January 30, 2019

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

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 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 makes changes that promote greater innovation, transparency, flexibility, and program simplification.

On December 20, 2018, we released for comment proposed changes to the Part C risk adjustment model used to pay for aged and disabled beneficiaries with a comment deadline of February 19, 2019. We are extending this deadline and are continuing to solicit comment on those proposed changes until Friday, March 1, 2019. 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 Medicare statute for CY 2020. Also included with this notice are proposed changes in the payment methodology for CY 2020 for Part D and annual adjustments for CY 2020 to the Medicare Part D benefit parameters for the defined standard benefit. For 2020, CMS will announce the MA capitation rates and final payment policies on Monday, April 1, 2019, 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 2020. Attachment III sets forth the changes in the Part D payment methodology for CY 2020. Attachment IV presents the annual adjustments for CY 2020 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 2020 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 Plans (MMPs); 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 2020 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 2020 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-2018-0154" 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 1, 2019 release of the final Announcement of Calendar Year 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern Standard Time on Friday, March 1, 2019.

/ 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, calculations of Fee for Service cost, IME phase out, MA benchmarks, EGWP rates, and ESRD rates discussed in Attachment II; Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2020 described in Attachment III and in Attachment IV.

/ s /
Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2020 ADVANCE NOTICE
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Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2020

For 2020, the MA county rates are based on the specified amount as defined in Attachment II Section A2 below. Section 1853(n)(2)(A) defines the specified amount as the base amount (which in rebasing years is the adjusted average FFS per capita cost) multiplied by the applicable percentage for the area (set under section 1853(n)(2)(B) through (D)). Section 1853(n)(4) of the Social Security Act requires that the benchmark for an area for a year (increased by quality bonus percentages where applicable) be capped at the level of the 1853(k)(1) applicable amount. The 2020 FFS cost is calculated, in part, using the FFS growth percentage. CMS intends to rebase the county FFS rates for 2020 as part of the calculation of the rates for 2020.

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 2020 is 4.84 percent. This estimate reflects an underlying trend change for CY 2020 in per capita cost of 3.757 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 2020

	Prior Increases	Current Increases			NPCMAGP for 2020 With §1853(c)(6)(C) adjustment[1]
	2003 to 2019	2003 to 2019	2019 to 2020	2003 to 2020	
Aged+Disabled	68.178%	69.936%	3.757%	76.320%	4.84%

[1] Current increases for 2003-2020 divided by the prior increases for 2003-2019

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 2020 divided by the prior projected FFS USPCC for 2019.

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 2020

	Total USPCC – Non-ESRD	FFS USPCC – Non-ESRD	Dialysis-only ESRD USPCC
Current projected 2020 USPCC	$958.90	$931.38	$7,949.52
Prior projected 2019 USPCC	$914.62	$891.07	$7,833.28
Percent increase	4.84%	4.52%	1.48%

Table I-3 compares last year's estimate of the total non-ESRD USPCC with current estimates for 2003 to 2022, 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 2022. 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.

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	383.94	383.95	376.79	376.81	760.73	760.76	1.000
2011	388.15	388.18	386.41	386.45	774.56	774.63	1.000
2012	377.72	377.72	392.97	392.97	770.69	770.69	1.000
2013	380.30	381.73	399.64	399.67	779.94	781.40	0.998
2014	372.59	372.77	418.60	418.59	791.19	791.36	1.000
2015	376.08	376.31	435.61	435.76	811.69	812.07	1.000
2016	379.90	380.07	445.65	446.33	825.55	826.40	0.999
2017	385.90	384.70	460.45	464.36	846.35	849.06	0.997
2018	391.53	390.02	489.44	488.79	880.97	878.81	1.002
2019	404.56	400.52	519.62	514.10	924.18	914.62	1.010
2020	415.59	412.19	543.31	537.91	958.90	950.10	1.009
2021	431.13	427.98	571.75	568.79	1,002.88	996.77	1.006
2022	451.96		603.07		1,055.03		

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	$371.20	$371.20	$374.92	$374.92	$746.12	$746.12	1.000
2011	371.70	371.70	384.70	384.70	756.40	756.40	1.000
2012	357.52	357.52	392.25	392.25	749.77	749.77	1.000
2013	364.32	366.28	396.04	396.04	760.36	762.32	0.997
2014	367.61	367.40	409.50	409.08	777.11	776.48	1.001
2015	372.34	372.76	428.66	429.23	801.00	801.99	0.999
2016	374.82	374.86	435.56	436.55	810.38	811.41	0.999
2017	378.52	376.30	450.84	456.25	829.36	832.55	0.996
2018	385.43	381.58	477.10	474.83	862.53	856.41	1.007
2019	394.17	391.63	502.64	499.44	896.81	891.07	1.006
2020	405.95	403.45	525.43	523.29	931.38	926.74	1.005
2021	421.68	417.97	553.72	552.01	975.40	969.98	1.006
2022	441.78		583.82		1,025.60		

These estimates are preliminary and could change when the final rates are announced, no later than April 1, 2019, in the Announcement of CY 2020 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 1, 2019 Announcement.

Attachment II. Changes in the Part C Payment Methodology for CY 2020

Section A. MA Benchmark, Quality Bonus Payments and Rebate

Section 1853(n)(2) requires that, in determining the specified amount, CMS use as the base amount the amount described in section 1853(c)(1)(D) for a rebasing year or, for years that are not a rebasing year, the base amount from the previous year increased by the national per capita MA growth percentage. 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 2020 using FFS claims data from 2013 through 2017. (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 2020, the applicable amount for 2020 is the greater of: (1) the county's 2020 FFS cost or (2) the 2019 applicable amount increased by the CY 2020 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:

(2020 FFS cost[1] minus IME phase-out amount) × (applicable percentage + applicable percentage quality increase)

Where:

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

[1] As described in more detail below in section B, the FFS cost is adjusted to exclude costs attributable to payments under sections 1848(o), and 1886(n), and 1886(h).

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 2020 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2019 average per capita FFS rate, because 2019 is the most recent rebasing year prior to 2020. 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 2020 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
4th (highest)	95%
3rd	100%
2nd	107.5%
1st (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 2020 payments. For CY 2020 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 2020.

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

Star Rating	2020 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 2020, 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 2020, 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),[2] 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 2020 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).

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

Contract Consolidations and QBP

Section 1853(o)(4) of the Social Security Act was amended by the Bipartisan Budget Act of 2018 to add subsection (D) regarding the determination of star ratings for consolidating MA plans. In the 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 Final Rule (CMS-4182-F) (83 FR 16440), CMS finalized regulations at §§ 422.162(b)(3) and 423.182(b)(3) to implement the amendment to section 1853(o)(4). Those regulations provide 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 the first year following the consolidation will 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. The regulations are applicable to contract consolidations that are approved on or after January 1, 2019 and therefore will affect the QBP ratings for contracts that have been consolidated for CY 2020. For example, if two contracts are consolidated into a single contract that starts January 1, 2021, the 2021 QBP rating for that contract would be based on the 2020 Star Ratings released in October 2019 using the November 2019 enrollment of the surviving and consumed contracts.

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 2020, 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 2020 that is less than the national monthly per capita cost for FFS for 2020.

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 2020 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 2019 Rate Calculation Data file (columns Y and AA) on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The 2020 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 2020 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). This provision requires 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 believes that section 1853(n)(4) of the Act prevents elimination of the rate cap or excluding 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	2020
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 2020.

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

Each year, CMS strives to improve the development of the USPCC and AGAs with refinements to how these figures are calculated. For 2020, we are proposing to continue to incorporate refinements developed and used 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 2020, ensures that the 2020 FFS rates for each county reflect the most current FFS fee schedules and payment rules.

For 2020, we are proposing to implement a refinement to the methodology used in the ratebook development to include Health Professional Shortage Areas (HPSAs) bonus payments. Specifically, we propose to tabulate the Health Professional Shortage Areas (HPSAs) bonuses by county of residence for years 2013–2017 and add these values to our ratebook FFS expenditures. The HPSA bonuses are disbursed quarterly to providers and are not reflected in the standard claim files. Because they are not reflected in the standard claim files, we have not previously incorporated the HPSA bonuses into the FFS expenditures used to estimate the USPCC.

With this Advance Notice, we are releasing the 2017 FFS cost data by county used in the development of the 2020 ratebook. This data is available on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Data.html. This data will not reflect adjustments for innovation model 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 2020

In the first step, CMS is proposing to add the 2017 cost and enrollment data to, and drop the 2012 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 2013–2017. 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 2017 claims. Comparable adjustments have been made to claims data in the development of the FFS rates starting with 2009, so the claims data for years prior to 2017 that are used in developing the FFS per capita cost for the 2020 ratebook have already been similarly adjusted.

For Puerto Rico, CMS will continue to only include claims and enrollment for beneficiaries with Part A and Part B enrollment for all of the years included in the rolling average of historical data. 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 the third step, CMS will re-price the historical inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2013–2017 to reflect the most current (i.e., FY 2019) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2019) Geographic Practice Cost Indices. For 2020, 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) 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 2019 Inpatient Prospective Payment System (IPPS) rule. Similarly, we are proposing to adjust the UCP represented in the FY 2014 through 1st quarter FY 2018 claims to reflect the requirements of the final FY 2019 IPPS rule. For 2020, 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 2013–2017 to reflect the most current DMEPOS prices associated with the Competitive Bidding Program (CBP). Section 1847(b)(5) of the Act requires that "single payment amounts" replace the Medicare DMEPOS fee schedule amounts for certain DMEPOS items furnished in competitive bidding areas (CBAs). Specific HCPCS codes for diabetic supplies were included in the National Mail Order (NMO) program. We will continue to use the latest single payment amounts for NMO DMEPOS items to reprice the historical payments for DMEPOS claims. In accordance with the American Taxpayer Relief Act, 2012 (Pub. L. 112–240, H.R. 8, 126 Stat. 2313, section 636), the fee schedule amounts for non-mail-order diabetic supplies, including testing strips, are equal to the single payment amounts established under the NMO competition for diabetic supplies. Section 1834(a)(1)(F) of the Act requires CMS to adjust the fee schedule amounts for DMEPOS items furnished on or after January 1, 2016 in non-CBAs based on information from the competitive bidding program. We propose to use a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts to reprice the non-CBA FFS claims in rural areas for 2013–2017. We propose using 100 percent of the adjusted payment amount to reprice the non-CBA FFS claims in non-rural areas for 2013-2017. These proposals are based on the updates to policies and payment rates in the final rule titled End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS (CMS-1691-F) (83 FR 56922).

As indicated in Table B1-1, we are proposing to continue to adjust historical FFS experience to reflect shared savings and losses or episode savings and losses experienced under innovation center models and demonstration programs. All adjustments of this type apply to the non-ESRD ratebook except for Comprehensive ESRD Care.

Table B1-1. Models and Demonstration Programs with ratebook adjustments

Model/Programs	Experience Years		Payment Type
	2019 Ratebook	2020 Ratebook	
Medicare Shared Savings Program (SSP)	2012-2016	2013-2017	Shared savings / losses
Pioneer ACO	2012-2016	2013-2016	Shared savings / losses
Comprehensive Care for Joint Replacement (CJR)	2016	2016-2017	Episode savings / losses
Next Gen ACO (NGACO)	2016	2016-2017	Shared savings / losses
Oncology Care Model (OCM)	N/A	7/1/2016-2017	Episode savings / losses
Comprehensive Primary Care (CPC)	2014-2016	2014-2016	Shared savings / losses
Bundled Payment for Care Improvement (BPCI)	2013-2016	2013-2017	Episode savings / losses
Medicare-Medicaid Managed FFS Model Under Financial Alignment Initiative	2013-2015	2013-2016	Shared savings
Pioneer ACO	2014-2016	2014-2016	Population-based payment
Next Gen ACO (NGACO)	2016	2016-2017	Population-based payment
Comprehensive Primary Care Plus (CPC+)	N/A	2017	Comprehensive Primary Care Payments
Comprehensive Primary Care Plus (CPC+)	N/A	2017	Performance Payment
ESRD			
Comprehensive ESRD Care (CEC)	2016	2016	Shared savings / losses

The key aspects of these adjustments are:

- The adjustments reflect an allocation of the savings and losses based on the distribution of the participating entity's enrollment by county of residence. With the exception of the Comprehensive ESRD Care Model, the adjustments exclude experience for beneficiaries in ESRD status as of July 1 of the experience year.
- The adjustments include the application of the two percent sequestration reduction on these ACO adjustments for claims incurred on or after April 1, 2013.
- Under the population-based payment options, 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.

- We are proposing no calendar year 2017 adjustments for the Comprehensive ESRD Care (CEC) model due to the expectation that the shared savings calculations will be finalized after April 1, 2019.
- Further information on these models may be found at: https://innovation.cms.gov/index.html.

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 2013-2017 period;[3] we are not taking fees of this type into account in our adjustments to historical FFS experience as they were funded from other sources, and were not payments made under Parts A or B (that is, they were not funded by Medicare Trust Funds). In addition, 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 continue to use for 2020, 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 of residence provided by the Social Security Administration, which is the same county assignment as the ratebook FFS claims and enrollment.

The statutory component of the Regional MA benchmarks will also continue to 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 2020 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

[3] Information about the various innovation models is available in the Report to Congress available at: https://innovation.cms.gov/Files/reports/rtc-2016.pdf.

adjustment is needed to exclude these payments from the FFS costs to comply with section 1853(c)(1)(D).

The following 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
- Veterans Affairs (VA) and Department of Defense (DoD): apply an adjustment to FFS per capita costs for beneficiaries dually enrolled in VA and/or the DoD health programs (the Uniformed Services Family Health Plan (USFHP) and/or the Veterans Health Administration (VHA)) pursuant to section 1853(c)(1)(D)(iii) of the Act. The VA/DoD adjustment is described in more detail below.

B2. Additional Adjustment to FFS per Capita Costs in Puerto Rico

For the past three years, the Secretary has 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, 2018 and 2019 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 2019 study analyzed experience for calendar years 2012 through 2016 and only considered FFS beneficiaries enrolled mid-year. On average, 14.5 percent of A&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 per-capita FFS costs in Puerto Rico of 4.5 percent for 2012 through 2016. Accordingly, a 4.5 percent adjustment was then applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2019 ratebook development.

We are considering whether a similar adjustment should be applied for 2020. The Office of the Actuary will perform an analysis that is similar to the prior analysis but with an updated five years of data: 2013–2017. We welcome comments regarding a similar update to Puerto Rico's experience in the development of the 2020 FFS rates. 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.

We are aware of concerns raised by stakeholders regarding the FFS data used to establish MA benchmarks in Puerto Rico, with particular regard to the impact of the hurricane that occurred in 2017. Stakeholders have suggested adjusting the 2017 FFS data used in the ratebook development for Puerto Rico. We have reviewed the trends in the 2017 FFS data, and found that while some counties in Puerto Rico did experience decreased per-capita costs, we noted that other counties beyond Puerto Rico, including counties that were not impacted by any natural disasters, also experienced decreases in per-capita costs in 2017. For ratebook development, we use five years of FFS experience for each county which mitigates annual fluctuations and anomalies in the data that may occur for a variety of reasons. This methodology provides for stability in the rates despite local or regional short-term events such as natural disasters. We have not made ratebook adjustments in prior years for select events in specific areas, such as for other natural disasters which may have impacted FFS experience.

B3. Adjustment to FFS per Capita Costs for VA and DoD Costs

For CY 2020, we are proposing to continue to apply the DoD and VA adjustments concurrently instead of an independent application of the adjustments, as discussed in the 2019 Advance Notice and finalized in the 2019 Rate Announcement. 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. We are proposing to adjust the FFS rates by the Veterans Affairs (VA) and the Department of Defense (DoD) ratios from a study based on FFS data from calendar years 2012–2016.

To develop 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.

Similar analysis was done for Department of Defense (DoD). 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.

We propose to apply the VA and DoD (USFHP) adjustments concurrently to the FFS rates using the ratios calculated.

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 2020, we will first calculate the 2020 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 2020 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 2020 is 6.6 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 2020 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section D. ESRD Rates

In developing the 2020 ESRD Medicare Advantage benchmarks, we obtain the FFS dialysis reimbursement and enrollment data for each state for the years 2013–2017. 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 2017 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2017 data above, and, using trend factors, develop the prospective 2020 FFS ESRD dialysis USPCC.

Last year we incorporated enhancements to the ESRD data system and projection methodology, and will continue to apply repricing adjustments to the CY 2020 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 2013-2017 to reflect the most current (i.e., FY

2019) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2019) Geographic Practice Cost Indices. We are proposing to reprice the ESRD PPS dialysis claims for the years 2014-2017, given that 2014 was the first year that the ESRD PPS 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) 2013 for each DSH hospital to reflect the reduction in DSH payments and the allocation of the UCP under the FY 2019 Inpatient Prospective Payment System (IPPS) final rule. Similarly, we are proposing to adjust the UCP represented in the FY 2014 through 1st quarter FY 2018 claims to reflect the allocation of the UCP under the FY 2019 IPPS final rule. For 2020, the adjustments will also include 2016 shared savings and shared losses performance based payments made under the Comprehensive ESRD Care model.

Pursuant to section 1853(a)(1)(H) of the Act, CMS must establish "separate rates of payment" with respect to ESRD beneficiaries enrolled in MA plans. The 2020 ESRD dialysis rates by state are determined by multiplying the 2020 FFS ESRD dialysis USPCC by the state AGA. The 2020 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. Location of Network Areas for PFFS Plans in Plan Year 2021

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 the list of network areas for plan year 2020 in the final Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. The list is available on the CMS website at https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html. We used January 1, 2018 enrollment data to identify the location of network areas for plan year 2020. In addition, we will include a list of network areas for plan year 2021 in the final Announcement of Calendar

Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. We will make this list available on the CMS website at https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html. We will use January 1, 2019 enrollment data to identify the location of network areas for plan year 2021.

Section F. 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 2020. 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 has been the case since 2017, for 2020 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 2020 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 responses to questions received by the Office of the Actuary are available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/ActuarialBidQuestions.html.

In connection with the continuation of this waiver, for 2020 CMS is also proposing to continue the payment methodology implemented for MA EGWPs finalized in the 2019 Rate Announcement.

Under this proposal, the calculations for the bid-to-benchmark (B2B) ratios would therefore be as follows:

> First: [(weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for 2019 individual market plan bids by February 2019 actual enrollment)/(weighted average of the county standardized benchmarks for 2019 individual market plans by February 2019 actual enrollment)] = 2019 individual market B2B ratios by quartile.[4]

[4] As in prior years, 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

Second: The 2019 individual market B2B ratios will be calculated separately for HMO plan types and PPO plan types by quartile.[5] The PPO B2Bs by quartile will be weighted by the total proportion of EGWP PPO plan type enrollment, and the HMO B2Bs by quartile will be weighted by the total proportion of EGWP HMO plan type enrollment to result in the final B2B ratios for 2020 by quartile.

As has been in effect since 2017, for 2020:

- The B2B ratios will be 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 will be compared to the corresponding published 5%, 3.5% and 0% bonus county benchmarks for the payment year (2020), which include adjustments for qualifying counties, to determine the amount of savings. The savings amount will be multiplied by the corresponding rebate percentage to determine the Part C EGWP county level rebate amount.
- The EGWP Part C base payment amount will be 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 would be: (base county payment rate + county rebate) × beneficiary level risk score.

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.

CY 2020 applicable percentages, CMS ranks counties from highest to lowest based upon their 2019 average per capita FFS costs and places the rates into four quartiles. When calculating the 2019 B2B ratios, CMS would group counties by the 2019 unblended quartiles and these B2B ratios would then be applied to the 2020 unblended quartiles.

[5] Consistent with 2019, HMO and HMOPOS plans have been combined into an "HMO plan type" and LPPO and RPPO plans have been combined into a "PPO plan type." "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. "PFFS" Private Fee-for-Service individual market plans are excluded from these calculations.

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 (Base County Payment Rate + Regional Rebate) × beneficiary level risk score where each is calculated as follows:

- Base County Payment Rate = Bid to Benchmark Ratio × 2020 MA Monthly Capitation Rate
- Regional Rebate = (1 − Bid to Benchmark Ratio) × 2020 Regional Rate × Rebate percentage
- The 2020 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 2020 Regional rate (i.e., no individual bids in a region), then the EGWP rate will be based solely on the statutory component.

As has been the case since 2017, for 2020 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.

For 2020, we are proposing an enhancement to this payment methodology to permit MA EGWPs to buy down Part B premiums for their enrollees, using a portion of the Part C payment. Under CMS waiver authority, which is intended to facilitate the offering of EGWPs, CMS is proposing to permit MA EGWPs to buy-down the Part B premium amount consistent with the rules permissible for individual market plans to do so. Presently, when an individual market MAO submits a bid, the MAO is permitted to use rebates to buy-down a portion of the Part B premiums for its enrollees by identifying the buy-down amount in the bid-pricing tool. CMS then retains the rebate amount identified by the MAO and coordinates directly with the Social Security Administration (SSA) to ensure that each beneficiary's Part B premium is appropriately calculated and withheld from the beneficiary's Social Security check or billed to the beneficiary. From 2017 through 2019, CMS prohibited EGWPs from buying down the Part B premium using the Part C payment calculated under the modified payment methodology for two reasons. First, because MA EGWPs could no longer distinguish between the amount paid for basic benefits and the amount paid for rebates, and second, due to changes in CMS operational systems that needed to be employed in order to collect and communicate this information to SSA. However, stakeholders commenting on this policy have convinced CMS that prohibiting EGWPs from having this capability hinders their ability to function in the market and unnecessarily restricts their benefit offering beyond what was intended in its implementation. While rebate dollars will continue to not be specifically identifiable, we believe that since the amount paid to MA EGWPs

represents the equivalent of a basic benefit capitation and rebate amount that would similarly be paid to an individual market MAO, permitting MA EGWPs to use a portion of the Part C payment to buy down the Part B premium is an appropriate use of these funds in the course of offering an MA benefit. Implementing this payment methodology should not unnecessarily restrict an MA EGWP's ability to offer this benefit and should instead be in equity with individual market plans in this regard. Implementing the waiver as described also facilitates the communication of this information from CMS to SSA by maintaining a similar operational structure to that which exists for individual market MAOs.

In order to facilitate the continued offering of MA EGWPs, we are proposing to collect a Part B premium buy-down amount in the EGWP's Plan Benefit Package (PBP) submission to CMS. Any MA EGWP that chooses to use a portion of its payment to buy down the Part B premium must do so in accordance with uniformity of benefit rules and apply such Part B premium buy-down amount consistently to every beneficiary enrolled in the EGWP. In order to permit this accommodation under the payment methodology proposed in connection with the bidding waiver, those MA EGWPs that choose to use a portion of their payment to buy-down the Part B premium for their enrollees will have that amount reduced from their capitated payment. For example, if an MA EGWP determines that under its benefit offering there will be a $5.00 reduction to each of its enrollee's Part B premium, $5.00 per member per month will entered into the requisite field in the PBP, and then $5.00 will be subtracted from the monthly capitated amount. For local MA EGWPs this would be reflected in the proposed payment formula described above as follows:

$$\text{Total payment} = (\text{base county payment rate} + \text{county rebate}) \times \text{beneficiary level risk score} - \textit{Part B buy down amount}.$$

MA EGWPs would continue to be prohibited from separately refunding Part B premiums for their enrollees outside of this proposed process.

Under this proposed policy, MA EGWPs would be subject to the same maximum CY 2020 Part B buy-down amount as non-EGWP plans. That is, EGWPs may only buy down the Part B premium up to the maximum amount displayed in the CY 2020 MA Bid Pricing Tool Worksheet 6. Additionally, similar to non-EGWP plans, the Part B buy-down amount cannot vary among beneficiaries under a plan. The Part B buy-down amount applies to every beneficiary under the plan ID. Therefore, if an EGWP would like to reduce the Part B premium for one employer group under the plan ID by $5 and reduce the Part B premium for another employer group by $10, then two separate EGWP plan IDs would need to be established/utilized. As an example, the PBP for plan 801 would contain a $5 buy-down amount and the PBP for plan 802 would contain a $10 buy-down amount.

In this 2020 proposal, the following rules will continue to apply as they have since 2017 under this proposed payment methodology:

- CMS will continue to waive the requirement that MA EGWPs must allocate rebate dollars to any specific purpose for 2020.
- MA EGWPs will not receive capitation payments for members that elect Hospice.
- MA-EGWPs will continue to be paid using the ESRD ratebook for their ESRD beneficiaries in Transplant and Dialysis status and the individual market 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 MA rate.
- MA EGWP MSA plans will not submit Bid Pricing Tools for 2020, but the 2020 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: 2020 MA Monthly Capitation County Rate x beneficiary risk score – 1/12 of the Annual MSA Deposit Amount. The 2020 Annual MSA Deposit Amount must be submitted in the appropriate Plan Benefit Package field. Given the different payment structure for MSA plans, and consistent with individual market MSA plans, MA EGWP MSA plans will not be able to use a portion of the Part C payment to buy down the Part B premium.

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 2020. MAOs must continue to make a good faith effort in projecting CY 2020 member months for each plan and place the amount in the appropriate section of the 2020 Plan Benefit Package (PBP) submissions to CMS.

Section G. CMS-HCC Risk Adjustment Model for CY 2020

On December 20, 2018, CMS published for public comment the proposed Part C risk adjustment model in Part I of the Advance Notice. As noted in Part I of the Notice, all comments must be submitted to https://www.regulations.gov/. Enter the docket number "CMS-2018-0154" in the "Search" field, and follow the instructions for "submitting a comment." As noted above, we have extended the comment deadline from February 19, 2018. Comments on Part I proposals will be accepted until 6pm EST on Friday, March 1, 2019. We will address comments in the 2020 Rate Announcement that will be released no later than April 1, 2019.

Section H. ESRD Risk Adjustment Model for CY 2020

CMS uses a separate model to calculate the risk scores applied in payment 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 CY2019, CMS recalibrated the ESRD risk adjustment model with more recent data and updated the Medicaid factors to be concurrent with the payment year (refer to the 2019 Advance Notice and Rate Announcement for more information regarding these updates). For CY2020, CMS proposes implementing a revised CMS-HCC ESRD risk adjustment model (CY2020 ESRD model) calibrated with diagnoses filtered using the approach we currently use to filter encounter data records to calculate encounter data-based risk scores for enrollees in MA plans and certain demonstrations (but not for enrollees in a PACE organization).

This change in filtering approach for the recalibration of the CMS-HCC ESRD model is the same change that we made for the CY2019 CMS-HCC risk adjustment model, used to calculate risk adjusted payments for non-ESRD beneficiaries enrolled in a MA plan (and as proposed for CY2020).[6] We propose that this CY2020 ESRD model be used to calculate the encounter data-based risk score, that is then blended with the RAPS-based risk score (see Section N).

Model specifications

- As with the ESRD model implemented for 2019 (i.e., CY2019 ESRD model), the CY2020 ESRD model:
    - Is calibrated using 2014 diagnoses to predict 2015 expenditures;
    - Incorporates Medicaid factors that are concurrent with the payment year and based on three sources of data (i.e., State-reported Medicaid data, Puerto Rico monthly Medicaid file, and Point of Sale data) and;
    - Includes the same HCCs.

- Proposed updates for 2020:
    - Select diagnoses for model calibration using the approach used to filter diagnoses from encounter data records (2014 diagnoses selected with filtering logic applied as we do with encounter data, e.g., using CPT/HCPCS codes to identify risk adjustment eligible diagnoses on professional encounters, predicting 2015 costs), and;
    - Make adjustments to the dialysis new enrollee, post-graft new enrollee, and post-graft LTI segments of the model to improve payment accuracy.

[6] 2019 Advance Notice Part I, available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2019Advance.html.

Model Recalibration

Specifically, for the CY2020 ESRD model that we are proposing, we selected 2014 diagnoses that met CMS's encounter data filtering criteria[7]: diagnoses submitted on professional claims were selected if the claim contained at least one risk adjustment allowable CPT/HCPCS code;[8] diagnoses submitted on outpatient claims were selected if the claim contained at least one risk adjustment allowable CPT/HCPCS code and a risk adjustment allowable type of bill; and diagnoses submitted on inpatient claims were selected if the claim had a risk adjustment eligible type of bill.[9]

The proposed CY2020 ESRD risk adjustment model is structurally the same ESRD model that we implemented for 2019 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 will be used in payment for 2019 (i.e., we have not made any changes to the HCCs from the ESRD 2019 model, which are being used to calibrate the HCPCS filtering based ESRD model for CY2020).

The proposed CY2020 ESRD HCPCS-based dialysis model has a 2015 denominator, which is minimally different from the 2015 denominator for the 2019 ESRD dialysis model. The change in coefficients resulting from the HCPCS-based filtering is balanced by the HCPCS-based filtering of the diagnoses used to calculate the denominator. The proposed CY2020 ESRD dialysis model has a different denominator because of the adjustment made to the dialysis new enrollee risk scores (see below for more information).

The denominator for the proposed 2020 ESRD HCPCS-based functioning graft model is the same as the denominator for the 2019 ESRD functioning graft model. The change in coefficients resulting from the HCPCS-based filtering is balanced by the HCPCS-based filtering of the diagnoses used to calculate the denominator, and results in the same predicted average cost. The adjustments to the functioning graft new enrollee and LTI segments (as discussed below) do not affect the denominator of the functioning graft model, since the denominator population is the non-ESRD population (see the 2019 Advance Notice and Rate Announcement for further discussion).

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[7] *Final Encounter Data Diagnosis Filtering Logic*, HPMS memo, December 22, 2015.

[8] For the list of allowable CPT/HCPCS codes in 2014, see https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/CPT-HCPCS.html.

[9] See *Final Encounter Data Diagnosis Filtering Logic*, HPMS memo, December 22, 2015, for the list of risk adjustment allowable types of bills.

Adjustments for Dialysis New Enrollee and Functioning Graft New Enrollee and LTI Subpopulations

Pursuant to the 21st Century Cures Act, CMS recently published the Report to Congress, Risk Adjustment in Medicare Advantage 2018, published on December 20, 2018 in accordance with Section 17006(f)(2)(A)(ii) of the 21st Century Cures Act (Public Law No: 114-255, enacted December 13, 2016). This report describes and provides predictive ratios (i.e., the ratio of the average predicted cost to the average actual cost) for model segments and a number of subpopulations, including post-graft new enrollee, post-graft LTI, and dialysis new enrollee, under the 2019 ESRD risk adjustment model.[10]

- Functioning graft new enrollee and institutional segments. As noted in the Report to Congress, the FFS functioning graft population is approximately only 105,000, of which 93 percent are community continuing enrollees, 1 percent are institutional, and 6 percent are new enrollees. None of these subsamples is large enough to reliably estimate a full regression model. Instead, the model's community, institutional, and new enrollee segments use most factors from a CMS-HCC model calibrated with the non-ESRD aged/disabled population, and supplemented with a few variables modeled on the functioning graft continuing enrollee sample. Some of these variables are "add on" factors, meant to predict the costs of the functioning graft population, beyond the prediction made using the non-ESRD population. These "add on" variables – which are incorporated into the community, institutional, and new enrollee model segments – are calibrated using the combined community and institutional functioning graft population. When we measure the accuracy of the functioning graft model, we use the actual functioning graft population. Because most of the functioning graft model subpopulation are community beneficiaries, the community functioning graft population is well predicted. However, the model under predicts for both the new enrollee (0.806; 19 percent under prediction) and LTI populations (0.836; 16 percent under prediction). This indicates that true functioning graft new enrollees and LTI enrollees have higher costs than the costs predicted by a model calibrated with the non-ESRD population and supplemented with factors calibrated on the entire continuing functioning graft population.

- Dialysis new enrollee segment adjustment. Similar to the functioning graft new enrollee and LTI segments, the population of true new enrollees receiving dialysis is too small to reliably estimate a model. Thus, the modeling sample also includes continuing enrollees who have been on dialysis for 3 years or less to increase its sample size for modeling purposes. As a result, the predictive ratio for dialysis new enrollees is 1.149, representing

[10] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/ReportToCongress.html.

approximately 15 percent over prediction. This indicates that true dialysis new enrollees have lower costs on average than the combination of new enrollees and continuing enrollees in the modeling sample.

To address the over prediction or under prediction for these unique subpopulations that are too small to independently estimate a model on, CMS proposes the following adjustments for the specified segments of the CY2020 ESRD risk adjustment model:

- Post-graft new enrollee and institutional segment adjustment. Adjust the coefficients by the applicable predictive ratio to set the entire segment predictive ratio to 1.0. Specifically, all coefficients for the post-graft new enrollee segment of the model were divided by 0.806 and all coefficients in the post-graft LTI segment were divided by 0.836. As a result, the prediction is improved for enrollees in most of the deciles of risk.

- Dialysis new enrollee segment adjustment. Adjust the coefficients by the dialysis new enrollee predictive ratio to set the entire segment predictive ratio to 1.0. Specifically, all demographic coefficients of the model were divided by 1.149. As a result, there is less over prediction for all deciles of risk.

Use of proposed model in CY2020 payment

CMS proposes to use the proposed CPT/HCPCS filtering-based ESRD model for the encounter data-based portion of the CY2020 ESRD risk score and the 2019 ESRD model for the RAPS-based portion of the risk score. Refer to Attachment II, Section N for the proposed blend of the encounter data based risk score and the RAPS-based risk score in payment for CY2020.

Attachment V provides the model relative factors for the recalibrated ESRD model for 2020. Refer to Attachment VI of the 2019 Rate Announcement for the relative factors for the 2019 ESRD model.

Section I. CMS-HCC Risk Adjustment Model Used for PACE Organizations in CY 2020

In the 2019 Rate Announcement, we stated that we would evaluate the CMS-HCC model that we use to pay PACE organizations for payment year 2020. The CMS-HCC model currently used to pay PACE organizations risk adjustment for non-ESRD enrollees, which we first implemented for PACE in CY 2012, is calibrated with 2006 diagnoses and 2007 costs and has a 2009 denominator. Due to the number of years between the calibration years and the payment year, we are proposing to update the model used to pay risk adjustment to PACE organizations in CY2020.

When we implemented the CMS-HCC model currently used to pay PACE organizations, our intention was not to maintain a separate model for PACE organizations.[11] Both the model currently used to pay PACE organizations and the models used to pay MAOs are calibrated on the same population (FFS beneficiaries entitled to Part A, enrolled in Part B, and not in ESRD or Hospice status) and with similar specifications. PACE organization risk scores under either model will reflect the higher risk of the population enrolled in PACE relative to the average FFS Medicare population. Therefore, for PY 2020 we are proposing to calculate risk scores for PACE organizations using the 2017 CMS-HCC model. First implemented in CY 2017, the 2017 CMS-HCC model has six independent segments for continuing enrollees (those with 12 months of Part B enrollment in the data collection year) who are residing in the community depending on whether they are entitled to Medicare due to age or disability and depending on whether they are full-benefit dual, partial-benefit dual, or non-dual. By moving to the 2017 CMS-HCC model, risk score calculations for PACE organizations will be aligned with one of the two risk adjustment models currently in use for Medicare Advantage organizations.

Further, upon evaluation, the 2017 CMS-HCC model has a similar impact on the average PACE risk score as would an updated recalibrated version of the CMS-HCC model currently used in payment for PACE organizations. In our evaluation, we analyzed the impact on CY 2016 risk scores for PACE enrollees. We compared PACE risk scores from the CMS-HCC model currently used to calculate risk scores for beneficiaries enrolled in PACE organizations ("PACE model") to risk scores under two other models: (1) a recalibrated "PACE model" with 2014 diagnoses predicting 2015 costs, and Medicaid status identified concurrently from three sources (the MMA State files, the Point of Sale data, and the monthly Medicaid file that the Commonwealth of Puerto Rico submits to CMS), and (2) the 2017 CMS-HCC model. Each set of risk scores was adjusted with the appropriate normalization factors. We then calculated the difference between the risk scores under the model currently used to pay PACE organizations and each of the models considered in the evaluation. When comparing the risk scores calculated using the recalibrated "PACE model" and the 2017 CMS-HCC model against the current "PACE model," on average across all PACE organizations, we measured only a 0.25 percentage point difference in the impacts (percentage change in the average risk scores) between the 2017 CMS-HCC model and the recalibrated "PACE model."

Model updates can produce changes in risk scores at the beneficiary level, as well as the contract level. Updating the underlying data to reflect more recent utilization, cost, and coding trends can change the marginal cost attributable to each demographic factor, HCC, and interaction term. Thus, these updates can change the risk measured for the contract or beneficiary relative to the average depending on each individual beneficiary's combination of diagnoses and demographic factors. Specifically, the risk score change will be different for each PACE organization under

[11] For more information about this CMS-HCC model, please refer to the 2011 Advance Notice and Rate Announcement, and the 2012 Advance Notice and Rate Announcement.

either of the newer models. In this analysis, more than half of PACE organizations in 2016 had higher scores under the 2017 CMS-HCC model. That is, the 2016 risk score under the 2017 CMS-HCC model was greater than the 2016 risk score under the recalibrated version of the current "PACE model" and, for many organizations, was also greater than the 2016 risk score under the current "PACE model."

The similar impact on the average PACE risk score of the two models further supports our belief that a separate risk adjustment model for PACE organizations is not warranted. In addition, we think the 2017 CMS-HCC model has several advantages over the model currently used for payment to PACE organizations. First, the 2017 CMS-HCC model is calibrated with more recent data (2013 diagnoses and 2014 cost) and has a more recent denominator (2015). The more recent data better reflects changes in disease and cost patterns since the previous calibration. Furthermore, the updated denominator shortens the number of years between the denominator and the payment year, effectively reducing the normalization factor applied to PACE organizations' risk scores. Second, the 2017 CMS-HCC model has six community segments: non-dual aged, non-dual disabled, partial benefit dual aged, partial benefit dual disabled, full benefit dual aged, and full benefit dual disabled. Most beneficiaries enrolled in the PACE program are full benefit dual eligibles and are expected to have higher costs than either partial benefit dual eligibles or non-duals. A model calibrated with separate segments based on dual status increases the predicted cost for beneficiaries entitled to Medicare and eligible for full Medicaid benefits because the model coefficients for the full dual segments are estimated specifically on that subpopulation. Finally, while the 2017 CMS-HCC model lacks a coefficient for dementia and related conditions, which are prevalent among the PACE population, the cost of dementia and related conditions is not excluded from the model. Some of the cost is predicted by the demographic variables, other conditions correlated with dementia, and, to the extent that dementia is correlated with the Activities of Daily Living that are used to calibrate the frailty factors (which predict the residual costs not explained by the model), the frailty factors.

For the tables of coefficients and additional information on the 2017 CMS-HCC model, please see the Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.

For payment purposes, we will use Medicaid data from three sources to identify Medicaid status when calculating risk scores with the 2017 CMS-HCC model: the MMA State files, the Point of Sale data, and the monthly Medicaid file that the Commonwealth of Puerto Rico submits to CMS. We will identify full benefit dual status for a month using dual status codes 02, 04, and 08, and presence on the Puerto Rico file to indicate full dual status. We will identify partial benefit dual status for a month using dual codes 01, 03, 05, and 06. The reliance on these three sources of Medicaid status aligns with how we currently calculate risk scores for Medicare Advantage Organizations and, starting in 2019, for ESRD beneficiaries, as well as how we are proposing to calculate Medicare Advantage and ESRD risk scores for 2020.

Section J. Frailty Adjustment for PACE Organizations and FIDE SNPs

Section 1894(d)(2) of the Social Security Act requires CMS to take into account the frailty of the PACE population when making payments to PACE organizations. In addition, section 1853(a)(1)(B)(iv) allows CMS to make an additional payment adjustment that takes into account the frailty of beneficiaries enrolled in Fully Integrated Dual Eligible (FIDE) Special Needs Plans (SNPs), if the average level of frailty in the FIDE SNP is similar to the PACE program.

CMS estimates frailty factors to explain additional costs not explained by diagnoses in the CMS-HCC model. CMS calibrates the frailty factors by regressing the residual, or unexplained, costs from the CMS-HCC risk adjustment model on counts of activities of daily living (ADLs).[12] We update the factors whenever the CMS-HCC model changes, since the frailty factors for a given model can vary and, therefore, the predicted residual costs will be different.

In CY 2020, we are proposing to implement the "Payment Condition Count" (PCC) model to calculate risk scores for Medicare Advantage enrollees. Thus, we are also proposing to implement updated frailty factors based on this model when calculating FIDE SNPs' frailty scores. Table II-4 presents the preliminary frailty factors for CY 2020 using the PCC model proposed in Part I of the Advance Notice, published December 20, 2018. In Part I of the 2020 Advance Notice we also provide an alternative Payment Condition Count (APCC) model for consideration. The frailty factors associated with the APCC model are in Table II-5 on the following page.

Consistent with CMS's proposal to blend the risk scores calculated for enrollees in MA plans, we also propose to blend the frailty score that is applied in FIDE SNP's payment. As proposed, we would blend 50 percent of the frailty score calculated from the proposed PCC model frailty factors with 50 percent of the frailty score calculated from the 2017 CMS-HCC model frailty factors. The blended frailty score will be compared with the PACE level of frailty in the same manner as CY 2019 to determine whether that FIDE SNP has a similar average level of frailty as PACE. The frailty factors associated with the 2017 CMS-HCC model are in Table II-6.

MAOs that are planning to sponsor a FIDE SNP and that wish to receive frailty payments in 2020, must contract with a certified vendor to field the 2019 Health Outcomes Survey (HOS), or the 2019 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 for FIDE SNPs.

Since we are proposing to calculate risk scores for PACE organizations with the 2017 CMS-HCC model, we are also proposing to calculate frailty scores for PACE organizations with the

[12] Refer to section 80 of Chapter 7 of the Medicare Managed Care Manual for frailty model calibration information: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf.

frailty factors associated with the 2017 CMS-HCC model. As previously stated, the frailty factors associated with 2017 CMS-HCC model are in Table II-6.

Table II-4. Frailty Factors associated with the proposed PCC model

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

Table II-5. Frailty Factors associated with the APCC model

ADL	Non-Medicaid	Medicaid
0	-0.078	-0.134
1-2	0.161	0.025
3-4	0.293	0.155
5-6	0.293	0.370

Table II-6. Frailty Factors associated with the 2017 CMS-HCC model

ADL	Non-Medicaid	Medicaid
0	-0.083	-0.093
1-2	0.124	0.105
3-4	0.248	0.243
5-6	0.248	0.420

Section K. Medicare Advantage Coding Pattern Adjustment

For PY2020, CMS proposes to apply the statutory minimum MA coding pattern adjustment of 5.90 percent.

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. The model estimates incremental cost for a variety of beneficiary characteristics (e.g., age and gender) and health conditions in a historical period (or "calibration year"). Each model variable's estimate of incremental cost, referred to as a dollar coefficient, is divided by the predicted average per capita expenditure for beneficiaries in Original Medicare in a given year (the denominator) 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 years other than the denominator year (prior or future years), the average risk score for Original Medicare beneficiaries may no longer be 1.0 due to an underlying trend that reflects changes such as those in coding and population characteristics between the denominator year and other years. CMS applies a normalization factor to risk scores in the payment year to account for this trend in the average Original Medicare risk score between the denominator year risk score (1.0) and the payment year. The normalization factor is a projection of this trend, and applying the factor effectively keeps the average risk score at 1.0 in the payment year for beneficiaries in Original Medicare.[13]

In determining the Part C normalization factor under each model, we use the observed trend to predict the average risk score of beneficiaries in Original Medicare in the payment year, calculated using the model that will be used in the payment year. In determining the RxHCC normalization factor, we use the predicted average risk score 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.

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, which are standardized to an average risk score of 1.0. A risk score accounts for the degree to which a beneficiary's health status results in expected costs 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, represent the expected cost of an average beneficiary in Original Medicare in the payment year. Normalization helps to ensure that risk adjusted payments for individual Medicare Advantage beneficiaries account for the underlying trend in FFS risk score.

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

Recently, the risk scores that underlie the normalization factor calculation have been increasing at faster rate. We believe there are a number of reasons for this increase, including changes in demographics, the reported health status in the Original Medicare population, and the implementation of ICD-10. We expect the effect on the change in average risk score from implementing ICD-10 to stabilize moving forward. However, we believe that demographic trends, an incentive to report diagnosis codes more completely in alternative payment models (which are increasing in penetration), and a changing case mix in Original Medicare may

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

continue to put upward pressure on Original Medicare risk scores. Therefore, for PY2020 we are proposing to maintain the same methodology as that used in PY2019 for calculating the normalization factor. We propose to project the slope calculated from the observed trend over five years of historical risk scores, from the denominator year to the payment year. We apply the equation (1+X)^n where X is the slope calculated from the trend of historical FFS risk scores and the exponent n is the number of years between the denominator year and the payment year to calculate the normalization factor. This proposed methodology results in an increase in the normalization factor relative to PY2019.

In Part I of the Advance Notice, published December 20, 2018, CMS proposed to blend 50 percent of the risk score calculated with the 2017 CMS-HCC model with 50 percent of the risk score calculated with the proposed "Payment Condition Count" (PCC) model. Consistent with that proposal, for payment year 2020, CMS proposes to calculate two normalization factors for Part C: one will be used to normalize the risk scores calculated with the 2017 CMS-HCC model, and the other will be used to normalize the risk score calculated with the proposed PCC model. We propose to normalize the PACE risk scores with the normalization factor for the 2017 CMS-HCC model, which is the model that we propose to implement for PACE risk score calculations as discussed in Section I.

The proposed Part C and PACE normalization factor for the 2017 CMS-HCC model is 1.075 and the proposed Part C normalization factor for the proposed PCC model is 1.069. The trend that the CMS-HCC model normalization factors are based on includes 2014 through 2018 risk scores. These years also apply to the normalization factor for the ESRD Dialysis model, and the ESRD Post-Graft model. The preliminary normalization factors for each of these models are in subsections L1 through L3.

We propose to use 2013 through 2017 risk scores to calculate the normalization factors for the RxHCC model calibrated on 2014/2015 data and the RxHCC model calibrated on 2015/2016 data. These preliminary normalization factors and annual trends are in subsection L4. The 2020 Rate Announcement, released no later than April 1, 2019, will contain the finalized CY2020 normalization factors for the model that we finalize for CY2020.

L1. Normalization for the CMS-HCC Model

The proposed 2020 normalization factor estimated from the 2017 CMS-HCC model for Part C and PACE is 1.075, and for Part C estimated from the proposed PCC model is 1.069. Both the proposed PCC model and the 2017 CMS-HCC model have a 2015 denominator. Between 2014 and 2018, the average annual trend estimated from the population of FFS beneficiaries, excluding ESRD and hospice, is 0.0146 for the 2017 CMS-HCC model and 0.0134 for the proposed PCC model. There are five years of trend between the denominator year and the payment year for both models. If we did not update the PACE model for PY2020, the average annual trend estimated from the current PACE model would be 0.0201, there would be eleven

years of trend between the denominator year and the payment year, and the normalization factor for PACE organizations would be 1.245.

The normalization factors for the CMS-HCC risk adjustment models are 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 2020 normalization factor for the 2017 CMS-HCC model and the proposed PCC model are included in Table II-7 Part C Normalization Factor Trend. The trends for the Alternative "Payment Condition Count" (PCC) model and current "PACE" model are provided in Table II-7 for reference.

Table II-7. Part C Normalization Factor Trend

Year	2017 CMS-HCC Model	Proposed PCC Model	Alternative Model[14]	Current "PACE" Model
2014	0.999	0.998	0.998	1.048
2015	1.000	1.000	1.000	1.051
2016	1.021	1.019	1.020	1.079
2017	1.034	1.030	1.030	1.098
2018	1.055	1.050	1.050	1.125

L2. Normalization for the ESRD Dialysis Model

The proposed 2020 normalization factor for the ESRD dialysis risk scores is 1.059. Both ESRD Dialysis models have a 2015 denominator. Between 2014 and 2018, the trend estimated from the population of FFS beneficiaries with ESRD is 0.0116. There are five years of trend between the denominator year and the payment year. CMS proposes to apply the same normalization factor to the risk scores calculated with the 2019 ESRD Dialysis Model and the 2020 ESRD Dialysis Model. The proposed factors for both models are the same because there is minimal difference between the denominator for each model, and the FFS risk scores calculated under each model for each year are the same. The difference between the 2020 ESRD Dialysis Model's coefficients and the 2019 ESRD Dialysis Model's coefficients is from the HCPCS-based filtering, which is balanced with the HCPCS-filtered diagnoses used to calculate the risk scores. The risk scores calculated for the trend include the adjustment that we propose to apply to the risk scores for new

[14] The alternative "Payment Condition Count" (PCC) model was provided for discussion in Part I of the 2020 Advance Notice published on December 20, 2018 and available here: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2020Advance.html.

enrollees (those with less than 12 months of Part B in the data collection year) who are receiving dialysis.

The normalization factor for the ESRD dialysis models is applied to dialysis, dialysis new enrollee, and transplant risk scores. The historical risk scores used to calculate the proposed normalization factor for the proposed 2020 ESRD Dialysis model are included in Table II-8 ESRD Dialysis Normalization Factor Trend.

Table II-8. ESRD Dialysis Normalization Factor Trend

Year	ESRD Dialysis Model
2014	0.997
2015	1.000
2016	1.015
2017	1.030
2018	1.040

L3. Normalization for the ESRD Functioning-Graft Model

The proposed 2020 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.084. The Functioning Graft segment of both the 2019 and the 2020 ESRD Functioning Graft models have a 2015 denominator. Between 2014 and 2018, the trend estimated from the population of Original Medicare beneficiaries with ESRD is 0.0163. There are five years of trend between the denominator year and the payment year. CMS proposes to apply the same normalization factor to the risk scores calculated with both the 2019 ESRD Functioning Graft Model and the 2020 ESRD Functioning Graft Model. The proposed factors for both models are the same because there is minimal difference between the denominator for each model, and the FFS risk scores calculated under each model for each year are the same. The change in the 2020 model's coefficients is from the HCPCS-based filtering, which is balanced with the HCPCS-filtered diagnoses to calculate the risk scores. The trend for the ESRD Functioning Graft model is calculated from a sample of beneficiaries who are entitled to Part A, enrolled in Part B, and who do not have ESRD, or who are not in Hospice status. As such, the adjustments proposed for beneficiaries who are in functioning graft status and who are either new enrollees, or are full risk beneficiaries living in an institution, are not included from the risk scores calculated for the trend.

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 Functioning Graft segment of the ESRD model are included below in Table II-9 ESRD Post-Graft Segment Normalization Factor Trend.

Table II-9. ESRD Post-Graft Segment Normalization Factor Trend

Year	ESRD Post-Graft Model
2014	0.998
2015	1.000
2016	1.023
2017	1.039
2018	1.060

L4. Normalization for the RxHCC Model

The 2020 normalization factor for the RxHCC model calibrated on 2014/2015 data is 1.043 and 1.035 for the RxHCC model calibrated on 2015/2016 data. The RxHCC model based on 2014/2015 data has a 2015 denominator and the model calibrated on 2015/2016 data has a 2016 denominator. Between 2013 and 2017, the trend estimated from the population of beneficiaries enrolled in a PDP or an MA-PD is 0.0085 for the model calibrated on 2014/2015 data and 0.0087 for the model calibrated on 2015/2016 data. 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 five years of trend between the denominator year and the payment year for the 2014/2015 recalibration and four years of trend for the 2015/2016 calibration.

The risk scores used to calculate the proposed 2020 normalization factor for the RxHCC model are included in Table II-10 RxHCC Normalization Factor Trend.

Table II-10. RxHCC Normalization Factor Trend

Year	RxHCC Model Calibrated on 2014/2015 Data	RxHCC Model Calibrated on 2015/2016 Data
2013	0.990	0.976
2014	0.996	0.981
2015	1.000	0.984
2016	1.015	1.000
2017	1.023	1.010

Section M. Medical Loss Ratio Credibility Adjustment

For CY 2020, we are not proposing any changes to the credibility adjustments for MA-PD and Part D stand-alone contracts. The applicable credibility adjustments are provided below in Table II-11 and Table II-12.

Table II-11. 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-12. 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 2020

On December 20, 2018, CMS published for public comment Part I of the CY2020 Advance Notice, which contained the proposed Part C risk adjustment model. Information regarding the use of encounter data as a diagnosis source for 2020 for risk adjustment payments for aged and disabled beneficiaries based on the Payment Condition Count CMS-HCC model and PACE model were also included in Part I of the Advance Notice. As noted in that notice, all comments must be submitted to www.regulations.gov, enter the docket number "CMS-2018-0154" in the "Search" field, and follow the instructions for "submitting a comment." As noted above, we have extended the comment deadline from February 19, 2018. Comments on the Part I proposals will be accepted until 6pm EST on Friday, March 1, 2019. We will address comments in the 2020 Rate Announcement that will be released no later than April 1, 2019.

As noted above in Section H, for CY2020 CMS is also proposing an updated ESRD dialysis and functioning graft model that are calibrated using diagnoses filtered using the same approach as used for encounter data records.

Specifically, for CY2020 we propose to calculate ESRD dialysis and ESRD functioning graft risk scores by summing:

- 50% of the risk score calculated with diagnoses from encounter data (supplemented with RAPS inpatient data) and FFS using the updated ESRD model for 2020 with 50% of the risk score calculated with diagnoses from RAPS and FFS using the 2019 ESRD model.

We envision the inclusion of inpatient RAPS data in the encounter data risk score as a temporary approach to minimize the potential impact on risk scores from incomplete data for the remaining plans that may face operational challenges submitting encounter data records.

For PACE organizations for CY2020, we propose to continue the same method of calculating ESRD risk scores that we have been using since CY2015, 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. We are not proposing to calculate risk scores for PACE organizations in CY2020 with the proposed 2020 ESRD model described above in Section H. We propose to continue using the recalibrated ESRD model implemented in CY2019 to calculate risk scores for ESRD enrollees in PACE organizations in CY2020.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2020

Section A. Update of the RxHCC Model

For CY2020, 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) to reflect the 2020 benefit structure.

The RxHCC model for CY2020 will have the same structure as the model implemented in PY2018, but will be updated based on the 2020 benefit structure gap parameters.

A1. Update to reflect the 2020 benefit structure

CMS recalibrated the RxHCC risk adjustment model to reflect the 2020 benefit structure. This update involved adjustments to the Prescription Drug Event (PDE) data from the prediction year to approximate the 2020 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 2020 plan liability in the coverage gap into the prediction year expenditure data. For 2020, plan liability for non-LIS beneficiaries in the coverage gap will be 75 percent for non-applicable (generic) drugs and 5 percent for applicable (brand and biosimilar) 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, changes in plan liability 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 RxHCC model used in CY2018 and CY2019 is calibrated on 2014 diagnoses and 2015 expenditure data from the PDE records. In the PY2019 Advance Notice, CMS expressed concern about using 2015 diagnoses for model calibration. The use of 2015 diagnoses and 2016 expenditures results in a mix of ICD-9 diagnoses (January 2015 – September 2015) and ICD-10 diagnoses (October 2015 – December 2015) for calibration. Further, the HCCs underlying our risk adjustment models are created using ICD-9 codes, and may be different when we recreate them using ICD-10 codes. We recommended the continued use of 2014/2015 data in order to maintain stability and reflect a year of diagnoses submitted under a single classification system. Calibrating the model based on the mixed ICD-9 and ICD-10 coding year could cause temporary decreases or increases in RxHCC coefficients that are reflective of shifts in diagnosis classification and not true changes in underlying cost patterns. Although we expressed concern

about using 2015 diagnosis data,[15] we understand that costs in the drug market may fluctuate more than medical costs and that the importance of having a more current year of PDE costs predicting plan liability may outweigh the instability of having a quarter of data that was coded to the new ICD-10 classification system in 2015. In addition, we have received comments expressing interest in a model calibrated on more updated data.

For 2020, we recalibrated two models. We are considering the implementation of one of the two following RxHCC models for CY2020:

- *2014/2015 RxHCC model:* In this model, CMS 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. 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 2020 recalibration. Beneficiaries in the 2014/2015 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).

- *2015/2016 RxHCC model:* Despite the concerns regarding the use of a mixed set of diagnoses described above, CMS is also providing information for a model calibrated on 2015/2016 data in response to requests from stakeholders for an RxHCC model with more updated data. This model uses diagnosis data from 2015 fee-for-service (FFS) claims and MA-PD RAPS files, along with expenditure data from 2016 PDE records. Because the RxHCCs are created using ICD-9 codes, the ICD-10 codes are mapped to the appropriate RxHCC using the mappings used to calculate risk scores. Beneficiaries in the 2015/2016 model sample had to be: (1) FFS or Medicare Advantage (MA-PD or MA-only) for all 12 months of the base year (2015); and (2) enrolled in a PDP or an MA-PD for at least one month in the prediction year (2016).

Consistent with existing methodology, coefficients for condition categories for both models 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).

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[15] Section A. Attachment III of the 2019 Advance Notice: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf.

In order to calculate risk scores for payment, the dollar coefficients must be denominated to create relative factors. To create the relative factors, we used a 2015 denominator for the 2014/2015 RxHCC model, and a 2016 denominator for the 2015/2016 RxHCC model. We divided the dollar coefficient for each demographic factor and RxHCC in the model by the average predicted per capita expenditure in 2015 for the 2014/2015 RxHCC model and by the average predicted per capita expenditure in 2016 for the 2015/2016 RxHCC model. The resulting relative factors for the model finalized for 2020 will be used to calculate risk scores for individual beneficiaries in the payment year. We developed the denominators for the recalibrated RxHCC risk adjustment models 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 2014/2015 RxHCC model is $1,036.61 and the denominator used to create relative factors for all segments of the 2015/2016 RxHCC model is $1,045.24.

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.

We welcome feedback on recalibrating the model on 2014/2015 versus 2015/2016 data, and seek comment from stakeholders regarding which version of the model should be finalized for PY2020.

In Attachment V of this Notice, we provide draft relative factors for both RxHCC models (i.e., the 2014/2015 calibration and the 2015/2016 calibration) for each segment of the model.

Section B. Encounter Data as a Diagnosis Source for 2020

For CY2019, CMS calculated 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 using RAPS and FFS diagnoses.

For CY2020, CMS proposes to calculate risk scores by adding 50% of the risk score calculated with diagnoses from encounter data (supplemented with RAPS inpatient data) and FFS with 50% of the risk score calculated using RAPS and FFS diagnoses.

As previously noted, we envision the inclusion of inpatient RAPS data in the encounter data risk score as a temporary approach to minimize the potential impact on risk scores from incomplete data for the remaining plans that may face operational challenges submitting encounter data records.

For PACE organizations for CY2020, we propose to continue the same method of calculating risk scores that we have been using since CY2015, 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.

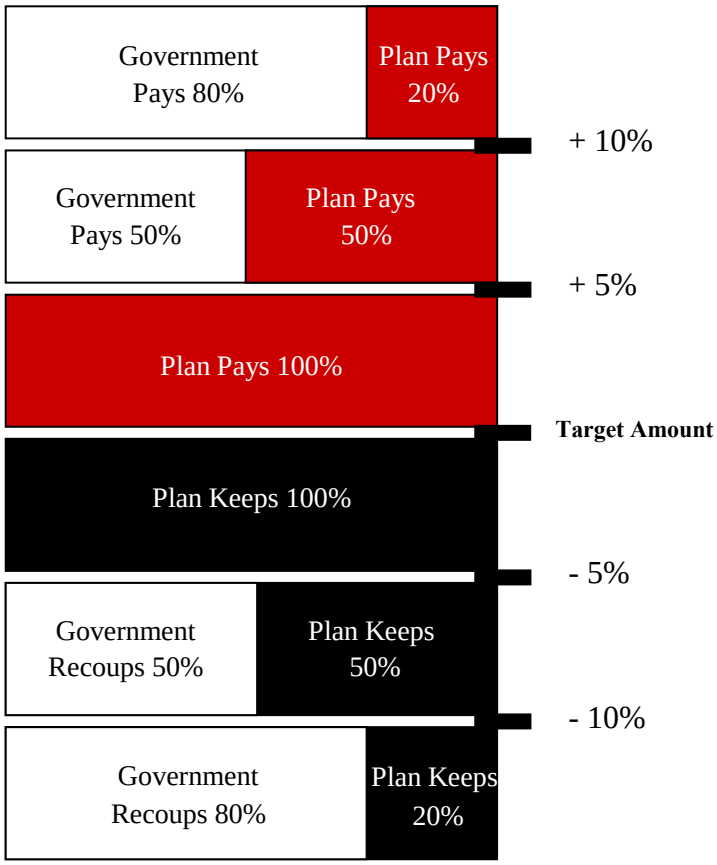
Section C. Part D Risk Sharing

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 2008–2017 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 2020. 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 2019. The risk percentages for the first and second thresholds remain at +/- 5 percent and +/- 10 percent of the target amount, respectively, for 2020. The payment adjustments for the first and second corridors are 50 percent and 80 percent, respectively. Figure 1 below illustrates the risk corridors for 2020.

Figure 1. Part D Risk Corridors for 2020



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 2020

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 threshold[16] 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

[16] See Section D1 below for a detailed discussion of the application of API to the out-of-pocket threshold calculation for 2020.

- 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 5.21 percent for 2020, as summarized by Table III-1 below. This increase reflects the 2019 annual percentage trend of 5.25 percent as well as a multiplicative update of -0.04 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 5.21 percent from their 2019 values.

Section 1860D-2(b)(4) of the Act modified how the out-of-pocket threshold was to be calculated for 2014 through 2019. For 2014 and 2015, the Act required that the out-of-pocket threshold be updated by the API minus 0.25 percentage point, while for contract years 2016 through 2019 the Act required that the out-of-pocket threshold be updated from the previous year by the lesser of (1) the API or (2) two percentage points plus the annual percentage increase in the July CPI.

For 2020 and subsequent years, the Act requires the out-of-pocket threshold to be calculated using the API. Moreover, for 2020, the out-of-pocket threshold must be calculated as if the calculation of the out-of-pocket threshold for years 2014 through 2019 had not be modified (i.e., as if the thresholds for each of years 2014 through 2019 had been updated using the API). Thus, the out-of-pocket threshold will be increased by 5.21 percent for 2020, before accounting for the increase resulting from not accounting for the methodology change for years 2014 through 2019.

See Attachment IV for additional information on the calculation of the annual percentage increase for the out-of-pocket threshold.

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 2019 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 2020. These maximum copayments will be increased by 2.59 percent for 2020 as summarized in Table III-1 below.

This increase reflects the 2019 annual percentage trend in CPI of 2.27 percent as well as a multiplicative update of 0.32 percent for prior year revisions.

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, 25 percent cost sharing for “non-applicable” drugs and 95 percent cost-sharing – consisting of 25 percent beneficiary coinsurance and 70 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 2019	Prior year revisions	Annual percentage increase for 2020
API: Applied to all parameters but (2)	5.25%	-0.04%	5.21%
September CPI (all items, U.S. city average): Applied to (2)	2.27%	0.32%	2.59%

Part D Benefit Parameters

	2019	2020
Standard Benefit		
Deductible	$415	$435
Initial Coverage Limit	$3.820	$4,020
Out-of-Pocket Threshold (1)	$5,100	$6,350
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,653.75	$9,038.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$8,906.55	$9,719.38
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$3.40	$3.60
Other	$8.50	$8.95
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/Biosimilar (6)	$1.25	$1.30
Other (6)	$3.80	$3.90
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/Biosimilar	$3.40	$3.60
Other	$8.50	$8.95
Above Out-of-Pocket Threshold	$0.00	$0.00

	2019	2020
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, 2019) or ≤ $14,340 (couples, 2019) [category code 1] (7)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug/Biosimilar	$3.40	$3.60
Other	$8.50	$8.95
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, 2019) or $28,150 (couples, 2019) [category code 4] (7)		
Deductible (6)	$85.00	$89.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug/ Biosimilar	$3.40	$3.60
Other	$8.50	$8.95
Retiree Drug Subsidy Amounts		
Cost Threshold	$415	$435
Cost Limit	$8,500	$8,950

(1) For 2020 the Act requires the out-of-pocket threshold to be calculated as if the out-of-pocket threshold for years 2014 through 2019 had been subject to the respective API values for those years. Pursuant to section 1860D-2(b)(4)(B)(i)(IV) of the Act, for 2019, the out-of-pocket threshold increase was 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 increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2019 values of $85.06, $1.27, and $3.80, respectively.
(7) The actual amount of resources allowable will be updated for contract year 2020. Additionally, these amounts include $1,500 per person for burial expenses. See the HPMS memorandum titled, “2019 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 continued through CY 2019 for applicable drugs and CY 2020 for non-applicable drugs, ultimately resulting in 95 percent cost-sharing for applicable drugs, prior to the application of the 70 percent manufacturer discounts required by statute, and 25 percent cost-sharing for non-applicable Part D covered 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(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA). Note that applicable drugs also include any biosimilar or interchangeable products licensed under section 351(k) of the PHSA, per section 1860D-14A(g)(2)(A) of the Act, as amended by section 53113 of the BBA of 2018. Non-applicable drugs generally are covered Part D drugs that do not meet the definition of an applicable drug, such as generic drugs. The reductions in cost-sharing, in conjunction with the Coverage Gap Discount Program, effectively served to close the Medicare Part D coverage gap for non-LIS beneficiaries in CY 2019 for applicable drugs and in CY 2020 for non-applicable drugs.

In 2020, the coinsurance for applicable beneficiaries under basic prescription drug coverage is reduced to 25 percent for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After applying the 70 percent manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage is reduced to 25 percent for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2020.

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

Year	Beneficiary Coinsurance	Plan Liability	Manufacturer Discount
2010	100% minus $250 rebate[17]	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+	25%	5%	70%

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

Year	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-pocket threshold. Moreover, Medicare beneficiaries enrolled in a qualified retiree prescription

[17] 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.

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 changes in 2020 – for non-applicable drugs, plan liability increases but for applicable drugs, plan liability remains as it was in 2019. In either case, plan liability amounts do not count toward TrOOP. Part D sponsors must account for the reductions in cost-sharing and changes in plan liability when developing their Part D bids for payment year 2020.

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 2020, applicable beneficiaries will pay 25 percent and plans will pay 75 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 2020 is PY 2017. The average PMPM actual reinsurance amount paid to Part D CY EGWPs for 2017 was $40.77.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2020

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 2020, and (3) the updated cost threshold and cost limit for qualified retiree prescription drug plans in 2020.

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);[18] 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 $415 in 2019 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $3,820 in 2019 and rounded to the nearest multiple of $10.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $3.40 per generic, preferred drug that is a multi-source drug or biosimilar and $8.50 for all other drugs in 2019, rounded to the nearest multiple of $0.05.

[18] As noted above, for 2020, the Act requires the out-of-pocket threshold to be calculated using the API as if the calculation of the out-of-pocket threshold calculation for years 2014 through 2019 had not be modified. See Attachment III, Section D1 for a more detailed description.

Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low-Income Full Subsidy Eligible Enrollees: From $3.40 per generic, preferred drug that is a multi-source drug, or biosimilar and $8.50 for all other drugs in 2019, rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $85[19] in 2019 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $3.40 per generic, preferred drug that is a multi-source drug, or biosimilar and $8.50 for all other drugs in 2019, rounded to the nearest multiple of $0.05.

Annual Percentage Increase for Out-of-Pocket Threshold

Section 1860D-2(b)(4) of the Act modified how the out-of-pocket threshold was to be calculated for 2014 through 2019. For 2014 and 2015, the Act required that the out-of-pocket threshold be updated by the API minus 0.25 percentage point, while for contract years 2016 through 2019 the Act required that the out-of-pocket threshold 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.

For 2020 and subsequent years, the Act requires the out-of-pocket threshold to be calculated using the API. Moreover, for 2020, the out-of-pocket threshold must be calculated as if the calculation of the out-of-pocket threshold for years 2014 through 2019 had not be modified (i.e., as if the thresholds for each of years 2014 through 2019 had been updated using the API). The threshold is increased from $5,100 in 2019 and rounded to the nearest multiple of $50.

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 $3.40 per generic, preferred drug that is a multi-source drug, or biosimilar, and from $8.50 for all other drugs in 2019 and rounded to the nearest multiple of $0.05 and $0.10 respectively.[20]

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[19] 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 2019 value of $85.06.

[20] Per section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2019 values of $1.27 for multi-source generic or preferred drugs, and $3.80 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 2020 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2018–July\ 2019}{August\ 2017–July\ 2018} = \frac{\$3{,}925.20}{\$3{,}729.35} = 1.0525$$

In the formula, the average per capita cost for August 2017 – July 2018 ($3,729.35) is calculated from actual Part D PDE data, and the average per capita cost for August 2018 – July 2019 ($3,925.20) is calculated based on actual Part D PDE data incurred from August 2018 – December 2018 and projected through July 2019.

The 2020 benefit parameters reflect the 2019 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 calculated 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	2.15%	2.15%
2013	2.53%	2.53%
2014	−3.14%	−3.14%
2015	10.12%	10.12%
2016	9.92%	9.90%
2017	4.00%	3.98%
2018	2.02%	1.90%
2019	3.96%	4.09%

Accordingly, the 2020 benefit parameters reflect a multiplicative update of -0.04% percent for prior year revisions. In summary, the 2019 parameters outlined in Section A are updated by 5.21% percent for 2020, as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2019	5.25%
Prior year revisions	-0.04%
Annual percentage increase for 2020	5.21%

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 for Out-of-Pocket Threshold

In accordance with Section 1860D-2(b)(4), we calculated the change in the Out-of-Pocket threshold using the 2013 threshold value of $4,750 as our starting point. To calculate the 2020 value, we applied the API values from years 2014 through 2019 as published in the respective final Rate Announcements for those years, and the 2020 API described above. The calculation is as follows:

1. The starting point is the 2013 Out-of-Pocket threshold of $4,750.
2. We apply the published API for 2014, as this is the percentage that would have been applied absent the modification
3. We round the resulting value to the nearest $50
4. We repeat steps 1 through 3 for each subsequent year through 2019
5. We apply the 2020 API and round to the nearest $50

Note that we are applying the published API for each year, rather than the revised API as of today. This is consistent with the requirement to calculate the threshold as though there had been no modification and ensures that the threshold value appropriately accounts for prior period restatements. The resulting 2020 Out-of-Pocket threshold value is $6,350.

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 2019, an estimate of the September 2019 CPI based on projections from the President’s FY2020 Budget.

The September 2018 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2020 is calculated as follows:

$$\frac{\text{Projected September 2019 CPI}}{\text{Actual September 2018 CPI}} \; or \; \frac{258.2}{252.4} = 1.0227^{21}$$

(Source: President's FY2020 Budget and Bureau of Labor Statistics, Department of Labor)

The 2020 benefit parameters reflect the 2019 annual percentage trend in the September CPI of 2.27 percent, as well as a revision to the prior estimate for the 2018 CPI increase over the 12-month period ending in September 2018. Based on the actual reported CPI for September 2018, the September 2018 CPI increase is now estimated to be 2.28 percent. Accordingly, the 2020 update reflects a 0.32 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 2.59 percent for 2020, as summarized by Table IV-3.

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

Annual percentage trend for September 2019	2.27%
Prior year revisions	0.32%
Annual percentage increase for 2020	2.59%

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 $405 and $8,350, respectively, for plans that end in 2018, and as $415 and $8,500 for plans that end in 2019. For 2020, the cost threshold is $435 and the cost limit is $8,950.

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

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

For 2020, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $9,719.38. 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.
- 25 percent beneficiary cost-sharing for non-applicable drugs purchased in the coverage gap phase of the benefit.
- 95 percent cost-sharing for the ingredient cost and sales tax for applicable drugs purchased in the coverage gap phase of the benefit—comprised of 25 percent beneficiary coinsurance and 70 percent Coverage Gap Discount Program discount.
- 25 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 0.105 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 75 percent reduction in cost-sharing for dispensing and vaccine administration fees results in an overall reduction of 0.074 percent to 94.93 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:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \qquad \$4{,}020 + \frac{\$5{,}018.75}{88.0579\%} = \$9{,}719.38$$

- *ICL* is the Initial Coverage Limit equal to $4,020

- *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:

  *(*OOP threshold) – (OOP costs up to the ICL) *or* $6,350 − $1,331.25= $5,018.75

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

  (Brand Gross Drug Cost Below Catastrophic [GDCB] % for non-LIS × 94.93% gap cost-sharing for applicable drugs) + (Generic GDCB % for non-LIS × 25% gap cost-sharing for non-applicable drugs)

  or

(90.18% × 94.93%) + (9.82% × 25%) =88.0579%[22]

- *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 2018 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) × (cost-sharing percentage)] + [(percentage of gross covered brand drug costs attributable to dispensing and vaccine administration fees) × (cost-sharing coinsurance percentage)]

    or

    94.93% = [(99.895% × 95%) + (0.105% × 25%)]
- *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 2018 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.

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

Attachment V. ESRD and RxHCC Risk Adjustment Factors

Table V-1. ESRD Model Continuing Enrollee Dialysis Relative Factors

Variable	Description Label	Relative Factors
Female		
0-34 Years		0.630
35-44 Years		0.577
45-54 Years		0.532
55-59 Years		0.545
60-64 Years		0.564
65-69 Years		0.647
70-74 Years		0.666
75-79 Years		0.670
80-84 Years		0.684
85-89 Years		0.684
90-94 Years		0.684
95 Years or Over		0.684
Male		
0-34 Years		0.537
35-44 Years		0.512
45-54 Years		0.487
55-59 Years		0.504
60-64 Years		0.507
65-69 Years		0.572
70-74 Years		0.622
75-79 Years		0.646
80-84 Years		0.664
85-89 Years		0.675
90-94 Years		0.675
95 Years or Over		0.675
Medicaid, Originally Disabled, and Originally ESRD Interactions with Age and Sex		
Medicaid_Female_Aged		0.068
Medicaid_Female_NonAged (Age <65)		0.067
Medicaid_Male_Aged		0.124
Medicaid_Male_NonAged (Age <65)		0.092
Originally Disabled_Female[2]		–
Originally Disabled_Male[2]		–
Originally ESRD_Female[3]		-0.079
Originally ESRD_Male[3]		-0.050
Disease Coefficients		
HCC1	HIV/AIDS	0.156
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.083
HCC6	Opportunistic Infections	0.053
HCC8	Metastatic Cancer and Acute Leukemia	0.301

Variable	Description Label	Relative Factors
HCC9	Lung and Other Severe Cancers	0.172
HCC10	Lymphoma and Other Cancers	0.139
HCC11	Colorectal, Bladder, and Other Cancers	0.078
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.047
HCC17	Diabetes with Acute Complications	0.249
HCC18	Diabetes with Chronic Complications	0.093
HCC19	Diabetes without Complication	0.067
HCC21	Protein-Calorie Malnutrition	0.056
HCC22	Morbid Obesity	0.075
HCC23	Other Significant Endocrine and Metabolic Disorders	0.014
HCC27	End-Stage Liver Disease	0.208
HCC28	Cirrhosis of Liver	0.087
HCC29	Chronic Hepatitis	0.071
HCC33	Intestinal Obstruction/Perforation	0.073
HCC34	Chronic Pancreatitis	0.075
HCC35	Inflammatory Bowel Disease	0.054
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.063
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.073
HCC46	Severe Hematological Disorders	0.183
HCC47	Disorders of Immunity	0.099
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.060
HCC51	Dementia With Complications	0.099
HCC52	Dementia Without Complication	0.046
HCC54	Drug/Alcohol Psychosis	0.049
HCC55	Drug/Alcohol Dependence	0.049
HCC57	Schizophrenia	0.145
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.092
HCC70	Quadriplegia	0.279
HCC71	Paraplegia	0.204
HCC72	Spinal Cord Disorders/Injuries	0.104
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.120
HCC74	Cerebral Palsy	0.037
HCC75	Polyneuropathy	0.060
HCC76	Muscular Dystrophy	0.063
HCC77	Multiple Sclerosis	0.070
HCC78	Parkinson's and Huntington's Diseases	0.067
HCC79	Seizure Disorders and Convulsions	0.067
HCC80	Coma, Brain Compression/Anoxic Damage	0.044
HCC82	Respirator Dependence/Tracheostomy Status	0.246
HCC83	Respiratory Arrest	0.117
HCC84	Cardio-Respiratory Failure and Shock	0.045
HCC85	Congestive Heart Failure	0.084
HCC86	Acute Myocardial Infarction	0.134

Variable	Description Label	Relative Factors
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.118
HCC88	Angina Pectoris	0.049
HCC96	Specified Heart Arrhythmias	0.094
HCC99	Cerebral Hemorrhage	0.079
HCC100	Ischemic or Unspecified Stroke	0.079
HCC103	Hemiplegia/Hemiparesis	0.088
HCC104	Monoplegia, Other Paralytic Syndromes	0.078
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.327
HCC107	Vascular Disease with Complications	0.129
HCC108	Vascular Disease	0.067
HCC110	Cystic Fibrosis	0.073
HCC111	Chronic Obstructive Pulmonary Disease	0.073
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.067
HCC114	Aspiration and Specified Bacterial Pneumonias	0.064
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.014
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	–
HCC124	Exudative Macular Degeneration	0.056
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.282
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.164
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.149
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.149
HCC161	Chronic Ulcer of Skin, Except Pressure	0.121
HCC162	Severe Skin Burn or Condition	0.043
HCC166	Severe Head Injury	0.044
HCC167	Major Head Injury	0.017
HCC169	Vertebral Fractures without Spinal Cord Injury	0.066
HCC170	Hip Fracture/Dislocation	0.051
HCC173	Traumatic Amputations and Complications	0.043
HCC176	Complications of Specified Implanted Device or Graft	–
HCC186	Major Organ Transplant or Replacement Status	0.157
HCC188	Artificial Openings for Feeding or Elimination	0.080
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.092
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	0.025
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.074
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.115
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.160

Variable	Description Label	Relative Factors
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.135
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.125
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.303
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 $80,612.96.
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 17-19.
   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-2. 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	0.703	0.945	0.993	1.177
35-44 Years	0.703	0.912	0.993	1.177
45-54 Years	0.777	0.913	0.993	1.213
55-59 Years	0.813	0.930	0.993	1.213
60-64 Years	0.864	0.986	1.047	1.229
65-69 Years	0.994	1.148	1.096	1.249
70-74 Years	1.056	1.239	1.180	1.280
75-79 Years	1.056	1.239	1.223	1.320
80-84 Years	1.082	1.239	1.223	1.320
85 Years or Over	1.032	1.289	1.223	1.320
Male				
0-34 Years	0.620	0.795	0.888	1.104
35-44 Years	0.620	0.817	0.888	1.104
45-54 Years	0.673	0.842	0.888	1.127
55-59 Years	0.767	0.900	0.915	1.146
60-64 Years	0.803	0.944	0.915	1.206
65-69 Years	0.909	1.107	0.915	1.206
70-74 Years	0.999	1.225	1.082	1.307
75-79 Years	1.047	1.225	1.111	1.307
80-84 Years	1.041	1.225	1.111	1.307
85 Years or Over	1.029	1.316	1.111	1.307

NOTES:
1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is $80,612.96.
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-3. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	**Kidney Transplant** *Actual Dollars*	**Kidney Transplant Relative Risk Factor**
Month 1	9,606	41,260.76	6.142
Months 2 and 3	18,651	6,126.29	0.912
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) x 12. The CMS ESRD Dialysis Denominator value used was $80,612.96.

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

Table V-4. 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		2.174
Aged 65+, with duration since transplant of 4-9 months		2.562
Aged <65, with duration since transplant of 10 months or more		0.840
Aged 65+, with duration since transplant of 10 months or more		1.121
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
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

Variable	Description Label	Relative Factors
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
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

Variable	Description Label	Relative Factors
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)	–
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

Variable	Description Label	Relative Factors
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
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 17-19.
   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-5. 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		2.600
Aged 65+, with duration since transplant of 4-9 months		3.064
Aged <65, with duration since transplant of 10 months or more		1.005
Aged 65+, with duration since transplant of 10 months or more		1.341
Female		
0-34 Years		1.015
35-44 Years		1.269
45-54 Years		1.187
55-59 Years		1.213
60-64 Years		1.216
65-69 Years		1.449
70-74 Years		1.340
75-79 Years		1.182
80-84 Years		1.030
85-89 Years		0.932
90-94 Years		0.778
95 Years or Over		0.579
Male		
0-34 Years		1.262
35-44 Years		1.143
45-54 Years		1.106
55-59 Years		1.162
60-64 Years		1.212
65-69 Years		1.516
70-74 Years		1.563
75-79 Years		1.549
80-84 Years		1.421
85-89 Years		1.317
90-94 Years		1.159
95 Years or Over		0.955
Medicaid and Originally Disabled		
Medicaid		0.089
Originally Disabled_Age ≥65		–
Disease Coefficients		
HCC1	HIV/AIDS	2.043
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.328
HCC6	Opportunistic Infections	0.679
HCC8	Metastatic Cancer and Acute Leukemia	1.542
HCC9	Lung and Other Severe Cancers	0.723
HCC10	Lymphoma and Other Cancers	0.539
HCC11	Colorectal, Bladder, and Other Cancers	0.340
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.232

Variable	Description Label	Relative Factors
HCC17	Diabetes with Acute Complications	0.446
HCC18	Diabetes with Chronic Complications	0.446
HCC19	Diabetes without Complication	0.197
HCC21	Protein-Calorie Malnutrition	0.302
HCC22	Morbid Obesity	0.513
HCC23	Other Significant Endocrine and Metabolic Disorders	0.429
HCC27	End-Stage Liver Disease	1.032
HCC28	Cirrhosis of Liver	0.572
HCC29	Chronic Hepatitis	0.572
HCC33	Intestinal Obstruction/Perforation	0.414
HCC34	Chronic Pancreatitis	0.505
HCC35	Inflammatory Bowel Disease	0.408
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.448
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.327
HCC46	Severe Hematological Disorders	0.916
HCC47	Disorders of Immunity	0.657
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.207
HCC51	Dementia With Complications	–
HCC52	Dementia Without Complication	–
HCC54	Drug/Alcohol Psychosis	0.134
HCC55	Drug/Alcohol Dependence	0.134
HCC57	Schizophrenia	0.260
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.260
HCC70	Quadriplegia	0.613
HCC71	Paraplegia	0.520
HCC72	Spinal Cord Disorders/Injuries	0.306
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.534
HCC74	Cerebral Palsy	–
HCC75	Polyneuropathy	0.387
HCC76	Muscular Dystrophy	0.354
HCC77	Multiple Sclerosis	–
HCC78	Parkinson's and Huntington's Diseases	0.168
HCC79	Seizure Disorders and Convulsions	0.078
HCC80	Coma, Brain Compression/Anoxic Damage	–
HCC82	Respirator Dependence/Tracheostomy Status	1.916
HCC83	Respiratory Arrest	0.557
HCC84	Cardio-Respiratory Failure and Shock	0.372
HCC85	Congestive Heart Failure	0.223
HCC86	Acute Myocardial Infarction	0.469
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.469
HCC88	Angina Pectoris	0.469
HCC96	Specified Heart Arrhythmias	0.295

Variable	Description Label	Relative Factors
HCC99	Cerebral Hemorrhage	0.126
HCC100	Ischemic or Unspecified Stroke	0.126
HCC103	Hemiplegia/Hemiparesis	–
HCC104	Monoplegia, Other Paralytic Syndromes	–
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.902
HCC107	Vascular Disease with Complications	0.359
HCC108	Vascular Disease	0.103
HCC110	Cystic Fibrosis	0.521
HCC111	Chronic Obstructive Pulmonary Disease	0.358
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.358
HCC114	Aspiration and Specified Bacterial Pneumonias	0.171
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.171
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.464
HCC124	Exudative Macular Degeneration	0.250
HCC134	Dialysis Status	–
HCC135	Acute Renal Failure	–
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	1.158
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.452
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.269
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.269
HCC161	Chronic Ulcer of Skin, Except Pressure	0.269
HCC162	Severe Skin Burn or Condition	–
HCC166	Severe Head Injury	–
HCC167	Major Head Injury	–
HCC169	Vertebral Fractures without Spinal Cord Injury	0.284
HCC170	Hip Fracture/Dislocation	–
HCC173	Traumatic Amputations and Complications	0.072
HCC176	Complications of Specified Implanted Device or Graft	0.716
HCC186	Major Organ Transplant or Replacement Status	0.089
HCC188	Artificial Openings for Feeding or Elimination	0.577
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.406
Disease Interactions		

Variable	Description Label	Relative Factors
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.227
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.498
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.271
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.540
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.352
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.190
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.264
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.301
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.415
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.481
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.146
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.647
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.314
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.631
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.561
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.535
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.536
NONAGED_HCC6	NonAged, Opportunistic Infections	0.375

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" and "NonAged interactions," the variables are defined as follows:

   Sepsis = HCC 2.
   Cardiorespiratory Failure = HCCs 82-84.
   Diabetes = HCCs 17-19.
   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-6. 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	3.695	3.899	–	–
35-44 Years	3.872	4.189	–	–
45-54 Years	3.957	4.317	–	–
55-59 Years	3.958	4.319	–	–
60-64 Years	4.103	4.444	–	–
65 Years	3.824	4.411	4.503	4.986
66 Years	3.818	4.291	4.503	4.986
67 Years	3.854	4.320	4.503	5.664
68 Years	3.920	4.358	4.772	5.664
69 Years	3.924	4.358	4.772	5.664
70-74 Years	4.035	4.401	4.772	5.664
75-79 Years	4.245	4.585	4.772	5.664
80-84 Years	4.437	4.857	4.772	5.664
85-89 Years	4.784	5.084	4.772	5.664
90-94 Years	4.784	5.290	4.772	5.664
95 Years or Over	4.784	5.290	4.772	5.664
Male				
0-34 Years	3.245	3.608	–	–
35-44 Years	3.512	4.011	–	–
45-54 Years	3.769	4.375	–	–
55-59 Years	3.818	4.456	–	–
60-64 Years	3.873	4.621	–	–
65 Years	3.821	4.599	4.204	5.426
66 Years	3.840	4.536	4.508	5.906
67 Years	3.901	4.607	4.572	5.906
68 Years	3.956	4.671	4.572	5.906
69 Years	4.035	4.671	4.915	5.906
70-74 Years	4.154	4.789	4.915	5.906
75-79 Years	4.493	4.925	4.915	5.906
80-84 Years	4.725	5.108	4.915	5.906
85-89 Years	5.010	5.383	4.915	5.906
90-94 Years	5.010	5.383	4.915	5.906
95 Years or Over	5.010	5.383	4.915	5.906

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-7. 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	2.040	2.244	–	–
35-44 Years	2.217	2.534	–	–
45-54 Years	2.302	2.662	–	–
55-59 Years	2.303	2.664	–	–
60-64 Years	2.448	2.789	–	–
65 Years	2.036	2.623	2.715	3.198
66 Years	2.030	2.503	2.715	3.198
67 Years	2.066	2.532	2.715	3.876
68 Years	2.132	2.570	2.984	3.876
69 Years	2.136	2.570	2.984	3.876
70-74 Years	2.247	2.613	2.984	3.876
75-79 Years	2.457	2.797	2.984	3.876
80-84 Years	2.649	3.069	2.984	3.876
85-89 Years	2.996	3.296	2.984	3.876
90-94 Years	2.996	3.502	2.984	3.876
95 Years or Over	2.996	3.502	2.984	3.876
Male				
0-34 Years	1.590	1.953	–	–
35-44 Years	1.857	2.356	–	–
45-54 Years	2.114	2.720	–	–
55-59 Years	2.163	2.801	–	–
60-64 Years	2.218	2.966	–	–
65 Years	2.033	2.811	2.416	3.638
66 Years	2.052	2.748	2.720	4.118
67 Years	2.113	2.819	2.784	4.118
68 Years	2.168	2.883	2.784	4.118
69 Years	2.247	2.883	3.127	4.118
70-74 Years	2.366	3.001	3.127	4.118
75-79 Years	2.705	3.137	3.127	4.118
80-84 Years	2.937	3.320	3.127	4.118
85-89 Years	3.222	3.595	3.127	4.118
90-94 Years	3.222	3.595	3.127	4.118
95 Years or Over	3.222	3.595	3.127	4.118

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-8. 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 a`nd 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
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.

Table V-9. RxHCC Model (2014/2015) Relative Factors for Continuing Enrollees

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		-	0.303	-	0.440	1.809
35-44 Years		-	0.449	-	0.632	2.057
45-54 Years		-	0.555	-	0.733	1.735
55-59 Years		-	0.524	-	0.711	1.582
60-64 Years		-	0.482	-	0.645	1.441
65-69 Years		0.238	-	0.394	-	1.504
70-74 Years		0.238	-	0.369	-	1.377
75-79 Years		0.224	-	0.358	-	1.266
80-84 Years		0.205	-	0.319	-	1.170
85-89 Years		0.183	-	0.285	-	1.078
90-94 Years		0.138	-	0.231	-	0.959
95 Years or Over		0.076	-	0.143	-	0.766
Male						
0-34 Years		-	0.265	-	0.480	1.845
35-44 Years		-	0.388	-	0.607	1.839
45-54 Years		-	0.489	-	0.674	1.697
55-59 Years		-	0.524	-	0.681	1.510
60-64 Years		-	0.499	-	0.628	1.382
65-69 Years		0.261	-	0.371	-	1.333
70-74 Years		0.268	-	0.346	-	1.285
75-79 Years		0.244	-	0.346	-	1.210
80-84 Years		0.186	-	0.307	-	1.159
85-89 Years		0.141	-	0.290	-	1.087
90-94 Years		0.086	-	0.242	-	0.994
95 Years or Over		0.051	-	0.227	-	0.874
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.108	-	0.201	-	0.073
Originally Disabled_Male		-	-	0.136	-	0.073
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	3.067	3.700	3.825	4.172	2.604
RXHCC5	Opportunistic Infections	0.268	0.122	0.177	0.164	0.182
RXHCC15	Chronic Myeloid Leukemia	7.278	7.417	8.231	10.015	4.951
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	3.876	4.091	3.263	3.703	1.102
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.727	1.677	1.618	1.605	0.584
RXHCC18	Lung, Kidney, and Other Cancers	0.287	0.255	0.328	0.319	0.070
RXHCC19	Breast and Other Cancers and Tumors	0.096	0.085	0.079	0.116	0.070
RXHCC30	Diabetes with Complications	0.408	0.448	0.507	0.702	0.476
RXHCC31	Diabetes without Complication	0.270	0.256	0.320	0.394	0.322
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.970	10.502	3.147	10.565	0.476

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
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.099	0.205	0.061	0.231	0.087
RXHCC42	Thyroid Disorders	0.101	0.182	0.100	0.167	0.078
RXHCC43	Morbid Obesity	0.055	-	0.075	0.069	0.174
RXHCC45	Disorders of Lipoid Metabolism	0.037	-	0.069	0.089	0.053
RXHCC54	Chronic Viral Hepatitis C	3.165	3.642	2.954	2.979	0.955
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.534	0.329	0.868	0.539	0.373
RXHCC65	Chronic Pancreatitis	0.253	0.192	0.160	0.206	0.174
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.104	0.192	0.117	0.206	0.119
RXHCC67	Inflammatory Bowel Disease	0.512	0.459	0.463	0.839	0.212
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.078	0.065	0.143	0.171	0.078
RXHCC80	Aseptic Necrosis of Bone	0.179	0.260	0.110	0.146	0.116
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.761	0.737	1.309	2.087	0.665
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.381	0.418	0.489	0.814	0.189
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.217	0.347	0.242	0.357	0.172
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.052	0.157	0.122	0.206	-
RXHCC95	Sickle Cell Anemia	0.090	0.270	0.048	0.797	0.349
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.945	1.121	0.780	0.717	0.549
RXHCC97	Immune Disorders	0.551	0.524	0.493	0.459	0.350
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.090	0.164	0.048	0.222	0.046
RXHCC111	Alzheimer`s Disease	0.468	0.238	0.179	0.035	-
RXHCC112	Dementia, Except Alzheimer`s Disease	0.195	0.107	0.041	-	-
RXHCC130	Schizophrenia	0.280	0.311	0.409	0.708	0.203
RXHCC131	Bipolar Disorders	0.269	0.296	0.287	0.449	0.203
RXHCC132	Major Depression	0.132	0.222	0.145	0.314	0.170
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.132	0.191	0.145	0.314	0.111
RXHCC134	Depression	0.132	0.179	0.139	0.208	0.111
RXHCC135	Anxiety Disorders	0.053	0.118	0.086	0.173	0.111
RXHCC145	Autism	0.132	0.191	0.372	0.378	0.111
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	-	0.191	0.372	0.338	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	-	-	0.243	0.160	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.097	0.033	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.370	0.584	0.392	0.580	0.183
RXHCC157	Spinal Cord Disorders	0.117	0.099	0.095	0.057	0.056
RXHCC159	Inflammatory and Toxic Neuropathy	0.173	0.392	0.171	0.334	0.081
RXHCC160	Multiple Sclerosis	2.297	3.846	2.034	4.112	0.980

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
RXHCC161	Parkinson`s and Huntington`s Diseases	0.501	0.702	0.319	0.440	0.228
RXHCC163	Intractable Epilepsy	0.298	0.546	0.315	1.042	0.094
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.126	0.082	0.049	0.150	-
RXHCC165	Convulsions	0.056	0.029	0.030	0.069	-
RXHCC166	Migraine Headaches	0.143	0.221	0.129	0.142	0.111
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.136	0.304	0.159	0.214	0.198
RXHCC185	Primary Pulmonary Hypertension	0.731	2.179	0.639	1.819	0.259
RXHCC186	Congestive Heart Failure	0.167	0.148	0.227	0.145	0.140
RXHCC187	Hypertension	0.124	0.073	0.191	0.109	0.060
RXHCC188	Coronary Artery Disease	0.123	0.012	0.143	-	0.012
RXHCC193	Atrial Arrhythmias	0.280	0.100	0.142	0.010	0.089
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.043	-	0.040	-	-
RXHCC207	Spastic Hemiplegia	0.190	0.151	0.033	0.162	-
RXHCC215	Venous Thromboembolism	0.148	0.197	0.096	0.108	0.050
RXHCC216	Peripheral Vascular Disease	-	-	0.021	-	-
RXHCC225	Cystic Fibrosis	0.729	5.452	0.368	5.320	1.168
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.325	0.140	0.368	0.260	0.204
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.325	0.140	0.176	0.260	0.041
RXHCC241	Diabetic Retinopathy	0.286	0.211	0.228	0.151	0.160
RXHCC243	Open-Angle Glaucoma	0.277	0.230	0.338	0.274	0.231
RXHCC260	Kidney Transplant Status	0.341	0.158	0.384	0.423	0.189
RXHCC261	Dialysis Status	0.227	0.460	0.490	0.939	0.411
RXHCC262	Chronic Kidney Disease Stage 5	0.092	0.115	0.085	0.043	0.056
RXHCC263	Chronic Kidney Disease Stage 4	0.092	0.115	0.085	0.043	0.056
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.161	0.171	0.103	0.100	0.056
RXHCC314	Pemphigus	0.365	0.662	0.197	0.124	0.049
RXHCC316	Psoriasis, Except with Arthropathy	0.206	0.249	0.413	0.728	0.282
RXHCC355	Narcolepsy and Cataplexy	0.829	1.358	0.656	1.365	0.253
RXHCC395	Lung Transplant Status	1.427	0.829	0.996	0.871	0.878
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.064	0.829	0.996	0.871	0.189
RXHCC397	Pancreas Transplant Status	0.002	0.158	0.384	0.235	0.189
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	0.916
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.278
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.277
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.184
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.226
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.113
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.192
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.341

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
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.250

NOTE: The Part D Denominator used to calculate relative factors is $1,036.61. 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-10. RxHCC Model (2014/2015) 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	0.701	1.020	-	-
35-44 Years	1.212	1.232	-	-
45-54 Years	1.312	1.560	-	-
55-59 Years	1.253	1.715	-	-
60-64 Years	1.240	1.914	-	-
65 Years	0.528	1.923	1.136	1.923
66 Years	0.577	1.923	1.161	1.923
67 Years	0.590	1.923	1.161	1.923
68 Years	0.608	1.923	1.161	1.923
69 Years	0.633	1.923	1.161	1.923
70-74 Years	0.661	1.923	1.048	1.923
75-79 Years	0.680	1.923	0.810	1.923
80-84 Years	0.615	1.923	0.615	1.923
85-89 Years	0.607	1.923	0.607	1.923
90-94 Years	0.354	1.923	0.354	1.923
95 Years or Over	0.354	1.923	0.354	1.923
Male				
0-34 Years	0.465	0.819	-	-
35-44 Years	0.850	1.247	-	-
45-54 Years	1.145	1.560	-	-
55-59 Years	1.216	1.782	-	-
60-64 Years	1.185	2.087	-	-
65 Years	0.587	1.936	1.019	1.936
66 Years	0.632	1.936	1.014	1.936
67 Years	0.648	1.936	1.014	1.936
68 Years	0.677	1.936	1.014	1.936
69 Years	0.698	1.936	1.014	1.936
70-74 Years	0.741	1.936	0.942	1.936
75-79 Years	0.768	1.936	0.768	1.936
80-84 Years	0.696	1.936	0.696	1.936
85-89 Years	0.653	1.936	0.653	1.936
90-94 Years	0.307	1.936	0.307	1.936
95 Years or Over	0.307	1.936	0.307	1.936

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,036.61. 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-11. RxHCC Model (2014/2015) 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	1.036	2.174	-	-
35-44 Years	1.548	2.223	-	-
45-54 Years	1.601	2.310	-	-
55-59 Years	1.482	2.428	-	-
60-64 Years	1.391	2.259	-	-
65 Years	0.911	2.210	1.263	2.210
66 Years	0.623	2.210	0.846	2.210
67 Years	0.594	2.210	0.846	2.210
68 Years	0.607	2.210	0.846	2.210
69 Years	0.607	2.210	0.846	2.210
70-74 Years	0.607	2.210	0.796	2.210
75-79 Years	0.671	2.210	0.671	2.210
80-84 Years	0.671	2.210	0.671	2.210
85-89 Years	0.671	2.210	0.671	2.210
90-94 Years	0.570	2.210	0.570	2.210
95 Years or Over	0.570	2.210	0.570	2.210
Male				
0-34 Years	0.892	2.273	-	-
35-44 Years	1.278	2.277	-	-
45-54 Years	1.478	2.357	-	-
55-59 Years	1.391	2.213	-	-
60-64 Years	1.303	2.165	-	-
65 Years	0.906	2.056	1.157	2.056
66 Years	0.585	2.056	0.750	2.056
67 Years	0.560	2.056	0.750	2.056
68 Years	0.506	2.056	0.750	2.056
69 Years	0.526	2.056	0.750	2.056
70-74 Years	0.533	2.056	0.598	2.056
75-79 Years	0.552	2.056	0.552	2.056
80-84 Years	0.552	2.056	0.552	2.056
85-89 Years	0.552	2.056	0.552	2.056
90-94 Years	0.416	2.056	0.416	2.056
95 Years or Over	0.416	2.056	0.416	2.056

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,036.61. 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-12. RxHCC Model (2014/2015) Relative Factors for New Enrollees, Institutional

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.812	2.825
35-44 Years	2.812	2.825
45-54 Years	2.500	2.825
55-59 Years	2.500	2.825
60-64 Years	2.140	2.825
65 Years	2.228	2.825
66 Years	1.952	2.825
67 Years	1.952	2.825
68 Years	1.952	2.825
69 Years	1.952	2.825
70-74 Years	1.819	2.825
75-79 Years	1.586	2.825
80-84 Years	1.443	2.825
85-89 Years	1.383	2.825
90-94 Years	1.101	2.825
95 Years or Over	1.101	2.825
Male		
0-34 Years	2.446	2.842
35-44 Years	2.632	2.842
45-54 Years	2.400	2.842
55-59 Years	2.189	2.842
60-64 Years	2.134	2.842
65 Years	2.086	2.842
66 Years	1.814	2.842
67 Years	1.814	2.842
68 Years	1.814	2.842
69 Years	1.814	2.842
70-74 Years	1.715	2.842
75-79 Years	1.721	2.842
80-84 Years	1.524	2.842
85-89 Years	1.359	2.842
90-94 Years	1.359	2.842
95 Years or Over	1.359	2.842

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,036.61. 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-13. List of Disease Hierarchies for RxHCC Model (2014/2015)

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-14. RxHCC Model (2015/2016) Relative Factors for Continuing Enrollees

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		-	0.302	-	0.459	2.099
35-44 Years		-	0.409	-	0.650	2.268
45-54 Years		-	0.517	-	0.737	1.803
55-59 Years		-	0.481	-	0.692	1.617
60-64 Years		-	0.436	-	0.619	1.486
65-69 Years		0.208	-	0.382	-	1.499
70-74 Years		0.218	-	0.356	-	1.349
75-79 Years		0.204	-	0.346	-	1.236
80-84 Years		0.181	-	0.302	-	1.129
85-89 Years		0.157	-	0.256	-	1.021
90-94 Years		0.105	-	0.192	-	0.883
95 Years or Over		0.043	-	0.095	-	0.690
Male						
0-34 Years		-	0.264	-	0.493	2.036
35-44 Years		-	0.363	-	0.626	1.968
45-54 Years		-	0.439	-	0.668	1.796
55-59 Years		-	0.463	-	0.655	1.563
60-64 Years		-	0.430	-	0.592	1.416
65-69 Years		0.228	-	0.353	-	1.345
70-74 Years		0.240	-	0.331	-	1.245
75-79 Years		0.222	-	0.329	-	1.177
80-84 Years		0.157	-	0.292	-	1.102
85-89 Years		0.099	-	0.263	-	1.019
90-94 Years		0.039	-	0.212	-	0.899
95 Years or Over		-	-	0.166	-	0.771
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.095	-	0.209	-	0.091
Originally Disabled_Male		-	-	0.149	-	0.091
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	3.102	3.711	4.037	4.406	2.574
RXHCC5	Opportunistic Infections	0.245	0.266	0.220	0.193	0.169
RXHCC15	Chronic Myeloid Leukemia	7.462	7.790	8.361	10.406	4.928
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	4.573	5.281	3.916	4.375	1.404
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	2.000	1.629	2.011	1.856	0.784
RXHCC18	Lung, Kidney, and Other Cancers	0.312	0.370	0.366	0.398	0.069
RXHCC19	Breast and Other Cancers and Tumors	0.104	0.089	0.092	0.153	0.069

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
RXHCC30	Diabetes with Complications	0.455	0.506	0.597	0.803	0.543
RXHCC31	Diabetes without Complication	0.248	0.211	0.315	0.361	0.319
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.856	11.640	3.959	11.320	0.439
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.097	0.196	0.040	0.265	0.101
RXHCC42	Thyroid Disorders	0.098	0.176	0.105	0.174	0.086
RXHCC43	Morbid Obesity	0.050	-	0.084	0.083	0.187
RXHCC45	Disorders of Lipoid Metabolism	0.031	-	0.070	0.088	0.059
RXHCC54	Chronic Viral Hepatitis C	1.530	1.754	1.798	1.771	1.049
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.537	0.582	0.895	0.706	0.516
RXHCC65	Chronic Pancreatitis	0.263	0.284	0.207	0.239	0.210
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.108	0.284	0.147	0.239	0.146
RXHCC67	Inflammatory Bowel Disease	0.521	0.462	0.513	0.938	0.229
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.065	0.054	0.139	0.156	0.090
RXHCC80	Aseptic Necrosis of Bone	0.194	0.168	0.139	0.194	0.134
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.749	0.707	1.628	2.562	0.933
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.336	0.360	0.589	0.975	0.231
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.204	0.313	0.275	0.378	0.153
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.046	0.160	0.131	0.231	-
RXHCC95	Sickle Cell Anemia	0.114	0.354	0.099	0.872	0.455
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	1.092	1.272	0.907	0.859	0.502
RXHCC97	Immune Disorders	0.611	0.571	0.500	0.447	0.487
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.114	0.174	0.099	0.193	0.023
RXHCC111	Alzheimer`s Disease	0.355	0.187	0.127	0.013	-
RXHCC112	Dementia, Except Alzheimer`s Disease	0.129	0.097	0.008	-	-
RXHCC130	Schizophrenia	0.264	0.311	0.396	0.723	0.178
RXHCC131	Bipolar Disorders	0.252	0.241	0.269	0.431	0.178
RXHCC132	Major Depression	0.121	0.180	0.134	0.275	0.152
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.121	0.158	0.134	0.275	0.087
RXHCC134	Depression	0.121	0.130	0.134	0.180	0.087
RXHCC135	Anxiety Disorders	0.051	0.085	0.087	0.169	0.056
RXHCC145	Autism	0.121	0.158	0.396	0.335	0.087
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	0.121	0.158	0.396	0.335	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	0.121	-	0.250	0.138	-

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
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	0.121	-	0.080	-	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.403	0.699	0.436	0.644	0.215
RXHCC157	Spinal Cord Disorders	0.147	0.125	0.065	0.059	0.055
RXHCC159	Inflammatory and Toxic Neuropathy	0.134	0.294	0.124	0.313	0.059
RXHCC160	Multiple Sclerosis	2.373	3.793	2.256	4.408	1.047
RXHCC161	Parkinson`s and Huntington`s Diseases	0.507	0.793	0.349	0.490	0.255
RXHCC163	Intractable Epilepsy	0.323	0.513	0.373	1.226	0.110
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.127	0.096	0.055	0.179	-
RXHCC165	Convulsions	0.052	0.060	0.046	0.073	-
RXHCC166	Migraine Headaches	0.127	0.194	0.126	0.135	0.087
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.138	0.302	0.192	0.259	0.229
RXHCC185	Primary Pulmonary Hypertension	0.861	2.658	0.751	2.173	0.286
RXHCC186	Congestive Heart Failure	0.165	0.157	0.227	0.148	0.158
RXHCC187	Hypertension	0.115	0.068	0.178	0.107	0.063
RXHCC188	Coronary Artery Disease	0.123	0.008	0.157	0.001	0.005
RXHCC193	Atrial Arrhythmias	0.348	0.122	0.198	0.062	0.130
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.043	-	0.046	-	-
RXHCC207	Spastic Hemiplegia	0.201	0.139	0.043	0.165	-
RXHCC215	Venous Thromboembolism	0.195	0.222	0.127	0.203	0.095
RXHCC216	Peripheral Vascular Disease	-	-	0.015	-	-
RXHCC225	Cystic Fibrosis	0.908	6.442	0.592	7.265	1.069
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.346	0.170	0.405	0.288	0.238
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.346	0.170	0.192	0.288	0.115
RXHCC241	Diabetic Retinopathy	0.298	0.187	0.263	0.196	0.170
RXHCC243	Open-Angle Glaucoma	0.289	0.211	0.363	0.308	0.265
RXHCC260	Kidney Transplant Status	0.284	0.211	0.453	0.447	0.322
RXHCC261	Dialysis Status	0.308	0.709	0.669	1.222	0.520
RXHCC262	Chronic Kidney Disease Stage 5	0.085	0.153	0.091	0.041	0.090
RXHCC263	Chronic Kidney Disease Stage 4	0.085	0.153	0.091	0.041	0.090
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.159	0.172	0.105	0.113	0.057
RXHCC314	Pemphigus	0.399	0.905	0.311	0.228	0.097
RXHCC316	Psoriasis, Except with Arthropathy	0.161	0.119	0.469	0.850	0.302
RXHCC355	Narcolepsy and Cataplexy	0.789	1.365	0.729	1.418	0.263
RXHCC395	Lung Transplant Status	1.309	0.211	0.686	0.447	0.322
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.003	0.211	0.686	0.447	0.322

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
RXHCC397	Pancreas Transplant Status	0.284	0.211	0.453	0.447	0.322
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	1.183
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.241
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.219
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.144
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.137
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.091
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	-
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.436
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.330

NOTE: The Part D Denominator used to calculate relative factors is $1,045.24. This Part D Denominator is based on the combined PDP and MA-PD populations.

SOURCE: RTI Analysis of 100% 2016 PDE, 2015 Carrier NCH, 2015 Inpatient SAF, 2015 Outpatient SAF, 2016 HPMS, 2016 CME, 2015-2016 Denominator, Part D Intermediate File, and 2015 Medicare Advantage Diagnoses File.

Table V-15. RxHCC Model (2015/2016) 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	0.679	1.048	-	-
35-44 Years	1.112	1.389	-	-
45-54 Years	1.268	1.710	-	-
55-59 Years	1.220	1.935	-	-
60-64 Years	1.220	2.209	-	-
65 Years	0.504	1.966	1.114	1.966
66 Years	0.504	1.966	1.104	1.966
67 Years	0.572	1.966	1.104	1.966
68 Years	0.600	1.966	1.104	1.966
69 Years	0.600	1.966	1.104	1.966
70-74 Years	0.645	1.966	1.055	1.966
75-79 Years	0.661	1.966	0.705	1.966
80-84 Years	0.607	1.966	0.607	1.966
85-89 Years	0.579	1.966	0.579	1.966
90-94 Years	0.400	1.966	0.400	1.966
95 Years or Over	0.400	1.966	0.400	1.966
Male				
0-34 Years	0.472	1.138	-	-
35-44 Years	0.859	1.300	-	-
45-54 Years	1.131	1.759	-	-
55-59 Years	1.140	2.014	-	-
60-64 Years	1.149	2.143	-	-
65 Years	0.565	2.021	1.014	2.021
66 Years	0.611	2.021	0.981	2.021
67 Years	0.627	2.021	0.981	2.021
68 Years	0.643	2.021	0.981	2.021
69 Years	0.680	2.021	0.981	2.021
70-74 Years	0.731	2.021	0.917	2.021
75-79 Years	0.779	2.021	0.779	2.021
80-84 Years	0.760	2.021	0.760	2.021
85-89 Years	0.604	2.021	0.604	2.021
90-94 Years	0.421	2.021	0.421	2.021
95 Years or Over	0.421	2.021	0.421	2.021

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,045.24. 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% 2016 PDE, 2015 Carrier NCH, 2015 Inpatient SAF, 2015 Outpatient SAF, 2016 HPMS, 2016 CME, 2015-2016 Denominator, Part D Intermediate File, and 2015 Medicare Advantage Diagnoses File.

Table V-16. RxHCC Model (2015/2016) 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	1.068	2.296	-	-
35-44 Years	1.623	2.524	-	-
45-54 Years	1.706	2.500	-	-
55-59 Years	1.551	2.682	-	-
60-64 Years	1.446	2.574	-	-
65 Years	0.954	2.400	1.266	2.400
66 Years	0.653	2.400	1.001	2.400
67 Years	0.653	2.400	1.001	2.400
68 Years	0.653	2.400	1.001	2.400
69 Years	0.653	2.400	1.001	2.400
70-74 Years	0.653	2.400	0.802	2.400
75-79 Years	0.703	2.400	0.703	2.400
80-84 Years	0.703	2.400	0.703	2.400
85-89 Years	0.703	2.400	0.703	2.400
90-94 Years	0.500	2.400	0.500	2.400
95 Years or Over	0.500	2.400	0.500	2.400
Male				
0-34 Years	0.930	2.662	-	-
35-44 Years	1.346	2.562	-	-
45-54 Years	1.527	2.577	-	-
55-59 Years	1.401	2.538	-	-
60-64 Years	1.309	2.502	-	-
65 Years	0.932	2.392	1.132	2.392
66 Years	0.594	2.392	0.709	2.392
67 Years	0.556	2.392	0.709	2.392
68 Years	0.556	2.392	0.709	2.392
69 Years	0.556	2.392	0.709	2.392
70-74 Years	0.556	2.392	0.580	2.392
75-79 Years	0.566	2.392	0.566	2.392
80-84 Years	0.566	2.392	0.566	2.392
85-89 Years	0.566	2.392	0.566	2.392
90-94 Years	0.395	2.392	0.395	2.392
95 Years or Over	0.395	2.392	0.395	2.392

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,045.24. 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% 2016 PDE, 2015 Carrier NCH, 2015 Inpatient SAF, 2015 Outpatient SAF, 2016 HPMS, 2016 CME, 2015-2016 Denominator, Part D Intermediate File, and 2015 Medicare Advantage Diagnoses File.

Table V-17. RxHCC Model (2015/2016) Relative Factors for New Enrollees, Institutional

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.986	3.155
35-44 Years	2.986	3.155
45-54 Years	2.596	3.155
55-59 Years	2.596	3.155
60-64 Years	2.217	3.155
65 Years	2.384	3.155
66 Years	2.113	3.155
67 Years	2.113	3.155
68 Years	2.113	3.155
69 Years	2.113	3.155
70-74 Years	1.851	3.155
75-79 Years	1.658	3.155
80-84 Years	1.394	3.155
85-89 Years	1.411	3.155
90-94 Years	1.008	3.155
95 Years or Over	1.008	3.155
Male		
0-34 Years	2.536	3.226
35-44 Years	2.677	3.226
45-54 Years	2.473	3.226
55-59 Years	2.332	3.226
60-64 Years	2.084	3.226
65 Years	2.253	3.226
66 Years	1.882	3.226
67 Years	1.882	3.226
68 Years	1.882	3.226
69 Years	1.882	3.226
70-74 Years	1.725	3.226
75-79 Years	1.635	3.226
80-84 Years	1.513	3.226
85-89 Years	1.328	3.226
90-94 Years	1.328	3.226
95 Years or Over	1.328	3.226

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,045.24. 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% 2016 PDE, 2015 Carrier NCH, 2015 Inpatient SAF, 2015 Outpatient SAF, 2016 HPMS, 2016 CME, 2015-2016 Denominator, Part D Intermediate File, and 2015 Medicare Advantage Diagnoses File.

Table V-18. List of Disease Hierarchies for RxHCC Model (2015/2016)

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.

Attachment VI. Draft CY 2020 Call Letter

Draft CY 2020 Call Letter
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How to Use This Call Letter

The draft CY 2020 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 2020 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 plan flexibilities so that patients have a range of health plan options and are empowered to choose the option that best meets their individual health care needs. 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: Cali Diehl at Cali.Diehl@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) plans, Medicare Advantage-Prescription Drug (MA-PD) plans, Prescription Drug Plans (PDPs), Medicare-Medicaid Plans (MMPs), 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.

2020*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 – March 31, 2019	Annual Medicare Advantage Open Enrollment Period.	✓			
January 9, 2019	Contract Year (CY) 2020 Initial and Service Area Expansion Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion Applications are released.	✓	✓	✓	✓
January 9, 2019	Model of Care (MOC) renewal submission period begins for D-SNPs and I-SNPs with Model of Care (MOC) approvals ending 12/31/2019.	✓			
January 2019	Industry training for CY 2020 MOC submissions.	✓			
January 10, 2019	Annual MOC submission period begins for C-SNPs	✓			
January 2019	Industry training on CY 2020 Applications.	✓	✓	✓	✓
February 13, 2019	CY 2020 Initial and Service Area Expansion Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion Applications are due in the Health Plan Management System (HPMS) by 8pm EST.	✓	✓	✓	✓
February 13, 2019	MOC renewal submissions for D-SNPs and I-SNPs with MOC approvals ending 12/31/2019 due in HPMS by 8pm EST.	✓			
February 13, 2019	Annual MOC submissions for C-SNPs due in HPMS by 8pm EST.	✓			
Late February, 2019	Submission of meaningful use HITECH attestation for qualifying MA EGWP and MA-affiliated hospitals.	✓			
February, 2019	CMS releases instructional memo concerning updates to Parent Organization designations in HPMS.	✓	✓	✓	✓
March 16, 2019	Parent Organization designation updates from MAOs and sponsors due to CMS (instructional memo released in February 2019).	✓	✓	✓	✓
Mid-Late March, 2019	Release of CY 2020 Formulary Reference File (FRF).	✓	✓	✓	✓
March 30, 2019	Release of the Fiscal Soundness Module in HPMS.	✓	✓	✓	✓
March/April, 2019	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2020.	✓	✓	✓	

2020*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, 2019	CY 2020 Out-Of-Pocket Cost (OOPC) model and OOPC estimates available for download to MAOs, 1876 cost plans submitting MA conversion bids, and Part D sponsors to assist in meeting meaningful difference (if applicable) and Total Beneficiary Cost (TBC) requirements prior to bid submission.	✓	✓	✓	
Early April, 2019	Release of guidance regarding CY 2020 renewal options, including crosswalks.	✓	✓		
April 1, 2019	Release of the 2020 Final Rate Announcement of MA Capitation Rates and MA and Part D Payment Policies, including the CY 2020 Call Letter.	✓	✓	✓	✓
April 2019	Conference call with industry on the CY 2020 Rate Announcement and Call Letter.	✓	✓	✓	✓
April 5, 2019	Release of the CY 2020 Plan Creation Module, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓	✓
April 10, 2019	Deadline for MAOs and cost plans to submit full contract consolidation requests for CY 2020.	✓		✓	
Mid-April, 2019	Release of CY 2020 MA Bid Review and Operational Guidance.	✓		✓	
April 22, 2019	Release of the CY 2020 Medication Therapy Management (MTM) Program Submission in HPMS (11:59 p.m. PDT).		✓		✓
April 17, 2019	Industry training on CY 2020 Part D Formulary and Benefit Submission/Compliance Training.	✓	✓	✓	✓
Late April, 2019	Release of CY 2020 TBC data.	✓			
May 6, 2019	Deadline for submission of CY 2020 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, 2019	Release of final CY 2020 ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for all organizations.	✓	✓	✓	
Early May 2019	Deadline for MA, MA-PD and PDP plans to notify CMS of their intention to non-renew a county (ies) or region(s) for individuals, but continue the county (ies) or region(s) for "800 series" EGWP members, to convert to offering employer-only contracts, or to reduce service areas at the contract level.	✓	✓	✓	
May, 2019	Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast.	✓	✓	✓	✓
May 4, 2019	Release of the CY 2020 Bid Upload Functionality in HPMS.	✓	✓	✓	✓
May 20, 2019	Deadline for submission of CY 2020 MTM Program attestations in HPMS (11:59 pm PDT).		✓		✓
May-July, 2019	Release of final state-specific MMP CY 2020 models: ANOC/EOC (Member Handbook), Summary of Benefits, Formulary, Provider and Pharmacy Directory, Member ID Card, and other MMP-specific models.				✓
May 14, 2019	Release of CY 2020 Formulary Submission Module in HPMS.	✓	✓	✓	✓
May 17, 2019	Release of CY2020 Actuarial Certification Module in HPMS.	✓	✓	✓	
Mid-Late May, 2019	Release of CY 2020 Formulary Reference File Update.	✓	✓	✓	✓

2020*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 25, 2019	Submission period begins for Plans/Part D sponsors to upload agent/broker compensation information in HPMS.	✓	✓	✓	✓
Late May, 2019	Qualification determinations provided to CY 2020 applicants for new contracts or service area expansions.	✓	✓	✓	✓
May 31, 2019	Release of the 2018 DIR Submission Module in HPMS.	✓	✓	✓	✓
June 1, 2019	Submission period begins Release of the CY 2020 Marketing Module in HPMS for Plans/Part D sponsors begin to submit upload 2020 marketing materials in CY 2020 Marketing Module.	✓	✓	✓	✓
June 3, 2019	Deadline for submission of CY 2020 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 2020 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2020 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 2020 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 2020.	✓	✓	✓	✓ *Non-bid related items only*
Early June to Late August, 2019	Completion of CMS's CY 2020 bid review and approval, to include pricing, plan benefit packages, and formularies. Deadline for Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications.	✓	✓	✓	✓
June, 2019	CMS conducts Network Adequacy Reviews	✓		✓	
June, 2019	Initial submission period begins for Plans/Part D sponsors to request crosswalk exceptions.	✓	✓	✓	
June 7, 2019	Deadline for submission of CY 2020 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).		✓		✓
June 7, 2019	Deadline for submission of Value-Based Insurance Design (VBID) file (Only applicable to MA plans that have been preapproved for Part D VBID benefits) (11:59 p.m. EDT).	✓			
June 7, 2019	Deadline for submission of Additional Demonstration Drug (ADD) file (MMPs only) (11:59 p.m. EDT).				✓
Mid to late June, 2019	Release of the CY 2020 Medicare Communications and Marketing Guidelines in HPMS.	✓	✓	✓	✓
Late June, 2019	Acknowledgement letter sent to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓	✓
July-August, 2019	Release of state-specific marketing guidance for MMPs.				✓

2020*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 July, 2019	Submission period for 2020 Medicare Plan Finder pricing tests.	✓	✓	✓	✓
Early July, 2019	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS.	✓			
Early July, 2019	Deadline for D-SNPs to submit their Fully Integrated Dual-Eligible (FIDE) SNP Matrix for review and qualification.	✓			
July 5, 2019	Deadline for plans to submit non-model Low Income Subsidy (LIS) riders for review.	✓			
Mid July, 2019	Release of CY 2020 FRF Update in advance of the Limited Formulary Update Window.	✓	✓	✓	✓
Mid-Late July, 2019	CY 2020 Limited Formulary Update Window.	✓	✓	✓	✓
Late July, 2019	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓	✓
July 2019	Second submission period begins for Plans/Part D sponsors to request crosswalk exceptions.	✓	✓	✓	
Late July, 2019	Release of the CY 2020 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, 2019	Rebate reallocation period begins after release of bid amounts.	✓	✓	✓	
No Later Than July 29, 2019	Deadline for informing currently contracted organizations of CMS's decision to not renew a contract for 2020.	✓	✓	✓	
August 1, 2019	Deadline to submit model LIS riders in HPMS.	✓	✓	✓	
August 17, 2019	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 16-20, 2019	Window for organizations to review 2020 Medicare & You Handbook data prior to printing (not applicable to EGWPs).	✓	✓	✓	✓
August 22-24, 2019	First CY 2020 Medicare Plan Finder (MPF) Preview and OOPC Preview in HPMS.	✓	✓	✓	✓ *MPF only*
August 31, 2019	CY 2020 MTM Program Annual Review completed.		✓		✓
Late August, 2019	Contracting Materials submitted to CMS.	✓	✓	✓	
Late August / Early September 2019	Deadline after which organizations with pending administrative appeals of Initial or Service Area Expansion applications may be suppressed from Medicare & You Handbook and Medicare Plan Finder.	✓	✓	✓	
End of August/Early September, 2019	Plan preview periods of Part C & D Star Ratings in HPMS.	✓	✓	✓	
Early September, 2019	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
Mid- September, 2019	All CY 2020 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓	

2020*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**
September 4-7, 2019	Second CY 2020 MPF Preview and OOPC Preview in HPMS.	✓	✓	✓	✓ *MPF only*
September 16 - 30, 2019	CMS mails the 2020 Medicare & You handbook to beneficiaries.	✓	✓	✓	✓
Late September, 2019	CMS notifies D-SNPs that requested review for FIDE SNP determination whether they meet required qualifications.	✓			
Late September, 2019	Deadline for Part D sponsors, cost-based plans, and MA and MA-PD organizations to request a plan correction to the PBP via HPMS.	✓	✓	✓	
September 30, 2019	Deadline for organization's to provide the following documents to current enrollees: • Standardized Annual Notice of Change (ANOC) for all MA, MA-PD, MMP, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • LIS rider	✓	✓	✓	✓
October 1, 2019	Date organizations may begin marketing their CY 2020 plans. Organizations may market both CY 2019 and CY 2020 simultaneously, but must clearly indicate which plan year is being discussed.	✓	✓	✓	✓
October 1, 2019	Tentative date by which plan and drug benefit data for CY 2020 is displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓	✓
October 2, 2019	Date by which 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 enrollees of non-renewing plans until after October 2, 2019.	✓	✓	✓	✓
October 9, 2019	Part C & D Star Ratings go live on medicare.gov **on or around** October 9, 2019.	✓	✓	✓	
October 15, 2019	Deadline for organizations to provide the following documents (or notification, if permitted) to current enrollees: • Evidence of Coverage (EOC) for all MA, MA-PD, MMP, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • Abridged or comprehensive formularies • Provider/Pharmacy directories	✓	✓	✓	✓
October 15, 2019	Part D sponsors must post prior authorization and step therapy criteria on their websites for CY 2020.		✓		✓
October 15, 2019	CY 2020 Annual Election Period begins. All MA organizations/PDP sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓		✓

2020*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**
Mid October, 2019	Release of the online CY 2021 Notice of Intent to Apply (NOIA) for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs).	✓	✓	✓	✓
November 12, 2019	Deadline for submission of NOIA for CY 2021 MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November, 2019	First display of Medicare Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval.	✓	✓	✓	✓
Late November, 2019	Part C & D display measures data are posted in HPMS for plan preview.	✓	✓	✓	
December 1, 2019	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	
December 7, 2019	CY 2020 Annual Election Period ends.	✓	✓		✓
Mid December, 2019	Part C & D display measures data on cms.gov updated.	✓	✓	✓	
December 31, 2019	Deadline for submitting Annual Chronic Care Improvement Program (CCIP) attestations in HPMS, as per §422.152 of Title 42 of the CFR.	✓			✓
2020					
January 1, 2020	Plan Benefit Period Begins.	✓	✓	✓	✓
January 1 – March 31, 2020	Annual Medicare Advantage Open Enrollment Period.	✓			
January 2020	Release of CY 2021 MAO/MA-PD/MMP/PDP/EGWP applications.	✓	✓		✓
January, 2020	Industry training on CY 2021 applications.	✓	✓	✓	✓
February 2020	CY 2021 Initial and Service Area Expansion Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion Applications are due.	✓	✓	✓	✓
June 1, 2020	CY 2021 Deadline for bid and formulary submission.	✓	✓	✓	✓ *Non-bid related items only*

Enhancements to the 2020 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. The Star Ratings support CMS's efforts to make the patient the focus in all of our programs. As part of this effort, it is key to empower patients to work with their health care providers to make health care decisions that are best for them. An important component of this effort is to provide Medicare beneficiaries and their family and caregivers with meaningful information about quality and costs to empower them to be that they can be active health care consumers engaged in care. Furthermore, it is critical that the information we provide to Medicare beneficiaries is complete, accurate, and reliable.

CMS regularly reviews the measures and 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 such as dually eligible beneficiaries and disabled. 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. A Technical Expert Panel (TEP), comprised of representatives across various stakeholder groups, convened on May 31, 2018 to provide feedback to CMS's Star Ratings contractor (currently RAND Corporation) on the Star Ratings framework, topic areas, methodology, and operational measures. Additional information about the TEP can be found at https://www.rand.org/health-care/projects/star-ratings-analyses.html.

In this draft Call Letter, we are proposing enhancements to the 2020 Star Ratings, as well as soliciting feedback on possible future measure updates and concepts. We have solicited comments on ways to improve the current methodology, but we strongly believe that although there are ways to enhance the current methodology, it is an accurate representation of industry performance. Except as noted below, the methodology and measures used to calculate the 2020 Star Ratings would remain the same as for the 2019 Star Ratings. For reference, the list of measures and a description of the methodology for the 2019 Star Ratings are included in the Technical Notes available on the CMS webpage: http://go.cms.gov/partcanddstarratings.

As part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program, CMS codified the methodology for the Part C and D Star Ratings program 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 Final Rule (hereafter referred to as CMS-4182-F), published in April 2018. Historically, the Part C and D Star Ratings methodology was adopted and updated through the Part C and D Call Letter, with additional

guidance issued in annual Technical Notes. Starting with the 2021 Star Ratings, any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes will be proposed and finalized through rulemaking. On November 1, 2018 CMS published in the Federal Register the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (83 FR 55021) ("CY2020 Proposed Rule") soliciting feedback on changes for the 2022 Star Ratings.

Reminders for 2020 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 2020 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 2018 IRE data must be made by June 30, 2019 for the 2020 Star Ratings). Please note reopenings are not taken into account under this deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measures, if a reopening occurs and is decided prior to May 1st, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1st, the original reconsidered determination is used. Plans should be aware that when underlying measure data are not reviewed timely and concerns are brought to CMS late in the process, operational constraints limit our ability to review and potentially adjust Star Ratings prior to the public release in early October. Any concerns with underlying measure data brought to our attention after the first plan preview will be reviewed, however any adjustments needed to a contract's Star Ratings may be made after the initial public release.

Similarly, for complaints data, any adjustments must be made in the Complaints Tracking Module (CTM) per the CTM Standard Operating Procedure (SOP) 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 2018 complaint data must be made by June 30, 2019 for the 2020 Star Ratings).

Measure Updates for 2020 Star Ratings

Medication Adherence (ADH) for Cholesterol (Statins) (Part D). The Pharmacy Quality Alliance (PQA) updated this measure for the 2018 measurement year to exclude beneficiaries with end-stage renal disease (ESRD). In the final CY 2019 Call Letter, we adopted our proposal to apply this exclusion to the 2020 Star Ratings (which are calculated 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 Diabetes 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 rule in order to accurately account for all CMRs received. We adopted this change in the final CY 2019 Call Letter to apply for the 2020 Star Ratings.

For beneficiaries who were enrolled in the contract's MTM program for less than 60 days at any time in the measurement year:

- Continue to exclude them from the measure calculation if they did not receive a CMR within this timeframe.
- (New) Include them in the denominator and the numerator if they received a CMR within this timeframe.

For example, a beneficiary was enrolled in the MTM program on November 2 of the measurement year through December 31 (less than 60 days of MTM program enrollment).

- If no CMR received by December 31, exclude from measure calculation.
- If CMR received by December 31, include in the denominator and the numerator.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D). In line with PQA measure updates for the 2018 measurement year, we propose to exclude beneficiaries who elected to receive hospice care at any time in the measurement period and apply this change to the 2020 Star Ratings (instead of applying a Proportion of Days (PDC) adjustment for hospice enrollment as is currently done). This change narrows the population covered by the measure with no other changes.

Statin Use in Persons with Diabetes (SUPD) (Part D). In the CY 2019 Call Letter, the SUPD measure was added to the 2019 Star Ratings with a weight of 1 as a first year measure.

Therefore, for the 2020 Star Ratings (based on 2018 data) and subsequent years, we propose a weight of 3 as is standard practice for an intermediate outcome measure.

Improvement measures (Part C & D). The measures proposed to be used to calculate the 2020 improvement measures are:

Table 1: 2020 Star Ratings Improvement Measures

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	Rheumatoid Arthritis Management	Process Measure	1	Yes
C	Reducing the Risk of Falling	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	Yes
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	3	Yes

*Starting with the 2021 Star Ratings, Patients' Experience and Complaints and Access measures will receive a weight of 2.

Temporary Removal of Measure from the 2020 Star Ratings

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, the National Committee for Quality Assurance (NCQA) is implementing updates to the Controlling High Blood Pressure measure for HEDIS 2019. NCQA has revised the blood pressure target to <140/90 mmHg. NCQA has also made some structural changes to the measure that include allowing two outpatient encounters to identify the denominator and removing the medical record confirmation for hypertension, allowing the use of telehealth services for one of the outpatient encounters in the denominator, adding an administrative approach that utilizes CPT category II codes for the numerator, and allowing remote monitoring device readings for the numerator. Given the change to the blood pressure target and our established methodology for moving measures with substantive changes to the display page (42 CFR 422.164(e)(1)(i)), we will move this measure to the display page for the 2020 and 2021 Star Ratings. We have proposed to move this back into the 2022 Star Ratings in the CY2020 Proposed Rule (83 FR 55021).

2020 Star Ratings Program and the Categorical Adjustment Index

The Categorical Adjustment Index (CAI) was first implemented in the 2017 Star Ratings Program 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.

The values and abridged details of the methodology are provided in the annual Medicare Part C & D Star Ratings 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 covered under the 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.[23] NQF has launched 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 adjustment for SES and other demographic factors (known as "risk adjustment" in this context) should be revised.

We have contracted with NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether any modifications to the specification would be appropriate.

The PQA examined their medication adherence measures, which are currently used in the Star Ratings Program, for potential risk adjustment (i.e., adjustment for SES and demographic factors)[24]. Beginning in 2018, the PQA included in the 2018 PQA Measure Manual 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.

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[23] NQF's Final Report can be assessed using the following link: http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx.

[24] The PQA summary can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars.

The PQA indicated that the risk-adjusted adherence measures will be submitted through the NQF consensus development process for maintenance of the measures (NQF Endorsed #0541). If endorsed by NQF, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures (for 2021 measurement year or beyond).

In the meantime, CMS plans to test the inclusion of stratifications by age, gender, dual eligibility/LIS status, and disability status in the Medication Adherence Patient Safety Reports to Part D sponsors beginning with the 2019 measurement year.

NCQA's 2019 HEDIS Volume 2 includes the revised specifications of four measures used in the MA Star Ratings. The revised specifications for Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions[25] are applicable to MA contracts to meet the MA program's reporting requirements. 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.[26] 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.

Based on stakeholders' feedback on previous Call Letters and the Contract Year 2019 Final Rule (CMS-4182-F) published in April 2018 (83 FR 16440), CMS is proposing to expand the adjusted measure set for the determination of the 2020 CAI values. The proposed methodology for the 2020 Star Ratings is the same methodology that has been finalized for the 2021 Star Ratings in the Contract Year 2019 Final Rule. *See* 42 CFR §§ 422.166(f)(2) and 423.186(f)(2). For the 2020 CAI adjusted measure set, CMS is proposing that all measures identified as candidate measures will be included in the determination of the 2020 CAI values. A measure will be included as a candidate measure if it remains after applying the following four bases for exclusions:

- The measure is already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures);

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[25] 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.

[26] 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-medicares-value-based-purchasing-programs.

- The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures);
- The measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or
- The measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures).

The candidate measure set for the 2020 CAI is as follows: Adult BMI Assessment, Annual Flu Vaccine, Breast Cancer Screening, Colorectal Cancer Screening, 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, Monitoring Physical Activity, Osteoporosis Management in Women who had a Fracture, Plan All-Cause Readmissions, Reducing the Risk of Falling, Rheumatoid Arthritis Management, Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, Medication Adherence for Cholesterol, Statin Therapy for Patients with Cardiovascular Disease, and Statin Use in Persons with Diabetes.

Previously, the decision criteria used to select measures from the candidate measure set for adjustment was (1) a median absolute difference 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. This selection rule was originally developed based on a goal of adjusting measures only when there are substantive LIS/DE within-contract measure disparities. The expansion of the adjusted measure set eliminates these additional criteria related to the size of the within-contract differences, which relied on the analysis of the variability of the within-contract differences of LIS/DE and non-LIS/DE beneficiaries. In keeping with our commitment to transparency, a summary of the analysis of the candidate measure set that includes the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences is posted at http://go.cms.gov/partcanddstarratings.

2020 Categorical Adjustment Index (CAI) Values

MA contracts have up to three mutually exclusive and independent CAI 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 2-13 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 2 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 3 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 50.5%, the contract's LIS/DE initial category is L8. 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.

Table 2: 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 5.676443
L2	5.676443 to less than 8.948963
L3	8.948963 to less than 11.175889
L4	11.175889 to less than 14.780296
L5	14.780296 to less than 19.828475
L6	19.828475 to less than 28.116922
L7	28.116922 to less than 44.240275
L8	44.240275 to less than 74.807539
L9	74.807539 to less than 100.00000
L10	100.000000

Table 3: 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 14.517881
D2	14.517881 to less than 20.616671
D3	20.616671 to less than 27.537428
D4	27.537428 to less than 39.480724
D5	9.480724 to 100.000000

Table 4 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 4: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L3	D1-D2	-0.042454
2	L4-L8	D1	-0.018356
	L4-L6	D2	
3	L1-L6	D3	-0.003555

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
4	L9-L10	D1-D2	0.039921
	L7-L8	D2-D3	
	L1-L8	D4	
	L1-L7	D5	
5	L9-L10	D3-D4	0.133626
	L8-L9	D5	
6	L10	D5	0.167650

Tables 5 and 6 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 5: 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 5.558118
L2	5.558118 to less than 8.585859
L3	8.585859 to less than 11.062133
L4	11.062133 to less than 14.516227
L5	14.516227 to less than 19.228066
L6	19.228066 to less than 27.355519
L7	27.355519 to less than 42.670760
L8	42.670760 to less than 74.043808
L9	74.043808 to less than 100.00000
L10	100.000000

Table 6: 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 14.322701
D2	14.322701 to less than 20.016933
D3	20.016933 to less than 27.192499
D4	27.192499 to less than 39.132112
D5	39.132112 to 100.000000

Table 7 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 7: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
1	L1-L9	D1	0.001152
	L1-L6	D2	
2	L7	D2	0.014974
	L1-L7	D3-D5	
3	L10	D1	0.080025
	L8-L10	D2-D4	
4	L8-L10	D5	0.095022

Tables 8 and 9 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 8: 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 5.789192
L2	5.789192 to less than 9.367454
L3	9.367454 to less than 11.360697
L4	11.360697 to less than 15.014489
L5	15.014489 to less than 21.634509
L6	21.634509 to less than 31.215753
L7	31.215753 to less than 53.136112
L8	53.136112 to less than 82.253813
L9	82.253813 to less than 100.00000
L10	100.000000

Table 9: Categorization of MA-PD Contracts into Disability Quintiles for the Part D Summary Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 14.909782
D2	14.909782 to less than 21.575847
D3	21.575847 to less than 28.825467

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D4	28.825467 to less than 41.935484
D5	41.935484 to 100.000000

Table 10 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 10: 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
1	L1-L7	D1	-0.082197
2	L1-L5	D2	-0.045536
3	L1-L5	D3	-0.004424
	L1-L4	D4	
4	L8	D1	0.028339
	L6-L8	D2-D3	
	L5-L6	D4	
	L1-L6	D5	
5	L9-L10	D1-D3	0.093944
	L7-L9	D4	
	L7	D5	
6	L8-L9	D5	0.210469
7	L10	D4-D5	0.255181

Tables 11 and 12 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 11: 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 1.812445
L2	1.812445 to less than 4.384002
L3	4.384002 to less than 27.635066
L4	27.635066 to 100.000000

Table 12: 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 7.499709
D2	7.499709 to less than 12.338617
D3	12.338617 to less than 21.856925
D4	21.856925 to 100.000000

Table 13 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 are 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 13: Final Adjustment Categories and CAI Values for the Part D Summary Rating for PDPs

Final Adjustment Category	LIS/DE Quartile	Disability Quartile	CAI Value
1	L1	D1-D2	-0.495192
2	L2	D1-D2	-0.320486
3	L1-L2 L3	D3-D4 D1-D4	-0.209888
4	L4	D1-D4	0.189815

Extreme and Uncontrollable Circumstances Policy

Extreme and uncontrollable circumstances such as natural disasters can directly affect our Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide beneficiaries with important medical care and prescription drug coverage. These extreme and uncontrollable circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program. We propose to adjust the 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period using a similar methodology to the one adopted for the 2019 Star Ratings in the CY 2019 Call Letter. To promote transparency around the disaster adjustments, in future data releases we plan to provide additional information on which contracts were eligible for disaster adjustments.

In the CY2020 Proposed Rule, published in the Federal Register on November 1, 2018 (83 FR 55021), we proposed a set of rules for adjusting the calculation of Star Ratings for the Parts C and D organizations that are impacted by extreme and uncontrollable circumstances that occurred during the performance period for the 2022 Star Ratings year and beyond. The Advance Notice/Call Letter process will be used for the 2020 Star Ratings. Below we describe how we propose to identify which contracts were impacted as well as how to adjust the Star Ratings measures, which mirrors in large part the policy proposed in CMS-4185-P. This policy is largely the same as that described in the final 2019 Call Letter and used for 2019 Star Ratings, with two substantive exceptions. First, we propose eliminating the difference-in-differences adjustment for survey data. The difference-in-differences adjustment showed no consistent, negative impact of extreme and uncontrollable circumstances on the 2019 Star Ratings; therefore, we are proposing to eliminate this adjustment to simplify the methodology. Second, we propose clarifying the rules around measures with missing or biased data in the prior or current year.

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 that take into account the effects of the extreme and uncontrollable circumstances.

We propose that affected contracts would be contracts that meet all of these criteria during the performance period for the Star Ratings:

(1) The service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act.

(2) The service area is within a county or county-equivalent entity designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under Section 1135 of the Act based on the same triggering event(s).

(3) A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and reward factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

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 ensures that the Star Ratings

adjustments focus 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" during an "emergency period" as defined in Section 1135(g) of the Act, and also is within a county or county-equivalent entity 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 the Federal Emergency Management Agency (FEMA) Web site at https://www.fema.gov/disasters. We propose to use the incident period start date to determine which year of Star Ratings could be affected, regardless of whether the incident period end date crosses the calendar year.

Table 14 lists all of the Section 1135 waivers that could affect the 2020 Star Ratings.

Table 14: List of Section 1135 Waivers Issued in Relation to the FEMA Major Disaster Declarations

Section 1135 Waiver Date Issued	Waiver or Modification of Requirements Under Section 1135 of the Social Security Act	FEMA Major Disaster Declaration	FEMA Incident Type	Affected State	Incident Start Date	Declared Major Disaster
12/03/2018	AK as the result of earthquake	None	Earthquake	AK	N/A	N/A
11/13/2018	CA as the result of wildfires	DR-4407	Wildfire	CA	11/08/2018	11/12/2018
10/25/2018	MP as the result of typhoon Yutu	DR-4404	Typhoon	MP	10/24/2018	10/26/2018
10/11/2018	GA as the result of hurricane Michael	DR-4400	Hurricane	GA	10/09/2018	10/14/2018
10/09/2018	FL as the result of hurricane Michael	DR-4399	Hurricane	FL	10/07/2018	10/11/2018
09/12/2018	VA as the result of hurricane Florence	DR-4401	Hurricane	VA	09/08/2018	10/15/2018
09/11/2018	SC as the result of hurricane Florence	DR-4394	Hurricane	SC	09/08/2018	09/16/2018
09/11/2018	NC as the result of hurricane Florence	DR-4393	Hurricane	NC	09/07/2018	09/14/2018

Table 15 lists the Individual Assistance counties from all of the FEMA major disaster declarations.

Table 15: Individual Assistance Counties in FEMA Major Disaster Declared States

FEMA Declaration	State	FEMA Individual Assistance Counties
DR-4393	North Carolina	Anson, Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Hyde, Johnston, Jones, Lee, Lenoir, Moore, New Hanover, Onslow, Orange, Pamlico, Pender, Pitt, Richmond, Robeson, Sampson, Scotland, Union, Wayne, Wilson
DR-4394	South Carolina	Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Marion, Marlboro
DR-4399	Florida	Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Leon, Liberty, Taylor, Wakulla, Washington
DR-4400	Georgia	Baker, Crisp, Decatur, Dougherty, Early, Grady, Lee, Miller, Mitchell, Seminole, Terrell, Thomas, Worth
DR-4401	Virginia	None
DR-4404	Northern Mariana Islands	Northern Islands, Rota, Saipan, Tinian

DR-4407	California	Butte, Los Angeles, Ventura

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 (https://www.fema.gov/disaster-declaration-process). 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 extreme and uncontrollable circumstance.

To determine whether a contract was impacted (such 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 extreme and uncontrollable circumstance 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 circumstance policy ensures that the policy applies 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 Florence and Michael, Typhoon Yutu, and the California wildfires trigger the extreme and uncontrollable circumstance policy as, during the performance period for the 2020 Star Ratings, 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 at the relevant time. During the measurement year for the 2020 Star Ratings, the effects of Hurricanes Florence and Michael, Typhoon Yutu, and the California wildfires were significant for Medicare beneficiaries, as well as for the Parts C and D organizations that provide medical care and prescription drug coverage for them. We propose to limit adjustments to the Star Ratings to affected contracts for these major disasters. MA plans complete many preventive screenings at the end of the calendar year so disasters in this period may have an inordinate impact on 2020 Star Ratings. Finally, beneficiaries responding to CMS surveys early in 2019 will be reflecting predominately on events in late 2018 so these disasters may impact survey results used for the 2020 Star Ratings.

Contracts that do not meet the definition of an "affected contract" or the parameters discussed below would not be eligible for any adjustments to the 2020 Star Ratings under this proposed policy.

CAHPS Adjustments:

For CAHPS, CMS is proposing to take into account the effects of these extreme and uncontrollable circumstances in the following two ways for affected contracts:

First, for all contracts (including affected contracts), the MA organization would be required to administer the 2019 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 2018 and it would be practically impossible to contact the required sample for the survey. We propose to make the exception available only to affected contracts that can demonstrate meeting this standard.

Second, our proposed adjustment is for affected contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. These affected contracts would receive the higher of the 2019 or 2020 Star Rating (and corresponding measure score for the Star Ratings year selected) for each CAHPS measure (including the annual flu vaccine measure). We propose the 25% threshold to 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 extreme and uncontrollable circumstances.

In some cases contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas that were affected by disasters that began in 2018 were also affected by disasters in 2017. We propose that these doubly-affected contracts would receive the higher of the 2020 Star Rating or what the 2019 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we would use the corresponding measure score for the Star Ratings year selected). For example, if a doubly-affected contract reverted back to the 2018 Star Rating on a given measure in the 2019 Star Ratings, the 2018 Star Rating would *not* be used in determining the 2020 Star Rating. Rather the 2020 Star Rating would be compared to what the 2019 Star Rating would have been absent any disaster adjustments. We are proposing this policy because we are concerned about older data continuing to be pulled forward in the Star Ratings.

For all adjustments, if the Star Rating is the same in both years we would use the Star Rating and measure score from the most recent year.

HOS Adjustments:

For the HOS survey, we will follow similar procedures as CAHPS but the adjustment for 2017 disasters (listed in Tables 15 and 16 of the final CY 2019 Call Letter) will be to the 2020 Star Ratings, and the adjustment for 2018 disasters (listed in Tables 14 and 15 of this CY 2020 Call Letter) will be to the 2021 Star Ratings. This is due to the longitudinal nature of the HOS data

collection. The HOS measures for the 2020 Star Ratings are based on HOS data collected from April through June 2018. The HOS methodology for the 2020 Star Ratings was finalized in the final 2019 Call Letter as it reflects data from an earlier timeframe. As we stated above, the difference-in-differences adjustment is not being used since it showed no consistent, negative impact of extreme and uncontrollable circumstances. The HOS data collected in 2019 are used for the 2021 Star Ratings and reflect health statuses over the past 12 months, so responses may reflect health statuses during 2018 disasters. For the HOS survey, we propose to follow similar procedures as CAHPS and have two adjustments for affected contracts:

First, the MA organization holding an affected contract would be required to administer the 2019 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 2018 and it would be practically impossible to contact the required sample for the survey. The exception would be available only for affected contracts that can demonstrate meeting this standard.

Second, we further propose that affected contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the 2021 or 2020 Star Rating (and corresponding measure score for the Star Ratings year selected) for each HOS outcome measure and HEDIS-HOS measure in the 2021 Star Ratings. We propose the 25% threshold to avoid including contracts with very few enrollees impacted. Please see discussion above for more details.

For all adjustments, if the Star Rating is the same in both years we would use the Star Rating and measure score from the most recent year. Our proposed policy for cut points for non-CAHPS measures used in the 2020 Star Ratings is addressed below.

HEDIS Adjustments:

For HEDIS, all 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 because the MA organization cannot obtain both administrative and medical record data necessary for HEDIS. Separate and apart from our Star Ratings methodology and adjustments, all contracts in disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review. For affected contracts with at least 25% of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we would take the higher of the 2019 or 2020 Star Rating (and corresponding measure score for the Star Ratings year selected) for each HEDIS measure. Please see discussion explaining our rationale for the 25% cutoff.

In some cases contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas that were affected by disasters that began in 2018 were also affected by

disasters in 2017. We propose that these doubly-affected contracts would receive the higher of the 2020 Star Rating or what the 2019 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we would use the corresponding measure score for the Star Ratings year selected).

For all adjustments, if the Star Rating is the same in both years we would use the Star Rating and measure score from the most recent year.

Other Star Ratings Measure Adjustments:

Subject to the exclusion below, we propose that for all other measures for affected contracts with at least 25% of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we would take the higher of the 2019 or 2020 measure Star Rating (and corresponding measure score for the Star Ratings year selected).

In some cases contracts with at least 25% of enrollees residing in FEMA-designated Individual Assistance areas that were affected by disasters that began in 2018 were also affected by disasters in 2017. We propose that these doubly-affected contracts would receive the higher of the 2020 Star Rating or what the 2019 Star Rating would have been in the absence of any adjustments that took into account the effects of the 2017 disaster for each measure (we would use the corresponding measure score for the Star Ratings year selected).

For all adjustments, if the Star Rating is the same in both years we would use the Star Rating and measure score from the most recent year.

We propose to exclude from this adjustment policy the following measures: Part C Call Center – Foreign Language Interpreter and TTY Availability and Part D Call Center – Foreign Language Interpreter and TTY Availability 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.

Improvement Measure(s) and Missing Data Rules:

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 affected contracts that revert back to the data underlying the 2019 Star Rating for a particular measure under our proposal to address the effects of an extreme and uncontrollable circumstance, we propose that measure would be excluded from the applicable improvement measure and excluded from 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 2020 (and, for HOS and HEDIS-HOS, 2021) 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. Contracts affected by disasters would not have the option of reverting to the prior year's improvement rating.

Except in cases where an exception was granted as described earlier, we propose that for all measures eligible for an extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate, it is too new, or it is too small), the final measure rating would come from the current year (that is, it would be treated as missing). This measure would be excluded from the contract's improvement score(s) following our usual rules.

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 extreme and uncontrollable circumstance. We are proposing that these contracts be excluded to ensure that any impact of the extreme and uncontrollable circumstance on their measure-level scores would not have an impact on the cut points or measure ratings for other contracts. However, these cut points calculated for all other contracts would be used to assess these contracts' 2020 measure Star Ratings (which would be compared to the contracts' 2019 measure Star Ratings to determine which is higher, and therefore used for the affected contracts' 2020 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.

2020 Star Ratings Measures

Members Choosing to Leave the Plan (Part C & D). CMS proposes to use additional data to identify beneficiaries leaving a contract due to a move out of the contract service area since a move out of the service area is considered an involuntary disenrollment. Currently, if a member has a disenrollment reason code (DRC) 92, the member is not included in the numerator for this measure since this code captures moves out of the contract service area. In some cases, moves out of the service area are being recorded in the CMS systems using codes other than DRC 92 and would, consequently, be included in the numerator. We propose to exclude moves out of service area that used codes other than DRC 92. These are involuntary disenrollments even if they are not coded DRC 92 and should not be counted against the measure. This proposal would exclude from the numerator disenrollees for which the new contract service area does not overlap with the old contract service area.

2020 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's 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 2019 display measures will continue to be shown as display measures on CMS.gov in 2020 unless noted below.

CMS will continue to solicit feedback on new and updated measures through the draft Call Letter, as well as continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Going forward as codified at § 422.164(c)(2-4), § 423.184(c)(2-4), § 422.164(d)(2), and § 423.184(d)(2), new measures and measures with substantive specification changes will be on the display page for at least two years prior to becoming a Star Ratings measure.

New 2020 Display Measures

Transitions of Care (Part C). CMS is working with NCQA to expand efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to home. The intent of the measure is to improve the quality of care transitions from an inpatient setting to home, as effective transitioning will help reduce hospital readmissions, costs, and adverse events.

The Transitions of Care measure excludes members in hospice and is based on the number of discharges, not members. The measure includes the percent of discharges for members 18 years or older who have each of the four indicators during the measurement year:

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 (for example, 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.

Based on analyses of the first year data submitted in June 2018, NCQA is removing the requirement of documenting medication allergies under the *Receipt of Discharge Information* indicator for the HEDIS 2019 specification. We are proposing to add this measure to the 2020

display page with the intent to propose this measure for inclusion in the Star Ratings in the future.

Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C). CMS is proposing to add to the 2020 display page 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 prevent the development of more severe complications. This measure includes the percentage of emergency department (ED) visits for members 18 years and older who have high-risk multiple chronic conditions who had a follow-up service within 7 days of the ED visit between January 1 and December 24 of the measurement year. The measure is based on ED visits, not members. The following are eligible chronic condition diagnoses. Members must have two or more from this list:

- COPD and asthma
- Alzheimer's disease and related disorders
- Chronic kidney disease
- Depression
- Heart failure
- Acute myocardial infarction
- Atrial fibrillation
- Stroke and transient ischemic attack

The following meet the criteria to qualify as a follow up service for purposes of the measure:

- An outpatient visit (with or without telehealth modifier)
- A behavioral health visit
- A telephone visit
- Transitional care management services
- Case management visits
- Complex Care Management

MPF Price Accuracy (Part D). As stated in the 2019 Call Letter, we propose enhancements to the MPF Price Accuracy measure to be first published as a display measure in 2020, and then to be considered to be applied to the Star Rating measure for 2022, pending rulemaking. Pending such a change, the current MPF measure will continue in the Star Ratings using the same methodology used for the 2019 Star Ratings. (See Attachment M of the 2019 Technical Notes available on the CMS webpage: http://go.cms.gov/partcanddstarratings.)

These enhancements will better measure the reliability of a contract's MPF advertised prices.

We will implement the following changes for the 2020 and 2021 display of this measure (please see Appendix 1 for a more detailed methodology of these changes):

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:
     (Total amount that PDE is higher than MPF + Total PDE cost) / (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:
     (Total number of claims where PDE is higher than MPF) / (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:
     - Price Accuracy Score = 100 – ((Price Accuracy Index - 1) x 100)
     - Claim Percentage Score = (1 – Claim Percentage Index) x 100
     - Measure Score = (0.5 x Price Accuracy Score) + (0.5 x Claim Percentage Score)

2. Increase the claims included in the measure:
   - Expand the days' supply of claims included from 30 days to include claims with fills of 28-34, 60-62, or 90-100 days.
   - Identify additional retail claims using the PDE-reported Pharmacy Service Type code. If the NPI in the Pharmacy Cost (PC) file represents a retail only pharmacy, all corresponding PDEs will be eligible for the measure. However, if the NPI in the PC file represents a retail and limited access pharmacy (such as Home Infusion or Long Term Care pharmacy), only the PDE where the pharmacy service type is identified as either Community/Retail or Managed Care Organization (MCO) will be eligible.

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 one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places, using traditional rounding rules.

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

The enhancements are largely those that had been previously finalized in the 2018 and 2019 Call Letters. We will continue to provide contracts their preliminary as well as final MPF Price Accuracy reports, which contain claim level information. We will also provide information to contracts about their Accuracy scores using the new specifications.

Retired Display Measure for 2020

Transition Monitoring Program Analysis (TMPA) and Formulary Administration Analysis (FAA) (Part D). Over the past several years, the TMPA and FAA have served as oversight monitoring projects to ensure Part D Sponsors were meeting Medicare Part D formulary administration and transition requirements. Since the inception of these analyses, CMS has seen an improvement in formulary administration and transition practices. In addition, these analyses are duplicative of other oversight monitoring projects, which has led to an increased burden on plans. As such, CMS has determined that we will not be continuing the TMPA and FAA for CY 2019 and we will discontinue display of these measures.

Changes to Existing 2020 Display Measures

Use of Opioids at High Dosage and from Multiple Providers (OHDMP) and Antipsychotic Use in Persons with Dementia (APD) (Part D). In line with PQA measure updates for the 2018 measurement year, we propose to implement an updated methodology for the 2020 display page measures (based on 2018 data) that calculate total days supply.

When calculating a beneficiary's total days supply, the following specifications will be applied:

- Any days supply that extends beyond the end of the measurement period will be excluded,
- In the case of multiple prescription claims with the same date of service, total days supply will only include the supply of the claim with the longest days supply, and
- In the case of multiple overlapping claims with different dates of service, there will be no adjustments for early fills or overlapping days supply.

Note, this change also applies to the Use of Opioids at High Dosage (OHD) and Use of Opioids from Multiple Providers (OMP) measures; also Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) measures (See Forecasting to 2021 and Beyond).

Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage Disenrollment Reasons Survey composite measures (Part D). The MA and PDP Disenrollment Reasons Survey asks Medicare beneficiaries who voluntarily disenroll from MA and PDP contracts to report their reasons for disenrollment. Survey responses

from disenrollees from MA-PD contracts are combined to create five composite measures of reasons for disenrollment; three of these composites are also calculated for PDP contracts.

CMS assesses the reliability of these composite measures of reasons for disenrollment annually. For many MA-PD and PDP contracts, scores on the Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage composite measures have very low reliability (less than 0.6 on a 0 to 1 scale), meaning that the survey results have low power to distinguish the contract's performance from the national average performance. The low reliability of these measures is primarily due to the relatively small differences between contracts on these categories of reasons for disenrollment.

To strengthen CMS's ability to monitor contract performance and increase the reliability of information provided to beneficiaries on the Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage measures, CMS proposes to pool the two most recent years of survey data for these composites and their component items for all contracts. That is, each of these composites would include two years of data instead of one. Plan reports distributed in 2019 based on the 2018 survey fielding would pool 2017 and 2018 survey data to generate the Problems Getting Information and Help from the Plan and Problems with Prescription Drug Benefits and Coverage composite measures.

In addition to being reported on the display page, these measures are also reported as drill-downs on Medicare Plan Finder to Members Choosing to Leave the Plan. For new contracts that only have data from the most recent year, the composite measures would be constructed with just that single year of data and be reported to plans and included in the Medicare Plan Finder *only if* the composite's reliability is 0.6 or greater. In that case, the plan report would explain that the score is based on only one year of data, and that in subsequent years two years of data would be combined to calculate the contract's score.

Forecasting to 2021 and Beyond

The following describes potential changes to existing measures and potential new measures for CY 2021 or later. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings for 2021 or later. As we add new measures, CMS will consider which existing measures are topped out or have little variation across contracts to transition them to the display page.

In the Contract Year 2019 Final Rule (CMS-4182-F), we stated that new measures or measures with substantive changes would be proposed through the Federal Register rulemaking process for the 2021 Star Ratings or beyond, while the Advance Notice/Call Letter process would continue to be used for the 2020 Star Ratings. As stated in the Contract Year 2019 Final Rule and codified at § 422.164(c)(2), § 423.184(c)(2), § 422.164(d)(2), and § 423.184(d)(2), new measures and substantive updates to existing measures would be added to the Star Ratings system based on

rulemaking; however, CMS would continue to solicit feedback on new measures and measures with substantive updates through the draft Call Letter process.

Health Outcomes Survey (HOS). For the 2019 survey administration, HOS Baseline is optional for Institutional Special Needs Plans (I-SNPs) per the HOS measure specifications. For 2020 survey administration, CMS proposes to exclude beneficiaries enrolled in I-SNPs at the plan benefit package (PBP) level from HOS Baseline. The proposed reporting requirements for MA contracts that offer one or more I-SNPs are as follows:

- Contracts with only one PBP, or with multiple PBPs that are all I-SNPs, are excluded from Baseline HOS.
- Contracts with at least one non-I-SNP PBP are required to report HOS Baseline if 500 or more enrollees remain after I-SNP enrollees are removed.

All MA contracts that reported HOS Baseline in 2018 are required to report HOS Follow-Up in 2020.

Potential Changes to Existing Star Ratings and Display Measures

Plan All-Cause Readmissions (Part C). NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019). The measure assesses the percentage of hospital discharges resulting in unplanned readmissions within 30 days of discharge. The changes made by NCQA are: adding observation stays as hospital discharges and readmissions in the denominator and the numerator, and removing individuals with high frequency hospitalizations. These changes were implemented by the measure steward (NCQA) based on the rise in observation stays to ensure the measure better reflects patient discharge and readmission volumes. Removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. To date, CMS has only included the 65+ age group in the Plan All-Cause Readmissions measure. CMS is proposing to combine the 18-64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. Given the substantive nature of the proposed updates for this measure, it would be moved to display for the 2021 and 2022 Star Ratings under § 422.164(d)(2). We proposed in the CY2020 Proposed Rule (83 FR 55022) to return this measure with the substantive updates by the measure steward to the 2023 Star Ratings using data from the 2021 measurement year with, as required by § 422.164(d)(2) and § 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

Medication Reconciliation (Part C). NCQA proposes to retire the standalone Medication Reconciliation Post-Discharge measure for HEDIS 2020 which covers the 2019 measurement year. HEDIS 2019 would be the last year for the collection of the standalone measure. However, medication reconciliation would continue to be collected and reported through the Transitions of Care measure, which includes a Medication Reconciliation Post-Discharge indicator. Currently,

organizations that use the hybrid method to report the Medication Reconciliation Post-Discharge and Transitions of Care measures may use the same sample for both measures. For the Transitions of Care measure, the medication reconciliation information must be found in the same medical record that is used for the reporting of the other three indicators within the measure, which should be that of the primary care practitioner or ongoing care provider who is managing the patient's care. Starting with the 2021 Star Ratings, we would use the Medicare Reconciliation Post-Discharge measure data that is collected under the Transitions of Care measure from HEDIS 2020 covering the 2019 measurement year.

Osteoporosis Measures (Part C). For HEDIS 2020, NCQA is reevaluating two measures that address osteoporosis in older women. The Osteoporosis Testing in Older Women measure assesses if women 65 and older have ever received a bone mineral density test to screen for osteoporosis, and data are currently collected through a question in the Medicare HOS. This measure is currently on the display page. The Osteoporosis Management in Women Who Had a Fracture measure, which is a current Star Ratings measure, assesses if women age 65 to 85 receive bone mineral density assessment or treatment for osteoporosis after a fragility fracture.

In June 2018 the U.S. Preventive Services Task Force (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/osteoporosis-screening1) updated the recommendation statement for osteoporosis screening. Based on this updated statement, along with updated guidelines from the American College of Physicians (https://www.acponline.org/acp-newsroom/american-college-of-physicians-issues-guideline-for-treating-low-bone-density-or-osteoporosis-to), NCQA will explore if any changes are needed for the measures. NCQA will also review the bone mineral density tests that are currently allowed for the osteoporosis management measure to assess their appropriateness in being used to assess or diagnose osteoporosis. Changes that are made to the measures, if approved, would be included in HEDIS 2020; we will evaluate whether these expected changes are substantive or non-substantive under § 422.164(d) to address whether the revised measure will be part of future Star Ratings once the necessary information is available.

Additionally, NCQA is exploring the development of a new measure that could leverage data from electronic health records and registries to assess osteoporosis screening. This new measure would be specified to use data from the Electronic Clinical Data Sources (ECDS) reporting method. If developed and approved, the new measure would likely be included for Medicare reporting in HEDIS 2021.

Care for Older Adults – Functional Status Assessment Indicator (Part C). NCQA is considering refining the hybrid specification for the Functional Status Assessment indicator in the Care for Older Adults measure. Currently, the specification states that documentation of a complete functional status assessment must include (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; (3) result of assessment using a standardized functional assessment tool; or (4) notation

that at least three of the following four components were assessed: (a) cognitive status; (b) ambulation status; (c) hearing, vision and speech; (d) other functional independence (e.g., exercise, ability to perform job). Because the clinical field of functional status assessment is moving toward agreement on assessment using ADLs, IADLs, or another standardized tool, and to improve the clarity of the specification, NCQA is considering removing the fourth option for meeting the numerator for this indicator. If approved, these measure changes would be implemented in HEDIS 2020 or HEDIS 2021. This would be considered a non-substantive update under § 422.164 since it clarifies documentation requirements and does not meaningfully impact the numerator.

Hospitalization for Potentially Preventable Complications (Part C). For HEDIS 2020, NCQA is recommending updating the small denominator limit to <150 for all risk-adjusted utilization measures, including Hospitalization for Potentially Preventable Complications, which is a current display measure.

In a future HEDIS revision, NCQA is also considering removing planned hospitalizations on the same admission and discharge date from the numerator, adding a more expansive exclusion for individuals with immunocompromised conditions to the acute measure indicator, and removing the toe amputation exclusion from the chronic measure indicator. NCQA is also considering updates to the risk adjustment model. The exact timing of these changes has not been decided, but they would likely be implemented for HEDIS 2020 or HEDIS 2021. We will evaluate whether these expected changes are substantive or non-substantive under § 422.164(d) to address whether the revised measure will be part of future Star Ratings once the necessary information is available.

Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D). Currently, the Proportion of Days calculation (PDC) adjusts for Part D beneficiaries' stays in inpatient (IP) settings for PDPs and MA-PDs, and stays in skilled nursing facilities (SNFs) for PDPs only. The Common Working File (CWF) is the data source for these stays. The days of the relevant stays occurring during the measurement period are essentially removed, or excluded, from the numerator and denominator of the PDC calculation. This is a non-substantive change that benefits the Star Ratings of the sponsoring organizations.

Beginning with the 2019 measurement year for the 2021 Star Ratings, we propose to include SNF stay data from the CWF if available for MA beneficiaries and MA-PDs. Based on analysis of 2017 data, when applying this adjustment to MA-PDs with available CWF SNF data, there was a negligible overall positive impact to the MA-PD measure rates (0.003% - 0.006%). Section 90.2 Medicare Billing Requirements for Beneficiaries Enrolled in MA Plans in Chapter 6 SNF Inpatient Part A Billing and SNF Consolidated Billing in the Medicare Claims Processing Manual states that SNF providers shall submit a claim to the "fee for service" A/B MAC (A) to

subtract benefit days from the CWF records. (Note: The plans do not send claims to CWF for SNF stays). Failure to send a claim to the A/B MAC (A) will inaccurately show days available.

For the future (i.e., 2022 Star Ratings based on 2020 measurement period), we tested using MA encounter data for IP and SNF stays for the PDC adjustment for MA-PDs, in addition to CWF data. Using 2017 data, we evaluated using this additional data source for IP and SNF stays. We found the completeness of encounter data admission and discharge dates to be similar to that of CWF data, and the timeliness of data submissions was adequate. After adding MA encounter data for the IP and SNF stay adjustments for MA-PDs, the overall rates increased slightly for the Diabetes, Hypertension, and Cholesterol Medication Adherence measures (on average by 0.30, 0.43, and 0.55 percentage points, respectively). Although the impact is small, this additional data source improves our ability to identify IP and SNF stays.

The proposed changes discussed above would be considered non-substantive updates under § 422.164 since it adds additional exclusions to the PDC adjustment which narrows the denominator and benefits the sponsors' Star Ratings.

Furthermore, we tested using encounter data to identify beneficiaries with an ESRD diagnosis for exclusion from the Diabetes and Hypertension Medicare Adherence measures for MA-PDs, instead of Risk Adjustment Process System (RAPS) RxHCC data. We simulated this alternative data source for identifying ESRD beneficiaries using 2017 data. The MA-PD rates increased on average by 0.05 and 0.15 percentage points. The impact of removing RAPS RxHCC data as a data source for PDPs was also negligible.

We will test using encounter data to obtain diagnosis code information for other Part D measures (not just the Medication Adherence measures), such as for exclusions. We will provide results from the testing when available. However, due to the complexity and size of these data files, we would need to change the frequency of the Patient Safety reports from monthly to quarterly. Based on past feedback, we understand that Part D sponsors would prefer to receive the reports on a monthly basis for their performance improvement and monitoring activities. We ask for feedback on the trade-off of less frequent reports versus including encounter data to improve our ability to identify IP and SNF stays, ESRD beneficiaries, and other exclusions.

Antipsychotic Use in Persons with Dementia (APD) and Statin Use in Persons with Diabetes (SUPD) (Part D). The PQA clarified the specifications to state that that the eligible population received ≥2 prescription claims on <u>different</u> dates of service. We propose to apply this non-substantive change to the 2021 measures (based on 2019 data) under § 423.184(d)(1).

Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS) (Part D). As discussed in the 2019 Call Letter, we began reporting these measures in the Patient Safety reports for the 2018 measurement year. This was also discussed in the April 6, 2018

HPMS memo, Updates – 2018 Medicare Part D Patient Safety Reports and Overutilization Monitoring System Reports. We plan to add the measures 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.

Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D). The PQA finalized changes to the three opioid measures for the 2019 measurement year in the 2019 PQA Measure Manual to better align with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain[27] as follows:

Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD): The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) over a period of ≥90 days.

Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The percentage of individuals ≥18 years of age who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.

Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The percentage of individuals ≥18 years of age who received prescriptions for opioids with an average daily dosage of ≥90 morphine milligram equivalents (MME) AND who received prescriptions for opioids from ≥4 prescribers AND ≥4 pharmacies within ≤180 days.

We tested the revised 2019 PQA measure specifications using 2017 PDE data. The analysis was limited to contracts with more than 30 denominator member-years (M-Y).

Table 16: Distribution of the Revised (2019) Opioid Overuse Quality Metric Rates by Medicare Part D Contract Type, 2017 Data

				Percentiles							
Measure	**Type**	**Count**	**Mean**	**MIN**	**10%**	**25%**	**50%**	**75%**	**90%**	**95%**	**MAX**
OHD	MA-PD	586	7.9%	0.0%	3%	5.4%	7.8%	10.0%	12.7%	15.0%	25.1%
	PDP	58	9.5%	0.4%	4.8%	6.3%	9.3%	11.4%	15.3%	18.2%	30.3%
OMP	MA-PD	586	0.8%	0.0%	0%	0.0%	0.6%	1.1%	2.0%	2.5%	6.8%
	PDP	58	0.6%	0.0%	0%	0.3%	0.5%	0.7%	1.2%	1.5%	1.7%
OHDMP	MA-PD	586	0.1%	0.0%	0%	0.0%	0.0%	0.1%	0.2%	0.4%	2.7%
	PDP	58	0.1%	0.0%	0%	0.0%	0.1%	0.2%	0.2%	0.3%	0.4%

Using these quality metrics that are now better aligned with CDC Guideline recommendations, CMS will be able to better track trends in Medicare Part D opioid overuse, especially high-risk beneficiaries who use 90 MME or more. We will implement these revisions in the Patient Safety reports for the 2019 measurement year and propose to include all three revised measures on the

[27] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

2021 display page (2019 data). We will consider the measures for the 2023 Star Ratings (2021 data), which would be proposed through rulemaking.

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

High Risk Medication (HRM) and Diabetes Medication Dosing (DMD) (Part D). We will retire these two display measures for 2021 and no longer report these measures in the Patient Safety reports for the 2019 measurement year.

In response to the draft 2019 Call Letter, some stakeholders expressed concerns about overlap between the HRM display measure and the new Polypharmacy measures. Therefore, we will retire the HRM measure so that sponsors can better focus their resources on the Polypharmacy measures.

The PQA-endorsed DMD measure rate is the percentage of Medicare Part D beneficiaries 18 years or older who were dispensed a dose higher than the daily recommended dose for biguanide, sulfonylurea, thiazolidinedione, and dipeptidyl peptidase (DPP)-IV inhibitor therapeutic classes of oral hypoglycemic drugs. DMD has been a display measure since 2010 (based on 2008 data).

As shown in Table 17, the DMD contract rates were never high, but the rates did decrease almost 70% from 2010 to 2017. Comparison of the 2016 and 2017 Part D contract rate distributions found no significant differences. We believe that the current rates have plateaued. For this reason, we will retire the DMD measure from the 2021 display page and no longer provide Patient Safety reports on this measure for the 2019 measurement year.

Table 17: Diabetes Medication Dosing (DMD) Measure Rates by Part D Contract Type, 2010, 2016 and 2017 YOS

Contract Type	DMD Rate							
	Year	N	Mean	Std Dev	Minimum	Median	95th Pctle	Maximum
MA-PD	2010	552	1.6%	4.5%	0.0%	1.2%	2.9%	98.4%
MA-PD	2016	613	0.7%	2.8%	0.0%	0.3%	1.8%	66.4%
MA-PD	2017	598	0.5%	0.7%	0.0%	0.3%	1.5%	10.3%
PDP	2010	81	1.5%	0.5%	0.0%	1.5%	2.3%	2.9%
PDP	2016	66	0.5%	0.4%	0.0%	0.4%	1.2%	1.6%
PDP	2017	59	0.5%	0.3%	0.0%	0.4%	1.1%	1.2%

Part D sponsors should continue to monitor for prescription fills greater than the daily recommended dose for diabetes medications, as well as, for other high risk drugs using safety edits at the point-of-sale (POS). CMS may also periodically analyze DMD and HRM contract rates to determine if the rates are trending higher and if there is a need to revisit implementation of this or any other retired measure in the future.

Potential New Measure Concepts

Cross-Cutting Topic – Measure Digitalization (Part C). For HEDIS 2020, NCQA is developing digital specifications for up to 20 existing HEDIS Effectiveness of Care measures. The process of converting the measures to a digital format allows for improvements to the HEDIS specifications by providing greater specificity and standardization of the language used to define the measure data elements. These digital specifications will be produced using the Quality Data Model (QDM), clinical quality language (CQL), and standard terminologies and will reference clinical concepts directly instead of using claims-based proxies for measure definitions. Through this effort, NCQA is working to align the HEDIS specifications with provider-level electronic clinical quality measures (eCQMs) wherever possible. These selected digital HEDIS measure packages will be available for HEDIS 2020. In the next year, NCQA will continue this digitalization process, converting another subset of existing HEDIS measures to the digital format.

Cross-Cutting Topic – Exclusions for Advanced Illness (Part C). NCQA is continuing work on the advanced illness and long-term care cross-cutting exclusions that were implemented in HEDIS 2019. 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, measures may not be clinically appropriate for certain individuals with advanced illness and may overlook the quality issues that are specific to these patients. For HEDIS 2020, NCQA is considering expanding the exclusions to allow clinical data to be used to identify individuals with advanced illness and frailty. NCQA is also exploring methods to identify individuals who require nursing home level care who reside in the community. If approved, updates to HEDIS measures for any additional exclusions would be incorporated in HEDIS 2020. CMS will review the updates at that time to determine whether §§ 422.164(d) and 423.184(d) permit incorporation of the updates into the Star Ratings without rulemaking.

Physician/Plan Interactions (Part C & D). In the CY 2019 proposed Part C & D Rule (CMS-4182-P) (82 FR 56336, 56337), CMS solicited and received feedback about conducting a survey of physicians about their interactions with plans on behalf of beneficiaries. Examples of such interactions include their efforts to appeal denials of coverage or to submit claims for payment. Some commenters saw value in a survey, but the vast majority of commenters recommended against a mandatory survey. Those opposed to the survey cited plan and provider burden, or that results could be skewed for highly integrated plans where physicians only interact with a single plan, many by which they are employed. Among less integrated plans, physicians work with many plans, but most of the interactions plans have are with a centralized staff, not with the physicians themselves. CMS welcomes feedback from stakeholders on alternative methods to measure the interactions of providers with plans on behalf of beneficiaries while being mindful of plan and provider burden, and for ways to accurately detect differences between plans. We are particularly interested in receiving feedback on the feasibility of developing and implementing a

measure specifically related to plan coverage and payment decisions, claims processing issues, and other common administrative processes that plans have in place.

Interoperability Measures (Part C). Interoperability, the ability of health systems to effortlessly exchange and use electronic health information, is critical to improving care and reducing costs for Medicare beneficiaries. The 21st Century Cures Act defines interoperability as "health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and does not constitute information blocking." CMS is seeking comment on ways to measure health plans' progress in maximizing their capabilities to exchange health information with other plans, health care providers, and others and to provide beneficiaries access to their health data.

Currently, CMS incentivizes interoperability through the Merit-based Incentive Payment System (MIPS)[28]. Through this program, Medicare clinicians are rewarded for meeting benchmarks in care coordination by using certified electronic health record technology (CEHRT) to share test results, visit summaries, and other information with the patient and other health care providers. The Part C and D Star Ratings use "interoperability-sensitive" measures, such the HEDIS Medication Reconciliation Post-Discharge measure and the CAHPS Care Coordination measure. Interoperability-sensitive measures are process and outcome measures impacted by interoperability (exchange and use of electronic health information from external sources). CMS will also be including the interoperability-sensitive HEDIS Transitions of Care measure in the 2020 display measures and is considering it for possible inclusion in the future for Star Ratings.

CMS welcomes commenters' suggestions for additional measures for MA plans that identify achievements in interoperability and patient access to health data. We ask commenters to consider measurements that address progress towards the adoption of interoperable technology as identified by the Office of the National Coordinator for Health Information Technology (ONC), such as capability for interoperable exchange, the flow and use of interoperable information, and the impacts of interoperability on improving healthcare.[29]

Patient-Reported Outcome Measures (Part C). Patient engagement is key to achieving high quality care. Patients are the ultimate source of information on patient outcomes. Patient-Reported Outcome Measures (PROMs or PROs) have the potential to capture aspects of quality that are best (or perhaps only) assessed by plan members themselves. PROs are widely used in clinical settings to gauge treatment outcomes and increasingly used as global measures to capture

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[28] See https://qpp.cms.gov/mips/overview.

[29] See https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf and https://www.healthit.gov/sites/default/files/measurementfinrpt.pdf.

health status, quality of life, and other health domains. CMS is considering using new and more targeted PRO measures to hold contracts accountable for the outcomes of care for their members. We are interested in obtaining feedback and suggestions on PRO measures, including targeted PRO measures and more general ones such as the existing HOS outcome measures.

Currently, CMS assesses two global PRO measures—improving or maintaining physical health and improving or maintaining mental health, both with approximately a two-year window for measured changes. These measures capture information from the patient's point of view and are not specific to a particular disease or condition. Among the more focused topics that have been discussed for PRO measure development are assessments of change in mobility, depression and change in depression over time, patient activation or engagement in the treatment process, physical activity, health-related quality of life, health behaviors (smoking, healthy eating, exercise, etc.), goal achievement, cognitive functioning, pain and how much it interferes with function, sleep quality, and social support. This is not an exhaustive list (the Centers for Disease Control and Prevention (CDC) has more than 1,800 Patient-Reported Outcomes Measurement Information System (PROMIS) measures for use in adults). It should also be noted that information on some of these topics (sleep and depression, for example) are already collected through current patient survey efforts, while others are not reflected in current efforts.

CMS would be interested in feedback from stakeholders about priorities, challenges, and successes plans have had using similar metrics internally, any synchronicities and/or efficiencies that could be gained from the MA program focusing on particular PROs, and suggestions for future measure development related to PROs.

Pain Management (Part C). NCQA is exploring the development of new measures assessing the use of non-opioid therapies (pharmacologic and non-pharmacologic) for pain and PROs (e.g., functional status, quality of life) to manage care for patients with chronic pain. These measures are meant to complement the new opioid overuse measures introduced in HEDIS2018 by evaluating whether patients with chronic pain are receiving appropriate pain management. As a first step, NCQA will hold discussions with plans and practices in the winter/spring of 2019 to assess the use of PROs in pain management. If approved, these new measures would likely be included in HEDIS 2021. CMS will consider whether to engage in rulemaking to incorporate such new measures into the Star Ratings.

Adherence to Antipsychotic Medications for Individuals with Schizophrenia (Part C). For HEDIS 2020, NCQA is considering expanding the existing HEDIS measure, Adherence to Antipsychotic Medications for Individuals with Schizophrenia, to include reporting for the Medicare health plans. This measure assesses adherence to antipsychotic medication among members with schizophrenia or schizoaffective disorder. Currently, the measure is only specified to assess care delivered to Medicaid enrollees ages 18-64. Testing of the measure in a Medicare claims database in fall of 2018 will allow NCQA to evaluate the feasibility and utility of expanding the measure to include Medicare plans and older adults. If approved, the measure

would potentially be reported by MA and cost plans for HEDIS 2020 with possible future reporting on the CMS display page.

Antibiotic Utilization Measures (Part C). For HEDIS 2020, NCQA is considering expanding three of its existing HEDIS measures to include reporting for the Medicare plans that focus on antibiotic prescribing practices related to three of the most common acute respiratory conditions for which inappropriate prescribing of antibiotics occurs frequently in the ambulatory care setting. Increased interest and alarm about the overuse of antibiotics led NCQA to consider whether the measures should be broadened to cover more of the population. Clinical guidelines strongly recommend against the use of antibiotics for the treatment of acute bronchitis, upper respiratory infections, and viral pharyngitis, across all age ranges. If approved, the expanded measures would be reported by MA and cost plans for HEDIS 2020 with possible future reporting on the CMS display page.

Diabetes Overtreatment (Part C). NCQA is exploring the development of a new measure assessing overtreatment in clinically complex, older patients with type 2 diabetes. For certain older adults (e.g., those with multiple comorbidities or functional impairment), there is growing recognition that the harms of pursuing intensive A1c targets may outweigh the benefits – for example, the American Diabetes Association recommends relaxing A1c goals for older adults with multiple coexisting chronic illnesses, cognitive impairment, or functional dependence. This measure would assess whether members are being overtreated (as defined by A1c level and medications). NCQA plans to begin testing this measure in 2019. If approved, this new measure would likely be included in HEDIS 2021. CMS will consider whether to engage in rulemaking to incorporate such new measures into the Star Ratings.

Removal of Measures from the 2022 Star Ratings

In the CY 2019 Final Rule (CMS-4182-F), CMS codified rules at §§ 422.164(e)(1) and 423.184(e)(1) for removing measures from the Star Ratings program. Under the regulation(s), CMS may remove a measure from the Star Ratings program when:

> (i) the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or
>
> (ii) the measure shows low statistical reliability.

CMS must announce in advance of the measurement period the removal of a measure based upon its application of this regulatory authority to remove a measure from the Star Ratings. The measurement/performance period that will begin after the release of the CY 2020 Call Letter (on April 1, 2019) will be the 2020 measurement year so the earliest CMS could remove the following measures is for the 2022 Star Ratings.

Adult BMI Assessment (Part C). Under § 422.164(e)(1), we will be removing Adult BMI Assessment from the Star Ratings program and transitioning it to the display page beginning with the 2020 measurement year and 2022 Star Ratings.

With the introduction of electronic health records, there have been rapid increases in the performance of contracts in this measure with the average performance across contracts increasing from 44% for the 2011 Star Ratings to 98% for the 2019 Star Ratings. Given the significant increase in performance and lack of variation across contracts, the reliability of this measure has declined; therefore, we are removing this measure from the Star Rating program.

Appeals Auto-Forward (Part D), Appeals Upheld (Part D). Under § 423.184(e)(1), we will be removing these Part D appeals measures beginning with the 2020 measurement year and 2022 Star Ratings.

CMS has determined that the Part D appeals measures are not statistically reliable. The appeals measures use the data recorded by the IRE as a proxy dataset to evaluate how well a Part D sponsor is processing beneficiaries' requests for coverage determinations and redeterminations. For example, the rate of auto-forwarded cases by enrollment represents a sponsor's untimeliness in making coverage determinations and redeterminations; however, we rely on sponsors adhering to the requirement to identify and send untimely cases to the IRE. Over time, CMS has put into place various methods to evaluate the data integrity of IRE data and safeguard against assigning falsely high ratings to sponsors. CMS is concerned, however, that outside of our data integrity checks, there may be broader issues with the reliability of these measures to evaluate how well Part D sponsors are processing requests for coverage determinations and redeterminations.

As part of our analyses, we want to ensure that we are accurately measuring the Part D appeals processing across contracts. The reliability of a measure decreases with small cell sizes and with low variation across contracts. We have considered both variation in scores across contracts and missing data due to not enough cases to reliably measure performance. Currently, we apply a minimum enrollment threshold for the Appeals Auto-Forward measure, a minimum number of cases reviewed by the IRE for the Appeals Upheld measure in order to address contract size, and we set separate cut points for MA-PDs and PDPs. The minimum number of cases is designed to address reliability issues with the measures.

The reliability of the Part D appeals measures has declined over time, based on standard statistical tests of reliability, defined in the 2019 Final Rule as a measure of the fraction of the variation among the observed measure values that is due to real differences in quality rather than random variation. We have not found this pattern to exist with other Star Rating measures, including the Part C appeals measures. It is unclear to CMS how we can improve our ability to reliably measure performance for these measures.

Due to the Part D appeals measures' low reliability, we will retire these measures from the Star Ratings beginning with the 2022 Star Ratings (based on 2020 data). We are soliciting feedback if

CMS should maintain them as display measures, or retire them completely. CMS has requested feedback each year on new measure concepts in the Part D appeals area, and we continue to be open to studying ideas for ways to monitor Part D access issues. As we consider whether there are replacement measures, we will continue to monitor the current Star Ratings measures that capture Part D access issues, including the Getting Needed Prescription Drugs CAHPS measure and the Complaints measure.

CMS continues to monitor sponsors' processing of Part C and D appeals through Part C and D program audits, annual reporting requirements, and other data and operations monitoring activities. We will continue to monitor plans for potential access to care issues and require plans to correct non-compliance by issuing compliance actions (i.e., notices of non-compliance, warning letters, corrective action notices) as well as imposing enforcement actions (i.e., civil money penalties, intermediate sanctions, or contract terminations) when serious or sustained non-compliance is identified.

Measurement and Methodological Enhancements Under Consideration

CMS is exploring the feasibility of testing web options for some existing beneficiary surveys. We are interested in any feedback plans have based on their experiences conducting web surveys with their members. We are also interested in feedback on the completeness and accuracy of plan data on member email addresses, for example, whether sponsors regularly collect email addresses from members, and if so, do they periodically update them to ensure accuracy.

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 2020, the bid submission deadline is June 3, 2019 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, including all required components, are submitted by the June deadline. Employer Group Waiver Plans are subject to the submission requirements that have not been waived. 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) 2019 Bid Upload Functionality in HPMS," dated May 4, 2018).

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 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 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 42 C.F.R. §422.254(a)(3) must be complete, timely, and accurate or CMS may use its authority to impose sanctions or may choose not to renew the contract (see also 42 C.F.R. §§422.256 and 423.265). Bids containing inaccurate information and/or that 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 42 C.F.R. §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 2020 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 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 2019 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. 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 may 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 2019.

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 Value-Based Insurance Design (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.

Value-Based Insurance Design (VBID) Model Test

In CY 2019, the VBID model is testing whether the additional flexibilities provided under the model allow and incentivize plans to develop and offer interventions that improve health outcomes and lower expenditures for Medicare enrollees; CMS is testing the model in 25 states, and has authorized fourteen MAOs from ten parent organizations in Arizona, Indiana, Massachusetts, Michigan, and Pennsylvania to participate in the model test.

Section 50321 of the Bipartisan Budget Act of 2018, "Adapting Benefits to Meet the Needs of the Chronically Ill Medicare Advantage Enrollees," amends section 1859 of the Social Security Act to require the Secretary to "revise the testing of the [VBID] model … to cover, effective not later than January 1, 2020, all States." For CY 2020, MA plans that meet model eligibility criteria may apply for participation in the VBID model for one or more VBID component(s). For more information, including additional details on the model for CY 2020, please visit the VBID model website at 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 2019. 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/.

Section II – Part C

Overview of CY 2020 Benefits and Bid Review

Portions of this guidance apply to section 1876 cost plans and MA plans (including EGWPs, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Condition 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 MA organizations in advance of the bid submission deadline, and therefore expects all MA organizations to submit their best, accurate, and complete bid(s) on or before the Monday, June 3, 2019 deadline. Any organization whose bid fails the Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, 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 used to review the bids of the various plan types identified in the column headings.

Table 18: 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
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) and 422.100(f)(2)	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 TBC requirements for CY 2020 and has provided guidance on these requirements in each applicable section below. Consistent with last year, MA organizations 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 notify MA organizations that operate non-SNP plans that have fewer than 500 enrollees and SNP plans that have fewer than 100 enrollees and have been in existence for three or more years as of March 2019 (three annual election periods) of CMS' decision not to renew these plans under 42 C.F.R. §422.506(b)(1)(iv) and (b)(2). Plans with low enrollment operating 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.

Upon receipt of this notification, organizations 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 2020, or (2) provide a justification to CMS for renewal. If CMS finds that the low enrollment justification is insufficient, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting justifications will be provided in CMS's notification to the organization. These requirements do not apply to Section 1876 cost plans, employer plans, or Medical Savings Account (MSA) plans.

CMS recognizes there may be certain factors, such as the specific populations served by and geographic location of the plan that led to a plan's low enrollment. SNPs, for example, may justifiably 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. MA organizations should follow CMS renewal/non-renewal guidance (see HPMS memo: Information about Renewal Options for 2020, to be issued in early April 2019 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.

Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Act to deny MA organization 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 2020 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 21, 2018 titled "Medicare Plan Finder (MPF) Plan Version of Out-of-Pocket Cost (OOPC) Model for CY 2019."

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 not evaluate TBC for EGWPs, D-SNPs, SNPs for End Stage Renal Disease (ESRD) Requiring Dialysis, and MSA plans. EGWP benefit packages are negotiated arrangements between employer groups and MA organizations so we believe that the employer would have taken these

costs into account in making such plans available. D-SNP benefits entered into the plan benefit package do not include state benefits and cost sharing relief, which means that a TBC evaluation would not be based on the full benefit and cost sharing package available to enrollees. SNPs for ESRD Requiring Dialysis are not effectively addressed by the OOPC model used for the TBC evaluation and these plans potentially experience larger increases and/or decreases in payment amounts. ESRD SNPs are subject to all other MA standards and CMS will contact plans if CMS identifies large benefit or premium changes (while taking into consideration payment changes) during bid review. Finally, MSAs have unique benefit designs that includes a medical savings account for purposes of paying costs below the deductible.

MA plans offering Part C supplemental benefits that take advantage of the flexibility CMS adopted last year in applying the uniformity requirements ("Part C uniformity flexibility") and/or participating in the VBID model test will be subject to the TBC evaluation for CY 2020; however, benefits and cost sharing reductions (entered in Section B-19 of the PBP) that are offered under Part C uniformity flexibility or as part of 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 MA organizations that the Office of the Actuary extends flexibility on margin requirements so MA organizations can satisfy the TBC requirement.

In mid-April 2019, as in past years, CMS will provide plan specific CY 2020 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 ($135.50).
- Payment Adjustments: (1) county benchmark, and (2) quality bonus payment and/or rebate percentages.

CMS is proposing to maintain the TBC change threshold, for most plans as discussed below, at $36.00 PMPM in CY 2020. 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 2020.

For CY 2020, 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 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 2019.

If CMS provides the MA organization an opportunity to correct CY 2020 TBC issues, following the bid submission deadline, the MA organization 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 MA organization 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 2019 via the HPMS Memorandum titled "CY 2020 MA Bid Review and Operations Guidance."

CMS will maintain the TBC evaluation used during CY 2019 for consolidating or crosswalking plans. CMS will include the operational details of this process in the annual HPMS Memo titled

"CY 2020 Medicare Advantage Bid Review and Operations Guidance," which will be issued in mid-April.

Maximum Out-of-Pocket (MOOP) Limits

Under 42 C.F.R. §§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 cost sharing (i.e., deductibles, coinsurance, and copayments) for Parts A and B services that do not exceed the annual limits set by CMS. In setting these limits under the regulation, CMS uses Medicare Fee-for-Service data to strike a balance between limiting maximum beneficiary out-of-pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. This standard was adopted in the recent final rule 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-F) (83 Fed. Reg. 16440 (Apr. 16, 2018)) and is applicable no earlier than January 1, 2020. As we are setting the limits for coverage beginning January 1, 2020, the new regulatory standard is applicable.

Local and regional PPO plans are required to have two MOOP limits established by CMS, including (a) an in-network and (b) a catastrophic (combined) limit which includes both in-network and out-of-network items and services covered under Parts A and B. HMO-POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or to a combined in- and out-of-network MOOP limit. Although the MOOP requirement is for Parts A and B services, an MA organization 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 19 below displays the CY 2020 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 19: CY 2020 Voluntary and Mandatory MOOP Range Amounts by Plan Type (Analysis Pending)

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

MOOP limits are based on a Medicare FFS data by using the 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 conducted an analysis to help determine the proposed MOOP amounts by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and Original Medicare. To minimize beneficiary disruption, the mandatory MOOP amount will continue to represent 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 will continue to represent approximately the 85th percentile of projected Original Medicare out-of-pocket costs. Although CMS has the authority to adjust MOOP limits annually, based on changes in market conditions and to ensure the sustainability of the MA program and benefit options, we intend to transition changes over time to avoid disruption to benefit designs and minimize potential beneficiary confusion. In addition, we intend to continue communicating MOOP limit changes through the annual Call Letter process to allow for public comment and MA organizations to plan and prepare bid submissions.

Although most dually eligible enrollees are not responsible for paying cost sharing, certain D-SNPs (Medicare Non-Zero-Dollar Cost Sharing Plans) enroll dually eligible enrollees who do pay cost sharing. Also, any dually eligible enrollee exempted from cost sharing who loses his/her Medicaid eligibility may be responsible for cost sharing for the period he/she has lost Medicaid coverage, and remain enrolled in the D-SNP. This also applies to Medicare Zero-Dollar Cost Sharing Plans that apply cost sharing in their Medicare Part A and B benefit package but enroll only dually eligible individuals who are exempt from cost sharing.

D-SNPs have the flexibility to establish zero dollars as the MOOP limit, thereby guaranteeing there is no cost sharing for 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) Cost Sharing Limits to Address Actuarial Equivalent (AE) Cost Sharing Limits and Anti-Discrimination Standards

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis[30] 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) and (6), CMS will evaluate actuarial equivalent cost sharing limits separately in the following service categories for CY 2020: 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 2020.

Whether in 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 (AE) 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.

[30] MA plans may establish lower cost sharing as a mandatory supplemental benefit. See 42 C.F.R. §§ 422.2 (definition of mandatory supplemental benefit) and 422.102(a)(4).

Table 20: 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	1.390	$35.18	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.068	$10.57	$0.26	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 reviews.

Part C Cost Sharing Standards

For CY 2020, 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 21 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. Pursuant to § 422.100, CY 2020 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 2020.

In past years, CMS monitored and required MA organizations to provide justification for cost sharing above a specified amount for cardiac rehabilitation, intensive cardiac rehabilitation and pulmonary rehabilitation. Based on feedback from commenters to simplify the evaluation

process, CMS is planning to add cost sharing standards in section B-3 of the PBP for cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, and supervised exercise therapy (SET) for peripheral artery disease (PAD) services for CY 2020. Please note that CMS intends to have separate PBP data entry for SET for PAD for CY 2020.

Table 21: CY 2020 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	$4,777
Inpatient Hospital – Acute - 10 days	1a	$2,721	$2,177
Inpatient Hospital – Acute - 6 days	1a	$2,461	$1,969
Inpatient Hospital Psychiatric - 60 days	1b	$3,048	$2,438
Inpatient Hospital Psychiatric - 15 days	1b	$2,204	$1,763
Skilled Nursing Facility – First 20 Days[1,2]	2	$20/day	$0/day
Skilled Nursing Facility – Days 21 through 100[1,2]	2	$178/d	$178/d
Cardiac Rehabilitation	3	$50	$50
Intensive Cardiac Rehabilitation	3	$100	$100
Pulmonary Rehabilitation	3	$30	$30
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)	3	$30	$30
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.

MA organizations 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 C.F.R. §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 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).

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 7a includes primary care 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).

MA organizations 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 2020 > 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. We remind organizations that they also must comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, sex, age or disability, including Section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Act of 1975.

Part C Optional Supplemental Benefits

As part of our evaluation to ensure a plan's bid and benefits do not discriminate against enrollees with specific (or high cost) health needs, CMS will review non-employer MA plans' bid submissions to verify that enrollees electing optional supplemental benefits are receiving reasonable value at the MA contract level. CMS considers plan designs for optional supplemental benefits to be non-discriminatory when the total value of the optional supplemental benefits offered by all plans under the contract meet 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 projections, but the plan bids submitted each year are evaluated based on that particular plan year.

Medicare-covered Opioid Treatment Program Services Beginning in CY 2020

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Public Law No. 115-271) establishes opioid use disorder treatment services furnished by Opioid Treatment Programs (OTPs) as a Medicare Part B service beginning in 2020. Opioid use disorder treatment services include: FDA-approved opioid agonist and antagonist treatment medications and the dispensing and administration of such medications; substance use counseling; individual and group therapy; toxicology testing; and other items and services that CMS determines appropriate (excluding meals and transportation). For Medicare coverage and payment, OTPs must be enrolled in Medicare, certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), accredited by a SAMHSA-approved entity, and meet any additional requirements that CMS determines are necessary for health and safety and to ensure the effective and efficient furnishing of OTP services. Medicare Health plans including all MA plan types (HMO, LPPO, RPPO, PFFS, MSA), Section 1876 & Section 1833 cost-based plans, and PACE organizations will be

required to provide OTP services as a Medicare-covered benefit and must enter cost sharing for OTP services in PBP service category B7k as appropriate.

Plans must provide enrollees with a level of access to Medicare-covered services that is consistent with prevailing community patterns of care in the areas where the network is being offered (§422.112(a)(10)).

Non-Opioid Pain Management Supplemental Benefits

CMS encourages MA organizations to consider Part C benefit designs for supplemental benefits that address medically-approved non-opioid pain management and complementary and integrative treatments. For example, "peer support services" delivered by qualified individuals may be effective in facilitating recovery and assist in navigating health care resources. For purposes of completing the PBP, peer support services and/or psychosocial services/cognitive behavioral therapy can be included in counseling services (PBP 14c). In addition, non-Medicare covered chiropractic services (PBP 7b), acupuncture (PBP 13a), and therapeutic massage (PBP B14c) furnished by a state licensed massage therapist, may also be incorporated into plan designs. "Massage" should not be singled out as a particular aspect of other coverage (e.g., chiropractic care or occupational therapy) and must be ordered by a physician or medical professional in order to be considered primarily health related and not primarily for the comfort or relaxation of the enrollee. The non-opioid pain management item or service must treat or ameliorate the impact of an injury or illness (e.g., pain, stiffness, loss of range of motion).

Potential Changes to MOOP and Cost Sharing Standards for CY 2021

CMS requests comments and suggestions on its application and interpretation of MOOP and cost sharing standards for CY 2021 and subsequent years. Under 42 C.F.R. §§ 422.100(f)(4), (5), and (6), and 422.101(d)(2) and (3), as revised in the final rule (CMS-4182-F) issued April 16, 2018, CMS has the authority to: (1) increase the voluntary MOOP limit to another percentile level of Medicare FFS; (2) increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount; and (3) implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits.

For CY 2021, CMS is considering whether to establish a third MOOP limit (referred to as the intermediate MOOP limit) that would be the approximate numeric midpoint between the mandatory and voluntary MOOP limits for the applicable year (i.e., mandatory MOOP limit, less approximately 50% of the numeric difference between the mandatory and voluntary MOOP amounts). CMS believes implementing more than two levels of MOOP and cost sharing limits would encourage plan offerings with lower MOOP limits and result in more favorable benefit designs for beneficiaries. In addition, the percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7% in CY 2011 to 71.0% in CY 2018. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51.2% in

CY 2011 to 22.8% in CY 2018. Although the MA program experienced a small increase in access and enrollment in plans with the lower, voluntary MOOP limit between 2017 and 2018, we believe it is important to maintain the lower MOOP limit near the existing $3,400 limit. As discussed earlier in this draft Call Letter, the Office of the Actuary conducts an 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 current voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs and CMS may adjust the percentile level accordingly for CY 2021 to maintain the lower MOOP limit at or very near the existing $3,400 limit. This approach is consistent with the regulatory standard of striking an appropriate balance between limiting beneficiary out-of-pocket costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages.

The table below illustrates the three MOOP limits (using current information to provide examples) that we are considering under this new application and interpretation of the standards in §§ 422.100(f) and 422.101(d).

Table 22: Proposed CY 2021 MOOP Limits and Examples

MOOP Limit	Approximate Original Medicare Percentile	Examples Based on Current MOOP limits	
		In-network	Combined In- & Out-of Network
Mandatory	95th	$5,001 to $6,700	$7,501 to $10,000
Intermediate	Approximate numeric midpoint*	$3,401 to $5,000	$5,101 to $7,500
Lower	85th	$0 to $3,400	$0 to $5,100

* The intermediate MOOP limit would be based on the mandatory MOOP limit, less approximately 50% of the numeric difference between the mandatory and voluntary MOOP amounts.

CMS is also considering additional flexibilities for the service category cost sharing standards described below for MA plans that elect to use the intermediate MOOP or the lower MOOP. These changes would afford such MA plans that adopt the lower or intermediate MOOP limits greater flexibility in establishing Parts A and B cost sharing than is available to MA plans that adopt the higher, mandatory MOOP limit. Flexibilities under consideration include:

- Adding one or two additional inpatient length of stay scenarios for both acute and psychiatric care. The cost sharing standard for mandatory and lower voluntary MOOP limits would continue to be based on 100% and 125% of estimated Medicare FFS cost sharing, respectively. The intermediate MOOP limit cost sharing standard would be

based on the approximate mid-point between the mandatory and lower voluntary cost sharing limits. (We note that overall MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis.)

- Establishing nominal cost sharing limits during the first 20 days of a SNF stay for both lower and intermediate voluntary MOOP limits. Per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount, and 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). For example, the per-day cost sharing limit during the first 20 days of a SNF stay could be $0 for mandatory, $10 for intermediate, and $20 for the lower MOOP limits, so long as the overall actuarial equivalence for the SNF benefit is met.

- Varying cost sharing limits across all three proposed MOOP limits for emergency care/post stabilization care (PBP B4a), home health services (PBP B6a), and physician specialist services (PBP B7d). We intend to include varying cost sharing across additional services in future years as part of this flexibility.

- Introducing new cost sharing limits for observation services (PBP B9a) and ambulance services (PBP B10a) that would use the same cost sharing across all three MOOP limits for CY 2021. As previously stated, we may vary cost sharing for these two services in future years as part of this flexibility.

CMS requests comment on its application and interpretation of MOOP limits and cost sharing standards for CY 2021, as well as changes for future years. Our goal is to support innovation, improve available benefit offerings, and provide beneficiaries with affordable MA plans that are tailored for their unique healthcare needs and financial situation.

Special Supplemental Benefits for the Chronically Ill (SSBCI)

In last year's Call Letter, CMS expanded its interpretation of how a benefit may be a "health care benefit" that is approvable as a supplemental benefit offered by an MA plan under section 1852(a)(3) of the Act; CMS has historically interpreted the statute as requiring a supplemental benefit to (1) not be covered by Original Medicare, (2) be primarily health related, and (3) require the MA plan to incur a non-zero direct medical cost. Specifically, CMS expanded its definition of "primarily health related" to consider items or services used to "diagnose, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization."

Separately, the Bipartisan Budget Act of 2018 (Public Law No. 115-123) amended section 1852(a) of the Act to further expand supplemental benefits that may be offered by Medicare Advantage plans, herein referred to as Special Supplemental Benefits for the Chronically Ill

(SSBCI). SSBCI include supplemental benefits that are not primarily health related and/or offered non-uniformly to eligible chronically ill enrollees, as discussed below. We believe the intended purpose of the new category of supplemental benefits is to enable MA plans to better tailor benefit offerings for the chronically ill population, address gaps in care, and improve specific health outcomes.

Section 1852(a)(3)(D)(ii), as amended, defines a chronically ill enrollee as an individual who:

1) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
2) has a high risk of hospitalization or other adverse health outcomes; and
3) requires intensive care coordination.

For CY 2020, CMS will consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.

MA plans do not have to submit the processes by which they identify chronically ill individuals that meet this definition. However, all three criteria must be met for an enrollee to be considered chronically ill, and thus eligible for the SSBCI authorized under section 1852(a)(3)(D) beginning CY 2020. CMS expects MA plans to develop and document mechanisms to identify chronically ill enrollees based on the definition above.

CMS solicits comment on whether plans should have flexibility to determine what is a chronic condition that meets the statutory standard ("is life threatening or significantly limits the overall health or function of the enrollee") and if CMS should consider alternative approaches to determining what meets this criterion. By CY 2021, CMS will convene a technical advisory panel to periodically update the list of chronic conditions for MA plans to use when determining if an enrollee is chronically ill for purposes of section 1852(a)(3)(D)(iii).

Beginning CY 2020, as amended, section 1852(a)(3)(D) does not require supplemental benefits to be primarily health related when they are provided to chronically ill enrollees if certain conditions are met. MA plans will have the ability to offer a "non-primarily health related" item or service to chronically ill enrollees if the SSBCI has *a reasonable expectation of improving or maintaining the health or overall function of the enrollee* as it relates to the chronic disease.

In general, MA organizations have broad discretion in developing items and services they may propose as SSBCI so long as the item or service has a *reasonable* expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic disease. Such items and services may include, but are not limited to, transportation for non-medical needs, home-delivered meals (beyond the current allowable limited basis), food and produce. However, such items and services may <u>not</u> include capital or structural improvements to the home of the

enrollee that could potentially increase property value (e.g., permanent ramps, and widening hallways or doorways) in order to ensure that enrollees are receiving an appropriate level of benefits and to avoid any anti-kickback implications or taxable improvements. Additionally, items and services may not be offered to induce enrollment.

MA coordinated care plans are required to "coordinate MA benefits with community and social services generally available in the area served by the MA plan" (§422.112(b)(3)). MA coordinated care plans may not classify such coordination or characterize otherwise available community services and resources as plan benefits. MA plans are reminded that the plan must incur a non-zero direct medical cost for all supplemental benefits; in the case of SSBCI, such incurred cost should be a non-administrative cost for providing the benefit. However, CMS notes that plans may contract with community-based organizations to provide new supplemental benefits. Community-based organizations can also help determine whether an individual meets the eligibility requirements for SSBCI. These organizations may already be providing services in the community and, in some cases, have contractual arrangements with Medicaid managed care or MA plans. CMS is soliciting comments on the limits of these supplemental benefits discussed here and whether we should permit consideration of other factors, like financial need, in determining permissible supplemental benefits for chronically ill enrollees.

The Act also allows CMS to waive the uniformity requirements with respect to SSBCI, effective in CY 2020. As discussed in the CY 2019 Final Rule (83 FR 16440, 16481-82), the waiver authorized under section 1852(a)(3)(D)(ii) of the Act gives CMS the authority to allow MA plans to offer chronically ill enrollees supplemental benefits that are not uniform, either for all enrollees or for all chronically ill enrollees. Thus, beginning CY 2020, CMS will use this waiver authority to allow MA plans to vary, or target, SSBCI as they relate to the individual enrollee's specific medical condition and needs. In other words, SSBCI under this waiver may not be provided to a chronically ill enrollee if that benefit does not have a reasonable likelihood of improving that specific enrollee's health or overall function as related to the specific chronic illness. We expect MA plans to develop objective criteria (e.g., health risk assessments) and maintain detailed documentation for determining when one chronically ill enrollee is eligible for a particular item or service and another is not. Note that maintaining detailed internal documentation is necessary to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS.

We remind plans that SSBCI are supplemental benefits and, therefore, must not be items or services covered by original Medicare. Non-primarily health related SSBCI offered under section 1853(a)(3)(D) may be proposed as supplemental benefits in a PBP. Plans are expected to briefly describe their benefits in the PBP in category B19 (CMS-HCC or ICD-10 codes must not be included in the note). The final determination of benefit status is made by CMS during the annual benefit package review.

We also remind MA plans that coverage requests from enrollees or providers, including requests for any supplemental benefits, should be treated similar to requests for other benefits furnished by an MA plan. If a request concerning coverage of a discrete item or service submitted to a plan fits within one of the actions defined as an organization determination under 42 C.F.R. § 422.566(b), then the coverage decision is subject to the Subpart M appeals process. Furthermore, MA plans are responsible for clearly identifying in the plan's Evidence of Coverage (EOC) what will and will not be covered. Any limitations on coverage should be clearly noted in the EOC, including the process and/or criteria for determining eligibility to receive a SSBCI under the new authority beginning CY 2020. We expect MA plans will establish reasonable safeguards to ensure enrollees are appropriately directed to care.

Provider Directories

The accuracy of MAO provider directories continues to be a concern. Inaccurate provider directories may impede access to care and bring into question the adequacy and validity of the MAO's provider network.

CMS recently concluded the third year of online provider directory reviews. We have reviewed the accuracy of at least one online provider directory from virtually every parent organization with a MA contract. Through the review process, we have gained tangible insight into directory accuracy, including what data elements are most likely to be inaccurate. We have shared individual results with each organization so they may correct their deficiencies. In addition, we have publicly posted a report on our CMS website each year. This report shared our review methodology, findings, and common drivers of deficiencies, as well as the individual plan results and corresponding compliance actions taken by CMS.

The data collected demonstrates there has been a lack of improvement in the accuracy of provider directories over the past three years. While we acknowledge and appreciate the efforts of MA organizations and others to improve directory accuracy, MA organizations still have not achieved acceptable levels of accuracy. However, we also recognize that achieving directory accuracy is a complex problem. One common struggle expressed by industry is that there is no centralized repository for provider directory data, often referred to as a "source of truth." As a consequence, the current process of verifying the accuracy of provider information can present an undue burden on providers, as multiple plans, in an effort to validate their directory information, ask providers the same validation questions. CMS will continue its focus on and work with stakeholders to improve provider directory accuracy.

Physical Exam Supplemental Benefit for Special Needs Plans (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 supplemental benefit offerings is one way to achieve this goal. Beginning CY 2020, SNPs may offer the Physical Exam supplemental benefit

that is currently available to Non-SNP MA plans. As discussed in section 30.1 of the Medicare Managed Care Manual, a supplemental physical exam benefit would provide services beyond those services required to be provided in the Annual Wellness Visit. Additionally, SNPs are still required to provide a higher level of care coordination and disease management as integral to the "special" care provided to their enrolled beneficiaries through the plan's development and CMS' approval of the SNP Model of Care (MOC) (42 CFR 422.152(g)). Therefore, the physical exam supplemental benefit would provide services beyond what is required as part of the SNP's regular care coordination and disease management responsibilities. To be considered an Annual Physical Exam that qualifies as a supplemental benefit by CMS, the exam would be provided by a qualified physician or qualified non-physician practitioner.

D-SNP Administrative Alignment Opportunities

CMS remains committed to providing administrative flexibility that facilitates efforts by state Medicaid agencies and MA organizations to use Dual Eligible Special Needs Plans (D-SNPs) to integrate coverage of Medicare and Medicaid benefits. That commitment is evidenced by our recent CY 2019 final rule (CMS-4182-F, 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) codifying our authority to permit default enrollment of newly Medicare- eligible individuals into integrated D-SNPs at 42 C.F.R. §422.66(c)(2) and, at 42 C.F.R. §422.60(g)(1)(iii), to allow passive enrollment to preserve continuity of care and integrated care related to D-SNP non-renewals or state Medicaid managed care organization procurements.

For those D-SNPs that provide both Medicare and Medicaid benefits to all their members—meaning D-SNPs with exclusively aligned Medicare and Medicaid enrollment—we have provided flexibility to integrate the description of Medicare and Medicaid benefits into the Summary of Benefits and other member materials. We are currently working with Massachusetts, Minnesota, and New Jersey to update or develop new state-specific models of integrated materials for fully integrated dual eligible SNP (FIDE SNP). For D-SNPs whose membership is exclusively comprised of dually eligible individuals who are exempt from Medicare cost sharing—zero-dollar cost sharing D-SNPs—we have provided the opportunity for plan materials and the Medicare Plan Finder on Medicare.gov to reflect the $0 for all benefits covered by Medicare Parts A and B.

Through the Medicare-Medicaid Coordination Office, we provide state Medicaid agencies with technical assistance and information on plan performance and audit results of their contracted D-SNPs so that the quality of Medicare services delivered by those D-SNPs can inform state contracting strategies. We have also provided states the opportunity to ensure that state expectations for the delivery of managed long term services and supports and behavioral health services are integrated into the model of care employed by the D-SNPs that deliver those benefits.

We seek comment from stakeholders on all the initiatives described above, including the operational challenges that MA organizations or states may face in accessing these mechanisms for Medicare-Medicaid integration and any requests to clarify relevant policies in our guidance. In addition, we seek suggestions for additional administrative alignment initiatives we could pursue either through rulemaking or through subregulatory guidance.

These administrative steps can improve the member experience in integrated D-SNPs and the number of beneficiaries who benefit from integrated Medicare and Medicaid coverage under such plans. Enrollment in FIDE SNPs has increased to 170,000 in 2018 from around 96,000 in June 2013.[31] We also note that our recent CY2020 Proposed Rule includes proposals under section 50311 of the Bipartisan Budget Act of 2018 (P.L. 115-123) to establish new standards for integration of Medicare and Medicaid services under D-SNPs and unify appeals and grievance procedures for certain D-SNPs.

Finally, the Bipartisan Budget Act of 2018 designates the Federal Coordinated Health Care Office (also known as the Medicare-Medicaid Coordination Office, or MMCO) to act as the Secretary's dedicated point of contact for states regarding the use of D-SNPs to integrate Medicare and Medicaid benefits and address misalignments between the two programs. We invite states with questions regarding D-SNP policy to contact MMCO via our dedicated mailbox at MMCO_DSNPOperations@cms.hhs.gov and to avail themselves of the technical assistance provided by the Integrated Care Resource Center at https://www.integratedcareresourcecenter.com/.

D-SNP "Look-alikes"

In its June 2018 report to Congress, the Medicare Payment Advisory Commission (MedPAC) described the recent emergence of MA D-SNP "look-alike" plans with high proportions of dually eligible enrollees.[32] MedPAC found that D-SNP look-alike plan benefit packages in California, which are approved by CMS as conventional MA products, are characterized by high cost sharing for Medicare Parts A and B benefits that most dually eligible beneficiaries are not required to pay, and Part D premiums and deductibles that are covered by the Part D Low Income Subsidy. Such benefit designs are unappealing to non-dually eligible Medicare beneficiaries who would have to pay these costs out-of-pocket. For CY 2019, we have seen bids for an increasing number of MA plans with plan benefit packages similar to those of current D-SNP look-alikes.

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[31] See Special Needs Plan (SNP) data at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html#.

[32] See June 2018 MedPAC Report to Congress at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.

D-SNP look-alike plans appeared in certain markets after California placed enrollment restrictions on D-SNPs in those areas with MMPs participating in the Financial Alignment Initiative—the managed care vehicle that the state is prioritizing for integration of Medicare and Medicaid coverage. Marketing of D-SNP look-alike plans appears to be highly targeted to dually eligible beneficiaries—95 percent of D-SNP look-alike plan members were dually eligible in 2016—and enrollment has surged from around 5,000 in 2013 to over 95,000 in 2017 within the California markets.

CMS has received a number of anecdotal reports from multiple sources across multiple states about misleading marketing and training materials for agents and brokers that misrepresent the characteristics of such look-alike plans and describe them as designed specifically for dually eligible beneficiaries. Marketing of such D-SNP look-alike plans to full benefit dually eligible beneficiaries may undermine state efforts to integrate Medicare and Medicaid benefits through their contracted D-SNPs or MMPs. To better serve the high need dually eligible population, the Medicare Improvements for Patients and Providers Act (MIPPA) and implementing regulations required D-SNPs to provide periodic health risk assessments (HRAs) and develop individualized care plans (ICPs) for their members, to develop and seek CMS approval for their model of care, and to enter into contracts with states to provide or arrange for Medicaid benefits. Further, the Bipartisan Budget Act imposes new integration requirements for D-SNPs beginning in CY2020. Because they are not D-SNPs, despite having membership almost exclusively of dually eligible beneficiaries, these look-alike plans do not have state contracts or approved models of care. D-SNP look-alike plans are also not required to implement quality improvement programs that include periodic HRAs of their members and development of ICPs for their members.

We remind MA organizations that section 30.7 of the 2019 Medicare Communications and Marketing Guidelines clarifies that MA plans that are not D-SNPs may not: (i) imply that their plan is designed for dually eligible beneficiaries; (ii) claim that they have a relationship with the state Medicaid agency, unless the MA plan (or its parent organization) has contracted with the state to coordinate Medicaid services, and the contract is specific to that MA plan (not for a separate D-SNP or MMP); or (iii) target their marketing efforts exclusively to dually eligible beneficiaries. This guidance is based generally on regulatory prohibitions on misleading or confusing Medicare beneficiaries about the MA plan in 42 C.F.R. § 422.2268. CMS plans to monitor D-SNP look-alike marketing, including through in-field surveillance, and is considering additional regulatory, subregulatory, and compliance steps to ensure that plans' marketing to dually eligible beneficiaries is compliant with CMS rules. Plans found to be out of compliance may be subject to compliance action.

We also seek comment on the impacts of D-SNP look-alike plans for Medicare beneficiaries, including dually eligible individuals; the MMPs, D-SNPs, and other healthcare providers who serve such beneficiaries; state Medicaid agencies; and the coordination of Medicare and Medicaid coverage. We are particularly interested in the extent to which the proliferation of D-SNP look-alike plans affects:

- Informed consumer choice by Medicare beneficiaries;
- Competition and innovation among Medicare Advantage plans;
- The provision of high-quality coordinated care that addresses the full spectrum of dual eligible individuals' care and service needs;
- State Medicaid policy and operations;
- Financial incentives for providers and plans across Medicare and Medicaid;
- The potential to reduce provider burden in billing for Medicaid payment of Medicare cost sharing; and
- Development and sustainability of integrated care products for dually eligible beneficiaries, through which an enrollee can receive all Medicare and Medicaid services from one organization.

Comments will inform future policy development. To the extent that D-SNP look-alike plans impede CMS or state policy priorities in these and other areas, we would consider future rulemaking.

Parts A and B Cost-sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program

In the 2017 and 2019 Call Letters, CMS reminded plans of their obligations under 42 C.F.R. §422.504(g)(1)(iii) to educate network providers about Qualified Medicare Beneficiary Program (QMB) billing rules and to maintain procedures that ensure network providers do not discriminate against enrollees based on their payment status, e.g., QMB.

All MA providers, suppliers, and pharmacies must refrain from collecting Medicare cost-sharing for covered Parts A and B services from individuals enrolled in the Qualified Medicare Beneficiary (QMB) Program (note: pharmacists may still collect Part D cost-sharing per 42 C.F.R. §423.782). As a reminder, Medicare-Medicaid Plans (MMPs) in the capitated model of the Financial Alignment Initiative (FAI) and Programs of All-Inclusive Care for the Elderly (PACE) do not charge coinsurance, copays, and deductibles for any Medicare Parts A or B services.[33]

To reinforce billing requirements, simplify compliance, and prevent improper billing, CMS has strongly encouraged organizations to affirmatively inform providers if member cost-sharing liability is zero dollars.

[33] Elimination of cost-sharing for enrollees of Medicare-Medicaid Plans may be found in the CMS Memorandum of Understanding with the state Medicaid agency for each demonstration, on the CMS website at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ApprovedDemonstrationsSignedMOUs.html; for PACE enrollees, it may be found in section 1894(b)(1)(A)(i) of the Social Security Act.

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. (See June 21, 2017 HPMS memo "Qualified Medicare Beneficiary Program Enrollee Status Resources.")

Prior to claims submission, MA plans can provide real-time information and indicators through automated eligibility-verification systems, online provider portals and phone query mechanisms; plans can also provide QMB status on member ID cards so that information is available when an individual presents the card at the pharmacy counter.

A new method exists for plans to notify pharmacies of a member's QMB status for Part B drugs claims at the point of sale. The National Council for Prescription Drug Plans (NCPDP) developed a new Benefit State Qualifier (BSQ) Value 51 to indicate to pharmacy providers that the individual is a QMB and cannot be liable for cost-sharing for Part B drugs.

The NCPDP description for BSQ value 51 is as follows:

Not paid under Part D, paid under Part C benefit (for MA-PD plan). Beneficiary is a Qualified Medicare Beneficiary - pharmacy should not attempt to collect cost-share, but instead should attempt to bill COB to Medicaid coverage.

CMS encourages MA-PDs to implement BSQ value 51 for additional protection for the QMB individual and to inform pharmacy providers and assist them in proper billing for this population.

Once claims are processed, plans can clearly indicate members owe $0 directly on the Explanation of Payment statements for providers. CMS has encouraged plans to incorporate Qualified Medicare Beneficiary (QMB) information in the Provider Remittance Advice (RA) based upon changes CMS reintroduced to the Medicare Fee for Service (FFS) RA on July 2, 2018 (see updated Change Request 9911, discussed in the CMS MLN Matters Number MM10433, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10433.pdf). CMS initially launched the FFS RA changes for QMB claims in 2017 but quickly suspended them to address formatting and other issues impacting states' ability to process QMB cost-sharing claims. CMS notified plans to rescind any RA changes based on the 2017 changes instead of the July 2018 changes to avoid the negative impacts on secondary claims processing. (See April 3, 2018 HPMS memo "Qualified Medicare Beneficiary Program Information in Remittance Advice and Explanation of Benefits.")

Medicare Advantage Organizations Crossing Claims over to Medicaid Agencies

For most dually eligible individuals, Medicaid is responsible for Medicare deductibles and coinsurance for services under Parts A and B, within certain limits. This is true regardless of whether the individual is in Medicare Fee or Service (FFS) or a MA plan. Since 2001, CMS automatically forwards claims under Medicare FFS to state Medicaid agencies and other

secondary payers to process for covering cost sharing. Under this automatic claims crossover process, providers do not need to submit separate claims to both Medicare and the state Medicaid agency, which greatly reduces provider burden.

A growing number of dually eligible individuals receive Medicaid benefits through Medicaid managed care plans, which may include the coverage of Medicare cost sharing. In 2016, we modified regulations at 42 C.F.R. §438.3(t) to require that certain Medicaid managed care plans, including Medicaid managed care organizations and prepaid health plans, responsible for Medicare cost sharing for dually eligible individuals enroll in Medicare's automated crossover process. In the recently published Notice of Proposed Rulemaking (see 83 FR 57264), we propose to modify the requirement so that the state's contract with a Medicaid managed care plan must ensure the plan receives Medicare crossover claims, but provides states the flexibility to determine on how to do so. We believe the proposed changes enhance state flexibility while continuing to reduce administrative burden on providers.

For providers serving dually eligible individuals in MA, however, there is no guarantee of an automated crossover process. This means the providers must directly bill Medicaid in addition to billing the MA plan. In areas in which a state Medicaid agency has delegated coverage of Medicare cost sharing to a Medicaid managed care plan, the provider has to take the extra step of identifying whether a state Medicaid agency or Medicaid managed care plan is responsible for covering the Medicare cost-sharing for dually eligible individuals, and then directly bill that state Medicaid agency or managed care plan.

We are seeking to identify ways to extend the benefits of the crossover process for cost-sharing claims for dually eligible individuals in MA plans. To that end, we seek comments on ways to promote MA plans automatically crossing over cost-sharing claims to state Medicaid agencies and Medicaid managed care plans for dually eligible individuals.

We welcome comments on the scope of the following issues related to MA plans crossing cost-sharing claims to Medicaid for dually eligible individuals:

- Challenges or opportunities faced by providers who are directly filing these claims with each secondary payer under the current system;
- Impact on providers and plans if MA plans were to implement an automated crossover process to the appropriate Medicaid secondary payer;
- Impact on the state when MA cost-sharing claims are not included with the existing Medicare FFS claims crossover process;
- Obstacles to implementing a standardized process to crossover cost-sharing claims; and
- Other prevalent challenges to aligning the cost-sharing claims between MA plans and state Medicaid agencies or Medicaid managed care plans.

Please include specific examples when possible while avoiding the transmission of protected information. Please also include a point of contact who can provide additional information upon request.

Interoperability and Prior Authorization Coordination

CMS is working with partners in the private sector to promote interoperability. In 2018, CMS began participating in the Da Vinci project, a private-sector initiative led by Health Level 7 (HL7), a standards development organization. For one of the use cases under this project – called "Coverage Requirements and Documentation Rules Discovery" – the Da Vinci project developed a Fast Healthcare Interoperability Resources (FHIR) standard that was balloted in September 2018 and performed ballot comment reconciliation between September 2018 and December 2018. In June 2018, in support of the Da Vinci project, the CMS Medicare FFS program began: (1) developing a prototype Documentation Requirement Lookup Service for the Medicare FFS program; (2) populating it with the list of items/services for which prior authorization is required by the Medicare FFS program; and (3) populating it with the documentation rules for oxygen and Continuous Positive Airway Pressure (CPAP) devices required by the Medicare FFS program. More information about the FFS Medicare program's efforts to support these Da Vinci use cases can be found at: http://go.cms.gov/MedicareRequirementsLookup.

We encourage all payers, including but not limited to Medicare Advantage organizations and Part D plan sponsors, to follow CMS's example and align with the Da Vinci Project's Coverage Requirements and Documentation Rules Discovery work by: (1) developing a similar lookup service; (2) populating it with their list of items/services for which prior authorization is required; and (3) populating it with the documentation rules for, at least, oxygen and CPAP. By taking this step, MA organizations and Part D plan sponsors can join CMS in helping to build an ecosystem that will allow providers to connect their EHRs or practice management systems and efficient work flows with up-to-date information on which items and services require prior authorization and what the documentation requirements are for various items and services under that patient's current plan enrollment.

Request for Information - Barriers for MA Plans or Providers in using Risk Based Arrangements for Pharmacy Benefits

CMS is soliciting comment on the potential use of risk based arrangements for pharmacy benefits in contracts between MA plans and contracted providers. Risk-based arrangements in contracting for pharmacy benefits may be another tool to drive down the cost of Part B drugs in MA and Part D drugs for MA-PD plans. CMS respectfully requests information on the barriers, feasibility, and benefits/drawbacks for these types of arrangements between MA plans and contracted providers. We note that Part D rules prohibit a Part D sponsor from requiring a pharmacy to accept insurance risk as a condition of participation in its contracted pharmacy

network. This request for information is not related to that Part D prohibition; our focus is to collect information about the potential for risk based arrangements between MA plans and non-pharmacy providers.

Section III – Part D

Formulary Submissions

CY 2020 Formulary Submission Windows

The CY 2020 HPMS formulary submission window will open this year on May 13, 2019 and close at 11:59 p.m. PDT on June 3, 2019. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 3, 2019 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 3 deadline will result in denial of that bid submission.

Following the review and approval of initial CY 2020 formulary submissions, a subsequent limited update window will be provided in August 2019. During this window, Part D sponsors may add drugs that are new to the Formulary Reference File (FRF), and may also make negative changes to existing formulary drugs, only if the affected drug is replaced by an equivalent generic or therapeutically similar drug (at the same or more enhanced formulary placement). We do not expect sponsors to make significant enhancements to existing formulary drugs during this window, since the formulary version that was initially submitted to CMS for review was considered in the bid and Part D benefits review. There will also be an enhancement-only formulary window in September.

CY 2020 Formulary Reference File

CMS intends to release the first CY 2020 FRF in March 2019. 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 2019, in order to assist plan sponsors in satisfying meaningful difference and MA TBC requirements prior to bid submission. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

CMS intends to update the CY 2020 FRF prior to the June 3 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2013 and 2015, 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 CY 2020 FRF and the June 3 deadline, CMS is unable to accommodate an updated version of the 2020 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS advises plan sponsors that any newly added drugs on the May release of the CY 2020 FRF will not be included in the 2020 OOPC model.

Changes for CY 2020 Formulary Submission

For the CY 2020 plan year, CMS is proposing changes to the following formulary-related files:

Excluded Drug File

The Excluded Drug file is a supplemental file submitted by plans sponsors who intend to provide coverage of Part D excluded drugs as part of their benefit offering. Only enhanced alternative plan designs have the ability to offer this type of benefit. The current file format is based on National Drug Codes (NDCs) that are submitted by Part D sponsors, which are then validated against an internal CMS excluded NDC file. NDCs that are submitted by sponsors but not contained within the CMS validation file are rejected, which necessitates a subsequent resubmission 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 Excluded Drug file submissions, CMS will provide plans with an Excluded Drug reference file for CY 2020. We propose that this file would mirror the format of the current FRF. Providing the file of acceptable RXCUIs in advance to plan sponsors will enable them to better prepare their files, significantly reduce the size of the files, and simplify the submission and review process.

Improving Access to Opioid-Reversal Agents

Combating the opioid crisis is a top priority for the U.S. Department of Health and Human Services (HHS). The HHS Opioid Strategy includes targeting the availability and distribution of opioid-reversal agents as one of its five pillars. On April 5, 2018, the Surgeon General released an advisory statement[34] emphasizing the importance of the opioid-reversal agent naloxone, recommending that more individuals have access to this potentially lifesaving drug, as well as calling for expanded access to evidence-based treatment for opioid use disorder. According to the Centers for Disease Control and Prevention (CDC), the leading cause of injury death is unintentional opioid overdoses, accounting for 42,249 deaths in 2016 alone.[35] The rate of opioid overdoses in 2016 was a record high, and five times that seen in 1999.[36] It is a top priority for CMS to address the prescription opioid overdoses by ensuring appropriate access to potentially lifesaving interventions such as naloxone. When naloxone is administered timely, it can rapidly reverse most opioid overdoses. Naloxone can save lives by blocking the effects of opioids and quickly restore normal breathing. Additionally, various naloxone formulations are on the market. More recently, there has been a call to increase access of naloxone through community-based distribution, state regulations, or other naloxone access laws. An estimated 45 states and the District of Columbia permit third-party prescriptions (i.e., prescriptions written to a third-party

[34] https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html.

[35] See https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.

[36] See https://www.cdc.gov/drugoverdose/epidemic/index.html.

who is not at risk of overdose but who can administer naloxone to an at-risk individual).[37] Also, an estimated 49 states permit non-patient specific prescriptions through pharmacy standing orders, collaborative practice agreements, or protocol orders to authorize pharmacists to dispense naloxone without a separate prescription written from the provider.[38]

Formulary and Benefit Designs

CMS is aware that high out-of-pocket costs could be a potential barrier to accessing opioid-reversal agents. In 2018, the top 10 PDPs and top 10 MA-PD plans by enrollment have placed naloxone prefilled syringes and nasal spray products primarily on Preferred Brand and/or Non-Preferred drug tiers, with average non-LIS beneficiary out-of-pocket costs of $31 and $42, respectively. In order to improve access to opioid-reversal agents, we strongly encourage Part D sponsors to, at a minimum, place naloxone products on their plan's generic tier(s). We further encourage the placement of these products on the Select Care Tier (i.e., a tier that provides for $0 or low cost-sharing) for those plans that utilize such a tier model. Providers should use clinical judgment to determine which dosage form would be most appropriate for their patients or their patients' caregivers. Benefit designs that inappropriately restrict access to naloxone products for beneficiaries for which the drug is clinically appropriate will not be approved.

Naloxone Co-Prescribing

Consistent with CDC Guideline recommendations[39] and HHS guidance,[40] CMS encourages the co-prescribing of naloxone with opioid prescriptions to beneficiaries who are at an increased risk for opioid overdose. Studies have indicated that the co-prescribing of naloxone with prescription opioids has significantly lowered emergency department visits and decreased the number of opioid-related deaths by 50%.[41,42]

In an effort to improve access to naloxone where clinically appropriate, CMS encourages plan sponsors to ensure authorizations are in place for beneficiaries who are more susceptible to opioid-associated harm (e.g., claims history of $\geq$ 50 morphine milligram equivalents per day, concurrent benzodiazepine use). Part D sponsors could also consider more innovative approaches, such as patient-specific pharmacy messaging to alert pharmacists to provide

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[37] See https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf.

[38] See https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf.

[39] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

[40] See https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf.

[41] Coffin PO, Behar E, Rowe C, Santos GM, Coffa D, Bald M, and Vittinghoff E. Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain. Ann Intern Med. 2016; 165:245-252.

[42] Albert S, Brason FW, Sanford CS, Dasgupta N, Graham J, Lovette B. Project Lazarus: Community-Based Overdose Prevention in Rural North Carolina. Pain Medicine. 2011; 12:S77-S85.

naloxone to at risk beneficiaries taking opioids in states that allow for standing naloxone orders. CMS also recommends targeted education of prescribers and enrollees on co-prescribing of naloxone to prevent accidental overdoses and to sensitively address the needs of persons with opioid use disorders. While CMS understands that co-prescribing of naloxone cannot guarantee the prevention of opioid overdose deaths, it is an accessible intervention that can potentially reverse prescription and illicit opioid overdoses very quickly.

We welcome comments from stakeholders on the feasibility of co-prescribing naloxone with concurrent opioid prescriptions when clinically appropriate as defined by the CDC Guidelines and HHS guidance.[43]

Because some patients may need naloxone to address opioid addiction for which they are not receiving legitimately prescribed medication, prescription of opioids at a certain morphine equivalent should not be the only factor considered by plans when determining the clinical appropriateness of naloxone prescribing.

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 initially noted in the CY 2017 Call Letter, 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. We also note that drug addiction may be considered a disability under Federal civil rights laws and a covered entity is required to provide nondiscriminatory access to its health care programs, including evidence-based opioid use disorder treatment and recovery services, such as MAT where the law requires.[44]

Part D PBP MRx Enhancements

CMS recognizes that full closure of the coverage gap in CY 2020 may potentially impact how sponsors want to design their Part D benefit. CMS conducted a survey of plan sponsors in October 2018 to understand if the current PBP structure provides sufficient flexibility to describe

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[43] See footnotes 17 and 18.

[44] See HHS' Office for Civil Rights website for more information about nondiscrimination and opioid use disorder at https://www.hhs.gov/civil-rights/for-individuals/special-topics/opioids/index.html.

intended benefits specifically related to the closure of the coverage gap. The feedback we received may be used to inform and guide future PBP system changes (i.e., for CY 2021 or beyond). Until such time that proposed enhancements can be considered, references to the coverage gap phase of the benefit will remain unchanged in the PBP, and in references noted below for the Part D Benefit Parameters section of the Call Letter.

Medication Therapy Management (MTM)

Annual Eligibility 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 specified in 42 C.F.R. §423.104(d)(5)(iv). The 2019 MTM program annual cost threshold is $4,044. The 2020 MTM program annual cost threshold will be the 2019 annual cost threshold adjusted based on the annual percentage increase and will be finalized in the 2020 Final Call Letter.

A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The 2020 MTM guidance memo will be released approximately one month before the 2020 MTM program submission deadline. The 2020 MTM guidance memo will include the MTM program submission template. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Comprehensive Medication Review Summary Standardized Format

Part D sponsors must offer each beneficiary enrolled in their MTM program a comprehensive medication review (CMR). An individualized, written summary in CMS' standardized format must be provided following each CMR. The current format, instructions, and frequently asked questions are posted on the CMS MTM web page at CMS.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html).

The standardized format must be approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA). OMB has approved the current version of the MTM standardized format (CMS-10396; OMB control number: 0938-1154) until August 31, 2020. In 2018, CMS gathered feedback from consumers as well as other stakeholders through a limited number of cognitive interviews to determine what improvements could be made to the

format. Based on the results of this feedback, we will propose revisions to the standardized format with the intent of optimizing the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors. The revised format will be available for public comment through the PRA process before submission to OMB for approval in 2020. An HPMS memo will be issued when the revised format is available for public comment.

Part D Benefit Parameters for Non-Defined Standard Plans

Part D sponsors have the ability to offer non-defined standard plans, under which they can modify certain benefit parameters, including tiered cost sharing. The CY 2020 Part D benefit parameters for Non-Defined Standard Plans are set forth in Table 23 below, addressing three key areas: PDP meaningful difference, tiered cost-sharing and Specialty Tier thresholds. Pursuant to 42 C.F.R. §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, as defined under §423.265(b)(2), with respect to key characteristics such as cost-sharing, formulary structure, or benefits offered. As part of the final rule (CMS-4182-F) issued in April 2018, CMS eliminated 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. As a result, we saw an increase of about 15% in the number of standalone PDPs, largely due to plan sponsors offering a second enhanced plan. 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. Pursuant to 42 C.F.R. §423.578(a)(6)(iii), Part D sponsors may exempt a formulary tier in which it places very high cost Part D drugs and biological product items from its tiering exception process, known as the Specialty Tier. CMS provides the Specialty Tier threshold amount for the upcoming contract year annually in the Call Letter. Please refer to the Specialty Tiers section below for additional detail. Each of these benefit parameters are based on data from the previous contract year, and are therefore subject to change from year to year.

Benefit Review

As part of the Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Notice of Proposed Rulemaking (NPRM), which appeared in the November 28, 2017 issue of the Federal Register, CMS sought stakeholder input on how to best define the meaningful difference between basic and enhanced stand-alone prescription drug plans (PDPs). Although we received very few specific recommendations, work is underway to refine the way in which we establish this requirement. We are mindful, however, that a common request from stakeholders is for stability in the meaningful difference threshold. Therefore, we propose to maintain the minimum monthly cost-sharing out-of-pocket costs (OOPC) difference between basic and enhanced PDP offerings at the $22 threshold which was established for CY 2019.

CMS makes all of the necessary tools and information available to sponsors in advance of the bid submission deadline, and therefore we expect all PDPs to submit bids that meet these standards. If CMS determines that a PDP sponsor is not meeting the CY 2020 meaningful difference standards following the submission deadline, the PDP will not be permitted to change its formulary (e.g., adding drugs) in a significant manner 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 processes. For example, portions of the annual formulary review process are based on outlier analyses. If a Part D sponsor were to be 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. To avoid meaningful difference issues, PDPs are strongly encouraged to make sure all Part D benefit and formulary changes are considered as part of their meaningful difference evaluation prior to submitting their final bids and formularies to CMS.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 23 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 15% 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.

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 23 below, to determine whether the coinsurance values are discriminatory. Similarly, we will continue to evaluate the drug composition of copay tiers in order to assess whether the formulary and benefit structure is providing a meaningful benefit.

Specialty Tiers

Part D sponsors may exempt a formulary tier in which it places very high cost Part D drugs and biological product items from its tiering exceptions process, consistent with 42 C.F.R. §423.578(a)(6)(iii). In order for a Part D drug to be placed on this specialty tier, the sponsor-negotiated price must exceed a dollar-per-month threshold established by CMS. Similar to past years, we analyzed CY 2018 prescription drug event (PDE) data to identify the percentage of monthly fills that exceed the current specialty tier threshold of $670. We believe that a threshold that identifies outlier claims is appropriate, to ensure that only the highest cost drugs are eligible

for placement on the specialty tier. Historically, around 99% of monthly PDEs have been below the specialty tier threshold; however, the current year's analysis indicates that this share has decreased, i.e., the percentage of 30 day-equivalent fills that exceeded $670 was slightly greater than 1%. In an effort to balance plan flexibility with beneficiary access, for CY 2020, we propose to maintain the specialty tier threshold at $670. We do, however, seek comment on the methodology that CMS should consider to evaluate specialty tier threshold changes.

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 a Non-Preferred Drug tier, but not both. As such, the inclusion of a significant number of generic drugs on a tier that is labeled as brand is misleading and may lead to beneficiary confusion. CMS will continue to evaluate the brand/generic composition of the Non-Preferred Brand tier as part of the bid review process. Similar to CY 2019, we intend to maintain a maximum threshold of 25% generic composition for the Non-Preferred Brand tier for CY 2020. We would like to remind Part D sponsors that they have the option to choose a tier model that incorporates a Non-Preferred Drug tier label if a larger proportion of generics will be included on that 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, including the ability to mix brand and generic drugs within the Non-Preferred Drug tier. To maintain transparency and meaningful benefit offerings for enrollees, we will continue 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, and would not otherwise discourage enrollment by certain types of 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 drugs on the Non-Preferred Drug tier, such as expected utilization, the formulary alternatives represented on more preferred tiers, and any tier placement strategy. 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 Adults in the United States, National Health Interview Survey, 2016, vaccination rates remain low for tetanus and diphtheria (Td) and tetanus and diphtheria with acellular pertussis (Tdap) for adults age 65 and older, at 58% and 20% respectively.[45] While

[45] Hung, M-C., Williams, W.W., Lu, P-J., et al. (2018). Vaccination Coverage Among Adults in the United States, Center for Disease Control and Prevention. National Health Interview Survey, 2016. Available at: https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2016.html.

the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70% of adults for whom the vaccine is recommended remain unprotected.[46] In a 2010 Government Accountability Office (GAO) Survey of State Health Insurance Assistance Programs (SHIPs), 40% of SHIPs reported difficulty affording the cost-sharing as a barrier to beneficiaries accessing herpes zoster vaccine.[47] A 2018 study of Tdap and herpes zoster vaccine claims in Part D demonstrated that higher out-of-pocket cost-sharing was associated with higher rates of cancelled vaccination claims, suggesting vaccination was abandoned.[48] In this study, cost-sharing of $51 or greater was associated with a 2 to 2.7-times greater rate of cancelled vaccination claims compared with $0 cost-sharing. In an effort to improve access to these and other Part D vaccines, we continue to encourage Part D sponsors to either offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

Improving Access to Generic and Biosimilar Medicines

The use of cost-effective therapeutic alternatives like generic and biosimilar medicines is critical to the current and long-term success of Medicare Part D. Robust price competition through generic and biosimilar medicines is important to ensuring patient access to therapy while constraining costs. Generic tiers provide meaningful out-of-pocket savings for seniors compared to the out-of-pocket costs for brands. The use of generic tiers benefits beneficiaries and taxpayers by encouraging the use of the lowest-cost preferred therapeutic option. Generic tiers lower out-of-pocket costs for beneficiaries and save the Medicare program money by offering an incentive to fill a lower-cost prescription. Therefore, CMS encourages Part D sponsors to prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products.

In order to encourage utilization of more affordable generics and lower out-of-pocket costs for seniors and avoid beneficiary confusion, CMS is considering, as an alternative to the tier composition policy outlined above, discouraging or prohibiting plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tier, and eliminating the non-preferred drug tier. Going forward, under such a policy, drug tiers would no longer include a mix of generic and brand products. Generics would be part of generic formulary tiers and brands would be part of brand formulary tiers. Moreover, CMS would expect that FDA-approved, therapeutically equivalent generics would be automatically included on a generic formulary tier immediately after launch as such tiers offer more favorable out-of-pocket costs for beneficiaries.

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[46] Office of Disease Prevention and Health Promotion. National Health Interview Survey, 2016. Available at: https://www.healthypeople.gov/2020/data-search/Search-the-Data#objid=4673.

[47] GAO-12-61 Medicare Part D Vaccinations. December 2011; https://www.gao.gov/assets/590/587009.pdf.

[48] Yan, S., DerSarkissian, M., Bhak, R.H., Lefebvre, P., Duh, M.S., & Krishnarajah, G. (2018) Relationship between patient copayments in Medicare Part D and vaccination claim status for herpes zoster and tetanus-diphtheria acellular pertussis, Current Medical Research and Opinion, 34:7, 1261-1269, DOI: 10.1080/03007995.2017.1416347.

CMS is interested in comments on the effects of such a potential policy. We solicit comments on all possible impacts of adopting this policy, but specifically are interested in commenters' thoughts on the impact of such a policy on:

- Plan ability to meet the actuarial equivalence tests in the bid pricing tool.
- Anticipated impact on premiums and beneficiary cost sharing, including CMS-established cost-sharing thresholds and other tier requirements.
- Formulary drug coverage and other formulary benefit design impacts, including sponsors' negotiations with manufacturers.

CMS currently encourages the placement of vaccines and naloxone agents on lower cost-sharing tiers. Please comment on if it is appropriate to provide specific exceptions to the proposed policy for these or other categories or classes of drugs. Please include clinical or other justification with your comments.

CMS is also interested in comment on whether or not biosimilars should be treated the same as generic medications for purposes of this policy, and if biosimilars and generic medications should be eligible for specialty tier placement if their cost exceeds the specialty tier threshold.

When providing comments please include data, including specifications or assumptions used for any analysis, to support comments, and any other information or statistics to help inform CMS's decision-making in this area.

Finally, please provide comment in consideration of an implementation timeline. We welcome comment on whether this policy should be adopted by CMS as an expectation for formularies for CY2020 in full or in any form or variation.

Table 23: Benefit Parameters for CY 2020 Threshold Values

	CY 2020 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)	S[2,3]
Preferred Generic Tier	<$20[4]
Generic Tier	$20
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

	CY 2020 Threshold Values
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S[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)	S[6]
Preferred Generic Tier	15%
Generic Tier	15%
Preferred Brand/Brand Tier	50%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	50%
Select Care/Diabetic Tiers[5]	50%
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$670

[1] The same Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold that was set for CY 2019 is proposed for CY 2020 (see above discussion under the Benefit Review section). The CY 2019 threshold was 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 manufacturer discounts. 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 2019 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 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 15% 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 70% manufacturer discount for applicable drugs.

PDP Crosswalk Policy and Solicitation of Comments

CMS is committed to promoting choice and flexibility in the Part D program while protecting beneficiaries' financial and health interests. Historically, this has included allowing stand-alone Part D plans (PDPs) that wish to terminate existing plan benefit packages (PBPs) at the end of a contract year to transfer, or crosswalk, enrollees to new plans in the following contract year under certain circumstances. CMS has also sought to minimize beneficiary disruption by restricting, under our statutory contracting authority, PDP sponsors' ability to reenter the PDP market for two years after they exit. While we are not proposing changes to these policies for CY2020, we wish to take this opportunity to invite you to submit ideas about updating the circumstances under which CMS allows plan sponsors to crosswalk beneficiaries from one PBP to another and on the application of the two-year ban that we may take into consideration for future policy changes.

Current policy permits such crosswalks when a PDP sponsor seeks to consolidate two existing PBPs into a single PBP under an existing contract or to consolidate two PBPs from different contracts held by the same parent organization in order to satisfy CMS requirements that parent organizations consolidate contracts after an acquisition. Beneficiaries may be crosswalked from:

- A basic benefit design (meaning either defined standard, actuarially equivalent standard, or basic alternative benefit design) to another basic benefit;
- An enhanced alternative benefit design to a basic benefit design; or
- An enhanced alternative benefit design to another enhanced alternative benefit design.

CMS describes the crosswalk requirements in its annual PDP Renewal and Nonrenewal Guidance (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PDP-Renewal-and-Non-Renewal-Guidance.pdf), the Annual Call Letter, and other guidance.

In the CY 2015 Call Letter, CMS announced that it would no longer accept proposals to crosswalk beneficiaries from a basic benefit design to an enhanced alternative benefit design. Previously, such crosswalks had been permitted if the PDP sponsor could demonstrate that the enhanced plan would have the same or lower premiums, the same or lower out-of-pocket costs,

and the same or better benefits. Additionally, the basic plan's premium had to be above the benchmark or de minimis premium. Few sponsors had expressed interest in such crosswalks and very few of those had been able to meet CMS requirements for granting such a crosswalk request. Moreover, CMS desired to minimize beneficiary disruption.

CMS has also sought to minimize beneficiary disruption by restricting, under our statutory contracting authority, PDP sponsors' ability to reenter the PDP market for a period of time after they exit. Specifically, organizations that nonrenew or mutually terminate their PDP contracts in a region have generally not been permitted to enter into a new PDP contract in that region for two years following the nonrenewal or termination. See 42 CFR §423.507(a)(3).

CMS is interested in ideas on changes to regulation, subregulatory guidance, policy, and procedures that would promote greater flexibility in the crosswalk policy while protecting beneficiaries from significant cost increases, benefit reductions, and other disruptions. CMS is particularly interested in comments regarding whether crosswalks from basic to enhanced alternative benefit designs should be approved in future years and, if so, under what circumstances. Also, CMS seeks comments on the extent to which, if at all, current policies governing plan offerings, including crosswalk policies and the two-year ban following a sponsor's decision to non-renew all of its plans in a PDP Region, affect a sponsor's decision to participate in a given region's individual plan market.

Please provide CMS with clear, concise comments that include data and specific examples that could be implemented within existing law. Language illustrating suggested approaches is also welcome so that CMS may precisely understand the suggestion.

Low Enrollment Plans (Stand-alone PDPs only)

CMS has the authority under 42 C.F.R. §423.509(a)(xiv) to terminate 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. Plans are deemed low enrollment plans if the plan enrollment is below 1,000, and 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 C.F.R. § 423.104(f)(2), and the organization's enhanced plan does not have low enrollment in the same region; (2) whether the plan has been in existence for three years or less; (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. We will notify affected low enrollment plans that do not meet at least one of the five criteria above by late March/early April 2019. In these circumstances, the Part D sponsor will have the option to consolidate or non-renew the plan, or they may alternatively submit a strategic plan that describes how enrollment will be increased for the upcoming plan year. We intend to terminate a plan if it continues to be low enrollment for a

second consecutive year despite a strategic plan aimed at increasing enrollment. In this instance, notice will be provided no later than August 1 for a termination effective December 31 of the same year, in accordance with 42 C.F.R. §423.509(a)(xiv). We will also notify Part D sponsors that meet low enrollment criteria (< 1,000 members and within the lowest quintile for a given PDP region) but possess one of the five relevant factors for informational purposes only. No action will be required for those sponsors.

PDP Non-Renewal Policy Clarifications

PDP sponsors who non-renew their Part D contracts with CMS are subject to a prohibition, under section 1860D-12(b)(3)(B) of the Social Security Act, from re-entering a new stand-alone PDP contract for two years following the effective date of the non-renewal. This provision incorporates into Part D by reference the two-year ban that applies to MA organization-initiated contract non-renewals pursuant to section 1857(c)(4) of the Act. This authority is also codified into the Part D regulations at 42 C.F.R. §423.507(a)(3), which state that CMS cannot enter into a new contract with the non-renewing organization in less than two years absent circumstances that warrant special consideration.

By preventing a sponsor's immediate re-entry into the PDP program following a contract non-renewal, the two-year ban promotes stability in the PDP market. In making a decision to non-renew, a sponsor must consider not just the market conditions for the immediately upcoming plan year, but also the potential cost of missing out on a second year of PDP business. The ban prevents sponsors from moving in and out of the stand-alone PDP program from year to year based on their own short-term analysis of the PDP market and their own financial and operational considerations without regard for the beneficiary disruption caused by a non-renewal. The rule places an incentive on sponsors to bid accurately and promotes the maintenance of a reasonably stable number of plans from which beneficiaries can make an election each year.

CMS believes the policy goals promoted by the two-year ban are applicable to a sponsor's non-renewal of its individual market plans in one or more PDP Regions but of less than its entire PDP sponsor contract. In effect, each PDP Region is its own micro version of the larger PDP market. PDP sponsors submit individual market plan bids on a per-PDP Region basis, and sponsors must offer enrollment in their plans to all eligible beneficiaries residing in that region. A sponsor exiting and re-entering a PDP Region on an annual basis would create an unstable set of plan choices for beneficiaries in that region, regardless of whether the sponsor continues to serve other PDP Regions. Also, a PDP sponsor contract is essentially the combination of several smaller contracts, each of which could stand on its own, governing the sponsor's Part D obligations for each PDP Region where the sponsor offers individual market PDPs and for which the sponsor has demonstrated that it meets requirements unique to that region, such as insurance licensure and pharmacy network adequacy. Accordingly, a sponsor's decision to discontinue offering individual market PDPs in a PDP Region is its own form of contract non-renewal, triggering the application of the two-year ban.

Since the start of the Part D program, CMS has informed sponsors that have advised us of their plans to non-renew individual market PDPs that a complete withdrawal from the individual PDP market in any PDP Region would make that sponsor ineligible to return to that same PDP Region for two years, even if it continues its PDP sponsor contract in other PDP Regions. We are describing here our policy regarding application of the two-year ban to make certain that it is being applied consistently and that all sponsors can consider the impact of the policy when making decisions about withdrawing from the individual PDP market in a given PDP Region. With this notice, we are also asking sponsors to comment on the impact of our two-year ban policy on their evaluation of whether to enter or exit the individual market in a PDP Region.

Finally, we emphasize that the two-year ban policy we describe here only applies to PDP Regions where a sponsor is discontinuing its participation in the individual market. The ban has no impact on a sponsor's eligibility to begin offering plans in another PDP Region, through a service area expansion, where it has not previously been offering individual market PDPs.

Improving Drug Utilization Review Controls in Medicare Part D

Medicare Part D Opioid Overutilization Policy

Opioid pain medications are effective at treating certain types of pain, and have serious risks such as increased tolerance, development of an opioid use disorder, and overdose. Addressing the nation's opioid epidemic is one of our top priorities, and we seek to employ bold, beneficiary-focused solutions.

CMS has been committed to a comprehensive strategy to combat this public health emergency with demonstrated success in the Part D program. Despite this progress, given the scope of the crisis, CMS published a roadmap in June 2018 to strengthen our efforts to address this issue. The roadmap details our three-pronged approach to combating the opioid epidemic going forward: 1) **prevention** of new cases of opioid use disorder (OUD); 2) **treatment** of patients who have already become dependent on or addicted to opioids; and 3) utilization of **data** from across the country to better target prevention and treatment activities.

Through our 2019 Medicare Part D opioid overutilization initiatives, CMS seeks to strengthen and broaden our commitment to address the opioid crisis. The new policies, which will continue for 2020, include drug management programs to better coordinate care when chronic high-risk opioid use is present, and improved safety alerts when opioid prescriptions are filled at the pharmacy. The policies are:

- **Drug Management Programs**, codified in the 2019 Parts C & D Final Rule. https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

  As required by the Comprehensive Addiction and Recovery Act (CARA), in this final rule, CMS finalized the framework under which Part D plan sponsors may adopt drug

management programs for beneficiaries who are at risk of misusing or abusing frequently abused drugs.

The rule codified many aspects of the retrospective Part D Opioid Drug Utilization Review (DUR) Policy and the Overutilization Monitoring System (OMS), with adjustments as needed to comply with CARA, by integrating them into the drug management program provisions. Under drug management programs, sponsors may limit at-risk beneficiaries' access to coverage of opioids and benzodiazepines to a selected prescriber(s) and/or network pharmacy(ies) (i.e., "lock-in"), and they may still implement beneficiary-specific claim edits for such drugs, for the safety of the beneficiary, as long as sponsors meet the regulatory requirements.

We also note that the SUPPORT for Patients and Communities Act, enacted on October 24, 2018, requires all Part D sponsors to have a DMP for plan years beginning on or after January 1, 2022.

- **Improved Opioid Safety Alerts,** announced in the 2019 Medicare Parts C&D Final Call Letter. https://https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

  In the 2019 Final Call Letter, CMS announced new strategies that took effect January 1, 2019 to further help Medicare Part D sponsors prevent and combat opioid overuse. Part D sponsors are expected to implement a real-time opioid care coordination safety edit at 90 morphine milligram equivalent (MME), at the time of dispensing, as a proactive step to engage both patients and prescribers about overdose risk and prevention. This safety edit may include prescriber/pharmacy counts. We recommend including a threshold of 2 or more opioid prescribers in these edit specifications. Sponsors continue to have the flexibility to implement hard safety edits at a threshold of 200 MME or more, with or without prescriber/pharmacy counts. Additionally, to reduce the potential for chronic opioid use or misuse, all Part D sponsors should implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7-day supply.

Residents of long-term care facilities, beneficiaries in hospice care, those receiving palliative or end-of-life care, and beneficiaries being treated for active cancer-related pain should be excluded from the Medicare Part D opioid policies. These policies also should not impact beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine.

Sponsors are also encouraged to work with their P&T committees to identify other vulnerable patient populations for exclusion from the opioid safety edits to avoid impeding critical access to needed medication. For example, the CDC Guideline for Prescribing Opioids for Chronic Pain stated that "given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based

Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease".[49] CMS also recently released a report on the challenges of pain management for beneficiaries with Sickle Cell Disease.[50]

Part D sponsors should focus on their efforts to successfully implement the policies referenced above. To support these efforts, CMS released comprehensive guidance for sponsors and educational materials for providers, beneficiaries, and other partners (pharmacies, professional organizations, advocacy groups, etc.), which are available on the Improving Drug Utilization Review Controls in Part D webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html. These documents include:

- Drug management program guidance memo, including new beneficiary notices with instructions
- Updated Overutilization Monitoring System (OMS) and MARx technical guides
- Opioid safety edit FAQ memo
- Other educational materials, including a Medicare Learning Network (MLN) Article: A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019 and slide decks and tip sheets for prescribers, pharmacists, and patients.

In 2019 and 2020, CMS will gain experience with the new strategies and closely monitor the impact on Medicare Part D prescription opioid overuse to evaluate the need for potential modifications or development of alternative or additional approaches in the future. The impact of our current policies to date is discussed later in this section.

New Draft 2020 Call Letter Proposals to Address the Opioid Epidemic

CMS is continuing to explore other initiatives to prevent new cases of opioid misuse, overdose, and death, and support beneficiaries who are already at-risk.

- CMS is proposing strategies to improve access to potentially lifesaving interventions and treatments, such as encouraging lower beneficiary cost-sharing (i.e., copays or coinsurance) for naloxone, as well as to promote co-prescribing of naloxone when clinically appropriate. See Improving Access to Opioid-Reversal Agents section, under Part D.
- CMS is reminding MA organizations that medically-approved non-opioid pain management can be offered as Part C supplemental benefits. CMS provided more guidance with the goal to increase the number of MA organizations who offer Part C

[49] National Heart Lung and Blood Institute. Evidence-based management of sickle cell disease. Expert Panel report. Washington, DC: National Institutes of Health; 2014.

[50] https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data-highlights/Understanding-Pain-Management-in-Medicare-Beneficiaries-with-Sickle-Cell-Disease-.html.

supplemental benefits to address the opioid addiction epidemic. See Non-Opioid Pain Management Supplemental Benefits section, under Part C.

- CMS is proposing to implement the revised PQA opioid overuse measures that better align with the CDC Guideline for Prescribing Opioids for Chronic Pain. Using these improved quality metrics, CMS will be able to better track trends in Medicare Part D opioid overuse, especially high-risk beneficiaries who use 90 MME or more. See Enhancements to the 2020 Part C & D Star Ratings and Future Measurement Concepts, under Parts C & D.

Future Changes to the Overutilization Monitoring System (OMS) Criteria

As noted above, we will gain experience with the drug management programs in 2019. We have made significant system changes and enhancements to the OMS to implement these programs. In doing so, we revised and added OMS response codes to receive information from sponsors about the review and case management process. These response codes will be used by sponsors in 2019 and will enable CMS to perform more robust analyses to evaluate drug management programs, including allowing the ability to better identify beneficiaries who are potentially at-risk of misusing or abusing frequently abused drugs.

The OMS criteria for 2019, which we are not proposing to change for 2020, are as follows:

Minimum OMS Criteria. All Part D sponsors with drug management programs must review beneficiaries who meet the minimum OMS criteria:

Use of opioids with an average daily MME greater than or equal to **90 mg** for any duration during the most recent 6 months and either: **3** or more opioid prescribers **and 3** or more opioid dispensing pharmacies, **OR 5** or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.

Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

Supplemental OMS Criteria. Part D sponsors with drug management programs may review beneficiaries who meet the supplemental OMS criteria as capacity allows:

Use of opioids (regardless of average daily MME) during the most recent 6 months with **7** or more opioid prescribers **OR 7** or more opioid dispensing pharmacies.

Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.

Pharmacies with multiple locations that share real-time data are counted as one pharmacy.

In concert with our program analysis, we seek feedback from Part D sponsors and other stakeholders on ways to expand and improve the OMS criteria to identify potential at-risk beneficiaries for 2021 and beyond. The OMS criteria (i.e., clinical guidelines) must be developed in accordance with 42 C.F.R. §423.153(f)(16) and:

- Are developed with stakeholder consultation;
- Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of these factors;
- Are derived from expert opinion and an analysis of Medicare data; and
- Include a program size estimate.

We are also exploring ways to improve identification of beneficiaries with active cancer-related pain and chain pharmacies with multiple locations that share real-time data. We will review the feedback received in response to this draft Call Letter and perform additional data analysis, including estimating the program size for alternative clinical guidelines. Then, we will consider proposing changes in the future and allow stakeholders opportunity to provide additional feedback prior to finalizing changes.

Opioid Potentiator Drugs

Concurrent use of other central nervous system-active drugs with opioids, especially benzodiazepines, can increase an individual's risk of opioid overdose and death. We have identified and reported concurrent opioid and benzodiazepine use to Part D sponsors through the OMS since 2016.

Prior to 2016, the percent of opioid users, excluding beneficiaries with cancer or enrolled in hospice, who had at least one concurrent day of benzodiazepine use was about 24% (Table 24). From 2015 to 2017, the rate has decreased by almost 10%. There was also a decrease in concurrent long-acting opioid use from a high in 2013 of 2.9% of opioid users to the low of 1.6% in 2017. Our expectation is that Part D sponsors' initiatives will further decrease inappropriate concurrent use. As finalized in the 2019 Call Letter, we expect sponsors to implement soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

On the other hand, the concurrent use of two other opioid potientators[51] is on the rise. As we discussed in the 2019 Call Letter, gabapentin was identified as an independent risk factor for opioid-related deaths and is reportedly misused due to the euphoria associated with high dose use.[52,53] CMS remains concerned about the increase in gabapentin and pregabalin use among opioid users. As the focus on inappropriate prescription opioid use and misuse is intensifying, clinicians and patients may be looking for alternatives for their pain treatment.[54]

Table 24: Opioid – Potentiator Drug Concurrent Use and Duplicative Use Trends, 2012-2017

Year	Concurrent Benzodiazepine Use	Concurrent Long-Acting Opioids*	Concurrent Gabapentin Use >=2400mg	Concurrent Pregabalin Use
	% Opioid** Users			
2012	N/A***	2.4%	3.9%	3.5%
2013	24.3%	2.9%	4.3%	3.7%
2014	24.3%	2.1%	4.7%	3.8%
2015	24.1%	2.0%	5.1%	3.9%
2016	23.3%	1.9%	5.6%	4.0%
2017	22.1%	1.6%	6.0%	4.1%

Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018

*Unique long-acting opioid is defined at the route, dosage form and strength.

** Opioids exclude powders, injectable, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, and opium tinctures.

***Part D coverage of benzodiazepines for all medically-accepted indications began January 1, 2013.

In the 2019 Call Letter, we announced the addition of information on the OMS reports to Part D sponsors on potential at-risk beneficiaries meeting the OMS criteria (based on opioid use) who are also receiving doses of gabapentin higher than 2400mg daily or pregabalin. We expect that when sponsors perform case management under the drug management program they consider the use of other drugs (e.g., benzodiazepines, gabapentin and pregabalin) in the review process.

We are continuing to work with the Office of the Inspector General (OIG) to identify potentiator drugs that may pose safety risks when combined with opioids. To date, seven states have added gabapentin to their Prescription Drug Monitoring Programs,[55] and some states are changing the

[51] 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's and the potentiator's abuse potential.

[52] 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.

[53] Evoy KE, Morrison MD, Saklad SR. Abuse and misuse of pregabalin and gabapentin. Drugs 2017;77:403-26.

[54] Goodman, CW, Brett, AS. "Gabapentin and Pregabalin for Pain — Is Increased Prescribing a Cause for Concern?" DOI: 10.1056/NEJMp1704633.

[55] http://www.nascsa.org/database/reports/stateProfiles.pdf.

classification of gabapentin to a Schedule V drug.[56,57] A study conducted in five areas of the United States showed that toxicology reports from 26% of opioid overdose deaths tested positive for gabapentin,[58] including 42% in Kentucky and 26% in North Carolina. In this study, gabapentin was less likely to be detected in decedents who tested positive for illicit drugs.

Furthermore, we believe it is important that Part D sponsors offer Medication Therapy Management (MTM) services to beneficiaries who are at risk of adverse events due to opioid overutilization or opioid users who are also taking potentiator drugs. These beneficiaries may benefit from MTM services including a Comprehensive Medication Review, targeted medication reviews, and interventions with their prescribers.

Impact of Medicare Part D Opioid Overutilization Policy

In 2013, CMS released a more robust Medicare Part D opioid overutilization policy. We have incrementally enhanced this policy over time and tracked its impact. We will also be in a position to track the objectives outlined in the President's Opioid Initiative[59] going forward.

The percent of Medicare Part D beneficiaries using opioids steadily decreased by 14% (36.3% to 31.3%) between 2010 and 2017, with the largest decrease (5%) from 2016 to 2017 (Figure 1). This is the result despite a 34% increase in Part D enrollment between 2012 and 2017. The absolute number of opioid users increased from 2012 to 2016, but in 2017 the trend was reversed and the number of users decreased by about 1.5% from 2016. Similarly, we observed a 13% decrease in opioid users from 2012 to 2017 after excluding beneficiaries with cancer or in hospice (data not shown).

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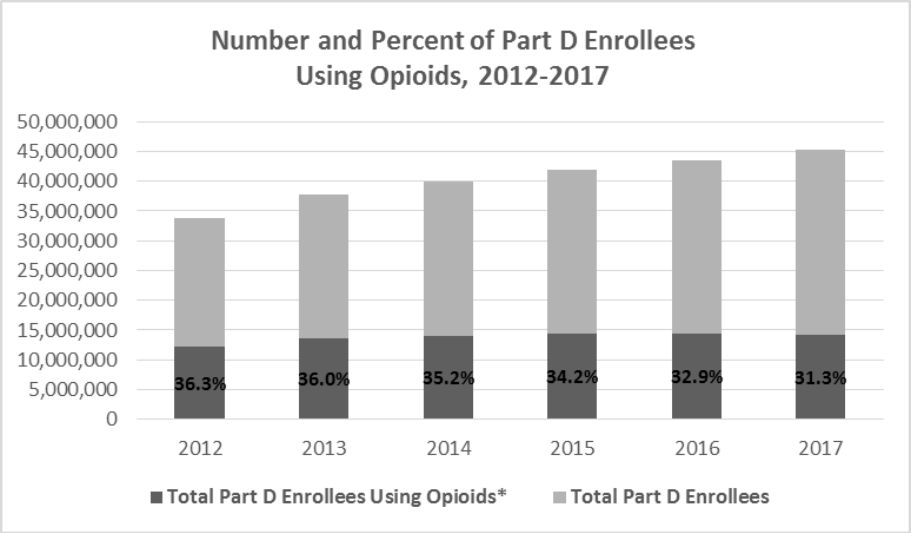
[56] https://www.michigan.gov/som/0,4669,7-192-29943_34759-466413--,00.html.

[57] https://www.deadiversion.usdoj.gov/schedules/.

[58] Slavova, Svetla et al. "Prevalence of gabapentin in drug overdose postmortem toxicology testing results". Drug Alcohol Dependence 2018 May 1;186:80-85.

[59] President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand. https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/.

Figure 1: Number and Percent of Medicare Part D Enrollees Using Opioids, 2012-2017

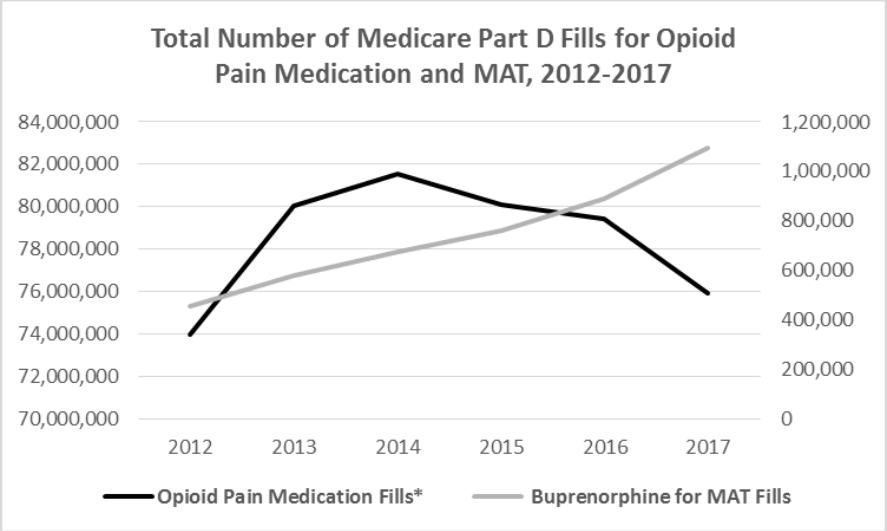


Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018.
*All Part D beneficiaries who received at least one opioid prescription, excluding powders, injectables, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, opium tinctures and buprenorphine for medication assisted treatment (MAT).

From 2012 to 2014, the number of prescription opioid pain medication fills increased (Figure 2), but decreased by 7% from 2014 to 2017 while overall Part D drug fills increased by 6% (data not shown). These results are a positive signal that opioid-related initiatives are reducing the opioid demand and supply in Medicare Part D.

More significantly, there was a 141% increase in the number of buprenorphine for MAT fills from 2012 to 2017, a positive trend indicative of access to treatment of opioid use disorder treatment. The results were similar when excluding beneficiaries with cancer or in hospice (data not shown).

Figure 2: Number of Medicare Part D Fills for Prescription Opioid Pain Medication and Medication-Assisted Treatment (MAT), 2012-2017

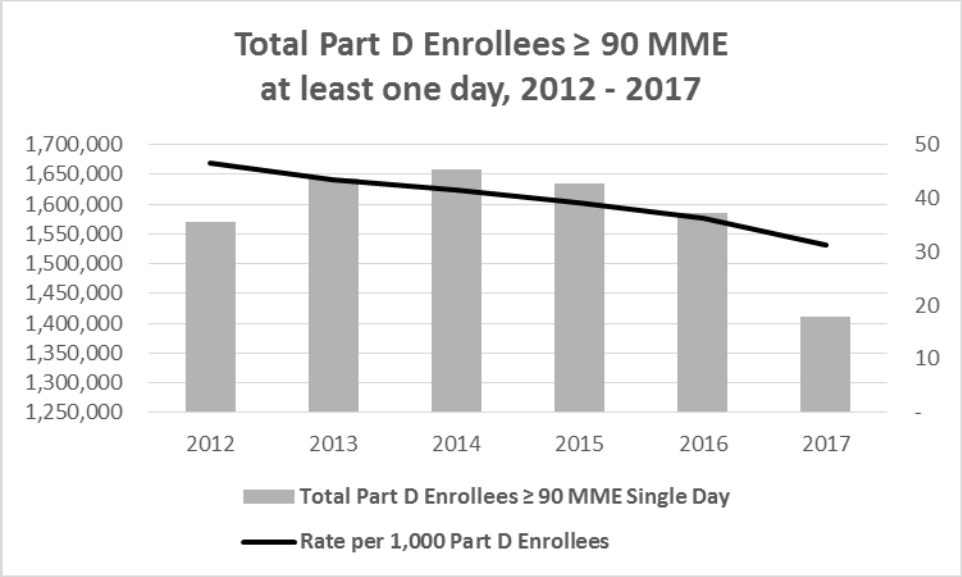


Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018;
*Opioid excludes powders, injectable, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, opium tinctures and buprenorphine for MAT.

Since 2013, we have encouraged Part D sponsors to use formulary-level controls at point of sale including safety edits. Some sponsors began to implement cumulative MME safety edits as early as 2015, and beginning in 2017, all sponsors were expected to implement soft and/or hard MME safety edits at point of sale. Prior to 2019, sponsors could set any soft opioid MME edit threshold at or above 90 mg per day and any hard MME edit at or above 200 mg per day.

We analyzed the number of Part D enrollees who met or exceeded 90 MME for at least one day with some exclusions (Figure 3). Overall, between 2012 and 2017, there was a 33% decrease in the share of Part D enrollees meeting or exceeding 90 MME for at least one day with the largest decrease (14%) in 2017 which coincided with CMS releasing more specific guidance for all Part D sponsors to implement MME edits and uptake of the CDC Guideline that was published the prior year. The absolute number of Part D enrollees receiving at least one day at 90 MME is at its lowest value in 2017. We expect to see continued progress with the implementation of the opioid care coordination safety edits at 90 MME in 2019.

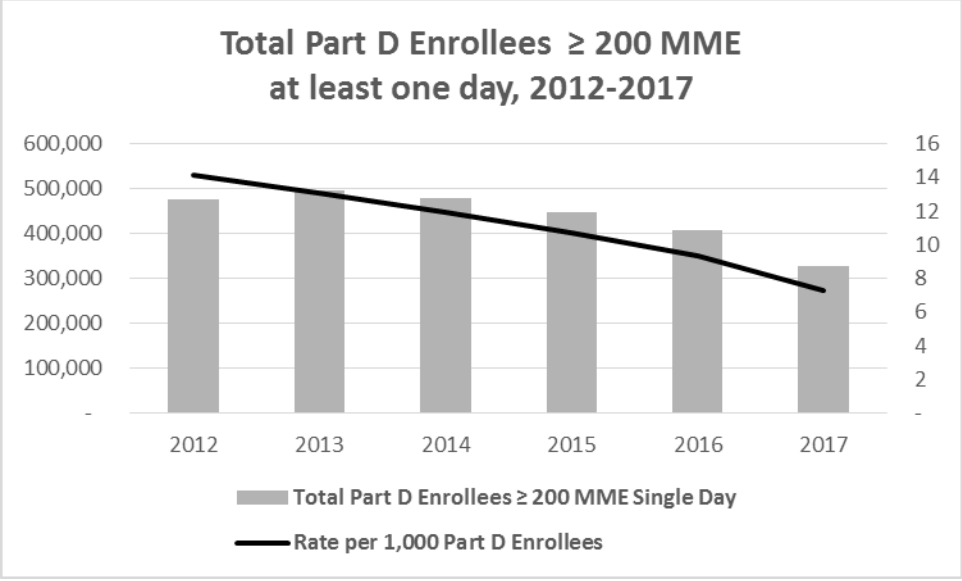
Figure 3: Total Number and Rate of Part D Enrollees who Met or Exceeded 90 Morphine Milligram Equivalents (MME) for at Least One Day, 2012-2017



Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018; Excludes beneficiaries with cancer, in hospice, or with overlapping dispensing dates for timely continued fills for the same opioid.

We also observed a larger 49% decrease in the number of Part D enrollees meeting or exceeding 200 MME for at least one day between 2012 and 2017 (Figure 4). Again, the greatest decrease (22%) was observed in 2017.

Figure 4: Total Number and Rate of Part D Enrollees who Met or Exceeded 200 Morphine Milligram Equivalents (MME) for at Least One Day, 2012-2017

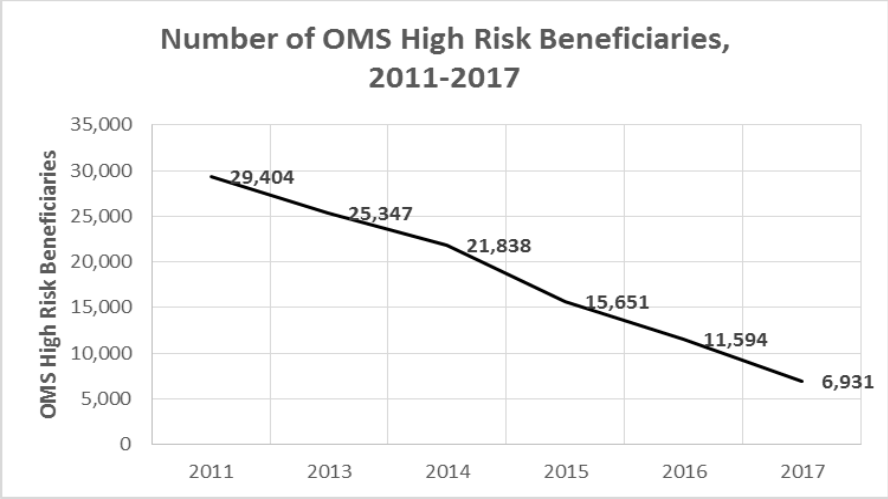


Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018; Excludes beneficiaries with cancer, in hospice, or with overlapping dispensing dates for timely continued fills for the same opioid.

The Part D enhanced retrospective opioid DUR policy and OMS began in 2013. The initial OMS criteria in place from 2013 to 2017 identified beneficiaries with at least 90 consecutive days with greater than 120 MME daily with more than three prescribers and more than three pharmacies contributing to their opioid claims, excluding beneficiaries with cancer or in hospice, during the previous 12 months.

In developing the OMS for 2013, we conducted pilots and testing in 2012. We use 2011 as the pre-pilot/pre-policy measurement period. As reported in the 2019 Call Letter, and presented in Figure E, the number of beneficiaries meeting the OMS criteria that was in place from 2013 to 2017 decreased by 76%. The greatest decrease (40%) was observed from 2016 to 2017.

Figure 5: OMS Part D Potential Opioid Overutilization Rates, 2011 – 2017



Source: Table 27 in 2019 Call Letter; 2011 = pre-policy/pilots; 2013 – 2017 OMS criteria: During previous 12 months, > 120 MME for at least 90 consecutive days with more than 3 opioid prescribers and more than 3 opioid dispensing pharmacies contributing to their opioid claims, excluding beneficiaries with cancer and in hospice.

We updated the OMS criteria in 2018 to incorporate best practices and the CDC Guidelines. Also, as already discussed, the OMS criteria was expanded again in 2019 with the implementation of the drug management programs.

Since January 2016, the OMS reports to Part D sponsors have included an Opioid Daily Dose metric for informational purposes:

- 120 MME Opioid Daily Dose rate: (# opioid days > 120 MME)/(1000 Opioid utilization days during the last 12 months).

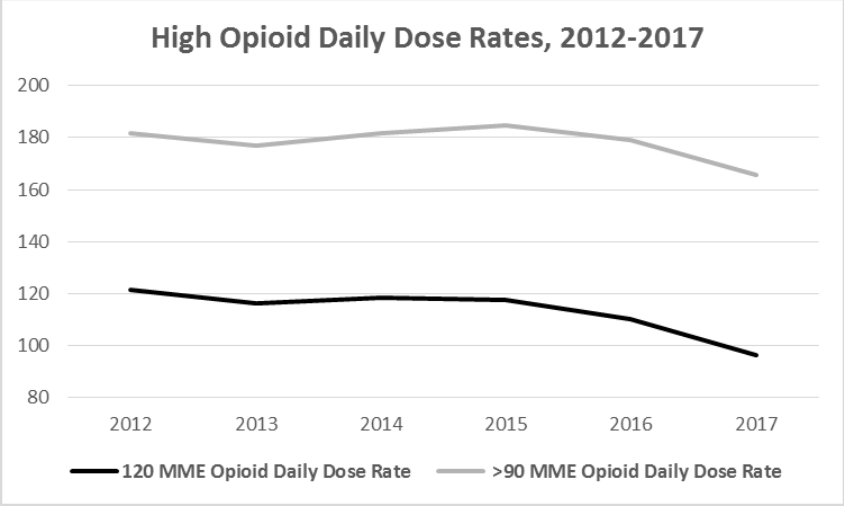
In 2018, CMS also began to report an additional Opioid Daily Dose metric with a 90 MME threshold and a 6-month measurement period.

- 90 MME Opioid Daily Dose rate: (# opioid days ≥ 90 MME)/(1000 Opioid utilization days during the last 6 months).

Furthermore, the 120 MME Opioid Daily Dose rate was revised to use a 6-month measurement period in 2018 and discontinued in the 2019 OMS reports as announced in the 2019 Call Letter. While we began to report these rates to Part D sponsors only more recently, we have tracked these rates since before the policy began. The rates have decreased significantly (Figure 6).

From 2012 to 2017, the annual rate of daily opioid use exceeding 120 MME per 1,000 opioid days decreased from 121.2 to 96.3 days, a 21% decrease. During the same period, we also observed a 9% decrease in the rate of daily opioid use that met or exceeded 90 MME. These rates exclude beneficiaries with cancer or in hospice. We expect larger decreases in the 90 MME rates since the OMS criteria threshold was lowered to 90 MME in 2018.

Figure 6: Opioid Daily Dose Rates for 90 MME or More or Greater than 120 MME per 1,000 Opioid Use Days, 2012-2017



Source: 2012 –2016 Standard Analytic File; 2017 Prescription Drug Event data as of 7/2/2018; Excludes beneficiaries with cancer or enrolled in hospice.
*Opioids excludes powders, injectable, intravenous, intrathecal, epidural, or intramuscular dosage forms, cough and cold products, opium tinctures and buprenorphine-containing medications.

CMS also uses quality measures developed by the PQA to track overall trends in opioid overuse across the Medicare Part D program. In 2016, we began to report three PQA-endorsed opioid overuse measures through the Patient Safety reports.

The current measures are:

- 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 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 MME for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

A lower rate represents better performance for all measures.

Table 25 provides the statistics for each of the three opioid overuse measures by contract type for 2016 and 2017. Two-tailed T-tests were performed to compare rates. Overall the mean, median, and maximum values from 2016 to 2017 decreased for all three quality measures within both MA-PDs and PDP contracts. The distributions were statistically different for the OMP and OHDMP measures.

Table 25: Opioid Overuse Quality Measure Rates by Medicare Part D Contract Type, 2016 and 2017*

Measure	Type	Year	N	Mean	Std. Dev	MIN	Median	MAX	P-value
OHD	MA-PD	2016	668	31.6	23.9	0.0	29.2	203.4	0.15
		2017	645	29.5	26.9	0.0	27.2	333.3	
	PDP	2016	67	41.8	26.9	0.0	37.9	169.3	0.43
		2017	60	38.1	25.6	0.0	33.1	161.1	
OMP	MA-PD	2016	668	14.4	16.1	0.0	10.6	106.4	0.00
		2017	645	10.1	11.9	0.0	7.4	96.5	
	PDP	2016	67	11.8	8.0	0.0	9.9	36.0	0.00
		2017	60	8.3	6.1	0.0	6.6	23.2	
OHDMP	MA-PD	2016	668	1.0	1.8	0.0	0.3	17.6	0.00
		2017	645	0.5	1.2	0.0	0.0	16.8	
	PDP	2016	67	1.0	1.1	0.0	0.7	4.8	0.00
		2017	60	0.5	0.6	0.0	0.4	2.4	

Source: 2016 Prescription Drug Event data as of July 31 2017 and as of June 29 2018. Excludes beneficiaries with cancer or enrolled in hospice.
*In 2017, the data sources for identifying cancer diagnoses expanded to include both Part A & B claims and RAPS RxHCC for all contracts.

As discussed in the Enhancements to the 2020 Part C & D Star Ratings and Future Measurement Concepts section, under Parts C & D, we look forward to implementing the revised PQA metrics to better track CDC Guideline recommendations through industry endorsed performance measures.

While some progress has been made, more must be done. We will continue to work with all stakeholders to help address this devastating epidemic. The commitment shown by Part D sponsors, providers, and our federal partners has been tremendous. Together, we can improve patient safety while continuing to protect patients' access to medically necessary opioids.

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 2020 COB user fee will be collected at a monthly rate of $0.1166 for the first 9 months of the coverage year for a total user fee of $1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2020 bids.

In contract year 2020, 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;
- Additional Beneficiary Information Initiatives (ABII) system for COB data; and
- Review of Workers' Compensation settlement set-aside.

Part D Mail Order Auto-Ship Modifications

After soliciting feedback on possible modifications to the mail order auto-ship policy in the 2019 Call Letter, CMS is proposing, starting in 2020, to permit interested Part D sponsors to offer an opt-in voluntary auto-ship program for refills of established therapies.

In the 2014 Call Letter, we stated that for auto-ship prescriptions 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. The Call Letter guidance was an attempt to decrease the waste and unnecessary costs associated with unneeded or unwanted prescriptions that either 1) automatically shipped when newly ordered by the provider or 2) automatically billed and shipped a refill after a certain number of days from the prior fill. We subsequently modified our position to permit exceptions in select cases.

This proposal for 2020 would replace the current affirmative prior consent step required for sending refills not initiated by the beneficiary and permit sponsors to offer an optional auto-ship option for refills of drugs that a beneficiary has been on for at least 4 consecutive months. We expect sponsors implementing an auto-ship program for refills of established therapies will

include no less than two shipping reminders prior to sending. We would expect reminders to be sent well in advance of shipment (e.g., 25 and 10 days prior), providing sufficient time and information for a beneficiary to easily modify or cancel an order if needed. We are proposing this notification process because we anticipate that a delivery going out after the second successful reminder, active or passive, has a higher likelihood of being a valid, wanted order than programs utilizing a single notification or reminder message. CMS is not recommending a specific method for how the pharmacy provides the two reminders, but recognizes that such notification could be achieved by phone, email, text, direct mailing, or other comparable means of communication (including in an alternative language if needed) and should be based on the beneficiary's stated preference. We would expect all types of reminders include all relevant information, including the name of the prescription medication, applicable cost sharing, scheduled shipping date, and how to cancel the order. A missed call with no message left, bounce back email reminders, or returned direct mailings would not count as successful shipping reminders and such members without reliable contact information would likely need to be evaluated for ongoing auto-ship interest or suitability.

Similar to the auto-ship exceptions in place currently, we expect pharmacies or sponsors to gather beneficiary confirmation/consent as a condition of enrollment in an auto-ship program at least annually and as needed (such as when a beneficiary reports an unneeded or unwanted order, or cannot be contacted). Once voluntarily opting into an auto-ship program for refills, beneficiaries must be given an opportunity to select on a drug-by-drug basis which, if any, of their medications they want refilled and shipped or delivered automatically. Given ongoing concerns about the potential for waste, we would not want auto-ship programs defaulted to refill all drugs automatically. Further, the design of such programs should account for regular early refill requests and have logic built in to address inappropriate medication accumulation. Sponsors cannot require a Part D beneficiary to use mail order or auto-ship. All of these expectations are the same whether the auto-ship refills are being offered by a sponsor's mail order pharmacy or by a retail pharmacy that offers automatic shipment or home-delivery of refills.

In addition, we would expect sponsors offering such programs to have a full refund policy (and to delete the PDE) for any refills auto-shipped that a beneficiary reports as unneeded or otherwise unwanted, regardless of whether the medication is returned by the beneficiary (or representative). Similar to the conditions in place for the current exceptions permitting auto-ship, we would expect pharmacies to promptly discontinue automatic deliveries after information becomes available from CMS that a beneficiary entered a skilled nursing facility or elected hospice coverage. A drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug is available (or would be available but for the application of a deductible) under Part A or B for that individual, such as during an inpatient hospital stay or home health episode.

We seek comment on this proposed change to the 2014 Call Letter guidance and all of the expectations described in this section. We specifically seek comment from those who implemented auto-ship programs in recent years and their ability to regularly and accurately assess current members' status regarding placement in a skilled nursing facility or hospice election.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2020

Since 2013, CMS – in collaboration with our state partners – has implemented eleven capitated model demonstrations in ten states under the Medicare-Medicaid Financial Alignment Initiative. In some states, 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, integrated care to individuals dually eligible for Medicare and Medicaid in CY 2020 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 2020 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 services and supports.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 26 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 26: Previously Released MMP Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance and Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPEnrollment.html
State-specific Marketing Guidance and Model Materials	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.html
MMP Application and Annual Requirements	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPApplicationandAnnualRequirements.html
MMP Reporting Requirements	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPReportingRequirements.html
MMP Audit Programs	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPAuditPrograms.html
MMP Encounter Data Reporting	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPEncounterDataReporting.html
MMP Quality Withhold Methodology and Technical Notes	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPQualityWithholdMethodologyandTechnicalNotes.html
MMP Chronic Care Improvement Programs and Quality Improvement Projects	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPChronicCareImprovementProgramsandQualityImprovementProjects.html

Network Adequacy Determinations

The Medicare medical provider and facility portion of MMPs' network information will be due to CMS on the third Tuesday in September 2019 (i.e., September 18, 2019). 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/MMPInformationandGuidance/MMPApplicationandAnnualRequirements.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 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 2020 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 3, 2019 at 11:59 p.m. PDT. Supplemental formulary files are due in HPMS on June 7, 2019 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. The ADD file may include drugs that have both Part D and non-Part D indications. Please note, however, that MMPs will not be permitted to submit these drugs for payment under the Part D program when prescribed for non-Part D indications. MMPs must ensure that they have measures in place to prevent inappropriate Part D claim submissions.

CMS will work with states to provide ADD file guidance to MMPs by May 2019. State guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC). 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.

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 X, 2019, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2020. In addition, CMS will release an online training module on the CY 2020 PBP software for plans on April X, 2019.

MMPs must submit their integrated PBPs to CMS no later than June 3, 2019 (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 2020)
- 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 2019. 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 2019 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 2019 (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 2019 (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 2019 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:

If the NPI in the Pharmacy Cost (PC) file represents a retail only pharmacy, all corresponding PDEs will be eligible for the measure. However, if the NPI in the PC file represents a retail and limited access pharmacy (such as Home Infusion or Long Term Care pharmacy), only the PDE where the pharmacy service type is identified as either Community/Retail or Managed Care Organization (MCO) will be eligible. 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]

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[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 reference NDC, we use First Data Bank (FDB) and Medi-Span to create an expanded list of NDCs for each reference NDC,

The reference NDC must be on the plan's formulary.

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.

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]

PDEs for compound drugs or non-covered drugs are not included.

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 cost,[64] 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,

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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.

then the claim receives a score equal to the difference between the PDE TC and the PF TC.[65,66] 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:

$$\text{Price Accuracy Index} = \left(\frac{\sum_i \max(TC_{iPDE} - TC_{iPF}, 0) + \sum_i TC_{iPDE}}{\sum_i TC_{iPDE}} \right)$$

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.

$$\text{Claim Percentage Index} = \left(\frac{\sum_i Claims_{iPDE>PF}}{\sum_i Claims_{iTotal}} \right)$$

where

$Claims_{iPDE>PF}$ 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:

$$\text{Claim Percentage Score} = (1 - \text{Claim Percentage Index}) \times 100$$

$$\text{Price Accuracy Score} = 100 - [(\text{Price Accuracy Index} - 1) \times 100]$$

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[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.

$$\text{PF Composite Price Accuracy Score} = (0.5 \times \text{Claim Percentage Score}) + (0.5 \times \text{Price Accuracy Score})$$

The score is rounded to the nearest whole number.

Example of PF Composite Price Accuracy Score Calculation

Example of PF Table 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 the 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