision of MLTSS and their integration with the medical and prescription drug benefits the plans provide under their Medicare contract may do so via their State Medicaid Agency contracts (which are required for all D-SNPs under 42 CFR §422.107). CMS offers interested states with integrated D-SNPs the opportunity to work with such contracted D-SNPs to include additional information in MOC submissions and to review the integrated MOC submissions concurrent with the review of the plans' MOCs by the National Committee for Quality Assurance pursuant to 42 CFR §422.152(g).

We have successfully implemented an integrated MOC submission and review process with MMPs under the Financial Alignment Initiative, as well as with the D-SNPs participating in the Minnesota Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience since 2014. As part of that effort, Minnesota has required plans to add information to their MOC submissions about how the training for care coordinators incorporates the state's MLTSS requirements; how the state MLTSS assessment and level of care tools are coordinated with the Health Risk Assessment process; and how the Individualized Care Plan (ICP) integrates Medicare and Medicaid services, including MLTSS, addresses the process for coordinating medical and social services identified in the ICP, and addresses state-required MLTSS care plan elements. Minnesota also requires that the MOC include information about Medicare and Medicaid services, including MLTSS, are communicated from the MLTSS care

coordinator to primary care or home health providers; how clinical practice guidelines are appropriate for and tailored to differences in frailty levels, including for members receiving MLTSS; and the measures the D-SNP uses that are tailored to the frail elderly, including those receiving MLTSS, and how these measures account for differences in care delivery models.

We emphasize that any collaboration between CMS and states in this area will maintain the integrity of the CMS MOC requirements and of NCQA's review of MOCs under 42 CFR §422.152(g).

CMS is interested in working with additional states to pursue similar efforts via additional requirements in the State Medicaid Agency Contracts and in providing technical assistance to such states. We welcome comments about the opportunities identified above, as well as any others. We are particularly interested in hearing from states interested in working with CMS to develop comprehensive administrative alignment work plans that include some or all of the options identified above.

We remind states that we are happy to discuss these and other opportunities to promote integration and better beneficiary experiences. We are also available to work with states on issues related to the required contracting between states and D-SNPs. Interested state Medicaid officials should contact the Medicare-Medicaid Coordination Office at: mmcocapsmodel@cms.hhs.gov.

Parts A and B Cost-sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program

In the 2016 Call Letter, CMS reminded plans of their obligations under 42 CFR §422.504(g)(1)(iii) to educate network providers about QMB billing rules and to maintain procedures that ensure network providers do not discriminate against enrollees based on their payment status, e.g., QMB.²⁷ During summer 2016, CMS engaged in strategic conversations with MA organizations to discover their technical assistance needs and learn about concrete strategies to promote compliance. During this process and in follow-up, MA organizations have asked for CMS help to identify the QMB status of enrollees and to recommend promising practices regarding QMB billing.

The QMB Program is a Medicaid benefit that pays Medicare premiums and cost sharing for certain low-income Medicare beneficiaries. Federal law prohibits Medicare providers from collecting Medicare Part A and Part B coinsurance, copayments, and deductibles from those enrolled in the QMB Program, including those enrolled in Medicare Advantage and other Part C plans. Timely access to enrollees' QMB status is critical to inform, monitor, and promote

²⁷ See Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter; Medicare Managed Care Manual, Ch. 4, Section 10.5.2.

provider compliance with these requirements. In June 2017, CMS informed plans about CMS sources of QMB information, including the Medicare Advantage Medicaid Status Data File, which provides the most current information about monthly dual status, including QMB, and corresponding dual status codes.²⁸ As a reminder, for Medicare-Medicaid Plans (MMPs) in the capitated model of the Financial Alignment Initiative and for Program of All-Inclusive Care for the Elderly (PACE) organizations, coinsurance, copays, and deductibles are zero for all Medicare Parts A/B services.

To reinforce billing requirements, simplify compliance, and prevent instances of improper billing, CMS encourages plans to affirmatively inform providers about enrollee QMB status and exemption from cost-sharing liability. Plans can provide real-time QMB status information and indicators through online provider portals and phone query mechanisms and clearly indicate the QMB patient owes \$0 directly on the Explanations of Payment document that they send to providers and on member identification cards. MMPs should make clear that all enrollees – regardless of whether they have QMB status or not – have zero Medicare Parts A/B coinsurance, copayments, and deductibles. In addition, plans can highlight that for any providers who are enrolled in Medicare, Medicare’s HETS eligibility query system will identify those who are QMB.

CMS also encourages plans to educate providers about the QMB billing requirements for Medicare Parts A/B deductibles and coinsurance. Potential strategies include holding recurring trainings, conducting targeted education to providers that improperly bill members, and adding language to provider-focused websites, provider newsletters, and/or provider manuals.

Plans may want to leverage CMS information for providers and plans on CMS’s QMB webpage at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/QMB.html>

Moreover, starting in March 2017, the Complaints Tracking Module (CTM) began distinguishing QMB complaints from other complaints. When appropriate, CMS encourages plans to use this source of information, alongside grievance and plan call center data, to identify further opportunities to strengthen provider education activities, improve internal call center messaging, and reduce future CTM complaints regarding QMB billing.

Encounter Data Listening Forums, Monitoring and Compliance Activities

Under 42 C.F.R. § 422.310, MA organizations are required to submit encounter data records for each item and service provided to an MA plan enrollee. The Medicare Advantage Encounter Data System (EDS) was implemented to receive encounter data beginning in 2012 and has collected over 3 billion encounter data records to date. PACE organizations are also required to submit encounter data.

²⁸ See HPMS memo, “Qualified Medicare Beneficiary Program Enrollee Status Resources” June 21, 2017.

In order to assist organizations in meeting requirements for submitting complete and accurate data, CMS conducts a range of activities aimed at providing feedback and technical assistance to, and soliciting input from, stakeholders. These efforts include distribution of quarterly report cards, site visits with submitters, one-to-one communication with plans, and monthly user group calls which provide updates, training, and an open-mic question and answer period.

Listening Forums. CMS has also initiated a series of listening forums with MA organizations, and MA organizations have expressed appreciation for the opportunity to participate in these forums. CMS has viewed them as successful and has gained important insight into submitters' experiences with the submission of encounter data. In light of the positive feedback received in response to these listening forums, CMS expects to continue holding listening forums in 2018 and will again be reaching out to plans to participate.

The listening forums have helped to highlight areas in the submission process where both plans and CMS can make improvements. A priority for CMS continues to be to ensure the completeness and accuracy of submissions and to seek feedback from stakeholders. CMS presented an approach to monitoring and compliance of encounter data in the 2018 Call Letter. CMS's framework for monitoring and compliance activity was categorized into three performance areas:

- **Operational Performance:** Refers to submitters' performance related to encounter data submission requirements such as certification to submit, non-submission, and frequency of submission.
- **Completeness Performance:** Refers to both the overall volume of encounter data records (e.g., whether encounter data records are being submitted for all services rendered) as well as to the completeness of data within an encounter data record (e.g., whether key fields are populated as expected).
- **Accuracy Performance:** Refers to the reasonableness of ED patterns. Measures addressing the reasonableness of specific data elements or reasonable patterns in submitted data would be considered under the area of accuracy (e.g., reasonable patterns of HCPCs and diagnosis codes).

Stakeholder feedback indicated support of this activity to ensure the completeness and accuracy of encounter data, but also suggested that CMS adopt an incremental approach and continue to seek out stakeholder feedback on monitoring and compliance.

CMS issued an HPMS memo entitled "CMS Monitoring and Compliance of Encounter Data, Performance Metrics and Thresholds – For Comment" on November 1, 2017 and requested feedback from stakeholders. CMS will review comments and finalize the performance and monitoring metrics and thresholds in an HPMS memo that will be distributed in early 2018.

Transparency & Timeliness with Prior Authorization Processes

CMS is aware of stakeholder concerns about the burdens imposed by coverage restrictions such as prior authorizations (PA) in the Part C program.

MAOs receive a capitated payment from CMS and are accountable for furnishing all medically necessary Part A and B services through a network of contracted providers. They are permitted to manage the delivery of benefits within their provider networks using utilization management tools such as prior authorization (PA).

CMS would like to remind MAOs that they should be transparent and provide adequate notice of any coverage restrictions, such as PA requirements, to providers and enrollees. Plans should specify the existence of any coverage restrictions, including what information is needed when submitting a PA request, in the plan's Evidence of Coverage (EOC), their contracts with providers and additional provider communications/materials (e.g., provider manuals). Where an enrollee or provider is attempting to satisfy a PA requirement and the plan requires or has a PA request form, the plan should make PA request forms available and easily accessible.

MAOs should ensure they are delivering timely decisions on PA requests. CMS reminds MAOs that requests for PA for a service (whether by an enrollee directly or by a provider on behalf of an enrollee) are requests for a pre-service organization determination. Therefore, these requests are subject to applicable pre-service organization determination adjudication timeframes and notice requirements under the MA regulations. See 42 CFR §§422.568 and 422.572.

Section III – Part D

Formulary Submissions

CY 2019 Formulary Submission Window

The CY 2019 HPMS formulary submission window will open this year on May 14, 2018 and close at 11:59 PM PDT on June 4, 2018. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 4, 2018 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid and therefore a failure to submit and link a formulary to each plan that uses a formulary by the June 4 deadline will result in denial of that bid submission.

CY 2019 Formulary Reference File

CMS publishes the Formulary Reference File (FRF) which is utilized by Part D sponsors for the purpose of submitting Part D formulary files into HPMS. The FRF is not intended to be a comprehensive list of Part D drugs – the presence on or absence from the FRF does not indicate whether a particular drug is eligible for Part D coverage. However, we do recognize that the FRF has expanded and now includes several drugs for which utilization under Part D would be extremely rare. We also understand that the inclusion of some of these drugs within the Medicare

Plan Finder may lead to beneficiary confusion when the drug is more commonly covered under Medicare Part B, for example. To that end, CMS is analyzing the Part D utilization of current FRF drugs and will be removing drugs from the FRF based on these results. We again emphasize that the removal from the FRF does not mean that the drug is not eligible for Part D coverage. The deletion of such drugs would be based on very infrequent utilization under Part D due to their indication, dosage and administration, and usual administration setting. For example, an intravenous antihypertensive with very little or no Part D utilization, that is only indicated for the short-term treatment of hypertension when the oral route is not feasible, potentially would be deleted from the FRF.

CMS will release a draft FRF that reflects these changes in February of 2018, and will provide Part D sponsors and other stakeholders the opportunity to comment on the FRF changes. A subsequent CY 2019 Formulary Reference File (FRF) will be published in March 2018. The March FRF release will be used in the production of the Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2018, in order to assist plan sponsors in preparing their bid submissions. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

CMS will update the 2019 FRF in mid to late May, prior to the June 4 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2012 and 2013, new Part D drugs cannot be included in the OOPC model since they would not have appeared in the survey. Further, given the limited timeframe between the May release of the 2019 FRF and the June 4 deadline, CMS is unable to accommodate an updated version of the 2019 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2019 FRF will not be included in the 2019 OOPC model.

CMS will offer a summer formulary update window and will publish an update to the FRF in advance of the window. The summer formulary update window will allow for the following formulary changes: 1) the addition of drugs that are new to the summer release of the FRF, and 2) the submission of negative changes on brand drugs, only if an equivalent generic or therapeutically similar drug is added to the summer FRF and corresponding formulary file within the same category and class, at the same tier or lower, and with no more restrictive utilization management than what was applied to the existing brand. Thus, plan sponsors need to carefully consider any newly added drugs to the May release of the 2019 FRF when they submit their formularies by the June 4 deadline since these additional restrictions will be imposed on the summer formulary update window.

In 2017, for the 2018 plan year, the update window was held from July 27 to July 31. Since the summer update window is the final opportunity for plan sponsors to remove drugs from their formularies prior to the start of the plan year, CMS intends to move this window later into the summer, with the goal being the inclusion of newly approved brands and generics that occur in

July and into August. We recognize, however, that Part D sponsors must finalize their formulary submissions for CY 2019 with enough time to meet printing deadlines. We thus seek stakeholder comment regarding the optimal submission window that balances the opportunity for additional formulary substitution versus the need to finalize formulary documents for printing.

Part D sponsors are reminded that they may enhance their formularies at any time, including prior to the start of the plan year, regardless of whether the new drugs have been added yet to the FRF. Such enhancements may entail adding Part D drugs (with or without utilization management restrictions), reducing beneficiary cost-sharing, or removing utilization management edits. These enhancements must be included in the Part D sponsor's marketing materials and must be submitted during the next available HPMS formulary submission window. Under the current formulary submission process, HPMS formulary files are not updated between the aforementioned summer update window and the first HPMS submission window during the plan year. Since the HPMS formulary files feed into the Medicare Plan Finder (MPF), MPF formulary information will not reflect any enhancements the Part D sponsor has made to its formulary files after the summer update. In an effort to provide more up-to-date information within the MPF, CMS will add an enhancement-only window that will occur in late fall. Likewise, we also intend to add a January 2019 formulary update window.

Changes for CY 2019 Formulary Submissions

For the CY 2019 plan year, CMS is proposing changes to the following formulary-related files:

Additional Demonstration Drug (ADD) File

The Additional Demonstration Drug (ADD) file is a supplemental formulary file submitted by Medicare-Medicaid Plans, which contains all non-Part D drugs required by the State. In an effort to streamline the submission process for Part D sponsors offering a Medicare-Medicaid Plan, CMS will make the ADD Validation File available via HPMS in advance of the ADD File submission deadline.

Non-Extended Day Supply (NDS) File

The Non-Extended Day Supply (NDS) file is a supplemental file for formularies that offer partial extended day supply coverage for at least one tier. Based on feedback from Part D sponsors, we understand that the maintenance of this supplemental file has been operationally challenging. Current systems logic has prohibited sponsors from having the flexibility to make some positive enhancements that would otherwise be allowed. Further, CMS's review of the CY 2017 NDC files have not identified any discriminatory activities or causes for concerns. We have concluded the burden of maintaining this supplemental file outweighs any benefit, as such, CMS is eliminating this supplemental file for CY 2019. Part D Sponsors will continue to identify in the

plan benefit package (PBP) if there are any drugs for which the plan imposes a limit of a one month supply, if the drugs are included on a tier that is otherwise available at an extended day supply.

Over-the-Counter (OTC) Validation File

Part D sponsors wishing to offer over-the-counter drug products (OTCs) as part of step therapy or as a utilization management strategy are required to submit an OTC supplemental file. The current file format is National Drug Codes (NDCs) submitted by Part D sponsors. The submitted files are validated against an internal CMS file that contains a universe of OTC NDCs that CMS believes could be offered as part of the sponsor's step therapy or utilization management strategy, consistent with the Chapter 7 of the Medicare Prescription Drug Benefit Manual. NDCs not contained within the CMS validation file are rejected, which necessitates a subsequent submission of a revised file by the Part D sponsor. In an effort to reduce the burden on Part D sponsors to create and submit these files, and to streamline the CMS review of the OTC submissions, CMS is proposing to provide plans with an OTC reference file for CY 2019 that uses a proxy code (e.g., RXCUI) to represent each unique drug ingredient, strength, route, and dosage form, but the file will not contain every possible branded OTC. Providing the file of acceptable OTCs, via proxy code, in advance to plan sponsors will enable them to prepare their files based on known CMS acceptable OTCs, significantly reduce the size of the OTC files, and simplify the submission and review process. For example, the current OTC validation file contains nearly 100 rows representing various products for ranitidine 75 mg oral tablets. These would be condensed to one row for CY 2019. We will provide Part D sponsors an opportunity to review a draft OTC reference file well in advance of the supplemental file submission deadline.

Expanding the Part D OTC Program

The definition of a Part D drug does not include over-the-counter drug products (OTCs). Therefore, Part D sponsors cannot cover OTCs under their basic prescription drug benefit or as a supplemental benefit under enhanced alternative coverage. However, given that OTCs may offer a significantly less expensive alternative to prescription medications, CMS allows Part D sponsors the option to provide OTCs as a utilization management strategy within their administrative cost structure, with the expectation that the use of the OTC medication will offset the use of a more costly Part D drug.

For those sponsors who elect to do so, OTCs offered through a Part D utilization management strategy are a component of the Part D plan premium and result in OTCs provided to the enrollee without any direct cost-sharing at the point-of-sale. The OTCs must be available for the full duration of the contract year and cannot be limited to certain benefit phases. Under this policy, OTCs do not have the same beneficiary protections, such as coverage determinations or temporary fills, required to ensure appropriate access to Part D drugs.

Currently, no standalone PDPs and only a very few MA-PDs offer OTCs under existing Part D policies, but there has been plan interest to broaden what could be provided. Consequently, CMS is contemplating allowing additional flexibilities for Part D plan sponsors to offer access to OTCs. For example, CMS could consider allowing sponsors to include additional OTC products such as dietary supplements and cough medicines, without the requirement that the OTC product offset the use of a Part D drug.

We recognize that any such expansion of the current policy could potentially increase program costs. Plan sponsors should note that the beneficiary inducement laws still apply. We are thus soliciting feedback from stakeholders on Part D OTC enhancements that could be considered for future policy. This feedback could include information on how well the current program is working, the deficiencies of the current program, what additional flexibilities would be helpful, and what the impact would be on spending, particularly premiums, as a result.

Medication Therapy Management (MTM) Annual Cost Threshold

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per 42 C.F.R. § 423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries is specified as costs for covered Part D drugs in an amount greater than or equal to \$3,000 increased by the annual percentage increase (API) in Part D drug expenditures, specified in 42 C.F.R. § 423.104(d)(5)(iv). The 2018 MTM program annual cost threshold is \$3,967. The 2019 MTM program annual cost threshold will be the 2018 annual cost threshold adjusted based on the API and will be finalized in the 2019 Call Letter.

Part D Benefit Parameters for Non-Defined Standard Plans

Each year, we set forth certain benefit parameters, which are based on updated data analysis, and therefore, are subject to change from year to year. Specifically, pursuant to §423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package (other than defined standard) or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered; and, pursuant to 42 C.F.R. §423.104(d)(2)(iii), tiered cost-sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. The benefit parameters for CY 2019 are set forth in Table 25 below.

CMS has included a proposal in the CMS-4182-P; Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs NPRM, published November 28, 2017, to eliminate the PDP enhanced alternative (EA) to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a

service area. We also announced our intent to reexamine how we define the meaningful difference between basic and enhanced plans, and sought stakeholder input. For CY 2019, we intend to follow the same methodology that was utilized to determine the CY 2017 and CY 2018 basic to enhanced meaningful difference threshold. We propose a minimum monthly cost-sharing out-of-pocket-costs (OOPC) difference between basic to enhanced PDP offerings of \$22. This value is based on the 50th percentile of the November CY 2018 Bid data run through the updated CY 2018 OOPC MPF model that incorporates CY 2018 Formulary Data, 2012/13 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates. Specific guidance related to the EA to EA PDP meaningful difference will be included as part of the Final Rule.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 25 have been met, we will continue to rely on the FDA Application Type to identify formulary drugs as applicable or non-applicable. The maximum coinsurance of 50% applies to tiers that contain only applicable drugs. If only non-applicable drugs or a combination of both non-applicable and applicable drugs are on a tier, then the maximum coinsurance of 17% applies. We remind sponsors that when cost-sharing reductions beyond the standard benefit are offered through a supplemental Part D benefit, the plan liability is applied to applicable drugs for applicable beneficiaries before the manufacturer discount.

Benefit Review

We will continue to scrutinize the expected cost-sharing amounts incurred by beneficiaries under coinsurance tiers in order to more consistently compare copay and coinsurance cost-sharing impacts. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty tiers that are greater than the standard benefit of 25%, we will compare the average expected cost-sharing amounts submitted by sponsors in the PBP to the established copay thresholds, as noted in Table 25 below, to determine whether the coinsurance values are discriminatory. Similarly, we will evaluate the drug composition of copay tiers in order to assess whether the formulary and benefit structure is providing a meaningful benefit.

Tier Composition

We expect Drug Tier Labels to be representative of the drugs that make up that tier. Sponsors will continue to have the option of selecting a non-preferred brand tier or non-preferred drug tier, but not both. CMS will continue to evaluate the brand/generic composition of the non-preferred brand tier as part of the bid review process. In recent years, we have communicated concerns based on an outlier analysis. Based on an analysis of CY 2018 formulary and benefits data, we propose a maximum threshold of 25% generic composition for the non-preferred brand tier for CY 2019. This threshold is based on the mean generic composition, submitted at the plan level, of the non-preferred brand tier for CY 2018. Since Part D sponsors have the option to choose between the non-preferred brand and non-preferred drug tier labels, the inclusion of a significant

number of generic drugs on a tier that is labeled as brand is unnecessary and may lead to confusion. While we continue to believe a coinsurance structure is the preferable cost-sharing structure for the non-preferred drug tier, CMS will continue to afford Part D sponsors the flexibility to determine the cost-sharing structure that is most appropriate for their benefit design, with the goal of maintaining transparency and a meaningful benefit offering for enrollees in a plan with non-preferred drug tiers that also balances a sponsor's ability to mix brand and generic drugs within the tier. We intend to conduct outlier tests for those Part D sponsors who choose a copay structure for the non-preferred drug tier. In order to demonstrate that the cost-sharing structure chosen provides a value for beneficiaries, we expect sponsors to evaluate and be prepared to provide written justification upon request. We expect the justification to include detailed information about the generic drugs on the non-preferred drug tier, such as expected utilization, the formulary alternatives represented on lower tiers, and any tier placement strategy with respect to utilization management. Sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.

Improving Access to Part D Vaccines

According to the Center for Disease Control and Prevention's (CDC) Surveillance of Vaccination Coverage among Adult Populations — United States, 2015, vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap)²⁹. While the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70% of adults for whom the vaccine is recommended remain unprotected. In an effort to improve access to these and other Part D vaccines, we encourage Part D sponsors to either offer a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

Table 25: Benefit Parameters for CY 2019 Threshold Values

	CY 2019 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC) ¹	
Enhanced Alternative Plan vs. Basic Plan	\$22
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	\$ ^{2,3}
Preferred Generic Tier	<\$20 ⁴
Generic Tier	\$20

²⁹ Williams WW, Lu P, O'Halloran A, et al. Surveillance of Vaccination Coverage among Adult Populations — United States, 2015. MMWR Surveill Summ 2017;66(No. SS-11):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.ss6611a1>

	CY 2019 Threshold Values
Preferred Brand/Brand Tier	\$47
Non-Preferred Drug Tier	\$100
Non-Preferred Brand Tier	\$100
Injectable Tier	\$100
Select Care/Diabetic Tiers ⁵	\$11
Vaccine Tier	\$0
Maximum Coinsurance: Pre-ICL (3 or more tiers)	\$ ^{2,3}
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	33%
Select Care/Diabetic Tiers ⁵	15%
Vaccine Tier	0%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)	\$ ⁶
Preferred Generic Tier	17%
Generic Tier	17%
Preferred Brand/Brand Tier	50%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	50%
Select Care/Diabetic Tiers ⁵	50%

	CY 2019 Threshold Values
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	\$670

¹ The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 50th percentile of the November CY 2018 Bid Data run through the CY 2018 OOPC MPF model which incorporates CY 2018 Formulary Data, 2012/13 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates. This threshold excludes plans that were waived of the meaningful difference requirements due to the transition period afforded during consolidation. For each parent organization, any cost-sharing OOPC comparison between a basic plan and EA plan in the same region must meet the minimum Enhanced Alternative Plan vs. Basic Plan threshold.

² These thresholds are based on the 95th percentile of the CY 2018 Bid Data. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary.

³ “S” in the above chart refers to “standard retail cost-sharing” at a network pharmacy. Standard retail cost-sharing (S) is cost-sharing other than preferred retail cost-sharing offered at a network pharmacy.

⁴ A separate maximum cost-share threshold for the Preferred Generic Tier has not been established. Cost-sharing for the Preferred Generic Tier need only be lower than that for the cost-sharing of the Generic Tier. Equivalent cost-sharing for the Preferred Generic and Generic tiers will not be accepted, except in the case when a sponsor buys down the cost-sharing to \$0 for both generic tiers.

⁵ The Select Care Drug and Select Diabetic Drug Tiers must provide a meaningful benefit offering with low or \$0 beneficiary cost-sharing for drugs targeting specific conditions (e.g., \$0 tier for drugs related to diabetes and/or smoking cessation). We continue to expect cost-sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be \$0.

⁶ Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this gap benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier (partial tier coverage). If the additional gap cost-sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 17% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 50% manufacturer discount for applicable drugs.

Specialty Tiers

Per 42 C.F.R. §423.578 (a)(7), a Part D sponsor may exempt a formulary tier in which it places very high cost and unique items from its tiering exception process. In order for a Part D drug to be placed on this specialty tier, the sponsor-negotiated price must exceed an established dollar-per-month threshold. Similar to past years, an analysis was performed utilizing CY 2017

prescription drug event (PDE) data to identify monthly fills that exceed the current specialty tier threshold of \$670. This analysis showed that just around 1% of 30 day-equivalent fills exceeded \$670 and as a result, CMS will maintain the \$670 threshold for CY 2019. We will continue to monitor this trend in future years to determine if specialty tier threshold increases are necessary.

Low Enrollment Plans (Stand-alone PDPs only)

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have a sufficient number of enrollees to establish that they are viable plan options. CMS evaluates plan enrollment at the PDP region level. Consistent with the methodology outlined in the CY 2012 Call Letter, plans are deemed as low enrollment plans if both of the following are true: 1) the plan enrollment is below 1,000 and 2) the plan is in the lowest quintile of enrollment within the specific PDP region. Prior to taking additional action on a low enrollment plan, CMS considers relevant factors such as: (1) whether the plan is a basic plan that is satisfying requirements set forth at 42 CFR § 423.104(f)(2), and the organization's enhanced plan does not have low enrollment in the same region; (2) whether the plan was a new plan and if it has been in existence for three or more years; (3) whether the plan is offered nationally; (4) the total number of plan offerings in the applicable region; and (5) if the plan's premium currently falls at or below the low income benchmark premium amount. When a plan is deemed to have low enrollment, the Part D sponsor will be provided the opportunity to provide a strategic plan that describes how enrollment will be increased for the upcoming plan year. Alternatively, the sponsor will have the option to consolidate or non-renew the plan. However, CMS proposes that if the plan is identified as a low enrollment plan for two consecutive years using the above criteria, CMS can exercise its authority to non-renew the plan. By April 2018, we will notify affected low enrollment plans with less than 1,000 enrollees of available options for consolidation/withdrawal options.

Improving Drug Utilization Review Controls in Medicare Part D

Part D Opioid Overutilization Policy

Opioid medications ("opioids") have serious risks such as addiction, overdose, and death. In response to the growing national opioid epidemic, CMS's Medicare Part D opioid overutilization policy has evolved incrementally to address prescription opioid overuse in Medicare Part D from a medication safety perspective while preserving beneficiary access to medically necessary drug regimens. Currently, in addition to improved formulary management, we expect sponsors to:

1. Retrospectively perform enhanced drug utilization review (DUR) to identify potential opioid overutilizers and provide appropriate case management aimed at coordinated care.
2. Prospectively manage drug utilization by implementing real-time safety alerts at the time of dispensing as a preventive step to ensure prescribers are aware that potentially

high risk levels of prescription opioids will be dispensed to their patients (concurrent DUR).

In the CY 2013 Call Letter and supplemental guidance, CMS described the enhanced DUR policy that focuses on cases that have the highest risk of adverse events.³⁰ Part D sponsors should identify potential opioid overutilizers and conduct retrospective reviews and case management. This approach can help identify beneficiaries at risk of adverse events due to prescription opioids. These efforts do not include beneficiaries with cancer or in hospice. Under our current policy, if sponsors cannot establish medical necessity due to unresponsive prescriber(s), or if misuse is verified with prescribers, with the prescribers' agreement, sponsors may implement a beneficiary-specific claim edit at all network pharmacies that will result in the rejection of claims or quantities in excess of the opioid dosing deemed medically necessary.

To facilitate compliance with this policy, CMS developed the Overutilization Management System (OMS) in July 2013. This system identifies those beneficiaries we consider at significant risk (high levels of opioids with potential coordination of care issues due to obtaining opioids from multiple prescribers and pharmacies). CMS expects plans to report back to us their results of implementing the review and case management policies through the OMS. Over time, CMS has modified the OMS opioid overutilization criteria based on stakeholder feedback and on the CDC Guideline for Prescribing Opioids for Chronic Pain.³¹ With regard to the latter, the OMS criteria incorporate a 90 morphine milligram equivalent (MME) threshold cited in the CDC Guideline, which was developed by experts as the level that prescribers should generally avoid reaching with their patients. CMS considers plan and provider burden along with beneficiary impact in developing the OMS criteria. We have also continued to modify OMS in other ways as relevant information and guidelines have become available. For example, in October 2016, we added a flag to OMS indicating potential opioid overutilizers who have also been prescribed a benzodiazepine, which is known to increase risk of overdose when taken together.

Although these efforts have reduced very high risk overutilization of prescription opioids in the Part D program, given the urgency and scope of the national opioid epidemic³², we will propose new strategies to more effectively address this issue in Part D. Most notably, these efforts will better manage chronic overuse among beneficiaries who are taking high levels of prescription opioids (e.g., beneficiaries with 90 MME or more without multiple prescribers and pharmacies

³⁰ An excerpt from the Final 2013 Call Letter, the supplemental guidance and additional information about the OMS are available on the CMS webpage, Improving Drug Utilization Controls in Part D (<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>).

³¹ See <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

³² See White House website <https://www.whitehouse.gov/presidential-actions/presidential-memorandum-heads-executive-departments-agencies/> and <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/>; and HHS website <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

who may not be addressed through the OMS) as well as opioid naïve patients. The proposals include:

- Enhancing the OMS by adding additional flags for high risk beneficiaries who use “potentiator” drugs (such as gabapentin and pregabalin) in combination with prescription opioids. OMS already flags concurrent benzodiazepine use.
- Implementing revisions to the PQA opioid quality measures used by CMS, and consideration of a new PQA measure, Concurrent Use of Opioids and Benzodiazepines. [See the Enhancements to the 2019 Star Ratings and Future Measurement Concepts section of the draft 2019 Call Letter]
- Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at a dosage level of 90 MME per day³³, with a 7 days supply allowance.
- Implementing a days supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day).
- Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits.

We welcome feedback on this important topic. All Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis.

Retrospective DUR

Comprehensive Addiction and Recovery Act of 2016 and the Overutilization Monitoring System (OMS)

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) includes provisions that permit Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries’ access to coverage for frequently abused drugs to certain prescribers and pharmacies.

In a recently published proposed rule (82 FR 56336), CMS included provisions to implement Section 704 for plan year 2019. As part of these provisions, we also proposed to codify the

³³ Please note that CMS will use the term “MME” going forward instead of morphine equivalent dose (MED), which CMS has used to date. CMS used the term MED in a manner that was equivalent to MME. We will update CMS documents that currently refer to MED as soon as practicable.

current Part D retrospective opioid overutilization policy and OMS reporting. We will consider the comments we received that were submitted in response to the notice of proposed rulemaking. We plan to publish a final rule with sufficient time for Part D sponsors to consider it in preparing their 2019 bid proposals.

OMS Metrics

The Opioid Daily Dose metric was added to the quarterly OMS reports in 2016 for informational purposes:

- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 12 months.

Since the January 2016 OMS report, we have observed a 10% decrease in the Opioid Daily Dose rate across all Part D contracts, from 122.4 to 109.7 per 1,000 opioid utilization days.

Beginning with the 2018 OMS reports, we propose to change the Opioid Daily Dose measurement period from 12 months to 6 months to align with the revised OMS criteria measurement period. In addition, we propose to report a second Opioid Daily Dose rate with a 90 MME threshold to further align with the revised 2018 OMS criteria. Therefore, in the April 2018 OMS reports, CMS will report:

- 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during the last 6 months.
- 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 6 months.

We propose to discontinue reporting the 120 MME Opioid Daily Dose rate in the 2019 OMS reports.

Opioid Potentiator Drugs

As previously mentioned, we added a concurrent benzodiazepine-opioid flag to OMS to alert Part D sponsors that concurrent use may be an issue that should be addressed during case management. In October 2016, when CMS began reporting the concurrent use of benzodiazepines among potential opioid overutilizers to Part D sponsors through OMS, we found that 64% of potential opioid overutilizers had a claim(s) for a benzodiazepine. A year later the percent dropped to 62%. Although the trend is going in the right direction, we find that the continued high use of benzodiazepines within this high risk population to be of concern and will continue to flag this use.

We have been working with the Office of the Inspector General (OIG) to identify other non-opioid potentiator³⁴ drugs that may pose safety risks when misused with opioids. Gabapentin, a

³⁴ A drug potentiator is defined as a chemical, herb, or other drug that is used to increase the effects of a substance and consequently, increasing both the substance and the potentiators abuse potential.

gabapentinoid, has been identified as an independent risk factor for opioid-related deaths and is reportedly misused due to the euphoria associated with use at high doses.^{35,36} The increasing use of gabapentin for off-label indications, despite the lack of evidence from clinical trials, has been documented in the literature.^{37,38} One such off label indication is non-specific chronic lower back pain, which is on the rise.³⁹ As the focus on opioid use is intensifying, clinicians and patients may be looking for alternatives for their pain treatment.⁴⁰ Currently, gabapentin is FDA-approved for the treatment of postherpetic neuralgia in adults and the treatment of partial onset seizures.

From 2015 to 2017, the rate of gabapentin users increased by 14% from 93 to 108 users per 1,000 Medicare Part enrollees based on 6-month measurement periods. Higher gabapentin use was observed among opioid users. From January to June 2017, there were 308 gabapentin users per 1,000 Part D chronic opioid users⁴¹, and 452 gabapentin users per 1,000 OMS potential opioid overutilizers.⁴² From January - June 2015 to January - June 2017, we observed a change in the percent of gabapentin users receiving very high (> 2,400 mg) doses among opioid users and chronic opioid users of 7.5% and 8.5%, respectively. CMS is concerned that the increase in gabapentin use and higher doses among opioid users may place beneficiaries at a higher risk for adverse events. These safety concerns extend to pregabalin, which is also a gabapentinoid. We propose to add a concurrent opioid-gabapentin/pregabalin flag to OMS. We are requesting feedback from stakeholders about what their experience has been with the potential overuse of gabapentin and pregabalin with opioids, whether this additional flag would be useful for Part D sponsors, and how the case management approach could help with gabapentin/pregabalin-opioid misuse and also with other potentiators. Furthermore, we seek comment on other potentiator drugs that should be added to the OMS and the utility of adding such drugs that may increase the risk for overdose when used with opioids. As with concurrent benzodiazepine and opioid use, we expect that when sponsors perform case management, they would include the

³⁵ Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. "Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case-control study." *PLoS Med* 14(10): e1002396.

³⁶ Evoy KE, Morrison MD, Saklad SR. Abuse and misuse of pregabalin and gabapentin. *Drugs* 2017;77:403-26.

³⁷ Mack, A. "Examination of the Evidence for Off-Label Use of Gabapentin" *J Manag Care Spec Pharm*, 2003 Nov;9(6):559-568.

³⁸ Fukada, Christine et al. "Prescribing Gabapentin off Label: Perspectives from Psychiatry, Pain and Neurology Specialists." *Canadian Pharmacists Journal* : CPJ 145.6 (2012): 280–284.e1. PMC. Web. 17 Nov. 2017.

³⁹ Shanthanna, Harsha et al. "Benefits and Safety of Gabapentinoids in Chronic Low Back Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials." Ed. Alexander C. Tsai. *PLoS Medicine* 14.8 (2017): e1002369. PMC. Web. 3 Nov. 2017.

⁴⁰ Goodman, CW, Brett, AS. "Gabapentin and Pregabalin for Pain — Is Increased Prescribing a Cause for Concern?" DOI: 10.1056/NEJMp1704633.

⁴¹ Opioid users are beneficiaries with at least one opioid claim; chronic opioid users are beneficiaries with an opioid episode of 90 days or more.

⁴² Based on analysis using the revised 2018 OMS criteria (e.g., beneficiaries with average MME >= 90 mg, 4 or more prescribers and pharmacies, or 6 or more prescribers).

use of other drugs (e.g., gabapentin and pregabalin) that can potentiate the risk of overdose within the case management.

Patient Safety Reporting

CMS also uses quality measures developed by the PQA to track trends in opioid overuse across the Medicare Part D program. The Enhancements to the 2019 Star Ratings and Future Measurement Concepts section of the draft 2019 Call Letter discusses the implementation of changes to the PQA-endorsed opioid overutilization measures in the Patient Safety reports and proposals for the display page, and consideration of a new PQA measure, Concurrent Use of Opioids and Benzodiazepines.

Since 2016, sponsors have received monthly Patient Safety reports based on the PQA opioid measures. We communicate with plans about their performance on these quality measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure should report actions they will take to improve performance.

Sponsors may use the reports to supplement their DUR programs to address overutilization of opioids across a population broader than OMS. CMS expects sponsors to routinely monitor these data to compare their performance to overall averages and assess their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.

Concurrent DUR

Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent DUR requirements for all Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the FDA-approved maximum dosing). We wish to strengthen this aspect of the current Part D opioid overutilization policy, as follows. We note that PACE organizations are expected to comply with these policies unless they do not adjudicate claims at POS.

Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users

Sponsors are currently expected to implement either soft and/or hard formulary-level safety edits for opioids based on a cumulative MME at POS to prevent potentially unsafe opioid dosing, as outlined and finalized in the 2017 and 2018 Call Letters. Plans may set any soft cumulative opioid claim edit MME threshold at or above 90 mg per day and any hard cumulative opioid claim edit at or above 200 mg per day.

These POS edits provide real-time information to help ensure providers are aware that potentially high risk levels of opioids will be dispensed to their patients, and to promote care coordination. Specifically, the POS edits are triggered at the pharmacy when a patient's total

opioid dose across all of their adjudicated prescriptions reaches a certain MME level per day. The pharmacist receives an alert and then action must be taken before the prescription can be covered. We also encourage pharmacists to review the patient’s records in their State’s Prescription Drug Monitoring Program (PDMP) system (See Medicare Learning Network (MLN) Matters® Article SE1250: Prescription Drug Monitoring Programs: A Resource to Help Address Prescription Drug Abuse and Diversion: <https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1250.pdf>).

As shown in Table 26, in 2017, the first year that sponsors were expected to have either a soft and/or hard edit, 51% of contracts (320 contracts) utilized a hard edit. In 2018, 50% of contracts (341 contracts) implemented a hard edit.

Table 26: Counts of Part D contracts with soft and/or hard MME edits

Contract	Contracts with Hard Edit only		Contracts with Soft Edit only		Contracts with both Hard and Soft edits		Total contracts
	Number	Percent	Number	Percent	Number	Percent	Number
2018	160	23.5%	340	49.9%	181	26.6%	681
2017	172	27.3%	310	49.2%	148	23.5%	630

Most contracts have implemented soft edits at 90 MME and hard edits at 200 MME, which are the “floor” of CMS’s guidance. Of those contracts with hard edits, 76% in 2017 and 67% in 2018 set a threshold at the minimum recommended MME of 200 mg. Furthermore, 95% of contracts with a soft edit set an MME threshold from 90 – 120 MME in 2017 and 2018. In 2018, the proportion of contracts with 90 MME thresholds increased from 3% in 2017 to 40% in 2018.

Table 27: Counts of Part D contracts with soft edits by MME level

Contract Year	90	100	120	200-300	>300	Total contracts with soft edits
2018	209 (40%)	119 (23%)	166 (32%)	26 (5%)	1 (0%)	521
2017	16 (3%)	92 (20%)	326 (71%)	2 (0%)	22 (5%)	458

Table 28: Counts of Part D contracts with hard edits by MME level

Contract Year	200	>200-300	360	>360	Total contracts with hard edits
2018	227 (67%)	49 (14%)	61 (18%)	4 (1%)	341
2017	244 (76%)	10 (3%)	50 (16%)	16 (5%)	320

In 2017, we provided additional guidance to sponsors regarding appropriate use of these edits.⁴³ As we stated in the memo, through review of complaints received via the CMS Complaint Tracking Module (CTM) during the first months of 2017, discussions with Part D sponsors, and receipt of questions from other stakeholders, we believed that some sponsors implemented these edits beyond their intended use as a safety edit. For example, the edits are not intended as a means to implement a prescribing limit or apply additional clinical criteria for the use of opioids, but instead to give physicians important additional information about their patients' opioid use. Since that time, we have observed few complaints per month in the CTM related to these edits.

Given the public health emergency and the fact that half of sponsors are already implementing hard MME edits, sponsors can and should do more to address chronic, high prescription opioid overuse. Therefore, we propose that all sponsors should implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME). This value aligns with the CDC Guideline, which recommends to generally avoid increasing the daily dosage of opioids to 90 MME.

Sponsors should not include multiple prescriber or multiple pharmacy criteria in these edits so that all beneficiaries using 90 MME per day or more regardless of the number of providers are identified. Sponsors should continue to apply specifications to account for known exceptions, such as hospice care; cancer diagnoses; reasonable overlapping dispensing dates for prescription refills⁴⁴ or new prescription orders for continuing fills; and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeals processes. It is also very important that sponsors

⁴³ HPMS memo, July 7, 2017, Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit.

⁴⁴ Prescription opioids are controlled substances under the Controlled Substances Act (CSA) and are assigned to Schedule II through V. Schedules are assigned based on the abuse potential and the severity of the psychological or physical dependence of the prescription opioid. A complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15. Schedule II opioids require a new prescription for each fill while prescriptions for schedule III through V do not and therefore, can include refills.

implement these edits in a way that beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine, is not impacted. Sponsors should not include buprenorphine products in this edit.⁴⁵

To balance beneficiary access to medically necessary drug regimens and reduce the potential for any unintended consequences for patients already on higher doses of opioids such as withdrawal symptoms, we propose that sponsors should implement these edits in 2019 to allow beneficiaries to receive a 7 days supply of the prescription that triggered the hard edit as written. This would provide a short term supply to patients to allow time to pursue coverage through the exceptions process. However, if the exception request is approved, the patient may need to obtain a new prescription from their prescriber for amounts beyond the 7 days supply. Alternatively, the patient could elect not to receive the partial 7 days supply fill (e.g., they are not out of the medication) and go through the exceptions process. In that case, if approved, the original prescription could be filled. Also, in the case of opioid prescriptions that trigger the 90 MME hard edit where the packaging is only available in a days supply greater than 7 days, we would not expect any supply to be provided. The beneficiary would need to obtain an approved exception in order to get the medication. Nonetheless, we are not aware of any State laws or labeling that would prohibit prescription opioids from being dispensed in a smaller quantity.

We additionally propose to only allow the 7 days supply once. That is, if the beneficiary attempts to fill a prescription for another opioid that triggers the MME hard edit, another 7 days supply would not be allowed. We request comment on this concept and stakeholder feedback on its operational feasibility. Should we finalize a policy whereby the 7 days supply is only available once after the 90 MME hard edit is triggered during a specific time period, if a patient presents at the pharmacy with multiple opioid prescriptions on the same day, if only one 7 days supply was allowed, the pharmacist would help assess the immediate needs of the patient to help determine which prescription should be filled for a 7 days supply. We further seek comment on when and how to best communicate to beneficiaries that the one-time 7 days supply would not be available for future prescriptions should the MME level remain at 90 mg or higher.

To estimate the number of beneficiaries who may be impacted by a cumulative MME edit at 90 MME per day, we analyzed 2016 PDE data across all Part D sponsors. In 2016, almost 1.6 million beneficiaries (3.8% of Part D enrollees) met or exceeded 90 MME for at least one day⁴⁶, excluding those with cancer, in hospice care, or with overlapping dispensing dates for timely

⁴⁵ All formulations of buprenorphine, including those for pain, have been removed from the most recent CDC MME conversion factor file. https://www.cdc.gov/drugoverdose/data-files/CDC_Oral_Morphine_Milligram_Equivalents_Sept_2017.xlsx

⁴⁶ The estimate is based on the MME daily dose calculated per opioid prescription. The daily dose is assigned to the prescription's covered days and calculated from the dispensing date and the days supply, and summed per day across all overlapping opioid fills. Methodology differs from the OMS average MME calculated from all opioid prescriptions dispensed during the measurement period.

continued fills for the same opioid (e.g., false positives). We seek feedback on whether all sponsors have the capacity to implement hard edits at 90 MME as well as the 7 days allowance proposal for 2019. We also request comment on other solutions to address prescription opioid overuse while balancing access to medically necessary drug regimens and reducing the potential for unintended consequences.

Furthermore, we reiterate that when the MME edit is triggered and cannot be resolved at the pharmacy, consistent with Section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual, the sponsor is required to notify their network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee (“Medicare Prescription Drug Coverage and Your Rights”, CMS-10147, OMB Approval No. 0938-0975). This notice instructs enrollees on how to contact their plan and explains their right to obtain a coverage determination from their plan, including information about the exceptions process.

Sponsors are reminded that an enrollee, the enrollee’s representative, or the enrollee’s prescriber has the right to request a coverage determination for a drug or drugs subject to the MME edit, including the right to request an expedited coverage determination. The timeframe for expedited coverage determination requests applies when the prescriber indicates, or the plan decides, that applying the standard timeframe may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function. We generally expect coverage determination requests seeking exceptions to the MME edit to meet the criteria for expedited review, which means the plan sponsor must issue a decision within 24 hours of receipt of the prescriber’s supporting statement (attestation).

Consistent with current guidance, if the only issue in dispute is the MME, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested. The authorization of the higher MME level should be considered an approved exception and be valid through the remainder of the plan year. The exception should apply to the cumulative MME level for the beneficiary, not just one specific drug, or one prescriber. In order to minimize unnecessary disruptions in therapy, Part D sponsors should consult with the prescriber(s) to determine whether dose escalation for the beneficiary is imminent, and authorize an increased MME accordingly. The sponsor should also remove the edit if it is determined that the beneficiary meets their established criteria for known exceptions (such as cancer or hospice).

As outlined in 42 CFR § 423.120(b)(7), a Part D sponsor that uses a formulary under its qualified prescription drug coverage must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. Accordingly, CMS expects sponsors’ network pharmacies and customer service representatives to be adequately trained with regard to these edits to ensure affected beneficiaries are given timely and appropriate information and instruction. It is important that these edits be implemented in a manner that minimizes disruption to beneficiaries. It is integral that sponsors have the ability to efficiently process associated

exceptions and appeals, including expedited requests. CMS expects sponsors to ensure that their staff are trained to appropriately identify enrollee requests for a coverage determination, including verbal requests made by enrollees affected by hard MME edits. Plans are not permitted to instruct an enrollee who is requesting coverage that only their prescriber can initiate the request.

Part D sponsors will continue to submit information on their cumulative MME safety edits using a template through HPMS. We will monitor implementation of these edits including complaints data. In addition, Part D sponsors report implementation outcomes of their MME POS edits, such as number of claims rejected due to edits, number of beneficiaries impacted, and number of rejected claims overridden or processed through the Part D reporting requirements. CMS will analyze these data once reported and validated. The first data collection will be in February 2018 for 2017 reporting requirements data and validated data by September 2018.⁴⁷

Days Supply Limits for Opioid Naïve Patients

The sixth recommendation of the CDC Guideline states that opioids prescribed for acute pain should be limited to three days or fewer, and that seven days are rarely necessary. Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use. Because the amount of opioid prescribed can often be in excess of the amount needed to treat an acute event, leftover supplies of opioids can become the source for misuse and diversion.⁴⁸ Limiting the initial amount of prescription opioids dispensed may reduce the risk that patients develop an affinity for these drugs and transition to chronic use or misuse.⁴⁹ Currently, at least sixteen States have or plan to add by statute or agency rule days supply (e.g., 5 or 7 days) and/or daily dose limits on the initial amount of opioids that clinicians can prescribe for ‘acute’ pain.⁵⁰ In addition, several large prescription benefit plans are implementing similar restrictions within their commercial, health plan, employer, and Medicaid clients.^{51,52}

In addition to the strategies described above to help better manage high, chronic prescription opioid use, CMS intends to establish a days supply limitation policy for opioid naïve patients in this year’s final 2019 Call Letter that balances reducing the harm posed by opioids with an

⁴⁷ See Part D reporting requirements: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html

⁴⁸ Centers for Disease Control and Prevention (CDC). Adult use of prescription opioid pain medications—Utah, 2008. MMWR Morb Mortal Wkly Rep. 2010;59(6):153-157.

⁴⁹ Bateman, BT, Choudhry, NK. Limiting the Duration of Opioid Prescriptions: Balancing Excessive Prescribing and the Effective Treatment of Pain. JAMA Intern Med. 2016;176(5):583-584. doi:10.1001/jamainternmed.2016.0544

⁵⁰ <http://www.astho.org/StatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/>

⁵¹ <https://cvshealth.com/thought-leadership/fighting-opioid-abuse-our-pbms-approach>

⁵² <http://drugtopics.modernmedicine.com/drug-topics/news/express-scripts-limits-opioid-prescriptions>

individual's need for access to appropriate pain relief. Ultimately, we seek to align our policy with other Government programs. For example, the FDA is seeking stakeholder input (82 FR 58572) on how the FDA might, under its Risk Evaluation and Mitigation Strategy (REMS) authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.

We expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. CMS understands that implementing such restrictions may create important challenges. Any restrictions should not compromise appropriate pain treatment or result in an excessive burden on clinicians and their patients. We request feedback from stakeholders, especially Part D sponsors, providers, and PBMs, on the implementation of a days supply limitation at 7 days or if an alternative days supply limit would be more appropriate (such as 3 days or 5 days), including their experience with such limitations or the basis for their recommendations. We also solicit comment on whether a days supply limit with or without a daily dose maximum (e.g., 50 MME per day) would be more effective. In particular, we request information on both inclusions and exceptions for specific clinical situations (i.e., whether and to what extent a supply limit could be based on specific indications or other criteria) and other parameters and what safeguards should be in place to protect appropriate beneficiary access.

Opioid Duplicative Therapy Safety Edits

Both the use of long-acting (LA) opioids and the number of opioid prescriptions are associated with a higher risk of mortality.^{53,54} Clinically, there is little support for maintaining a patient on multiple different opioids and such use creates other health care issues. First, the use of multiple opioids that compete for similar pain receptors may provide little improvement in analgesia while increasing the risk of adverse events. In addition, prescriptions for multiple opioids (whether LA or short-acting (SA)) and/or multiple strengths increases the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.⁵⁵ Therefore, additional DUR controls at the POS like a soft edit may help reduce excess opioid supplies and reduce adverse events.

Beneficiaries who receive multiple LA and/or multiple SA opioids may lack coordinated care and be at higher risk of opioid overdose. Some plans and PBMs already implement therapeutic duplication edits that check for opioid prescriptions whose days supply overlap before a certain percent has expired or overlap for a minimum number of days. If the prescription overlap criteria

⁵³ Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14;315(22):2415-23.

⁵⁴ Baumlatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796-801.

⁵⁵ Manchikanti, L. Helm II, S, Fellows, B. Janata, J.W. Pampati, V., Grider, J.S. Boswell, M.V. Opioid Epidemic in the United States. Pain Physician 2012; 15:ES9-ES38

are met, the plan sends an alert to a pharmacy at POS. However, many of these edits are message only and may not cause a pharmacist to check a patient profile or his/her State's PDMP.

As a result of these concerns, CMS designed an analysis to investigate duplicate opioid use in Medicare Part D. In this context, we defined “duplicate” or “multiple” as more than one LA or more than one SA opioid prescription with overlapping days supply. This does not, however, mean a combination of LA and SA opioids with each other. Duplicate LA use was defined as a second prescription for an LA that occurred before 75% of a prior LA opioid's days supply expires. We defined duplicative therapy as fills for different LA opioids unique at the generic entity, dosage form, and strength. For example, methadone 10mg and methadone 5mg tablets would trigger the opioid duplicative edit. We used 2016 prescription drug event (PDE) claims for LA opioids to generate beneficiary counts. For purposes of this analysis, LA opioids are defined⁵⁶ as oral /buccal formulations that can be taken every 8 hours or greater, or are transdermal.

In 2016, 12.9 million out of 43.6 million Part D enrollees had at least one claim for an opioid.⁵⁷ The results of the analysis are outlined in Table 29 below. We found that over 1.3 million enrollees used LA opioids.

Table 29: Annual Count and Rate of Unique Beneficiaries with Duplicative LA Opioid Use, 2016

Criterion number	Criterion	Number Part D Enrollees Meeting Criterion	Percent of LA Opioid Users
Criterion 1	LA opioid usage	1,305,469	100%
Criterion 2	Duplicate LA use: Criterion #1 and at least 1 fill of an LA opioid before 75% of prior claim's days supply expired	253,056	19.4%
Criterion 3	Duplicative therapy: Criterion #2 and different LA opioids at the generic entity, dosage form, and strength	203,828	15.6%
Criterion 4	Multiple providers: Criterion #3 with different prescribers	66,360	5.1%

Of the beneficiaries who used LA opioids in 2016, over 250,000 (or almost 20% of LA opioid users) had at least one fill of an LA opioid before 75% of prior claims' days supply expired (criteria #2). Next, we identified how many of these beneficiaries had duplicative LA opioid

⁵⁶ Opioid Analgesics, Long-acting USP class from USP Medicare Model Guidelines v7.0

⁵⁷ Reported in 2018 Call Letter available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>. Hospice and cancer patients were excluded from opioid user counts.

therapy, meaning fills for different LA opioids at the generic entity, dosage form, and strength (criteria #3). This yielded over 200,000 beneficiaries (15.6%). Lastly, we recognize that multiple LA opioid prescriptions of different strengths can be clinically appropriate so we examined the impact of requiring different opioid prescribers (criteria #4). Of those beneficiaries with duplicative LA opioid therapy, over 66,000 (5.1%) were from different prescribers.

Some additional key findings from the analysis included: (1) more than half of MA-PD contracts and more than 70% of PDP contracts had greater than 100 beneficiaries with duplicative LA opioid therapy (criteria #3), and (2) adding different prescribers to the overlapping criteria (criteria #4) decreased the number of contracts with greater than 100 beneficiaries identified to less than 10% of MA-PD contracts and less than 40% of PDP contracts.

Based on these findings, we expect all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion. When such an edit is triggered for concurrent use of opioids and buprenorphine, the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims.

Ultimately, such safety edits may proactively address potentially unsafe cumulative opioid regimens at the time of dispensing to promote care coordination, and before beneficiaries are identified by the OMS. We also recognize that multiple opioid POS edits could potentially generate a combination of messages and soft or hard rejects that may cause confusion. Therefore, we recommend that contracts create a hierarchy for the opioid POS edit messaging in an effort to reduce confusion.

We are requesting feedback from stakeholders, especially Part D sponsors and PBMs, on the proposed expectation that sponsors to implement a soft duplicative LA opioid therapy POS edit (e.g., current experience in implementing such edits or concerns with the complexity or capacity to be able to implement for 2019) and recommendations on the most effective edit specifications (e.g., the specifications used in CMS's analysis or other specifications). We also seek feedback on how best to manage multiple opioid POS edits that a single prescription may trigger, for instance, a duplicative therapy and cumulative MME POS edit. In addition, we request feedback on extending the specifications in the future to include SA opioids and defining duplicative therapy as previously described for LA opioids (i.e., generic entity, dosage form, strength and/or differing prescribers) or another unique drug classification scheme (e.g., removing strength). We will delay specifying the parameters for the duplicate SA opioid POS edit until additional testing can be completed and we have a better idea of the feasibility and operational considerations for such edits.

Concurrent Use of Opioids and Benzodiazepines

In the Enhancements to the 2019 Star Ratings and Future Measurement Concepts section of this draft 2019 Call Letter, CMS requests feedback on the Concurrent Use of Opioids and Benzodiazepines measure.

In 2016, the FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently.⁵⁸ Sponsors can reduce the concurrent use of opioids and benzodiazepines, as well as other potentially problematic concurrent medication use at POS. Prospective drug use review can identify and evaluate the appropriateness of concurrent use prior to dispensing. We propose that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit. We are requesting feedback from stakeholders, especially Part D sponsors and PBMs, on their experience with concurrent or duplicative soft POS edits including an opioid and benzodiazepine and other drug combinations.

Access to Medication-Assisted Treatment

While CMS continues to work closely with Part D sponsors and other stakeholders to help combat inappropriate opioid utilization, it is imperative to also ensure that Medicare beneficiaries have appropriate access to medication-assisted treatment (MAT). As noted in previous Call Letter guidance, CMS will closely scrutinize formulary and benefit submissions with respect to formulary inclusion, utilization management criteria, and cost-sharing of Part D drugs indicated for MAT. Benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved. We continue to expect Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for MAT in brand tiers. As noted in previous Call Letter guidance, PA criteria that duplicates those requirements already set forth in the FDA Risk Evaluation and Mitigation Strategies and Drug Addiction Treatment Act of 2000 for applicable MAT products will not be approved.

On September 20, 2017, FDA announced that they recently had strengthened labeling requirements for buprenorphine MAT products to emphasize that treatment may be required indefinitely, as long as the use contributes to the intended treatment goals (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm576752.htm>).

Consistent with FDA's position, CMS will not approve PA criteria that requires a beneficiary to need an authorization any more frequently than once during a plan year. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, we expect that the sponsor would carry that authorization through to the next plan year.

⁵⁸ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm>

Coordination of Benefits (COB) User Fee

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. The 2019 COB user fee will be collected at a monthly rate of \$0.XX for the first 9 months of the coverage year (for an annual rate of \$0.0XX per enrollee per month) for a total user fee of \$x.xx per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2019 bids.

In contract year 2019, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The Benefit Coordination and Recovery Center (BCRC) operation and maintenance;
- Drug data processing system management, which is used to collect prescription drug event (PDE) data for Part D payment purposes and to produce invoices for the coverage gap discount program;
- Medicare Advantage and Prescription Drug (MARx) system management of COB data; and
- Review of Workers' Compensation settlement set-aside

LIS Enrollee Cost-sharing for Out-of-Network Part D Drugs

Current regulations require that Part D enrollees will be afforded adequate access to covered Part D drugs dispensed at out-of-network (OON) when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine. This includes situations in which Part D enrollees are provided covered Part D drugs dispensed by an OON institution-based pharmacy while they are patients in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting, and as a result cannot get their prescriptions filled at a network pharmacy. Part D enrollees must pay (or be billed) the institution-based pharmacy's usual and customary price at the point-of-sale, submit a paper claim to the Part D sponsor, and wait for reimbursement from the sponsor.

Beneficiary advocates have raised concerns about the disproportionate financial impact of paper claim-based reimbursement for low income beneficiaries receiving outpatient services in hospitals. We remind Part D sponsors that they cannot bill enrollees receiving LIS for any differential between the plan's negotiated price for a drug and the pharmacy's U&C cost – that is, LIS enrollees must be reimbursed the entire amount of the claim minus their applicable LIS cost-sharing amount.

We also remind Part D sponsors of their obligation to process direct member reimbursements (DMRs) from all enrollees timely. Delays in DMRs can have serious adverse consequences on enrollees, especially for those with limited financial resources. DMRs are coverage

determinations as provided under § 423.566(b). For reimbursement requests, Part D sponsors must issue a decision and reimbursement, if applicable, no later than 14 days from receipt of the request for the coverage determination (both the decision and the actual check, if applicable). The timeframe for plan and IRE appeals (levels 1 and 2) are 7 days for a decision (and up to 30 days to make payment).

Timely Updates to LIS Status Based on Best Available Evidence

Part D sponsors are obligated to use best available evidence when determining the cost-sharing levels for Part-D covered prescriptions. When situations arise that result in incorrect LIS cost-sharing data at the point-of-sale, Part D sponsors must comply with the “Best Available Evidence” (BAE) policy (see 42 CFR 423.800(d), Section 70.5 of Chapter 13 of the Medicare Prescription Drug Benefit Manual). This policy requires sponsors to update their systems to reflect the appropriate cost-sharing subsidy for Part D eligible individuals who are full or partial benefit Medicare/Medicaid dual eligible individuals, or receiving SSI-only, when presented with evidence that cost-sharing levels in their systems are incorrect. Sponsors should also ensure that key staff have needed resources to apply the policy quickly, as well as transmit any updates to CMS so we can update the status in our records on a timely basis.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs

A) Immunosuppressants Used to Prevent Transplant Rejection

Part D sponsors are responsible for determining whether immunosuppressants that are being used to prevent transplant rejections are coverable under Part D because immunosuppressants that are used for Medicare covered transplants are covered under Part B. To make these determinations, sponsors generally have relied on either information from the prescriber or, in the case of renal transplants, information in MARx that confirms that Medicare covered the transplant (i.e. paid for in whole or in part).⁵⁹ However, as a result of CMS Program Integrity audits, we have learned that information obtained directly from prescribers often times is not reliable or conflicts with CMS information that is provided later.

In order to streamline the coverage determination process and establish CMS as the single source for transplant information, CMS is proposing new guidance on how Part D sponsors should determine whether a drug is a Part B drug and when to revise its findings if the information from CMS changes. Though it is well established that Part D plans may not pay for drugs that would otherwise be paid under Part B, this proposal establishes CMS’ expectations around how Part D plans perform due diligence to ensure that this does not occur. In all cases Part D sponsors

⁵⁹ MARx currently provides information on renal transplants only.

should document the basis for their determinations to cover immunosuppressants and make such documentation available upon audit.

1. No Prior Part D Claims History for Immunosuppressants

a) The plan has received information from CMS (e.g. via MARx) indicating that Medicare covered the enrollee's transplant or, in the case of a Medicare Advantage enrollee, the MA Plan has medical claims history of a covered transplant regardless of previously received information from a prescriber on whether or not the transplant was covered by Medicare.

In this situation, plans are expected to rely on the CMS information (or in the case of an MA plan, its own medical claims history) and cannot cover immunosuppressants under Part D even if information is also provided by the prescriber that indicates that the transplant was not Medicare covered.

b) The plan has NOT received information from CMS (via MARx or otherwise) indicating that Medicare covered the transplant for the enrollee; in the case of a Medicare Advantage enrollee, the MA Plan does not have medical claims showing a history of a covered transplant; and the plan has not previously received information from a prescriber that the transplant was covered by Medicare.

In this situation, CMS expects plans to default to covering the immunosuppressants under Part D and no longer expects plans to reach out to prescribers to inquire about Medicare coverage of the transplant. Such outreach is burdensome for plans and prescribers, and has been shown to be unreliable for accurately determining if Medicare covered a transplant. Nevertheless, the plan should approach this coverage decision using the best available information; if the plan has previously reached out to the prescriber and received information indicating that the that the transplant was covered by Medicare (in full or in part), the Part D plan may not cover immunosuppressants under D.

2. Prior Part D Claims History AND MARx currently indicates that Medicare covered the transplant:

A plan might have covered the drugs under Part D previously because either:

- MARx information was updated after the Part D sponsor relied on prior information from the prescriber that the transplant was NOT covered/ paid by Medicare; or
- The Part D sponsor had relied solely on information from the prescriber that the transplant was NOT covered/paid by Medicare without regard to MARx.

Under either scenario, the Part D sponsor must now rely on the MARx information **going forward** and notify the enrollee that the plan can no longer cover the immunosuppressant(s) because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.

3. Prior Part D Claims History , no MARx indicator or MA plan medical claims history of a covered transplant BUT the Part D sponsor receives information from CMS that the transplant was covered by Medicare (e.g. Part D sponsor receives the information from CMS as part of a CMS Program Integrity audit or otherwise).

Under this scenario, the Part D sponsor must now rely on the CMS information **going forward** and provide notice to the enrollee that the plan will no longer cover the immunosuppressant(s) under Part D because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.

B) Inhalation Durable Medical Equipment (DME) Supply Drugs

Previous guidance documents indicate that inhalation drugs administered in a long term care setting where the stay is not covered under Medicare Part A can be covered under Part D. We are now clarifying how Part D plans can determine that a beneficiary is residing in a long term care facility.

Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities).

Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. While Part D sponsors generally have relied on the prescriber's statement that the beneficiary resides in long-term care facility to authorize Part D coverage, since 2013 CMS has required sponsors to report the patient residence code on prescription drug events (PDEs). We expect that patient residence codes submitted to CMS are accurate and because they represent a recent dispensing event; the residence codes offer a more timely view of patient's location than previous information communicated by the prescriber. Therefore, CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned).

Part D Mail-Order Refill Consent Policy– Solicitation for Comments

In the 2014 Call Letter, we stated that Part D sponsors should require their network retail and mail-order pharmacies to obtain patient consent to deliver a new or refill prescription prior to each delivery in an attempt to decrease the waste and unnecessary costs associated with unneeded or unwanted prescriptions. Subsequently, we modified this policy to permit exceptions,

subject to certain conditions, that allow Employer Group Waiver Plan (EGWP) mail-order auto-ship programs that do not obtain patient consent prior to delivery for both new prescriptions and refills. We also modified the policy for all Part D plans with respect to automatic shipments of new prescription orders received directly from the prescriber, regardless of whether prior patient consent was received.

Consequently, since January 1, 2014, Part D sponsors of non-EGWP plans have obtained consent from beneficiaries prior to shipping refills of mail-order prescriptions. We have received requests to further modify or eliminate this policy. Some stakeholders suggest that the current policy creates an unnecessary burden and interferes with improving medication adherence via automatic refill shipments. However, we remain concerned that auto shipments of refills not specifically requested by beneficiaries increase shipments of unnecessary or unwanted prescription refills, leading to increased waste and potentially inappropriate drug therapy when a discontinued medication is shipped.

We are therefore interested in any information and data associated with mail-order auto-ship programs (other than those detailing on-time refills, medication possession ratio, or proportion of days covered) that indicate actual improved adherence by patients resulting from automatic (not patient-initiated) refills. We also are interested in any information or data that rebuts concerns that such programs increase waste (to include unwanted or unneeded medications that go unused, as well as additional cost to the beneficiary or Part D program).

Finally, we are specifically interested in receiving feedback on possible modifications to the current policy if we determine that a change is warranted. For example:

- Replacing affirmative prior consent for refills with a refill shipping reminder, prior to shipping, which provides sufficient time for a beneficiary to cancel an order.
- Eliminating affirmative prior consent for refills but expecting plans to implement a full refund policy for any refills auto shipped that a beneficiary reports or returns as unneeded or otherwise unwanted. We welcome feedback on possible approaches to confirm medications reported as unwanted were partially or fully unused.
- Modifying the current condition of annual beneficiary confirmation to continue automatic deliveries to be more frequent, such as bi-annual.
- Modifying the current condition of annual beneficiary confirmation to continue automatic deliveries but with an opt-in on a per drug basis.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2019

Contract Year (CY) 2019 will be the sixth contract year since the implementation of the first capitated model under the Medicare-Medicaid Financial Alignment Initiative. Since that time, CMS – in collaboration with our state partners – has implemented eleven capitated model demonstrations in ten states. While most initial implementation challenges and many opportunities have been addressed, we will continue to build on the strong partnerships both CMS and the states have developed with participating Medicare-Medicaid Plans (MMPs) to provide high-quality, seamless and integrated care to individuals dually eligible for Medicare and Medicaid in CY 2019 and beyond.

Prior to each contract year, CMS provides information about the Medicare requirements and timeframes for renewal of MMP contracts. This section of the Call Letter reminds MMPs of those requirements and their timeframes. We will also provide guidance shortly after the issuance of the CY 2019 Final Call Letter about the applicability of the provisions in other sections of the Call Letter to MMPs.

As is the case for other Medicare Advantage (MA) and Part D plans, MMPs must submit a formulary, medication therapy management (MTM) program, and plan benefit package (PBP) each contract year, and annual submission timelines for MMPs are aligned with the standard MA and Part D schedule.

In addition to the requirements for MA and Part D plans, MMPs must also submit:

- On an annual basis, information to ensure the plan has a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid service providers, including long-term supports and services.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 30 below catalogues previously released guidance for MMPs or guidance that may be of particular interest to MMPs. CMS will release updated or new guidance as necessary; where more recent guidance exists or is released for topics that appear in previously released documents, MMPs should use the most recent document.

Table 30: Previously Released MMP Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPEnrollmentManual090216.pdf
Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
State-specific Marketing Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
Waiver of Part D LIS Cost-Sharing Amounts	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf

Network Adequacy Determinations and Provider Directory Best Practices

The Medicare medical provider and facility portion of MMPs' network information will be due to CMS on the third Tuesday in September 2018. This submission will ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. MMPs may assess the Medicare portion of their networks at any time using the organization initiated upload functionality in the HPMS Network Management Module (NMM). The current reference file, as referenced in the three-way contracts, that provides the MMP standards is available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html> as well as on the reference page within the NMM. CMS will release additional guidance on the submission process, including how MMPs will be able to submit exception requests, in the summer of 2018.

CMS remains committed to working with MMPs to improve their directories to ensure that enrollees and prospective enrollees have the information they need to make informed decisions about their healthcare choices. CMS interviewed a sample of Medicare-Medicaid enrollees in

two states in March and April 2017 to get their feedback on MMP directories. CMS also completed its monitoring study of CY 2017 MMP provider and pharmacy directories and hosted a webinar for all MMPs in June 2017 to focus on best practices and lessons learned, recognize areas where MMPs have made improvements since the CY 2016 monitoring study, and discuss how to address remaining gaps. Resources from the webinar and the Frequently Asked Questions (FAQ) document released in July 2017 are available under the *General Marketing Guidance* heading at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html>. CMS will continue to provide assistance in this area and collaborate with states and MMPs to make additional improvements to MMP directories in CY 2019.

Formulary and Supplemental Drug Files

Each contract year, MMPs must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. The required submissions for the integrated formulary are: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2019 Part D formulary guidance; and (2) an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs. Base formularies are due no later than June 4, 2018. Supplemental formulary files are due in HPMS on June 8, 2018 at 11:59 a.m. EDT.

MMPs must also submit an ADD file that includes non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. CMS will work with states to provide ADD file guidance to MMPs by May 2018. State guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). It is at the states' discretion whether to require MMPs to include one proxy NDC or multiple NDCs on the ADD file for each covered product.

As follow-up to feedback received on the CY 2018 Draft Call Letter, CMS is also working on options to facilitate more direct access of the ADD validation file for MMPs starting for CY 2019. In an effort to streamline the submission process, CMS is proposing to make the ADD validation file available via HPMS in advance of the ADD File submission deadline. We are also continuing to evaluate whether additional efficiencies are possible with respect to the timing of the file's completion.

State reviewers are solely responsible for reviewing and approving the ADD file. CMS will approve all other submitted formulary files. Reviews will begin immediately after the submission deadlines and will continue until all deficiencies have been resolved.

In the draft Call Letter, we clarified that mid-year ADD file change submissions – that is, changes to the ADD file after the contract year has begun – are at the discretion of each state.

CMS will work with states to open HPMS gates for ad hoc and/or regular ADD file resubmissions as necessary. We further clarify that an MMP requesting a mid-year ADD file update can contact either the state or CMS by sending an email to mmcocapmodel@cms.hhs.gov. CMS coordinates with each state to consider the request and open ADD file gates for mid-year changes as necessary.

Plan Benefit Package (PBP)

MMPs' plan benefit packages (PBPs) are reviewed annually to ensure that MMPs accurately describe the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits. CMS will launch the HPMS PBP module on April 6, 2018, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2019. In addition, CMS will release an online training module on the CY 2019 PBP software for plans on April 6, 2018.

MMPs must submit their integrated PBPs to CMS no later than June 4, 2018 (11:59 p.m. PDT). Non-timely submission of a PBP is considered a plan notice of non-renewal. In addition, to the PBP, MMPs are required to submit the following as part of a complete bid submission:

- Service Area Verification
- Plan Crosswalk (NOTE: This is only for renewing contracts in CY 2019)
- Formulary Crosswalk

CMS will work with states to issue PBP guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits by the time the PBP module is launched in April 2018. The PBP review is conducted jointly between CMS and states to ensure the data entry is consistent with minimum coverage and cost-sharing requirements under Medicaid, Medicare Parts A, B, and D, and each state's demonstration.

MMPs are provided some degree of flexibility with respect to PBP revisions after the time of final PBP approval. This flexibility is necessary to accommodate certain mid-year changes unique to MMPs, including but not limited to mid-year legislative changes to Medicaid benefits, as well as the timing of payment rate finalization.

CMS applies the following criteria to MMP requests to change or correct PBPs:

- PBP revisions to add or remove plan-offered supplemental benefits between the time of the release of the National Average Monthly Bid Amount in early August and sign-off of PBPs in HPMS in late August 2018 are permissible. This timeframe allows plans to accommodate any approved benefit changes in their required documents (including the Annual Notice of Change, Evidence of Coverage/Member Handbook, and Summary of Benefits) during the Annual Election Period.

- Rate-related PBP corrections are permissible during the Center for Medicare's annual correction window in September 2018 (see the calendar in this Call Letter for more information), but only for purposes of adding supplemental benefits to PBPs. MMPs that elect to correct their PBPs must work with their contract management team on an appropriate member communication strategy (e.g., issuance of corrected or revised information for materials that have already been mailed to members; corrections or updates of hard copy and online versions of other materials for prospective members). We clarify that there will be no compliance penalty for a PBP correction provided an MMP meets these conditions.
- PBP corrections unrelated to rates and supplemental benefits that are requested during the Center for Medicare's annual correction window in September 2018 (see the calendar in this Call Letter for more information) will be considered changes due to plan error. As such, these PBP corrections (or any resultant corrections to MMPs' Annual Notice of Change and/or Evidence of Coverage/Member Handbook, which must be submitted in HPMS through the errata submission process in the Marketing Module) may be subject to compliance action, regardless of whether they are positive or negative changes.
- Any PBP corrections after the Center for Medicare's annual correction window in September 2018 will be considered on a case-by-case basis. In cases where a PBP correction is due to a midyear legislative change to Medicaid benefits (or a benefit change made in a three-way contract amendment) and an MMP's previously approved PBP submission included a more generous supplemental benefit than the new Medicaid or demonstration benefit, the MMP will be required to continue to provide the more generous supplemental benefit for the remainder of the contract year. PBP corrections (or any resultant corrections to MMPs' Annual Notice of Change and/or Evidence of Coverage/Member Handbook, which must be submitted in HPMS through the errata submission process in the Marketing Module) due to plan error maybe subject to compliance action, regardless of whether they are positive or negative changes.

Appendix 1: Methodology for Plan Finder (PF) Composite Price Accuracy Display Measure

CMS's drug pricing performance measure evaluates the accuracy of prices displayed on Medicare Plan Finder (PF) for beneficiaries' comparison of plan options. The accuracy score is calculated by comparing the PF price to the PDE price and determining the magnitude and frequency of differences found when the latter exceeds the former. This document summarizes the methods currently used to construct each contract's accuracy index.

Contract Selection

This measure relies in part on the submission of pricing data to PF. Therefore, only contracts with at least one plan meeting all of the following criteria are included in the analysis:

- Not a PACE plan
- Not an employer plan
- Part D plan
- Plan not terminated during the contract year

Only contracts with at least 30 claims throughout the year are included in the accuracy measure. This ensures that the sample size of PDEs is large enough to produce a reliable accuracy score.

PF Composite Price Accuracy Score

To calculate the PF Composite Price Accuracy Score, the point-of-sale cost (ingredient costs plus dispensing fee) reported on each PDE claim is compared to the cost resulting from using the unit price reported on Plan Finder.⁶⁰ This comparison includes only PDEs for which a PF cost can be assigned. In particular, a PDE must meet seven conditions to be included in the analysis:

1. The NPI number for the pharmacy on the PDE claim must appear in the pharmacy cost file as either a retail only pharmacy or a retail and limited access only pharmacy, regardless of pharmacy service type reported on PDE. Claims for pharmacies that are listed as retail in the pharmacy cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) are included as well. NCPDP numbers are mapped to their corresponding NPI numbers. The corresponding reference NDC must appear under the relevant price ID for the pharmacy in the pricing file.⁶¹

⁶⁰ Plan Finder unit costs are reported by plan, drug, days of supply, and pharmacy. The plan, drug, days of supply, and pharmacy from the PDE are used to assign the corresponding Plan Finder unit cost posted on medicare.gov on the date of the PDE.

⁶¹ Plan Finder prices are reported at the reference NDC level. A reference NDC is a representative NDC of drugs with the same brand name, generic name, strength, and dosage form. To map NDCs on PDEs to a

2. The reference NDC must be on the plan's formulary.
3. Because the retail unit cost reported on Plan Finder is intended to apply to a 1, 2, or 3-month supply of a drug, only claims with a Days Supply of 28-34, 60-62, or 90-93 are included.⁶² Claims reporting a different day supply value are excluded.
4. PDEs for dates of service during which the plan was suppressed from Plan Finder or where the relevant pharmacy or drug was not reported in Plan Finder are not included since no Plan Finder cost can be assigned.⁶³
5. PDEs for compound drugs or non-covered drugs are not included.
6. The PDE must occur in Quarter 1 through 3 of the year. Quarter 4 PDEs are not included because PF prices are not updated during this last quarter.

The PF Composite Price Accuracy Measure factors in both how much and how often PDE prices exceeded the prices reflected on the PF. The contract's PF Composite Price Accuracy score is the average of the Price Accuracy Score, which measures the difference between PDE total cost and PF total cost⁶⁴, and the Claim Percentage Score, which measures the share of claims where PDE prices are less than or equal to PF prices.

Once PF unit ingredient costs are assigned, the PF ingredient cost is calculated by multiplying the unit costs reported on PF by the quantity listed on the PDE. The PDE cost (TC) is the sum of the PDE ingredient cost paid and the PDE dispensing fee. Likewise, the PF TC is the sum of the PF ingredient cost and the PF dispensing fee that corresponds to the same pharmacy, plan, and days of supply as that observed in the PDE. Each claim is then given a score based on the difference between the PDE TC and the PF TC. If the PDE TC is lower than the PF TC, the claim receives a score equal to zero. In other words, contracts are not penalized when point-of-sale costs are lower than the advertised costs. However, if the PDE TC is higher than the PF TC, then the claim receives a score equal to the difference between the PDE TC and the PF TC.^{65,66}

reference NDC, we use First Data Bank (FDB) and Medi-Span to create an expanded list of NDCs for each reference NDC, consisting of NDCs with the same brand name, generic name, strength, and dosage form as the reference NDC. This expanded NDC list allows us to map PDE NDCs to PF reference NDCs.

⁶² If a plan's bid indicates a 1, 2, or 3 month retail days supply amount outside of the 28-34, 60-62, or 90-93 windows, then additional days supply values may be included in the accuracy measure for the plan. For example, a plan that submits a 3 month retail supply of 100 days in their bid will have claims with a days supply of 90-100 included in their accuracy measure calculation.

⁶³ Because sanctioned plans typically are not suppressed on MPF and display data to the plan's current enrollees only, non-suppressed sanctioned plans will have their data during the sanction counted towards the measure.

⁶⁴ PF total costs are rounded to the nearest cent. For example, if the PF total cost is \$10.237, then it is rounded to \$10.24. PF unit costs are not rounded.

⁶⁵ To account for potential rounding errors, this analysis requires that the PDE cost exceed the rounded PF cost by at least a cent (\$0.01) in order to be counted towards the accuracy score. For example, if the PDE cost is \$10.25 and the rounded PF cost is \$10.24, the 1-cent difference would be counted towards plan's accuracy score. However, if the rounded PF cost is higher than \$10.24, the difference would not be considered problematic, and it would not count towards the plan's accuracy score.

⁶⁶ The PF data includes floor pricing. For plan-pharmacy drugs with a floor price, if the PF price is lower than the floor price, the PDE price will be compared against the floor price.

The contract level PF Price Accuracy Index is the sum of the claim level scores and PDE TC across all PDEs that meet the inclusion criteria, divided by the PDE TC for those same claims. The PF Claim Percentage Index is the percent of all PDEs that meet the inclusion criteria with a PDE TC higher than the PF TC. Note that the best possible PF Price Accuracy Index is 1, and the best possible PF Claim Percentage Index is 0. This occurs when the PF TC is never lower than the PDE TC. The formulas below illustrates the calculation of the contract level PF Price Accuracy Index and PF Claim Percentage Index:

$$\text{Price Accuracy Index} = \left(\frac{\sum_i \max(\text{TC}_{iPDE} - \text{TC}_{iPF}, 0) + \sum_i \text{TC}_{iPDE}}{\sum_i \text{TC}_{iPDE}} \right)$$

where

TC_{iPDE} is the ingredient cost plus dispensing fee reported in PDE_i , and TC_{iPF} is the ingredient cost plus dispensing fee calculated from PF data, based on the PDE_i reported NDC, days of supply, and pharmacy, then rounded to the nearest cent.

$$\text{Claim Percentage Index} = \left(\frac{\sum_i \text{Claims}_{iPDE > PF}}{\sum_i \text{Claims}_{iTotal}} \right)$$

where

$\text{Claims}_{iPDE > PF}$ is the total number of claims where the PDE price is greater than the rounded PF price

Claims_{iTotal} is the total number of claims

We use the following formulas to convert the Claim Percentage Index and Price Accuracy Index into the PF Composite Price Accuracy score:

$$\begin{aligned} \text{Claim Percentage Score} &= (1 - \text{Claim Percentage Index}) \times 100 \\ \text{Price Accuracy Score} &= 100 - [(\text{Price Accuracy Index} - 1) \times 100] \\ \text{PF Composite Price Accuracy Score} &= (0.5 \times \text{Claim Percentage Score}) \\ &\quad + (0.5 \times \text{Price Accuracy Score}) \end{aligned}$$

The score is rounded to the nearest whole number.

Example of PF Composite Price Accuracy Score Calculation

Example of PF CTable M-1 shows an example of the PF Composite Price Accuracy Score calculation. This contract has 4 claims, for 4 different NDCs and 4 different pharmacies. This is an abbreviated example for illustrative purposes only; in the actual accuracy index, a contract must have 30 claims to be evaluated. From each of the 4 claims, the PDE ingredient cost, dispensing fee, and quantity dispensed are obtained. Additionally, the plan ID, days of supply, date of service, and pharmacy number are collected from each PDE to identify the PF data that had been submitted by the contract and posted on Medicare.gov on the PDE dates of service. The NDC on the claim is first assigned the appropriate reference NDC, based on the brand name, generic name, strength and dosage form. Using the reference NDC, the following PF data are obtained: brand/generic dispensing fee (as assigned by the pharmacy cost file) and unit cost (as assigned by the Price File corresponding to that pharmacy and days of supply on the date of service). The PDE cost is the sum of the PDE ingredient cost and dispensing fee. The PF cost is computed as the quantity dispensed from PDE multiplied by the PF unit cost plus the PF brand/generic dispensing fee (brand or generic status is assigned based on the NDC), and then rounded to the nearest cent. The last column shows the amount by which the PDE cost is higher than the rounded PF cost. When the PDE cost is less than the rounded PF cost, this value is zero. The Price Accuracy Index is the sum of the last column plus the sum of PDE costs divided by the sum of PDE cost. The Claim Percentage Index is the number of rows where the last column is greater than zero divided by the total number of rows.

Table M-1: Example of PF Composite Price Accuracy Score Calculation

NDC	Pharmacy Number	PDE Data					Plan Finder Data				Calculated Values			
		DOS	Ingredient Cost	Dispensing Fee	Quantity Dispensed	Days' Supply	Biweekly Posting Period	Unit Cost	Dispensing Fee		Brand or Generic Status	Total Cost		Amount that PDE > PF
									Brand	Generic		PDE	PF	
A	111	1/8/2016	3.82	2.00	60	60	1/4/16-1/17/16	0.014	2.25	2.75	B	5.82	3.09	2.73
B	222	1/24/2016	0.98	2.00	30	60	1/18/16-1/31/16	0.83	1.75	2.50	G	2.98	27.40	0
C	333	2/11/2016	10.48	1.50	24	28	2/1/16-2/14/16	0.483	2.50	2.50	B	11.98	14.09	0
D	444	2/21/2016	47.00	1.50	90	30	2/15/16-2/28/16	0.48	1.50	2.25	G	48.50	45.45	3.05
											Totals	69.28		5.78
											Price Accuracy Index			1.08343
											Claim Percentage Index			0.5
											PF Price Accuracy Score			71