February 1, 2017

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

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter

In accordance with section 1853(b)(2) of the Social Security Act, we are notifying you of planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2018. Also included with this notice are proposed changes in the payment methodology for CY 2018 for Part D and annual adjustments for CY 2018 to the Medicare Part D benefit parameters for the defined standard benefit. For 2018, CMS will announce the MA capitation rates and final payment policies on Monday, April 3, 2017, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Beginning for 2018, the Securing Fairness in Regulatory Timing Act of 2015 (SFRTA) (Pub. L. 114-106) also requires CMS to publish the Advance Notice of Methodological Changes no fewer than 60 days before the publication of the Rate Announcement, and establishes a minimum 30-day period for the public to comment on the proposals in the Advance Notice.

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 2018. Attachment III sets forth the changes in the Part D payment methodology for CY 2018. Attachment IV presents the annual adjustments for CY 2018 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 2018 Call Letter for MA organizations; section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; Medicare-Medicaid Plan (MMP); and employer and union-sponsored MA or Part D group plans, including both employer/union-only group health plans and direct contract plans. The CY 2018 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.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2018@cms.hhs.gov.

Comments may be made public, so submitters should not include any confidential or personal information. In order to receive consideration prior to the April 3, 2017 release of the final Announcement of Calendar Year 2018 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 3, 2017.

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Attachments

2018 ADVANCE NOTICE
TABLE OF CONTENTS

Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2018

The Affordable Care Act, by amendments to section 1853 of the Social Security Act, establishes a new methodology for calculating each MA county rate as a percentage of Fee for Service (FFS) spending in each respective county. The Affordable Care Act provides for a transitional period during which each county rate is calculated as a blend of the pre-Affordable Care Act rate set under section 1853(k)(1) of the Social Security Act (the "applicable amount") and the new FFS-based Affordable Care Act rate set under section 1853(n)(2) of the Social Security Act (the "specified amount"[1]). For 2018, all counties will be fully transitioned to the new rate methodology.

For 2018, the MA county rates are based on the specified amount as defined in Section A2 below. Section 1853(n)(4) of the Social Security Act requires that the benchmark (increased by quality bonus percentages where applicable) be capped at the level of the 1853(k)(1) applicable amount. The 2018 FFS cost is calculated, in part, using the FFS growth percentage. CMS intends to rebase the county FFS rates for 2018 as part of the calculation of the rates for 2018.

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 2018 is 2.70 percent. This estimate reflects an underlying trend change for CY 2018 in per capita cost of 2.77 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 2018

	Prior Increases	Current Increases			NPCMAGP for 2018 With §1853(c)(6)(C) adjustment[1]
	2003 to 2017	2003 to 2017	2017 to 2018	2003 to 2018	
Aged+Disabled	54.84%	54.73%	2.77%	59.02%	2.70%

[1]Current increases for 2003-2018 divided by the prior increases for 2003-2017

[1] The statute defines the "blended benchmark" as the "amount specified in [section 1853(n)(2)(A) of the Act] for the area for the year," which does not include blending after the transition period is completed.

Section B. FFS Growth Percentage

Section 1853(n)(2) of the Act, as amended by the Affordable Care 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 2018 divided by the prior projected FFS USPCC for 2017.

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 2018

	Total USPCC – Non-ESRD	FFS USPCC – Non-ESRD	Dialysis-only ESRD
Current projected 2018 USPCC	$864.82	$848.21	$7,085.79
Prior projected 2017 USPCC	$842.06	$825.20	$7,023.24
Percent increase	2.70%	2.79%	0.89%

Table I-3 compares last year's estimate of the total non-ESRD USPCC with current estimates for 2003 to 2020, 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 2020. 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.

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	$383.93	$383.93	$367.93	$367.93	$751.86	$751.86	1.000
2010	$382.98	$382.99	$376.82	$376.82	$759.80	$759.81	1.000
2011	$387.06	$389.78	$386.24	$386.31	$773.30	$776.09	0.996
2012	$378.95	$379.28	$392.75	$392.90	$771.70	$772.18	0.999
2013	$381.12	$381.32	$399.50	$399.73	$780.62	$781.05	0.999
2014	$371.63	$371.80	$418.65	$418.58	$790.28	$790.38	1.000
2015	$374.01	$372.10	$435.80	$432.53	$809.81	$804.63	1.006
2016	$374.42	$375.95	$446.31	$441.72	$820.73	$817.67	1.004
2017	$380.63	$386.02	$460.86	$456.04	$841.49	$842.06	0.999
2018	$388.24	$397.89	$476.58	$473.50	$864.82	$871.39	0.992
2019	$403.69	$410.97	$508.01	$503.55	$911.70	$914.52	0.997
2020	$422.89		$536.64		$959.53		

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	$369.90	$369.90	$374.91	$374.91	$744.81	$744.81	1.000
2011	$370.16	$373.81	$384.39	$384.47	$754.55	$758.28	0.995
2012	$359.17	$359.57	$391.91	$392.07	$751.08	$751.64	0.999
2013	$365.40	$365.58	$395.77	$395.99	$761.17	$761.57	0.999
2014	$365.67	$365.88	$409.03	$408.86	$774.70	$774.74	1.000
2015	$369.52	$368.23	$429.21	$426.30	$798.73	$794.53	1.005
2016	$367.21	$370.33	$437.42	$431.08	$804.63	$801.41	1.004
2017	$372.90	$378.95	$453.13	$446.25	$826.03	$825.20	1.001
2018	$382.45	$390.23	$465.76	$462.98	$848.21	$853.21	0.994
2019	$397.35	$402.64	$494.78	$491.86	$892.13	$894.50	0.997
2020	$415.71		$521.90		$937.61		

These estimates are preliminary and could change when the final rates are announced on April 3, 2017 in the Announcement of CY 2018 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 3, 2017 Announcement.

Attachment II. Changes in the Part C Payment Methodology for CY 2018

Section A. MA Benchmark, Quality Bonus Payments and Rebate

As noted in Attachment I, the Affordable Care Act (ACA) amended section 1853 of the Act to establish a different methodology for calculating each MA county rate as a percentage of FFS spending in each county. The Affordable Care Act provided for a transitional period during which each county rate was calculated as a blend of the pre-Affordable Care Act rate set under section 1853(k)(1) of the Social Security Act (the "applicable amount") and the new FFS-based Affordable Care Act rate set under section 1853(n)(2) of the Social Security Act (the "specified amount"). (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.)

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, 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 2018.

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

A1. Applicable Amount

The applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1) of the Act. As CMS will rebase the rates in 2018, the applicable amount for 2018 is the greater of: (1) the county's 2018 FFS cost or (2) the 2017 applicable amount increased by the CY 2018 National Per Capita Medicare Advantage Growth Percentage. Note that, in 2018, the MA county rates are fully transitioned to the specified amount. However, as discussed in Section A6, 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:

(2018 FFS cost minus IME phase-out amount) × (applicable percentage + applicable percentage quality increase)

Where:

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

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

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

Section 1853(n)(2)(C) of the Act requires CMS to determine applicable percentages for a year based on county FFS rate rankings for the most recent year that was a rebasing year. To determine the CY 2018 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2017 average per capita FFS rate, because 2017 is the most recent FFS rate rebasing year prior to 2018. CMS will then place the rates into four quartiles. For the territories, CMS will assign an applicable percentage to each county based on where the county rate falls in the quartiles established for the 50 States and the District of Columbia.

For 2018, we propose to update the county codes used in the ratebook in order to be consistent with the FY 2017 IPPS rule. As a result, one county (49088 Bedford City, Virginia) will be removed from the ranking of 2017 FFS costs and removed from the 2018 ratebook.

CMS is publishing the 2018 applicable percentages by county with the Advance Notice at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. Each county's applicable percentage is assigned based upon its quartile ranking, as follows:

Table II-1. FFS Quartile Assignment Rules under the Affordable Care Act

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 Affordable Care Act provides for CMS to make quality bonus payments to MA organizations that meet quality standards measured under a five-star quality rating system.[2] 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 2018 payments. For CY 2018 payments, plans with fewer than 4 stars will not receive a QBP percentage increase to the county rates, and plans with 4 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 A7 for rebate percentages for CY 2018.

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

Star Rating	2018 QBP Percentage*
Fewer than 3 stars	0%
3 stars	0%
3.5 stars	0%
4 stars	5%
4.5 stars	5%
5 stars	5%

*The QBP percentage is a percentage point increase to the applicable percentage for a county in a qualifying plan's service area.

An MA plan's Star Rating is the rating assigned to its contract. MA plans with a Star Rating of 4 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 2018, MA plans with a Star Rating of fewer than 4 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) amount – that is, what the benchmark would have been under the pre-ACA rules, per section 1853(n)(4) of the Act.

[2] Star Ratings are determined at the contract level; the contract rating is applied to each plan under that contract.

New MA Plans

The method for determining the QBP percentage for a new MA plan is different from the method described above. 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. 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. As discussed below, all rates are capped at the section 1853(k)(1) amount (determined after application of the QBP percentage) – that is, what the benchmark would have been under the pre-ACA rules, per section 1853(n)(4) of the Act.

Note 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. CMS finalized this policy in the 2012 Announcement (page 2), found on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html, and will continue to apply it for 2018.

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 the first three years as a converted MA plan receiving deemed enrollment, the converted plan shall not be treated as a new MA plan as defined in section 1853(o)(3)(A)(iii)(II).

Low Enrollment Plans

Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at § 422.258(d)(7)(iv)(B),[3] 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

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

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. As in 2017, for 2018 payments, we propose 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 interpret section 1853(o)(3) of the Act as establishing two types of qualifying plans for purposes of applying the QBP, with the amount of the QBP determined by the basis for treatment of the plan as a qualifying plan (i.e., whether the amount is based on the score produced under the Star Rating system or based on the default increase specified in the case of new MA plans). Because the rationale for treating new MA plans as qualifying plans is the same as doing so in the case of low enrollment plans (i.e., there is no reliable data on which to assign a star value), we believe that new MA plans and low enrollment MA plans should receive the same treatment for the purpose of establishing the amount of quality bonus payments. Further, this is consistent with our treatment of low enrollment contracts for purposes of determining the rebate available to the plan under section 1854 of the Act.

A4. Qualifying County Bonus Payment

Beginning with payment year 2012, section 1853(o)(2) of the Act extends a double QBP percentage to a qualifying plan located in a "qualifying county." Section 1853(o)(3)(B) of the Act defines a qualifying county as 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 2018 that is less than the national monthly per capita cost for FFS for 2018.

The third criterion requires the calculation of per capita costs at both the national and county level. When calculating county per capita costs for the 2012 through 2017 payment rates, we *excluded* the portion of the claim payments to hospitals for the costs of direct graduate medical education (GME). However, when calculating the national per capita cost for the same years, we *included* payments for GME costs. We propose to remedy this inconsistency by including GME costs in both the county and national per capita cost calculations for payment year 2018. We believe this will result in a fairer comparison of per capita FFS spending between the county and the national level. This proposed change to the treatment of GME is limited to the qualifying

county determination and has no impact of the removal of GME from the FFS county cost as required by section 1853(c)(1)(D)(i) of the Act.

This proposed change would cause county per capita costs to increase. As a result, fewer counties would satisfy the third criterion of "qualifying counties" listed above, and the number of qualifying counties would decrease. For example, in the 2017 county rate file there are 234 qualifying counties, which would have been decreased by 15 counties as a result of this change.

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 a qualifying county in that plan's service area, an additional 5 percentage points would 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) amount (determined after application of the QBP percentage) – that is, what the benchmark would have been under the pre-ACA rules, as per section 1853(n)(4) of the Act.

CMS will publish a complete list of qualifying counties in the final 2018 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 2017 Rate Calculation Data file (columns Z and AA) on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The 2018 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 2018 Announcement.

A5. Affordable Care Act County Rates Transitional Phase-In

The specified amount and applicable amount were blended to set the county benchmarks on a transitional basis. This transition began in 2012 and was completed in 2017.

A6. Cap on Benchmarks

Section 1853(n)(4) of the Act requires that the benchmark (determined taking into account application of the QBP percentage) for a county must be capped at the level of the county's applicable amount determined under section 1853(k)(1). We interpret this provision as requiring that the QBP increase must be included in the benchmark before the comparison is made to determine if the cap is applied. Thus, for all counties, post-QBP percentage rates are capped at the section 1853(k)(1) amount – that is, what the benchmark would have been under the pre-ACA rules.

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 concur that a primary goal of developing the star rating system for MA has been 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, as noted in the 2017 Rate Announcement, published on April 4, 2016, CMS continues to believe that the Secretary does not have the discretion under section 1853(n)(4) of the Social Security Act to eliminate the application of the pre-ACA rate cap or exclude the bonus payment from the cap calculation when calculating the MA benchmarks.

A7. Rebate

Under section 1854(b)(1)(C) of the Act, except for MSA plans, the level of rebate for each plan is tied to the plan's Star Rating. Rebates for each plan are calculated as a percentage of the difference between the risk-adjusted service area benchmark and the risk-adjusted bid. Under § 422.266(b), plans may use rebates to fund 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-4.

Table II-4. MA Rebate Percentages

Star Rating	2018
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 did for 2017, CMS is proposing to treat low enrollment plans as having a Star Rating of 3.5 stars for purposes of determining the rebate percentage for 2018.

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

Section B. Calculation of Fee for Service Cost

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

In the 2017 Announcement, we announced updates and refinements to the AGA calculation methodology to reflect changes in FFS payment rules. Historical claims data were repriced to reflect the most current wage and cost indices. CMS re-priced hospital inpatient, hospital outpatient, skilled nursing facility, and home health claims to reflect the most current wage indices, and re-tabulated physician claims with the most current Geographic Practice Cost Index.

In 2017, we repriced historical claims to account for the changes made by the ACA to payments to disproportionate share hospitals. We also repriced durable medical equipment claims to account for the change in prices associated with the competitive bidding program.

Also in 2017, we revised the tabulation of county-level risk scores, which are used to standardize the AGAs for the risk profile of the population.

For 2018, we are proposing to update the claims data used to calculate the AGAs and to continue the repricing of historical data in the AGA calculation. Repricing historical claims, in conjunction with rebasing rates for 2018, ensures that the 2018 FFS rates for each county reflect the most current FFS fee schedules and payment rules.

Section 1853(b)(4) of the Act requires CMS to annually publish county specific per capita fee-for-service (FFS) expenditures, computed separately for Part A and Part B of Medicare.

The FFS expenditures have also been reported separately for Aged (age 65 and over), and Disabled (under age 65) beneficiaries, even though the statute only requires publication of aggregated information about the Aged and Disabled population, excluding the population of ESRD beneficiaries. The separate Aged and Disabled FFS experience was directly used in the development of demographically-based rates, which were rates based on factors which varied by age, gender, Medicaid, institutional, and "working aged" statuses. The separate Aged and Disabled FFS experience is no longer directly used in the development of demographically-based rates in the Medicare Advantage program, thus publishing this data distinguishing between the Aged and Disabled populations is no longer informative or necessary.

As required by section 1853(a)(3) of the Act, in 2000 we began a transition to rates based on risk adjustment methodology, which reflects, among other factors, the expected relative health status of each Medicare Advantage (MA) enrollee. The transition to risk-based rates was completed in 2007, at which point payments to MA plans were made exclusively on the risk-based payment rates, and the demographically-based payments were discontinued.

Unlike those earlier demographic rates, the risk rates are the same for Aged and Disabled beneficiaries. However, we have continued to publish separate Aged and Disabled FFS experience in support of the MA ratebook. Given that the separate Aged and Disabled experience is not required for the development of the risk ratebook, we propose to stop releasing county FFS expenditure data separately for the Aged population and the Disabled population beginning with the calendar year 2018 ratebook. Under this proposal, all of the spreadsheets that are published in support of the ratebook FFS rates will contain the combined FFS expenditures for the Aged and Disabled beneficiaries. This change includes the payment data in the files supporting the repricing of FFS claims; it also includes the claims payment data contained in the Microsoft Excel workbook which provides details on the development of the FFS rate for each county in the rate book year.

B1. AGA Methodology for 2018

In the first step, CMS is proposing to add the 2015 cost and enrollment data, and drop the 2010 cost and enrollment data, to 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 2011 – 2015. CMS would 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 2015 claims. Comparable adjustments were previously made to 2011 – 2014 claims data in the development of the FFS rates for prior years.

For Puerto Rico, CMS will continue to only include claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment for all five years (2011 – 2015). While most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in Puerto Rico must take affirmative action to opt-in to Part B coverage. CMS continues to believe it is appropriate to adjust the FFS rate calculation in Puerto Rico used to determine MA rates so that it is based on beneficiaries who are enrolled in both Part A and Part B in order to produce a more accurate projection of FFS costs per capita in Puerto Rico.

In 2017, the Secretary had directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the nationwide propensity of beneficiaries with zero claims.

For the 2017 Rate Announcement, the Office of the Actuary evaluated experience exclusively for beneficiaries that were enrolled in both Parts A and B and were not dually eligible for Veterans Affairs (VA) coverage. The study analyzed experience for calendar years 2011 through 2013 and only considered FFS beneficiaries enrolled mid-year. On average, 14.3 percent of A&B Puerto Rico FFS beneficiaries were found to have no Medicare claim reimbursements per year. This compared to a nationwide, non-territory, proportion of 6.1 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 an average increase in the standardized FFS costs in Puerto Rico of 4.4 percent for 2011 through 2013. Accordingly, a 4.4 percent adjustment was applied to the pre-standardized Puerto Rico FFS costs supporting the CY 2017 ratebook development.

We are considering whether a similar adjustment should be applied for 2018. The Office of the Actuary will perform a similar analysis as to the analysis performed in 2017, but with five years of data: 2011-2015. We welcome comments regarding a similar update to Puerto Rico's experience in the development of the 2018 FFS rate. We will review the results of this study and the submitted comments, and determine in the final Rate Announcement any adjustment that may be necessary.

In the third step, CMS will re-price the historical inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2011 – 2015 to reflect the most current (i.e., FY 2017) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2017) Geographic Practice Cost Index including the revised methodology used to calculate GPCIs in the physician fee schedule payments in Puerto Rico as set forth in the 2017 Medicare Physician Fee Schedule for Calendar Year (CY) 2017 Final Rule published in November 2016. For 2018, CMS will also continue to adjust historical FFS claims to account for section 3133 of the ACA, which replaced 75 percent of hospital Medicare Disproportionate Share Hospital (DSH) Payments with uncompensated care payments (UCP) beginning on October 1, 2013. Consistent with the methodology implemented for 2016 and again used in 2017, CMS would adjust claims for fiscal year (FY) 2011 through FY 2014 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 2017 Inpatient Prospective Payment System (IPPS) rule. Similarly, we are proposing to adjust the UCP represented in the FY 2015 and 1st quarter FY 2016 claims to reflect the requirements of the final FY 2017 IPPS rule. For 2018, 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 Social Security Act.

Also for 2018, we will continue re-pricing Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims from 2011 – 2015 to reflect the most current DMEPOS prices associated with the Competitive Bidding Program (CBP), and will continue using the Round 1 and Round 2 prices in making these adjustments. Section 1847(b)(5) of the Social Security Act requires that "single payment amounts" replace the current Medicare DMEPOS fee schedule amounts for selected DMEPOS items in specific competitive bidding areas (CBAs). Included in Round 2, 8 HCPC codes for diabetic supplies were expanded beyond CBAs to be part of a National Mail Order (NMO) program. In addition to previous re-pricing of historical FFS claims for CBP adjustments, we are proposing to also include in the single payment amounts for NMO DMEPOS items to re-price the historical payments for DMEPOS claims. We are proposing to use the fully adjusted fees to adjust the FFS claims to reflect the payments that will be in place

for 2018. We are also investigating whether additional changes to this proposed methodology are warranted based on requirements of the 21st Century Cures Act.

Due to system limitations, in CY 2017 and earlier, the repricing of claims other than inpatient for Puerto Rico beneficiaries included those with Part A eligibility or Part B enrollment. We are proposing that beginning with CY 2018, the repricing of all Part A claims paid on behalf of Puerto Rico beneficiaries be restricted to beneficiaries with Part A eligibility and Part B enrollment. This approach is consistent with the FFS claim tabulation for Puerto Rico beneficiaries.

As in 2017, we are proposing to make an additional adjustment to the 2012, 2013, and 2014 claims to account for shared savings payments and shared losses made to Medicare Shared Savings Program (SSP) ACOs and Pioneer ACOs. For 2018, the adjustments will be expanded to include 2015 shared savings and losses under SSP and the Pioneer ACO model and also to include the shared savings payments made under the Comprehensive Primary Care (CPC) Initiative for 2014 and 2015.

The adjustment reflects an allocation of the shared payments and losses based on the distribution of the ACO's enrollment by county. Subject to the below discussion on sequestration, the adjustments for 2012-2014 are the same as in the 2017 FFS rate development.

ACO experience for 2015 may be found at https://innovation.cms.gov/initiatives/Pioneer-ACO-Model/ for the Pioneer model and at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/ for SSP.

The key aspects of these adjustments are:

- Allocate ACO shared savings or shared loss amounts geographically, as applicable based on each ACO's unique experience, according to the distribution of counties in which each ACO's assigned beneficiaries reside.
- Represent such allocated shared savings payments and shared losses on per-capita basis based on total FFS enrollment as of July 1 of the experience year.
- Exclude per-capita shared savings and losses attributed to beneficiaries in ESRD status as of July 1 of the experience year.
- Similar to last year, shared savings payments made to ACOs in SSP and Pioneer ACO model will be reflected as additional expenditures in the experience (i.e., when the payments were incurred rather than when they were paid) year. Additional adjustments will be made for 2018 to reflect shared savings payments made under the CPC model and episode savings payments tied to the Bundled Payment for Care Improvement (BPCI) model. Shared losses will be included as negative expenditures in the experience year. The amounts will be represented in the county level Part A and Part B expenditures proportional to the Part A and Part B share of the FFS USPCC for the experience year.

- We are also proposing an adjustment for a limited number of claims from 2014 and 2015 affected by population-based payment under the pioneer ACO model. Under this optional feature of the model, certain participants receive a monthly fee that ultimately offsets a percentage reduction in marginal FFS payments over the same year. For each affected claim, the reduction amount represents the portion of the fee associated with that particular claim and is therefore added back to the reduced FFS amount so that the total reimbursement amount is represented.
- A further adjustment is being proposed for shared savings payments made under the Medicare-Medicaid managed fee-for-service financial alignment model for 2013-2014 experience. The payment will be allocated by county based on the distribution of the program enrollment.
- The AGA supporting the 2017 FFS rates reflected an adjustment to the 2012, 2013, and 2014 claims to account for shared savings payments and shared losses made to SSP ACOs and Pioneer ACOs. These adjustments did not reflect the adjustment for sequestration for claims incurred in 2013 and 2014. To be consistent with the historical claim payment and other adjustments to FFS claims, for the 2018 rates we will apply the two percent sequestration reduction on these ACO adjustments for claims incurred on or after April 1, 2013. We expect that this sequestration adjustment will have a minimal impact on the 2018 county rates.

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 2011-2015 period.[4] 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. Also, the fees paid under several other innovation models were financed by administrative accounts authorized by section 1115A of the Act. Funds appropriated and used under section 1115A are not from the Part A and Part B Trust Funds, from which Medicare claims are disbursed, so we do not consider those payments to be part of FFS costs. Accordingly, there will be not be any adjustment to historical FFS claims to account for payments made from the funds appropriated under section 1115A under the following innovation models during the 2011-2015 period: Advance Payment ACO Model, the Comprehensive Primary Care Initiative, and the Federally Qualified Health Center Advanced Primary Care Practice Demonstration.

We are also proposing to continue to use, 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 fee-for-service (FFS) beneficiary was based on the zip code associated with the beneficiary's mailing

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

address. Beginning with the 2017 ratebook, we used the county provided by the Social Security Administration, which is the same county assignment as the ratebook FFS claims and enrollment.

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

As in prior years, (1) CMS will make additional adjustments to the FFS costs for the items detailed below, and (2) the average of the five year geographic indices, based on the adjusted claims data, will be divided by the county's average five-year risk score from the 2018 risk model in order to develop the AGA for that county.

Additional Adjustments

As in prior years, CMS will make additional adjustments to the FFS costs for certain items listed below. Note that incentive payments for adoption and meaningful use of electronic health record (EHR) technology are not included in the claims used to develop the FFS costs and therefore no explicit adjustment is needed to exclude these payments from the FFS costs.

These adjustments are made after the AGA is calculated:

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

Some of these adjustments are described in more detail below.

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

For CY 2018, we are proposing to continue to adjust the FFS costs by both the Department of Defense (DoD) and the Veterans Affairs (VA) ratios.

In the 2017 FFS rates, the majority of counties had an adjustment for VA, whereas less than six percent, or 179 of 3,247, of the county FFS rates reflected an adjustment for DoD dual-benefit eligibles. Further, the average absolute value of the adjustment for the counties with a DoD adjustment averaged only 0.18 percent in 2017. Despite the relatively small impact of the DoD adjustment, there could be interaction between the VA and DoD adjustment that was not accounted for in the methodology used in the CY 2017 rate development.

We are proposing to apply the DoD and VA adjustments concurrently for CY 2018 instead of the independent application of the adjustments for CY 2017. We believe that concurrent calculation of the adjustment will have minimal impact versus independent application of the adjustments, and may eliminate possible double-counting of the impact of DoD and VA dual-benefit eligibles.

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 post-ACA 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 2018, we will first calculate the 2018 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 2018 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 2018 is 5.4 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 2018 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section D. ESRD Rates

In developing the 2018 ESRD Medicare Advantage benchmarks, we obtain the FFS dialysis reimbursement and enrollment data for each state for the years 2011 – 2015. 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 2015 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2015 data above, and using trend factors, develop the prospective 2018 FFS ESRD dialysis USPCC. The 2018 ESRD dialysis rates by state are determined by multiplying the 2018 FFS ESRD dialysis USPCC by the state AGA. The 2018 ESRD dialysis rate is adjusted by

removing the direct graduate medical education (GME) expenses and the gradual phase-out of indirect medical education (IME) expenses.

Section E. Clinical Trials

In 2018, CMS will continue to pay on a fee-for-service basis for qualified clinical trial items and services provided to MA enrollees in clinical trials that are covered under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (Medicare NCD Manual, Pub. 100-3, Part 4, Section 310.1). The payment and coverage standards applicable to NCDs under 42 CFR 422.109 apply to NCD 310.1 as it is used to provide coverage under original Medicare for clinical trials that meet its criteria and are not addressed by a separate NCD. CMS has previously made the determination that all clinical trials covered under NCD 310.1 trigger the significant cost threshold such that coverage and payment are controlled by § 422.109(c).

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

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

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

If an MAO conducts its own clinical trial, the MAO can explain to its enrollees the benefits of participating in its clinical trial; however, the MAO may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the MAO, nor may it create impediments to an enrollee's participation in a non-MAO-sponsored clinical trial, even if the

MAO believes it is sponsoring a clinical trial of a similar nature. However, an MAO may request, but not require, that enrollees notify the MAO when they choose to participate in Medicare-qualified clinical trials.

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

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

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

Section F. Location of Network Areas for PFFS Plans in Plan Year 2019

Section 1852(d) 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 not less than the rates that apply under original Medicare and having providers deemed to be contracted as described in § 422.216(f).

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

NetworkRequirements.html. We will use January 1, 2017 enrollment data to identify the location of network areas for plan year 2019.

Section G. MA Employer Group Waiver Plans

We are proposing to continue to waive the Bid Pricing Tool bidding requirements for all MA employer/union-only group waiver plans (EGWPs) for 2018. CMS is proposing, as a condition of the waiver of the bidding requirements and the waivers otherwise provided to EGWPs, to establish payment amounts as described herein. As in 2017, for 2018, 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 2018 Part C bid pricing information will facilitate the offering of Part C plans for employers and unions seeking to establish high quality coverage for their Medicare eligible retirees by avoiding the cost and administrative burden of submitting the complex bids required from non-EGWPs. We refer the reader to the detailed discussion of our rationale and responses to commenters' questions in the CY 2017 Rate Announcement, Attachment III, Section F (pages 27-44) for additional information, and to responses to questions received by the Office of the Actuary, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/ActuarialBidQuestions.html. In connection with this waiver, for 2018 CMS is proposing the following alternate payment policy for EGWPs as a consequence of the waiver of submission of bid pricing information.

In the 2017 Rate Announcement, we indicated that we intended to use the weighted average bid-to-benchmark ratio for individual market plan bids, including RPPOs, from the prior payment year (2017) to calculate the Part C base payment amounts for EGWPs for the 2018 MA EGWP payment rates.

We are soliciting comment as to whether we should fully implement this policy for 2018, using only individual market plan bids from 2017 to calculate the bid-to-benchmark ratios in calculating the 2018 MA EGWP payment rates, or whether we should continue to use the bid-to-benchmark ratios applied in calculating the 2017 MA EGWP payment rates in calculating the 2018 MA EGWP payment rates. The bid-to-benchmark ratios applied in calculating the 2017 MA EGWP payment rates reflected a blend of individual market plan bids and EGWP bids from 2016, with individual market plan bids weighted by 50 percent and EGWP bids weighted by 50 percent.

Table II-5. 2016 Bid-to-Benchmark Ratios applied in calculating 2017 MA EGWP Payment Rates

Applicable Percentage	Ratio
0.95	88.7%
1	92.2%
1.075	93.3%
1.15	93.6%

Specifically, we are proposing to calculate the 2018 EGWP county payment rates as follows:

- First, CMS will either use the bid-to-benchmark ratios detailed in Table II-5, or, as reflected in the 2017 rate announcement, a weighted average bid-to-benchmark ratio for 2018 will be calculated at the quartile level using 2017 individual market plan bids with February 2017 enrollment.[5] If the bid-to-benchmark calculations are updated using 2017 individual market plan bids only to calculate the bid-to-benchmark ratios, the calculation will be: (weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts by actual enrollment)/(weighted average of the county standardized benchmarks by actual enrollment) = percentage by quartile.[6]

- The ratios are applied to each of the published 5%, 3.5%, and 0% bonus county ratebook rates for the payment year to establish Part C base payment amounts for EGWPs based on their star rating for each county.

- In order to calculate a county rebate payment, each county level EGWP Part C base payment amount is compared to the corresponding published 5%, 3.5% and 0% bonus county benchmarks for the payment year (2018), which include adjustments for qualifying counties, to determine the amount of savings. The savings amount is multiplied by the corresponding rebate percentage to determine the Part C EGWP county level rebate amount.

- The EGWP Part C base payment amount is added to the Part C EGWP rebate amount to establish the county level local EGWP total payment amount.

[5] To determine the CY 2018 applicable percentages, CMS ranks counties from highest to lowest based upon their 2017 average per capita FFS costs and places the rates into four quartiles. When calculating the 2017 bid-to-benchmark ratios CMS would group counties by the 2017 unblended quartiles and these bid-to-benchmark ratios would then be applied to the 2018 unblended quartiles. These bid-to-benchmark ratios would be published in the 2018 Rate Announcement.
[6] Territories will not be included in the weighted average bid-to-benchmark ratio, but will be assigned the weighted average of the quartile within which their counties fall.

- The total payment amount will be risk adjusted in payment using beneficiary-specific risk scores. Therefore, the formula applied for local EGWP payment will be: (base county payment rate + county rebate) × beneficiary level risk score.

For RPPO EGWPs, the weighted average bid-to-benchmark ratios will be calculated as described in the first bullet above. To establish the Part C base RPPO EGWP payment amount, we will then also apply the same methodology as described in the second bullet above.

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

The RPPO EGWP Payment Formula is (Base County Payment Rate + Regional Rebate) x beneficiary level risk score where each is calculated as follows:

- Base County Payment Rate = Bid to Benchmark Ratio × 2018 MA Monthly Capitation Rate

- Regional Rebate = (1 - Bid to Benchmark Ratio) × 2018 Regional Rate × Rebate percentage

- The 2018 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 2018 Regional rate (i.e., no individual bids in a region), then the EGWP rate will be based solely on the statutory component.

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

As a result of this proposal, each 3-star EGWP in a given county would receive the same payment amount that includes the same rebate amount, multiplied by their beneficiaries' risk scores. MA EGWPs would not be able to distinguish between the amount they are paid for basic benefits and the amount they are paid for rebates. In light of this, CMS proposes to continue to waive the requirement for MA EGWPs to allocate rebate dollars to any specific purpose for 2018; further, MA EGWPs would also not be permitted to buy down Part B premiums for their enrollees from the Part C payment.

Under current rules, when a non-EGWP MAO uses rebates to buy-down a portion of the Part B premiums for their beneficiaries, CMS retains the rebate amount identified by the MAO and coordinates directly with the Social Security Administration to ensure that each beneficiary's Part B premiums is appropriately calculated and withheld from the beneficiary's Social Security

check or billed to the beneficiary. However, under this payment methodology for MA EGWPs, specific rebate amounts would not be identifiable; therefore, this process would continue to be unavailable to MA EGWPs in 2018. MA EGWPs would also continue to be prohibited from separately refunding Part B premiums for their enrollees.

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

- MA EGWPs will receive $0.00 payment for each of their members that elect Hospice given that rebate amounts are not identifiable under the proposed payment methodology.

- MA-EGWPs will continue to be paid using the ESRD ratebook for their ESRD beneficiaries in Transplant and Dialysis status, and the MA ratebook for those beneficiaries in Functioning Graft status in keeping with the current payment policy for non-EGWP MAOs.

- Consistent with how CMS pays capitation for Part B-only enrollees in the non-EGWP context, Part B-only MA EGWPs will continue to receive only the Part B portion of the EGWP payment amount determined by multiplying it by the Part B percentage of the rate.

- MA EGWP MSA plans will not submit Bid Pricing Tools for 2018, but the 2018 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: 2018 MA Monthly Capitation County Rate x beneficiary risk score – 1/12 of the Annual MSA Deposit Amount. The 2018 Annual MSA Deposit Amount must be submitted in the appropriate Plan Benefit Package field.

Notwithstanding the proposed payment policies as described above, entities offering MA EGWPs must continue to meet all of the CMS requirements that are not otherwise specifically waived or modified, including, but not limited to, submitting information related to plan service areas, plan benefit packages and formularies in accordance with the rules for 2018.

Organizations must make a good faith effort in projecting CY 2018 member months for each plan and place the amount in the appropriate section of the 2018 Plan Benefit Package (PBP) submissions to CMS.

Section H. Medicare Advantage Coding Pattern Adjustment

For 2018, CMS proposes to update the MA coding adjustment factor to the statutory minimum of 5.91 percent.

Section I. Normalization Factors

When we calibrate a Part C risk adjustment model, we use diagnosis and cost information for beneficiaries in FFS during a historical period ("calibration year") to estimate incremental costs for a variety of beneficiary characteristics (e.g., age and gender) and health conditions. Each incremental cost, known as a dollar coefficient, is divided by the predicted average per capita FFS expenditure in a given denominator year to create relative factors. The relative factors are used to calculate risk scores for beneficiaries and, if applied to beneficiaries in FFS, would result in an average FFS risk score of 1.0 in the denominator year. When a model is used to predict expenditures in future years, however, the average risk score in FFS may no longer be 1.0 due to changes in coding and population. CMS applies a normalization factor to each year's risk scores to account for coding and population changes that are expected to occur in FFS between the denominator year and the payment year.[7] Effectively, the normalization factor keeps the average FFS risk score at 1.0 in the payment year.

A normalization factor is the predicted average FFS risk score for a model in a payment year. We calculate each normalization factor annually with historical risk score data, using the model to be used in the payment year. This annual update serves two purposes. First, it is important to keep the average FFS risk score at 1.0 so that risk scores align with the FFS rates. A risk score is intended to account 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 FFS beneficiary. The rates, which are the benchmarks for bidding, are standardized to represent the cost of an average FFS beneficiary. Normalization helps to ensure that risk adjustment results in payments for individual beneficiaries that are adjusted for relative differences in expected costs but, on average, would not change the expected FFS per capita cost if Medicare Advantage enrolls beneficiaries with the same risk profile as FFS.

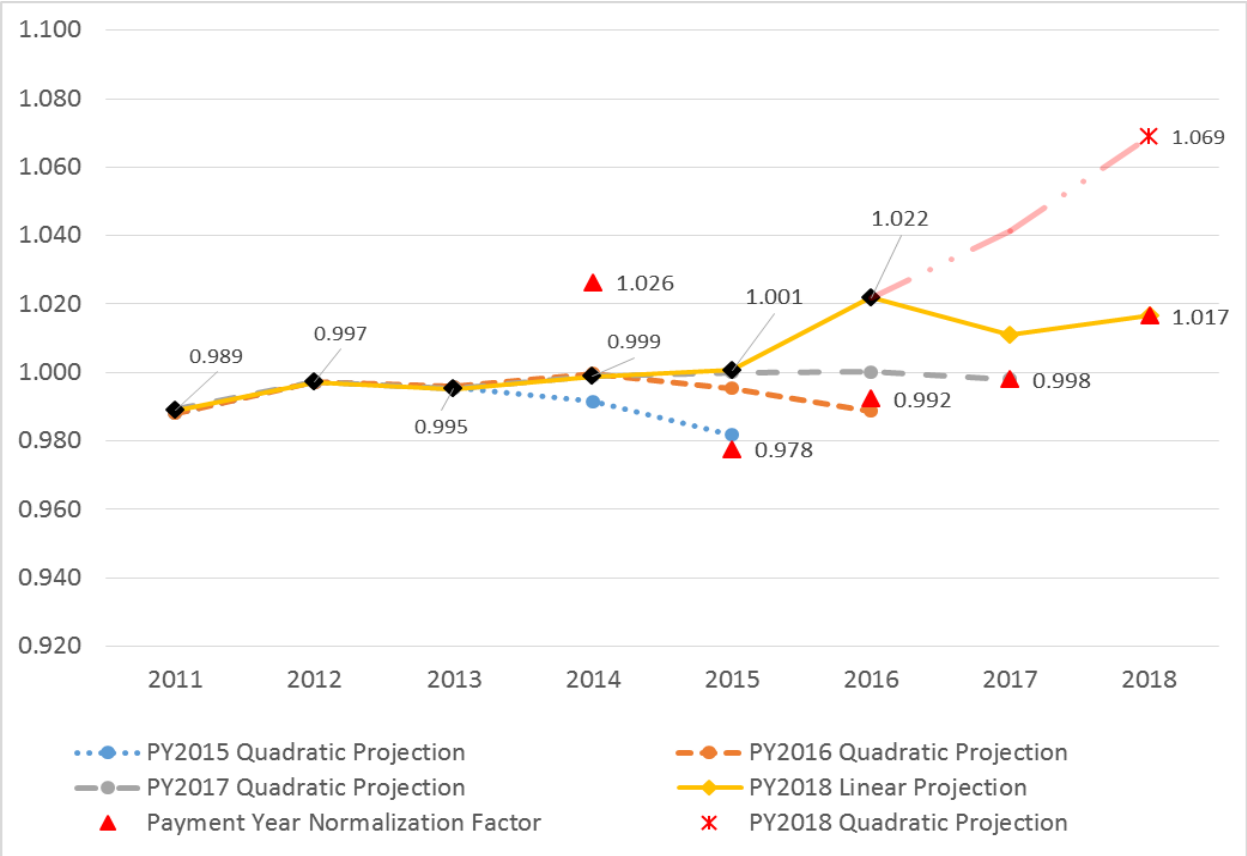
The second reason for updating the normalization factor annually is to stabilize payments between model calibrations. Periodically, CMS updates the risk adjustment model with more current FFS data, which resets the year for which the average FFS risk score is 1.0 (i.e., the denominator year). Applying a normalization factor to risk scores to account for trend between the denominator year and the payment year provides year-over-year stability and avoids the volatility that would otherwise occur in risk scores in years when the model is updated. Prior to 2015, CMS predicted the normalization factor each year by fitting a linear trend through a rolling five years of FFS risk scores to determine the average annual change in risk score. This annual trend was then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor. In 2015, CMS changed the normalization factor calculation methodology to better capture the increased proportion of younger beneficiaries known as "baby boomers". The baby boomers aging into Medicare resulted in FFS

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

risk scores increasing at a slower, less predictable, rate. By fitting a quadratic function to historical risk score data, CMS better accounted for the variation in the historical risk score data.

When the historical trend data was updated with the 2016 risk score to calculate the 2018 normalization factor, we observed a large increase in the average FFS risk score that was not consistent with prior year's observations. The quadratic method (used from PY2015 to PY2017) is highly sensitive to year over year changes in the average FFS risk score and, when incorporating this large increase in scores, predicts a Part C normalization factor for PY2018 of 1.069[8]. While normalization factors have been this large in prior years, we are not confident that the average FFS risk score will increase from 1.022 in 2016 to 1.069 in 2018.

Figure 1: Normalization Trends



*Black markers indicate actual FFS risk score values

[8]The quadratic method fits a quadratic function to five years of historical risk score data with an ordinary least squares regression. The formula used is $Risk\ Score = Intercept + \beta_1 \times Year + \beta_2 \times Year^2$. In chronological order from 2012 to 2016, the five data points with the quadratic method are as follows: 0.997, 0.995, 0.999, 1.001, and 1.022.

For PY 2018 we propose a Part C normalization factor of 1.017, estimated with the linear methodology used prior to PY2015. In this approach, we use a historical set of risk scores to estimate a linear trend and determine an annual average growth in risk scores. We then compound this annual average to project the risk scores from the denominator year, when the FFS risk score is 1.0, to the payment year. We believe that this approach results in a normalization factor that is consistent with the historical growth in FFS risk scores, including both the less than 1% annual increase prior to 2016, and the substantial increase in average FFS risk score between 2015 and 2016. We believe that any value lower than this amount risks under-normalizing for PY2018, which as stated previously would make 2018 MA payments less accurate, and would likely result in more significant increases in the normalization factor in future payment years.

We propose to use 2012 through 2016 risk scores to calculate the normalization factor for the CMS-HCC model, PACE model, ESRD Dialysis model, and Functioning Graft model. The preliminary normalization factors and annual trends for each of these models are shown below in I1 through I4.

We propose to use 2011 through 2015 risk scores to calculate the normalization factor for the RxHCC model; these factors and annual trends are shown in I5. The normalization factors for payment year 2018 will be finalized in the 2018 Announcement, to be released April 3, 2017.

CMS is requesting comment on our proposed methodology and the data included in the calculation. Specifically, we are interested in comments that address whether or not the linear trend is the best method to account for the expected changes in FFS population and coding practice, and which data points should be considered in the projection.

I1. Normalization for the CMS-HCC Model

The proposed 2018 normalization factor for the model implemented in 2018 is: 1.017.

The revised CMS-HCC model has a 2015 denominator. Between 2012 and 2016, the annual average trend estimated from the population of FFS beneficiaries, excluding ESRD and hospice, is 0.005. The trend is compounded by a factor of three, to adjust for the three years between the denominator year and the payment year.

The Part C normalization factor for the CMS-HCC risk adjustment models is applied to the following risk scores: 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 aged/disabled, aged/disabled new enrollee, and C-SNP new enrollee.

The 2012-2016 risk scores used to calculate the proposed linear annual trend for the CMS-HCC model for 2018 are included below:

2011: 0.989
2012: 0.997
2013: 0.995
2014: 0.999
2015: 1.001
2016: 1.022

I2. Normalization Factor for the PACE Model

The proposed 2018 normalization factor for the CMS-HCC risk adjustment model used for the PACE program is 1.082.

The CMS-HCC model for PACE, Functioning Graft, and ESRD beneficiaries has a 2009 denominator. Between 2012 and 2016, the trend estimated from the population of FFS beneficiaries excluding ESRD and Hospice is 0.009. The trend is compounded by a factor of nine, to adjust for the nine years between the denominator year and the payment year.

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

The 2012 – 2016 risk scores used to calculate the proposed linear annual trend for the PACE model for 2018 are included below:

2011: 1.030
2012: 1.042
2013: 1.042
2014: 1.048
2015: 1.052
2016: 1.082

I3. Normalization Factor for the ESRD Dialysis Model

The proposed 2018 normalization factor for the ESRD dialysis model is 1.080.

Between 2012 and 2016, the trend estimated from the population of FFS with ESRD is 0.009. The trend is compounded by a factor of nine, to adjust for the nine years between the denominator year and the payment year.

The normalization factor for the CMS-HCC ESRD model is applied to the following risk scores: dialysis, dialysis new enrollee, and transplant.

The 2012 – 2016 risk scores used to calculate the proposed linear annual trend for the ESRD Dialysis model for 2018 are included below:

2011: 0.956
2012: 0.971
2013: 0.973
2014: 0.980
2015: 0.985
2016: 1.008

I4. Normalization Factor for Functioning Graft Model

The proposed 2018 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.082.

Between 2012 and 2016, the trend estimated from the population of FFS beneficiaries excluding ESRD and Hospice is 0.009. The trend is compounded by a factor of nine, to adjust for the nine years between the denominator year and the payment year.

The normalization factor for the CMS-HCC functioning graft model is applied to the following risk scores: functioning graft community, functioning graft institutional, and functioning graft new enrollee. The trend is calculated on the population of FFS beneficiaries.

The 2012 – 2016 risk scores used to calculate the proposed linear annual trend for the CMS-HCC model for 2018 are included below:

2011: 1.030
2012: 1.042
2013: 1.042
2014: 1.048
2015: 1.052
2016: 1.082

I5. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The proposed 2018 normalization factor for the RxHCC model is 1.005.

The revised RxHCC model has a 2015 denominator. Between 2011 and 2015, the trend estimated from the population of FFS beneficiaries excluding ESRD and Hospice, and MA-PD beneficiaries is 0.002. The trend is compounded by a factor of three, to adjust for the three years between the denominator year and the payment year.

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.

The 2011 – 2015 risk scores used to calculate the proposed linear annual trend for the RxHCC model for 2018 are included below:

2010: 0.983
2011: 0.991
2012: 0.998
2013: 0.991
2014: 0.996
2015: 1.000

Section J. Medical Loss Ratio Credibility Adjustment

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

In the Medicare MLR final rule at 78 FR 31295, we published two sets of credibility adjustments: one for MA-PD contracts and one for Part D stand-alone contracts. For CY 2018, we are not proposing any changes to the credibility adjustments for MA-PD and Part D stand-alone published in the final rule. The applicable credibility adjustments are provided below in Table II-5 and Table II-6.

Table II-6. 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-7. 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 K. Encounter Data as a Diagnosis Source for 2018

For Payment Year (PY) 2017, CMS continued the transition to Encounter Data-based risk scores by calculating the payment risk score as a blend of two risk scores, weighting the risk score calculated with diagnoses from Risk Adjustment Processing System (RAPS) and FFS by 75 percent and the risk score calculated with diagnoses from the Encounter Data System (EDS) and FFS by 25 percent. For PY 2018, we propose to maintain the same blend as that used for PY 2017.

In addition, for PY 2018, we are seeking comment on applying a uniform industry-wide adjustment to the encounter data-based portion of the blended risk score under the Part C and ESRD models. In response to MA organizations' concerns about the potential impact on their risk scores, we are seeking comment on such an adjustment as a method to provide stability as we and plans transition to the use of encounter data for payment.

Further, we are seeking comment on details regarding the development of such an adjustment, including the extent to which such a uniform adjustment would address the concerns described above and how this approach would provide an incentive for organizations to submit complete encounter data. To this end, we are requesting comment on what the level of a potential uniform industry-wide adjustment should be, the rationale and calculations for deriving such an adjustment, and whether a uniform adjustment should apply to only full risk beneficiaries, or could be modified to apply to all beneficiaries (including new enrollees), and whether to apply an adjustment to MAPD's Part D scores. Under any approach, CMS would reassess the need and level of such an adjustment for each payment year.

For PACE organizations for PY 2018, we propose to continue the same method of calculating risk scores that we have been using since PY 2015, which is to pool risk adjustment-eligible diagnoses from the following sources to calculate a single risk score (with no weighting): (1)

encounter data, (2) RAPS, and (3) FFS claims. Since the risk score for PACE organizations is not weighted between the encounter data risk score and the RAPS risk score, no encounter data adjustment will be applied.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2018

Section A. Update of the RxHCC Model

For 2018, we are proposing to implement an updated version of the RxHCC risk adjustment model used to adjust direct subsidy payments for Part D benefits offered by stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs). The 2018 model will encompass the following changes:

1) Update to reflect the 2018 benefit structure; and,
2) Updates to the data years used to calibrate the model.

A1. Update to reflect the 2018 benefit structure

CMS recalibrated the RxHCC risk adjustment model to reflect the 2018 benefit structure. This update involved making adjustments to the Prescription Drug Event (PDE) data from the prediction year to approximate the 2018 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 2018 plan liability in the coverage gap into the prediction year (2015) expenditure data. For 2018, plan liability for non-LIS beneficiaries in the coverage gap will be 56 percent for non-applicable (generic) drugs and 15 percent plan liability for applicable (brand) drugs in the coverage gap. In addition, we mapped all PDEs to the defined standard benefit across all phases of the Part D benefit. All other things being equal, the increase in plan liability due to the reduction in beneficiary cost sharing for non-applicable drugs and applicable drugs will differentially affect the risk scores of LIS and non-LIS beneficiaries. This is because plan liability for non-LIS populations, relative to LIS populations, will increase.

A2. Update to the data years used to calibrate the model

The model being used for PY 2017 is calibrated on 2013 diagnoses and 2014 expenditure data from the PDE records. As part of this recalibration for 2018, we updated the underlying data, using diagnosis data from 2014 fee-for-service (FFS) claims and MA-PD RAPS files, along with expenditure data from 2015 PDE records.

A3. Recalibration

To recalibrate the model for payment year 2018, 2014 diagnoses from FFS and MA-PD beneficiaries enrolled in a Part D plan were used to predict 2015 expenditures. Beneficiaries in the model sample had to be: (1) FFS or Medicare Advantage (MA-PD or MA-only) for all 12 months of the base year (2014); and (2) enrolled in a PDP or an MA-PD for at least one month in the prediction year (2015).

Coefficients for condition categories were estimated by regressing the plan liability, adjusted as discussed in A1, for the Part D basic benefit for each beneficiary onto their demographic factors

and condition categories, as indicated by their diagnoses. The resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (for example, age/sex group, low income subsidy status, disability status).

In order to calculate risk scores for payment, the dollar coefficients must be denominated to create relative factors. For the PY 2018 model calibration, we divided the dollar coefficient for each demographic factor and RxHCC in the model by the average predicted per capita expenditure in 2015. These relative factors are then used to calculate risk scores for individual beneficiaries in the payment year. We developed the denominator for the revised RxHCC risk adjustment model using data from Medicare beneficiaries enrolled in both MA-PDs and PDPs, which results in an average risk score for the enrolled Part D population in the denominator year of 1.0. The denominator used to create relative factors for all segments of the model, is $1,047.96. In a final step, we imposed hierarchies on the condition categories, ensuring that more advanced and costly forms of a condition are reflected in a higher coefficient.

When recalibrating a model based on more recent data, differences between the current model and the revised model will occur for several reasons. Changes in the condition category coefficients between model recalibrations are the result of changes in utilization and changes in plan expenditures for Medicare Part D benefits. Changes in the relative (denominated) factors can occur when the marginal cost attributable to an RxHCC changes differently than the average beneficiary cost. Recalibration of the RxHCC model can result in changes in risk scores for individual beneficiaries and for plan average risk scores, depending on each individual beneficiary's combination of diagnoses.

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

Section B. Encounter Data as a Diagnosis Source for 2018

For Payment Year (PY) 2017, CMS continued the transition to encounter data-based risk scores by calculating the payment risk score as a blend of two risk scores, weighting the risk score calculated with diagnoses from Risk Adjustment Processing System (RAPS) and FFS by 75 percent and the risk score calculated with diagnoses from the Encounter Data System (EDS) and FFS by 25 percent. For PY 2018, we propose to maintain the same blend as that used for PY 2017.

For PACE organizations for PY 2018, we propose to continue the same method of calculating risk scores that we have been using since PY 2015, which is to pool risk adjustment-eligible diagnoses from the following sources to calculate a single risk score (with no weighting): (1) encounter data, (2) RAPS, and (3) FFS claims. Since the risk score for PACE organizations is not weighted between the encounter data risk score and the RAPS risk score, the encounter data adjustment will not be applied.

For readers interested in CMS' solicitation of comments on the application of a uniform adjustment to encounter data-based risk score used in the blended risk score, please reference Section K. in Attachment II.

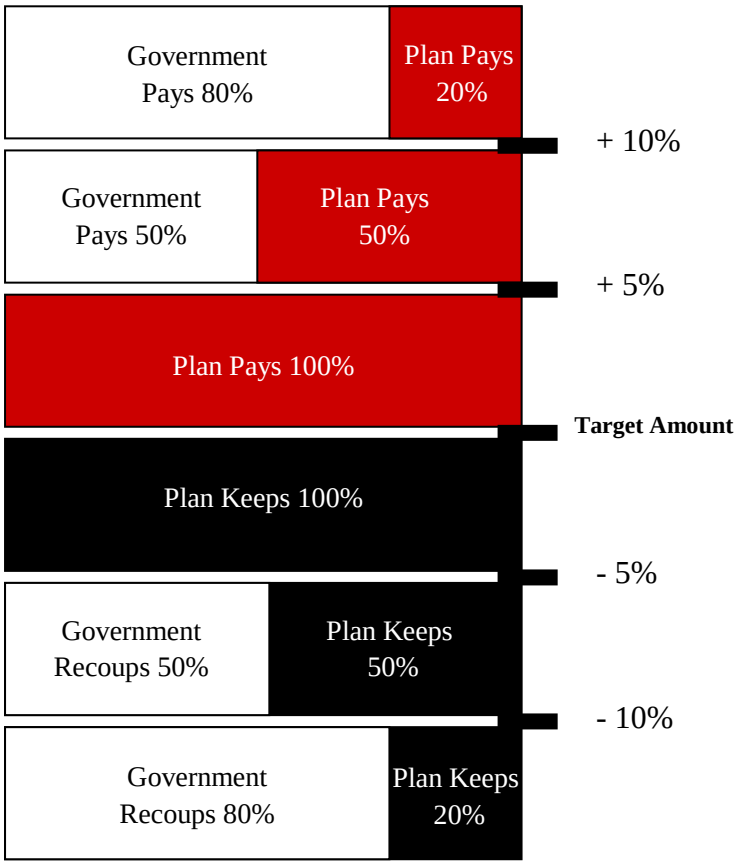
Section C. Part D Risk Sharing

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 – 2015 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 2018. 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 2017. The risk percentages for the first and second thresholds remain at 5 percent and 10 percent of the target amount, respectively, for 2018. The payment adjustments for the first and second corridors are 50 percent and 80 percent, respectively. Figure 2 below illustrates the risk corridors for 2018.

Figure 2. Part D Risk Corridors for 2018



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 2018

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[9] 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

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

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

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

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

The benefit parameters indexed to the API will be increased by 1.22 percent for 2018, as summarized by Table III-2 below. This increase reflects the 2017 annual percentage trend of 3.94 percent as well as a multiplicative update of -2.62 percent for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase.

Per § 423.886(b)(3) of our regulations, the cost threshold and cost limit for qualified retiree prescription drug plans are also indexed to the API. Thus, the cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 1.22 percent from their 2017 values.

D2. Annual Percentage Increase in Consumer Price Index

Section 1860D-14(a)(4) of the Act requires CMS to use the annual percentage increase in the CPI for the 12 month period ending in September 2017 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 line for 2018. These maximum copayments will be increased by 2.20 percent for 2018 as summarized in Table III-2 below.

This increase reflects the 2017 annual percentage trend in CPI of 2.41 percent as well as a multiplicative update of -0.20 percent for prior year revisions.

Additionally, section 1860D-2(b)(4) of the Act requires that the out-of-pocket threshold for contract years 2016 through 2019 be updated from the previous year by the lesser of (1) the API or (2) two percentage points plus the annual percentage increase in CPI. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The cumulative annual percentage increase in CPI for 2017 as of July 2017 is 2.17 percent. This figure reflects the 2017 annual percentage increase in CPI of 2.47 percent as well as a multiplicative update of -0.30 percent for prior year revisions. This value plus two percentage points is greater than the 1.22 percent cumulative API described above. Thus, the out-of-pocket threshold will be increased by 1.22 percent for 2018.

Please 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, 44 percent cost sharing for non-applicable (generic) drugs and 85 percent cost sharing for applicable (brand) 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-2 below.

Table III-2. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases

	Annual percentage trend for 2017	Prior year revisions	Annual percentage increase for 2018
API: Applied to all parameters but (1) and (2)	3.94%	−2.62%	1.22%
July CPI (all items, U.S. city average): Applied to (1)	2.47%	−0.30%	2.17%
September CPI (all items, U.S. city average): Applied to (2)	2.41%	−0.20%	2.20%

Part D Benefit Parameters

	2017	2018
Standard Benefit		
Deductible	$400	$405
Initial Coverage Limit	$3,700	$3,750
Out-of-Pocket Threshold	$4,950	$5,000
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,425.00	$7,508.75
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$8,071.16	$8,417.60
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (6)		
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 (5) (category code 3)	$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 (1)		
Generic/Preferred Multi-Source Drug (6)	$1.20	$1.25
Other (6)	$3.70	$3.70
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Above Out-of-Pocket Threshold	$0.00	$0.00

	2017	2018
Full Subsidy-Non-FBDE Individuals		
Applied or eligible for QMB/SLMB/QI or SSI and income at or below 135% FPL and resources ≤ $8,890 (individuals) or ≤ $14,090 (couples) (7) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,820 (individual) or $27,600 (couples) (7) (category code 4)		
Deductible (6)	$82.00	$83.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$3.30	$3.35
Other	$8.25	$8.35
Retiree Drug Subsidy Amounts		
Cost Threshold	$400	$405
Cost Limit	$8,250	$8,350

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

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

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

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

(5) Per section 1860D-14(a)(1)(D)(i) of the Act, full-benefit dual eligibles 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 2017 values of $82.46, $1.22, and $3.65, respectively.

(7) These resource limit figures will be updated for contract year 2018.

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

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

In 2018, the beneficiary coinsurance under basic prescription drug coverage is reduced to 44 percent for *non-applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After having applied the 50 percent manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage is reduced to 35 percent for *applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2018.

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

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

Table III-4. Cost Sharing for Non-Applicable Drugs in the Coverage Gap

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

To be eligible for reduced cost sharing, a Part D enrollee must have incurred gross covered drug costs above the initial coverage limit but true out-of-pocket costs (TrOOP) below the out-of-pocket threshold. Moreover, Medicare beneficiaries enrolled in a qualified retiree prescription drug plan or those entitled to the low-income subsidy are not eligible for this reduced cost sharing.

As beneficiary liability for covered Part D drug costs in the coverage gap decreases, plan liability increases. The increased plan liability amounts do not count toward TrOOP. Part D sponsors must account for the reductions in cost sharing and increased plan liability when developing their Part D bids for payment year 2018.

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

As described in the previous section, the ACA 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. The Part D sponsor will pay the remainder of the dispensing fee (and vaccine administration fee, if any). In 2018, applicable beneficiaries will pay 35 percent and plans will pay 65 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

In early 2007, CMS waived the Part D bid submission requirement for EGWPs beginning with payment year (PY) 2008. This included waiving the requirement that EGWPs provide an estimate of their per capita reinsurance costs, which CMS uses to provide Part D sponsors with monthly prospective reinsurance payments during a payment year. As a result, EGWPs did not receive prospective reinsurance payments from 2008-2016. However, with the recent trend in specialty drug costs, catastrophic drug costs for EGWP Part D sponsors have increased significantly and will likely continue to do so in the future. Given these increased costs, treating Calendar Year EGWPs differently from non-EGWP Part D plans for the purposes of prospective reinsurance has been considered to no longer be appropriate. For PY 2017, CMS began making prospective reinsurance payments to all Calendar Year EGWP Part D Sponsors based on the average per member per month (PMPM) actual reinsurance amounts paid to Calendar Year EGWP Part D Sponsors for 2014.

For 2018, CMS is proposing to make prospective reinsurance payments to all Calendar Year EGWPs offering Part D based on the average per member per month (PMPM) actual reinsurance amounts paid to Calendar Year EGWPs for 2015. The 2015 reconciliation data is the most current actual total reinsurance amount available for publication in the 2018 Advance Notice/Rate Announcement. CMS is proposing this methodology as it is based on the most currently available actual CY EGWP experience. The average PMPM reinsurance amount paid to Calendar Year EGWPs for 2015 reconciliation was $32.00. This proposal will apply to all CY EGWPs offering Part D. CMS is not proposing to change the current policy of not paying reinsurance payments to non-calendar year EGWPs.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2018

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 statutorily required 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. Included in this notice are (1) the methodologies for updating these parameters, (2) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2018, and (3) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

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

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

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

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

Deductible: From $400 in 2017 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $3,700 in 2017 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,950 in 2017 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $3.30 per generic or preferred drug that is a multi-source drug and $8.25 for all other drugs in 2017, rounded to the nearest multiple of $0.05.

Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low Income Full Subsidy Eligible Enrollees: From $3.30 per generic or preferred drug that is a multi-source drug and $8.25 for all other drugs in 2017, rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $82[10] in 2017 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $3.30 per generic or preferred drug that is a multi-source drug and $8.25 for all other drugs in 2017, rounded to the nearest multiple of $0.05.

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

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

Section 1860D-14(a)(4) of the Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used 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 line. These copayments are increased from $1.20 per generic or preferred drug that is a multi-source drug and $3.70 for all other drugs in 2017, rounded to the nearest multiple of $0.05 and $0.10, respectively.[11]

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

Additionally, section 1860D-2(b)(4) of the Act requires that the "annual percentage increase" applied to the out-of-pocket threshold in 2018 be the lesser of the API or CPI+2%. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The API over the 12-month period ending in July of 2017 is lower than the change in CPI during that period, and, therefore, the API will apply to the out-of-pocket threshold. The threshold is increased from $4,950 in 2017 and rounded to the nearest multiple of $50.

[10] Consistent with the statutory requirements of section 1860D-14(a)(4)(B) of the Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2017 value of $82.46.

[11] Consistent with the statutory requirements of section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2017 values of $1.22 per generic or preferred drug that is a multi-source drug, and $3.65 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 2018 benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2016\text{–}July\ 2017}{August\ 2015\text{–}July\ 2016} = \frac{\$3{,}659.97}{\$3{,}521.22} = 1.0394$$

In the formula, the average per capita cost for August 2015 – July 2016 ($3,521.22) is calculated from actual Part D PDE data, and the average per capita cost for August 2016 – July 2017 ($3,659.97) is calculated based on actual Part D PDE data incurred from August 2016 – December 2016 and projected through July 2017.

The 2018 benefit parameters reflect the 2017 annual percentage trend as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table IV-1.

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

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	7.30%	7.30%
2008	5.92%	5.92%
2009	4.69%	4.69%
2010	3.14%	3.14%
2011	2.36%	2.36%
2012	2.16%	2.16%
2013	2.53%	2.53%
2014	−3.13%	−3.14%
2015	10.03%	10.09%
2016	9.91%	9.90%
2017	6.99%	4.14%

Accordingly, the 2018 benefit parameters reflect a multiplicative update of -2.62 percent for prior year revisions. In summary, the 2017 parameters outlined in Section A are updated by 1.22 percent for 2018, as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2017	3.94%
Prior year revisions	−2.62%
Annual percentage increase for 2018	1.22%

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

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

To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in September 2017 includes an estimate of the September 2017 CPI based on projections from the President's FY2018 Budget.

The September 2016 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2018 is calculated as follows:

$$\frac{\text{Projected September 2017 CPI}}{\text{Actual September 2016 CPI}} \; or \; \frac{247.245}{241.428} = 1.0241$$

(Source: President's FY2018 Budget and Bureau of Labor Statistics, Department of Labor)

The 2018 benefit parameters reflect the 2017 annual percentage trend in the September CPI of 2.41 percent, as well as a revision to the prior estimate for the 2016 CPI increase over the 12 month period ending in September 2016. Based on the actual reported CPI for September 2016, the September 2016 CPI increase is now estimated to be 1.46 percent. Accordingly, the 2018 update reflects a -0.20 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 line are updated by 2.20 percent for 2018, as summarized by Table IV-3.

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

Annual percentage trend for September 2017	2.41%
Prior year revisions	−0.20%
Annual percentage increase for 2018	2.20%

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

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

As is the case when calculating the annual CPI trend as of September 2017, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in July 2017 includes an estimate of the July 2017 CPI based on projections from the President's FY2018 Budget.

The July 2016 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2018 is calculated as follows:

$$\frac{\text{Projected July 2017 CPI}}{\text{Actual July 2016 CPI}} \; or \; \frac{246.580}{240.628} = 1.0247$$

(Source: President's FY2018 Budget and Bureau of Labor Statistics, Department of Labor)

The 2018 benefit parameters reflect the 2017 annual percentage trend in the July CPI of 2.47 percent as well as a revision to the prior estimate for the 2016 CPI increase. Based on the actual reported CPI for July 2016, the CPI increase over the 12 month period ending in July 2016 is estimated to be 0.83 percent. The prior year revision here reflects the difference between this actual 0.83 percent increase in CPI observed in July 2016 and the 2016 CPI increase estimate from the CY 2017 Rate Announcement.

In summary, the cumulative annual percentage increase in July CPI for 2018 is 2.17 percent, as summarized by Table IV-4. This value plus two percentage points is greater than the 1.22 percent cumulative API for 2018 described above. Thus, the out-of-pocket threshold will be increased by 1.22 percent for 2018.

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

Annual percentage trend for July 2017	2.47%
Prior year revisions	−0.30%
Annual percentage increase for 2018	2.17%

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) of our regulations, 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 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 $360 and $7,400, respectively, for plans that end in 2016, and, as $400 and $8,250, respectively, for plans that end in 2017. For 2018, the cost threshold is $405 and the cost limit is $8,350.

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

For 2018, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $8,417.60. 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
- 44 percent beneficiary cost sharing for non-applicable (generic) drugs purchased in the coverage gap phase of the benefit.
- 85 percent cost sharing for the ingredient cost and sales tax for applicable (brand) drugs purchased in the coverage gap phase of the benefit—comprised of 35 percent beneficiary coinsurance and 50 percent Coverage Gap Discount Program discount.
- 35 percent cost sharing for the dispensing and vaccine administration fees for applicable (brand) drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is also assumed that the dispensing and vaccine administration fees account for 0.08 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 65 percent reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.04 percent to 84.96 percent in cost sharing for applicable (brand) drugs in the coverage gap.

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

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad \textit{or} \quad \$3{,}750 + \frac{\$3{,}758.75}{80.5286\%} = \$8{,}471.60$$

- *ICL* is the Initial Coverage Limit equal to $3,750

- *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* $5,000 − $1,241.25 = $3,758.75

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

  (Brand GDCB % for non-LIS × 84.96% gap cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 44% gap cost sharing for non-applicable drugs)

  or

  (89.18% × 84.96%) + (10.82% × 44%) = 80.528%

- *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 (brand) drugs, as reported on the 2016 PDEs.

- *Gap cost sharing for applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for applicable (brand) 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

  84.96% = [(99.92% × 85%) + (0.08% × 35%)]

- *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 (generic) drugs as reported on the 2016 PDEs.

- *Gap cost sharing for non-applicable drugs* is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for non-applicable (generic) drugs in the coverage gap.

Attachment V. RxHCC Risk Adjustment Factors

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

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.306	-	0.435	1.791
35-44 Years		-	0.450	-	0.625	2.035
45-54 Years		-	0.553	-	0.725	1.716
55-59 Years		-	0.524	-	0.704	1.565
60-64 Years		-	0.485	-	0.638	1.424
65-69 Years		0.239	-	0.389	-	1.488
70-74 Years		0.239	-	0.365	-	1.362
75-79 Years		0.225	-	0.355	-	1.254
80-84 Years		0.205	-	0.316	-	1.159
85-89 Years		0.182	-	0.282	-	1.068
90-94 Years		0.135	-	0.228	-	0.950
95 Years or Over		0.072	-	0.141	-	0.759
Male						
0-34 Years		-	0.271	-	0.474	1.827
35-44 Years		-	0.389	-	0.600	1.818
45-54 Years		-	0.489	-	0.667	1.679
55-59 Years		-	0.524	-	0.674	1.493
60-64 Years		-	0.502	-	0.621	1.366
65-69 Years		0.263	-	0.367	-	1.319
70-74 Years		0.270	-	0.342	-	1.271
75-79 Years		0.245	-	0.342	-	1.199
80-84 Years		0.185	-	0.304	-	1.148
85-89 Years		0.140	-	0.287	-	1.077
90-94 Years		0.083	-	0.240	-	0.986
95 Years or Over		0.047	-	0.224	-	0.867
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.102	-	0.198	-	0.072
Originally Disabled_Male		-	-	0.135	-	0.072
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	3.192	3.871	3.783	4.127	2.577
RXHCC5	Opportunistic Infections	0.261	0.097	0.175	0.162	0.177
RXHCC15	Chronic Myeloid Leukemia	7.383	7.519	8.142	9.906	4.907
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	3.946	4.179	3.227	3.663	1.094
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.771	1.708	1.601	1.588	0.579

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC18	Lung, Kidney, and Other Cancers	0.294	0.260	0.324	0.316	0.069
RXHCC19	Breast and Other Cancers and Tumors	0.096	0.085	0.079	0.115	0.069
RXHCC30	Diabetes with Complications	0.425	0.461	0.501	0.695	0.475
RXHCC31	Diabetes without Complication	0.280	0.262	0.316	0.389	0.321
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.990	10.494	3.113	10.451	0.468
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.100	0.201	0.060	0.228	0.087
RXHCC42	Thyroid Disorders	0.101	0.178	0.099	0.166	0.076
RXHCC43	Morbid Obesity	0.056	-	0.074	0.068	0.171
RXHCC45	Disorders of Lipoid Metabolism	0.038	-	0.068	0.088	0.052
RXHCC54	Chronic Viral Hepatitis C	3.202	3.685	2.922	2.947	0.945
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.521	0.335	0.859	0.533	0.371
RXHCC65	Chronic Pancreatitis	0.265	0.188	0.159	0.203	0.173
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.105	0.188	0.116	0.203	0.117
RXHCC67	Inflammatory Bowel Disease	0.527	0.461	0.458	0.830	0.211
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.076	0.061	0.142	0.169	0.077
RXHCC80	Aseptic Necrosis of Bone	0.177	0.248	0.109	0.144	0.112
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.769	0.738	1.295	2.065	0.655
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.377	0.409	0.483	0.805	0.185
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.212	0.333	0.239	0.354	0.168
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.052	0.153	0.121	0.204	-
RXHCC95	Sickle Cell Anemia	0.086	0.288	0.048	0.789	0.343
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.959	1.135	0.772	0.710	0.546
RXHCC97	Immune Disorders	0.553	0.509	0.488	0.454	0.342
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.086	0.155	0.048	0.220	0.044
RXHCC111	Alzheimer`s Disease	0.476	0.243	0.177	0.034	-
RXHCC112	Dementia, Except Alzheimer`s Disease	0.196	0.104	0.041	-	-
RXHCC130	Schizophrenia	0.261	0.291	0.404	0.700	0.199
RXHCC131	Bipolar Disorders	0.255	0.278	0.284	0.444	0.199
RXHCC132	Major Depression	0.127	0.207	0.143	0.311	0.166

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.127	0.172	0.143	0.311	0.108
RXHCC134	Depression	0.127	0.172	0.137	0.206	0.108
RXHCC135	Anxiety Disorders	0.051	0.113	0.085	0.171	0.108
RXHCC145	Autism	0.127	0.172	0.368	0.374	0.108
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	-	0.172	0.368	0.334	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	-	-	0.240	0.158	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.096	0.033	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.361	0.565	0.388	0.574	0.179
RXHCC157	Spinal Cord Disorders	0.114	0.088	0.094	0.057	0.054
RXHCC159	Inflammatory and Toxic Neuropathy	0.171	0.385	0.169	0.331	0.079
RXHCC160	Multiple Sclerosis	2.350	3.951	2.012	4.067	0.970
RXHCC161	Parkinson`s and Huntington`s Diseases	0.505	0.699	0.316	0.436	0.224
RXHCC163	Intractable Epilepsy	0.298	0.550	0.311	1.031	0.093
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.121	0.075	0.048	0.148	-
RXHCC165	Convulsions	0.053	0.024	0.029	0.068	-
RXHCC166	Migraine Headaches	0.138	0.207	0.127	0.141	0.110
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.134	0.294	0.157	0.212	0.193
RXHCC185	Primary Pulmonary Hypertension	0.740	2.201	0.633	1.800	0.255
RXHCC186	Congestive Heart Failure	0.166	0.146	0.225	0.143	0.138
RXHCC187	Hypertension	0.123	0.072	0.189	0.108	0.059
RXHCC188	Coronary Artery Disease	0.125	0.012	0.141	-	0.011
RXHCC193	Atrial Arrhythmias	0.288	0.100	0.140	0.010	0.087
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.044	-	0.040	-	-
RXHCC207	Spastic Hemiplegia	0.191	0.148	0.032	0.160	-
RXHCC215	Venous Thromboembolism	0.145	0.189	0.094	0.107	0.049
RXHCC216	Peripheral Vascular Disease	-	-	0.021	-	-
RXHCC225	Cystic Fibrosis	0.745	5.449	0.364	5.262	1.159
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.334	0.139	0.364	0.257	0.201
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.334	0.139	0.174	0.257	0.039

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC241	Diabetic Retinopathy	0.307	0.231	0.226	0.150	0.160
RXHCC243	Open-Angle Glaucoma	0.280	0.235	0.335	0.271	0.228
RXHCC260	Kidney Transplant Status	0.330	0.163	0.380	0.419	0.187
RXHCC261	Dialysis Status	0.246	0.508	0.484	0.928	0.409
RXHCC262	Chronic Kidney Disease Stage 5	0.093	0.119	0.084	0.043	0.057
RXHCC263	Chronic Kidney Disease Stage 4	0.093	0.119	0.084	0.043	0.057
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.162	0.166	0.102	0.099	0.055
RXHCC314	Pemphigus	0.356	0.650	0.195	0.123	0.041
RXHCC316	Psoriasis, Except with Arthropathy	0.205	0.249	0.408	0.720	0.277
RXHCC355	Narcolepsy and Cataplexy	0.806	1.332	0.649	1.351	0.251
RXHCC395	Lung Transplant Status	1.201	0.781	0.985	0.861	0.871
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.039	0.781	0.985	0.861	0.187
RXHCC397	Pancreas Transplant Status	0.330	0.163	0.380	0.233	0.187
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	0.907
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.276
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.275
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.184
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.224
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.113
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.189
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.327
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.246

Note: The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.

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

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

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.697	0.946	-	-
35-44 Years	1.208	1.208	-	-
45-54 Years	1.312	1.583	-	-
55-59 Years	1.255	1.744	-	-
60-64 Years	1.245	1.930	-	-
65 Years	0.531	1.930	1.142	1.930
66 Years	0.581	1.930	1.168	1.930
67 Years	0.595	1.930	1.168	1.930
68 Years	0.612	1.930	1.168	1.930
69 Years	0.637	1.930	1.168	1.930
70-74 Years	0.666	1.930	1.057	1.930
75-79 Years	0.685	1.930	0.803	1.930
80-84 Years	0.620	1.930	0.620	1.930
85-89 Years	0.614	1.930	0.614	1.930
90-94 Years	0.351	1.930	0.351	1.930
95 Years or Over	0.351	1.930	0.351	1.930
Male				
0-34 Years	0.462	0.840	-	-
35-44 Years	0.853	1.251	-	-
45-54 Years	1.149	1.584	-	-
55-59 Years	1.223	1.793	-	-
60-64 Years	1.194	2.101	-	-
65 Years	0.594	1.948	1.029	1.948
66 Years	0.639	1.948	1.024	1.948
67 Years	0.656	1.948	1.024	1.948
68 Years	0.686	1.948	1.024	1.948
69 Years	0.706	1.948	1.024	1.948
70-74 Years	0.751	1.948	0.951	1.948
75-79 Years	0.778	1.948	0.778	1.948
80-84 Years	0.705	1.948	0.705	1.948
85-89 Years	0.659	1.948	0.659	1.948
90-94 Years	0.314	1.948	0.314	1.948
95 Years or Over	0.314	1.948	0.314	1.948

Notes:

1. The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

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

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

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	1.024	2.151	-	-
35-44 Years	1.531	2.198	-	-
45-54 Years	1.583	2.285	-	-
55-59 Years	1.466	2.401	-	-
60-64 Years	1.376	2.234	-	-
65 Years	0.901	2.185	1.249	2.185
66 Years	0.601	2.185	0.836	2.185
67 Years	0.601	2.185	0.836	2.185
68 Years	0.601	2.185	0.836	2.185
69 Years	0.601	2.185	0.836	2.185
70-74 Years	0.606	2.185	0.787	2.185
75-79 Years	0.664	2.185	0.664	2.185
80-84 Years	0.664	2.185	0.664	2.185
85-89 Years	0.664	2.185	0.664	2.185
90-94 Years	0.564	2.185	0.564	2.185
95 Years or Over	0.564	2.185	0.564	2.185
Male				
0-34 Years	0.883	2.248	-	-
35-44 Years	1.264	2.252	-	-
45-54 Years	1.462	2.331	-	-
55-59 Years	1.376	2.189	-	-
60-64 Years	1.289	2.141	-	-
65 Years	0.896	2.033	1.145	2.033
66 Years	0.579	2.033	0.742	2.033
67 Years	0.554	2.033	0.742	2.033
68 Years	0.509	2.033	0.742	2.033
69 Years	0.509	2.033	0.742	2.033
70-74 Years	0.527	2.033	0.591	2.033
75-79 Years	0.545	2.033	0.545	2.033
80-84 Years	0.555	2.033	0.555	2.033
85-89 Years	0.528	2.033	0.528	2.033
90-94 Years	0.412	2.033	0.412	2.033
95 Years or Over	0.412	2.033	0.412	2.033

Notes:

1. The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

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

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

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.783	2.796
35-44 Years	2.783	2.796
45-54 Years	2.431	2.796
55-59 Years	2.512	2.796
60-64 Years	2.116	2.796
65 Years	2.204	2.796
66 Years	1.929	2.796
67 Years	1.929	2.796
68 Years	1.929	2.796
69 Years	1.929	2.796
70-74 Years	1.802	2.796
75-79 Years	1.570	2.796
80-84 Years	1.430	2.796
85-89 Years	1.367	2.796
90-94 Years	1.090	2.796
95 Years or Over	1.090	2.796
Male		
0-34 Years	2.419	2.812
35-44 Years	2.603	2.812
45-54 Years	2.374	2.812
55-59 Years	2.166	2.812
60-64 Years	2.109	2.812
65 Years	2.063	2.812
66 Years	1.794	2.812
67 Years	1.794	2.812
68 Years	1.794	2.812
69 Years	1.794	2.812
70-74 Years	1.699	2.812
75-79 Years	1.699	2.812
80-84 Years	1.508	2.812
85-89 Years	1.343	2.812
90-94 Years	1.343	2.812
95 Years or Over	1.343	2.812

Notes:

1. The Part D Denominator used to calculate relative factors is $1,047.96. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

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

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

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

How Payments are Made with a Disease Hierarchy EXAMPLE: 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 2018 Call Letter

CY 2018 Call Letter
Table of Contents

How to Use This Call Letter

The 2018 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 2018 bids.

CMS has designed the policies contained in this Call Letter to improve the overall management of the Medicare Advantage and Prescription Drug programs with four major outcomes in mind. These outcomes are: 1) improvement in quality of care for individuals, 2) promotion of alternative payment models, 3) program integrity and beneficiary/tax-payer value, and 4) improvement in beneficiary experience. This year, to achieve these outcomes, CMS's Call Letter activities follow four major themes: improving bid review, decreasing costs, promoting creative benefit designs, and improving beneficiary protections.

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

Section I – Parts C and D

Annual Calendar

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

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
January 10, 2017	Release of Contract Year CY 2018 Initial and Service Area Applications for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansions.	✓	✓	✓	✓
January 10, 2017	MOC Renewal Submission period begins for SNP and MMP MOCs with approvals ending 12/31/2017.	✓			✓
January 2017	Industry Training and Technical Assistance for CY 2018 Model of Care (MOC) Submissions.	✓			✓
January 11 & 18, 2017	Industry training on 2018 Applications.	✓	✓	✓	✓
February 15, 2017	CY 2018 Initial and Service Area Expansion Application for MA/MA-PD/PDP, MMP, SNP, EGWP, and 1876 Cost Plan Expansion are due in the Health Plan Management System (HPMS) by 8pm EST.	✓	✓	✓	✓
February 15, 2017	MOC Renewals Submissions for SNP and MMP MOCs with approvals ending as of 12/31/2017 are due in HPMS by 8pm EST.	✓			✓
Late February, 2017	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓			
February, 2017	CMS releases instructional memo concerning updates to Parent Organization designations in HPMS.	✓	✓	✓	✓
March 17, 2017	Parent Organization Update requests from MAOs and sponsors due to CMS (instructional memo released in February 2017).	✓	✓	✓	✓
Mid-Late March, 2017	Release of CY 2018 Formulary Reference File (FRF).	✓	✓	✓	✓
March 24, 2017	Release of the Fiscal Soundness Module in HPMS.	✓	✓	✓	✓
March/April, 2017	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2018.	✓	✓	✓	
Early April, 2017	CY 2018 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs, 1876 cost plans submitting MA conversion bids, and Part D sponsors for download from the CMS website. Information will assist plans in meeting meaningful difference and Total Beneficiary Cost (TBC) requirements prior to bid submission.	✓	✓	✓	

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early April, 2017	Information about renewal options for CY 2018 (including HPMS crosswalk charts) provided to plans.	✓	✓		
April 3, 2017	Release of the 2018 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released, including the CY 2018 Call Letter.	✓	✓	✓	✓
April, 2017	Conference call with industry to discuss the Rate Announcement and CY 2018 Call Letter.	✓	✓	✓	✓
April 5, 2017	Industry training on CY 2018 Part D Formulary and Benefit Submission/Compliance Training.	✓	✓	✓	✓
April 7, 2017	Release of the CY 2018 Plan Benefit Package (PBP) online training module.	✓	✓	✓	✓
April 7, 2017	Release of the CY 2018 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓	✓
April 11, 2017	Deadline for MAOs and cost plans to submit requests for full contract consolidations for CY 2018.	✓		✓	
Mid-April, 2017	Release of HPMS Memo: Contract Year 2018 Medicare Advantage Bid Review and Operations Guidance.	✓			
April 17, 2017	Release of the CY 2018 Medication Therapy Management (MTM) Program Submission in HPMS (11:59 p.m. PDT).		✓		✓
Mid-Late April, 2017	MAOs submit plan requests for tiering of medical benefits and justifications to CMS for review and consideration.	✓			
Late April, 2017	Total Beneficiary Cost data for CY 2018 Bid Preparation Release.	✓			
May, 2017	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, pharmacy directory, and MMP models for CY 2018 available for all organizations.	✓	✓	✓	✓
May 1, 2017	MA, MA-PD and PDP plans to notify CMS of intention to non-renew, as applicable, a county (ies) or region(s) for individuals, but continue the county (ies) or region(s) for "800 series" EGWP members, convert to offering employer-only contracts, or reduce its service area at the contract level. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓	
May 1, 2017	Deadline for submission of CY 2018 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, 2017	2017 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast.	✓	✓	✓	✓
May 5, 2017	Release of the CY 2018 Bid Upload Functionality in HPMS.	✓	✓	✓	✓
May 15, 2017	Deadline for submission of CY 2018 MTM Program attestations in HPMS (11:59pm PDT).		✓		✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
May 15, 2017	Release of CY 2018 Formulary Submission Module in HPMS.	✓	✓	✓	✓
May 19, 2017	Release of CY 2018 Actuarial Certification Module in HPMS.	✓	✓	✓	
Mid-Late May, 2017	Release of CY 2018 Formulary Reference File Update.	✓	✓	✓	✓
May 26, 2017	Plans/Part D sponsors begin to upload agent/broker compensation information in HPMS.	✓	✓	✓	✓
May 26, 2017	Release of the CY 2018 Marketing Module in HPMS. Plans/Part D sponsors begin to submit 2018 marketing materials.	✓	✓	✓	✓
Late May/Early June, 2017	Release of the CY 2018 Medicare Marketing Guidelines in HPMS.	✓	✓	✓	✓
Late May, 2017	CMS sends qualification determinations to applicants based on review of the CY 2018 applications for new contracts or service area expansions.	✓	✓	✓	✓
June 2017	Release of state-specific marketing guidance for MMPs.				✓
June 1, 2017	Release of the 2016 DIR Submission Module in HPMS.	✓	✓	✓	✓
June 5, 2017	Deadline for submission of CY 2018 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 2018 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2018 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 2018 contract non-renewal, service area reduction notice to CMS 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 2018.	✓	✓	✓	✓ *Non-bid related items only*
Early June to Early September, 2017	CMS completes review and approval of CY 2018 bid data, to include pricing, plan benefit packages, and formularies. Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications.	✓	✓	✓	✓
June 6-9, 2017	Window for submitting first round of crosswalk exception requests through HPMS.	✓	✓	✓	
June 9, 2017	Deadline for submission of CY 2018 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, Home Infusion file, and Non-Extended Day Supply file through HPMS (11:59 a.m. EDT).		✓		✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
June 9, 2017	Deadline for submission of Medicare Advantage Value Based Insurance Design (VBID) file *(Only applicable to Medicare Advantage Plans that have been preapproved for Part D VBID benefits)* (11:59 a.m. EDT).	✓			
June 9, 2017	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)* (11:59 a.m. EDT).				✓
June, 2017	2017 MA and PDP Audit and Enforcement Conference and Webcast.	✓	✓	✓	✓
Late June, 2017	CMS sends an acknowledgement letter to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓	✓
Early July, 2017	2018 Plan Finder pricing test submissions begin.	✓	✓	✓	✓
July 1, 2017	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS.	✓			
July 1, 2017	Deadline for D-SNPs requesting to be reviewed as Fully Integrated Dual-Eligible (FIDE) SNPs to submit their FIDE SNP Matrix to HPMS.	✓			
July 5, 2017	Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓			
Mid July, 2017	Release of CY 2018 FRF Update in advance of the Limited Formulary Update Window.	✓	✓	✓	✓
Mid-Late July, 2017	CY 2018 Limited Formulary Update Window.	✓	✓	✓	✓
Late July, 2017	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓	✓
Mid-Late July, 2017	Second window for submitting HPMS crosswalk exceptions.	✓	✓	✓	
Late July / Early August, 2017	CMS releases the 2018 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, 2017	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓	
No Later Than July 29, 2017	CMS informs currently contracted organizations of its decision to not renew a contract for 2018.	✓	✓	✓	
August 1, 2017	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓	
August 18, 2017	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 17-21, 2017	CY 2018 preview of the 2018 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
August 23-25, 2017	First CY 2018 Medicare Plan Finder (MPF) Preview and Out- of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ *MPF only*
August 31, 2017	CY 2018 MTM Program Annual Review completed.		✓		✓
Late August, 2017	Contracting Materials submitted to CMS.	✓	✓	✓	
End of August/Early September, 2017	Plan preview periods of Part C & D Star Ratings in HPMS.	✓	✓	✓	
Early September, 2017	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓	
Mid- September, 2017	All 2018 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓	
September 5-8, 2017	Second CY 2018 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓	✓ *MPF only*
September 16 -30, 2017	CMS mails the 2018 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓	✓
Late September, 2017	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications.	✓			
Late September , 2017	Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS.	✓	✓	✓	
September 30, 2017	Deadline for plans to provide the following documents to current enrollees: • Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • The multi-language insert should be sent with the ANOC/EOC and the SB. • Standardized ANOC with the Summary of Benefits for D-SNPs and MMPs that choose to separate the ANOC from the EOC. • Abridged or comprehensive formularies • LIS rider • Pharmacy/Provider directories The documents identified above are the only CY 2018 documents permitted to be sent prior to October 1, 2017.	✓	✓	✓	✓

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
October 1, 2017	Organizations may begin marketing their CY 2018 plan benefits. Note: Once an organization begins marketing CY 2018 plans, the organization must cease marketing CY 2017 plans to anyone other than beneficiaries who are eligible for valid enrollment (e.g. age-ins and special enrollment periods (SEP)). Organizations may still provide CY 2017 materials upon request, conduct one-on-one sales appointments, and process enrollment applications.	✓	✓	✓	✓
October 1, 2017	Tentative date for CY 2018 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓	✓
October 2, 2017	The final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, MMP and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, MMPs and cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2017.	✓	✓	✓	✓
October 11, 2017	Part C & D Star Ratings go live on medicare.gov on or around October 11, 2017.	✓	✓	✓	
October 15, 2017	Part D sponsors must post prior authorization and step therapy criteria on their websites for CY 2018.		✓		✓
October 15, 2017	2018 Annual Election Period begins All organizations/sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓		✓
Mid October, 2017	Release of the online CY 2019 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs).	✓	✓	✓	✓
November 13, 2017	Notices of Intent to Apply (NOIA) for CY 2019 due for MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November, 2017	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval.	✓	✓	✓	✓
Late November, 2017	Part C & D display measures data are posted in HPMS for plan preview.	✓	✓	✓	
November – December, 2017	CMS issues "close out" information and instructions to MA plans, MA-PD plans, MMPs, PDPs, and cost-based plans that are non- renewing or reducing service areas.	✓	✓		✓
December 1, 2017	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.			✓	

2018*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
December 1, 2017	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	
December 7, 2017	End of the Annual Election Period.	✓	✓		✓
Mid December, 2017	Part C & D display measures data on cms.gov updated.	✓	✓	✓	
December 31, 2017	Deadline for MMPs that separated the ANOC from the EOC to provide the EOC to enrollees.				✓
2018					
January 1, 2018	Plan Benefit Period Begins.	✓	✓	✓	✓
January 1 – February 14, 2018	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓			
Early January 2018	Release of CY 2019 MAO/MA-PD/MMP/PDP/SAE/EGWP applications.	✓	✓		✓
Mid-January, 2018	Industry training on CY 2019 applications.	✓	✓	✓	✓
Mid-February 2018	Applications due for CY 2019.	✓	✓	✓	✓
June 4, 2018	CY 2019 Deadline for bid and formulary submission.	✓	✓	✓	✓ *Non-bid related items only*

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, PDPs and cost-based plans are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY 2018, the bid submission deadline is June 5, 2017 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),
- 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).

MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids are submitted by the June deadline. Consistent with past years, CMS reminds organizations that all required components of an organization's bid must be submitted by the deadline in order for the bid to be considered complete. If any of the required components are not successfully submitted by the deadline, the bid submission will be considered incomplete and not accepted by CMS absent extraordinary circumstances. This policy is consistent with previous years (for example, please refer to the memo "Release of Contract Year (CY) 2017 Bid Upload Functionality in HPMS," dated May 6, 2016).

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

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

Inaccurate Submissions

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

- An MA-PD bid that does not offer required prescription drug coverage throughout its service area as required under §423.104(f)(2) (see also section 20.4.4 of Chapter 5 of the Prescription Drug Benefit Manual),

- A PDP bid for a non-defined standard plan that does not meet the Part D Benefit Parameters set forth in the applicable law and defined benefit thresholds specified in the CY 2018 Call Letter, or
- A Part D bid that includes an incorrect PBP-to-formulary crosswalk.

CMS will issue a compliance notice or request for a corrective action plan to organizations and sponsors that submit clearly inaccurate bids on June 5, 2017 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.

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 2017 and the specific dates will be announced in future guidance. The only changes to the PBP that will be allowed during the plan correction period are those that modify the PBP data to align with the BPT. No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide organizations and sponsors the guidance and tools necessary for a complete and accurate bid submission. These tools will include a Medicare Plan Finder (MPF) summary table report that will be released in HPMS in May. Organizations and sponsors can upload their bid multiple times in HPMS prior to bid submission so that they can confirm that MPF data are being displayed accurately. Organizations and sponsors are encouraged to use this time prior to the submission deadline to verify their bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance action and will be suppressed in MPF until the first MPF update in November. In addition, CMS may issue more severe compliance actions such as warning letters and requests for corrective action plans to organizations and sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice for CY 2017.

Enhancements to the 2018 Star Ratings and Beyond

One of CMS' most important strategic goals is to improve the quality of care and general health status for Medicare beneficiaries. For the 2018 Star Ratings, CMS continues to enhance the Star Ratings methodology to further align with our policy goals. In this draft CY 2018 Call Letter, we describe enhancements for the 2018 Star Ratings and beyond. Except as noted below, the methodology to calculate the ratings will remain the same as the 2017 Star Ratings.

CMS publishes the Part C and D Star Ratings each year to: measure both 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 for them, and determine MA Quality Bonus Payments. Further, the Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by physicians, hospitals, and other providers.

Given the pivotal role of the Star Ratings in achieving our goals, CMS continually reviews the measures included in the ratings and the methodology used to generate them to improve the process, incentivize plans, and provide information that is a true reflection of the performance of the plans and experience of the enrollees. We remain cognizant of the unique challenges of serving traditionally underserved subsets of the population. In addition to conducting our own research, CMS stays abreast of the related research and listens carefully to any concerns about the Star Ratings. CMS works in collaboration with beneficiaries, stakeholders, measure developers, researchers, and other HHS collaborators to improve the measures.

For reference, the list of measures and a description of the methodology for the 2017 Star Ratings are included in the Technical Notes available on the CMS webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

CMS assigns stars for each numeric measure score by applying one of three methods: clustering, relative distribution and significance testing, or fixed cut points. Each method is described in detail in the Technical Notes. Relative distribution and significance testing are applied to determine valid star cut points for CAHPS measures. The Beneficiary Access and Performance Problems measure uses fixed cut points. Clustering is applied to other Star Ratings measures. We welcome feedback on the cut point methodologies. The cut points to determine star assignments for all measures and case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated for 2018 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.

It is important that Part C and D sponsors regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. CMS expects sponsors to routinely monitor these data 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 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 2016 IRE data must be made by June 30, 2017 for the 2018 Star Ratings).

We appreciate the feedback we received on the 2018 Request for Comments.

New and Returning Measures for 2018

- **Medication Reconciliation Post Discharge (Part C)**. The Medication Reconciliation Post-Discharge (MRP) measure assesses the percentage of discharges from acute or non-acute inpatient facilities for members 66 years of age and older for whom medications were reconciled within 30 days of discharge. This measure has been collected in SNP HEDIS since 2008 but was expanded for the 2016 measurement year to all MA plans, rather than only Medicare SNPs, and was expanded to cover all members age 18 years and older. Both of these changes are seen as important steps to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. CMS included this measure on the 2017 display page and proposes to move the revised measure into the 2018 Star Ratings. Going forward and depending on the performance of the wider range of plans, CMS is considering rolling this indicator into a more comprehensive measure of care transitions with other indicators. A more comprehensive measure might be more time sensitive to deficits in quality than a measure that is more focused on individual measures. Please refer to the NCQA HEDIS 2017 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications. This measure would be weighted 1 for the 2018 Star Ratings, and we are proposing to weight it 3 as an intermediate outcome starting with the 2019 Star Ratings to reflect its role in assisting to improve a beneficiary's overall health status. Please see the section on Care Coordination measures for more information about a potential care transitions measure with multiple items included.

- **Improving Bladder Control (Part C).** This measure, collected through the Health Outcomes Survey (HOS), assesses the percentage of beneficiaries with urine leakage who discussed their problem with their provider and received treatment for the issue. NCQA made three changes to this measure. First, NCQA changed the denominator of both indicators to include all adults with urinary incontinence, as opposed to limiting the denominator to those who consider urinary incontinence to be a problem. This action removed a potential bias toward only sampling patients who were treated unsuccessfully. Second, NCQA changed the treatment indicator to assess whether treatment was discussed, as opposed to it being received. This changed the measure focus from

receiving potentially inappropriate treatments, which often have adverse side effects, to shared decision making between the patient and provider about the appropriateness of treatment. Third, NCQA added an outcome indicator to assess the degree to which urinary incontinence impacts beneficiaries' quality of life.

The revised questions were first used in the survey administered in 2015. As a result of these changes, and consistent with past policy regarding measures that have a specification change, this measure was temporarily moved to the display page in the 2016 and 2017 Star Ratings. CMS intends to move this measure from the display page and return it to the Star Ratings beginning in 2018. For the 2018 Star Ratings, this process measure would revert to the original weight of 1.

Changes to Measures for 2018

CMS' general policies regarding specification changes to Star Ratings measures include the following:

- If a specification change to an existing measure is announced in advance of the measurement period, the measure remains in the Star Ratings and it will not be moved to the display page.

- If the change announced during the measurement period significantly expands the denominator or population covered by the measure, the measure is moved to the display page for at least one year.

- If the change announced during the measurement period does not significantly impact the numerator or denominator of the measure, the measure will continue to be included in the Star Ratings (e.g., when during the measurement period additional codes are added that would increase the number of numerator hits for a measure).

Other modifications we are proposing for the 2018 Star Ratings include:

- **Improvement measures (Part C & D).** As in prior years, we plan to update the measures list used for each improvement measure to account for measures with at least two years of data. Refer to Appendix 1, Improvement Measures (Part C & D), for updates to the measures to be used to calculate the 2018 improvement measures.

  As announced in the CY 2017 Call Letter, CMS is implementing updates to the MA & PDP CAHPS surveys to reflect the CAHPS 5.0 Health Plan Survey starting in 2017. The 5.0 update applies recent improvements in survey design that resulted from development and testing of the Clinician & Group Surveys. The 5.0 version of the CAHPS Health Plan Survey incorporates some minor changes into the wording of core items, and a change in the placement of one core item that also resulted in the deletion of a screener item. Consistent with past practice, we propose to use the following

standard for deciding whether the change is significant enough to exclude the measure from the improvement measure calculation: (1) at least one item within the measure changed in wording, had a wording change in its screener, or had a wording change in the immediately preceding item, and (2) the measure score in version 5.0 was significantly different from the measure score in version 4.0, using data from the 5.0 experiment we conducted in 2015 to understand if/how performance on CAHPS measures differs between versions 4.0 and 5.0. Three MA measures meet this standard: Getting Care Quickly, Customer Service, and Care Coordination. Thus, these three measures would be excluded from the Part C improvement measure for the 2018 Star Ratings.

- **Members Choosing to Leave the Plan (Part C & D).** CMS proposes to modify the list of exclusions in the Technical Notes in this measure by removing the exclusions for "Members who moved out of the service area" and "SNPs disproportionate share members who do not meet the SNP criteria." CMS enrollment/disenrollment systems identify and exclude these members earlier in the process of data transmission. Therefore no active reference to exclusion of these data from the numerator is needed in the specification. This change does not affect the data or methodology of how this measure is calculated, it only changes the description of the measure in the Technical Notes.

- **SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D).** No changes are being proposed to the specifications for these measures. However, we propose to change the display of these measures for the 2018 Star Ratings from a percentage with one decimal point to an integer. The measure values would be rounded to an integer using standard rounding rules prior to applying the clustering methodology to calculate star assignments.

- **Call Center – Foreign Language Interpreter and TTY Availability (Part C & D).** As discussed in the CY 2017 Call Letter, when testing interpreter availability, CMS will allow the interpreter an extra 60 seconds to answer an introductory question. Interpreters will be permitted up to eight minutes to answer the introductory question and up to seven minutes to answer each of the three accuracy questions that follow.

- **MPF Price Accuracy (Part D).** As discussed in the CY 2016 and CY 2017 Call Letters, CMS plans to enhance this measure for the 2018 Star Ratings, using 2016 Medicare Plan Finder (MPF) pricing and PDE claims. Details about the methodology changes can be found in the CY 2016 Call Letter. These changes would 1) modify the PDEs to be included in this measure, and 2) account for the frequency and magnitude of difference between PDE and MPF prices when a contract's PDE prices are higher than the MPF prices. These changes are intended to better depict the accuracy of a contract's MPF

posted prices. Simulations of these changes show generally little impact to contracts' performances, relative to others. Similar to other measures, this measure's cutpoints would be generated based on current data. CMS is aware that while the MPF display is updated every two weeks, real time pricing at the point of sale can change as often as every day. Some sponsors have expressed concern that in order to perform well in this measure, they cannot offer lower prices at point of sale in real time than the prices are displayed on MPF. We note that PDEs priced lower than MPF displayed pricing do not lower a contract's score in this measure. For consistency, these changes will also be made to the 2018 display measure, Plan Submitted Higher Prices for Display on MPF.

- **Complaints about the Health Plan (Part C) and Complaints about the Drug Plan (Part D).** In the December 16, 2016 HPMS memo, Upcoming Complaints Tracking Module (CTM) Redesign, CMS announced that a redesigned CTM will be launched on March 18, 2017. Revisions will be made to the complaint categories and subcategories, including labels to indicate if they are excluded from the Star Ratings complaints measures. For the 2019 Star Ratings, we plan to apply the current exclusions to the complaints measures for January 1 – March 17, 2017 and apply the revised exclusions for March 18, 2017 to December 31, 2017.

Removal of Measures from Star Ratings

- **High Risk Medication (Part D).** The Pharmacy Quality Alliance (PQA) High Risk Medication (HRM) measure calculates the percentage of Medicare Part D beneficiaries 65 years and older who received two or more prescription fills for the same HRM drug with a high risk of serious side effects in the elderly. Based on feedback to the draft CY 2017 Call Letter, the HRM measure remained in the Star Ratings for 2017 (based on 2015 data). We indicated in the final CY 2017 Call Letter that we would move this measure to the display page for 2018 (based on 2016 data) and would continue to provide HRM measure reports to Part D sponsors through the Patient Safety Analysis website and to identify outliers.

Adjusting Star Ratings for Audits and Enforcement Actions

In an HPMS memo released on March 8, 2016, CMS suspended the reduction in the overall and summary Star Ratings of contracts that are under sanction while CMS re-evaluates the impact of sanctions, audits, and civil money penalties (CMPs) on the Star Ratings. A new policy to address the impact of enforcement actions and audits on Star Ratings must align with CMS' policy goals of adjustments that reflect the magnitude of the issue and transparency in both the development and application of any adjustment. The integrity of the Star Ratings, their value in incentivizing contracts to provide the best quality of care to beneficiaries, and the ability of the ratings to aid in the selection of a plan must not be compromised.

In the process of our review, CMS received input from many stakeholders including Medicare Advantage (MA) Organizations, Prescription Drug Plan (PDP) Sponsors, beneficiary advocates, and providers in response to the draft 2017 Call Letter and the MA & PDP Fall Conference and Webcast on September 8, 2016[12]. CMS released a formal Request for Comments (RFC): Enhancements to the Star Ratings for 2018 and Beyond on November 10, 2016[13]. CMS appreciates the careful consideration by commenters of the use of audit findings and enforcement actions in the Star Ratings Program. The valuable feedback helped guide the framework of the proposed policy. In response to the comments received, CMS will move forward with proposing a revision to the Beneficiary Access and Performance Problems (BAPP) measure.

The current BAPP measure is based on CMS' sanctions, CMPs, and Compliance Activity Module (CAM) data and has been in use for Star Ratings since 2010. (The detailed BAPP measure specification can be found in the 2017 Star Ratings Technical Notes[14] on pages 50 and 51.) Currently, the BAPP measure receives a weight of 1.5 and is classified as an access measure. The data timeframe for the measure spans from January 1st to December 31st of the measurement period for the Star Ratings year. (For example, for the 2017 Star Ratings, the timeframe used for the BAPP measure was January 1, 2015 through December 31, 2015.) Every contract begins with a BAPP measure score of 100. A contract's score is then reduced contingent on its sanction status, CAM score, and each CMP related to beneficiary access. Contracts under sanction have their score reduced to 0 and receive one star for this measure. The CAM portion of the BAPP score combines information on the notices of non-compliance, warning letters (with or without business plan), and ad-hoc CAPs and their severity. The CAM score per contract is calculated and then converted to deductions ranging from 0 to 80 in increments of 20 (see the Technical Notes for details). The CMP portion of the BAPP measure currently carries a 40 point deduction per CMP.

In the November 10, 2016 RFC, CMS outlined a number of options to incorporate audit findings and enforcement actions in the Star Ratings. The proposed revisions to the BAPP measure included: (a) increasing the weight of the measure to 3; (b) changing the data timeframe to allow use of more recent data; (c) revising the CMP deduction methodology; and (d) modifying the BAPP cut points. In addition, CMS sought comments on retaining both the BAPP measure score reduction for contracts under sanction and the CAM deductions. The RFC provided an opportunity for MA Organizations, PDP sponsors, advocates, and other stakeholders to provide comments in advance of the draft 2018 Call Letter.

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[12] https://www.cms.gov/outreach-and-education/training/cteo/event_archives.html

[13] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Request-for-Comments-2018-Stars.pdf

[14] The 2017 Technical Notes can be accessed using the following link: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ PerformanceData.html.

Many commenters expressed a strong preference to separate the audit findings and enforcement actions from the Star Ratings for reasons including the difference in methodologies and goals of compliance and audits compared to Star Ratings, the perceived subjectivity of the audits, and the absence of audit information for each plan each year. Advocates, however, expressed concern about the increasing disconnect between the audit process and the Star Ratings Program. The majority of commenters, excluding advocates, did not support the change in the weight of the BAPP measure to 3. The opponents of the weight change cited the lack of alignment with the overall structure of the weighting for the Star Ratings Program. Most commenters supported including the revised BAPP measure on the display page before including it in the Star Ratings. There was support to follow CMS' usual procedures to employ the weight of 1 for the first year the revised measure is in Star Ratings and a weight of 1.5 in the subsequent years. Many commenters supported using more recent data. Some commenters expressed concern about the measurement period going across contract years. Of those who expressed a preference for a revised CMP methodology, the majority preferred that a consistent deduction be applied to all contracts cited in the CMP notice using a ratio of the unadjusted CMP amount to enrollment at the time of the enforcement action, using pre-set thresholds. There was widespread support for both the proposed CMP deduction cap of 40 points and the revision of the BAPP cut points. There was a general consensus for maintaining both the sanction and CAM portion and associated deductions of the BAPP measure.

After consideration of the feedback, CMS is proposing a number of revisions to the BAPP measure for the 2018 Star Ratings. At this time, CMS is not proposing to reinstate the reduction in the overall and summary Star Ratings of contracts that are under sanction. In order to be responsive to the request to use more recent data for the CMP portion of the BAPP measure, CMS is proposing to change the data timeframe to the time period from July of the measurement year to June of the following year. For example, the timeframe for the 2018 Star Ratings would be July 2016 through June 2017.

CMS is also proposing to employ the first option outlined in the RFC for the methodology for determining the CMP deduction for the revised BAPP measure that results in the same deduction for each contract held by a parent organization cited in a CMP notice. The scaled CMP deduction per contract is based on a ratio of the unadjusted CMP amount to total enrollment of the cited contracts at the time of the enforcement action. For example, if a parent organization with two contracts cited in the CMP notice (one contract with 15,000 enrollees and the other with 35,000 enrollees at the time of the enforcement action resulting in a total of 50,000 enrollees) received a total unadjusted CMP value of $100,000 during the measurement period, the ratio would be $100,000/50,000 or 2.00. The ratio takes into account the total number of beneficiaries in the cited contracts and the severity of the issue indicated by the unadjusted CMP amount. The ratio rescales the CMP of the parent organization to a per-beneficiary value by taking the unadjusted CMP amount divided by the total enrollment in the contracts included in

the CMP notice. To determine the CMP deduction for each contract cited in the CMP notice, the ratio would be converted to a BAPP deduction for CMPs using the proposed values in Table 1.

Table 1: Ratio Conversion to BAPP Deduction

Ratio	BAPP Deduction per Cited Contract in the CMP Notices
Under 5.00	10 points
5.00 to less than 10.00	20 points
10.00 to less than 15.00	30 points
15.00 and above	40 points

In the example above, if the parent organization had a ratio of 2.00, each of the two contracts cited in the CMP notice would receive a 10 point deduction for the CMP portion of the revised BAPP measure score.

In addition, we propose that the total deduction for a contract for CMPs be capped at 40 points, instead of 40 points per CMP. We propose retaining both the current BAPP measure score reduction for contracts under sanction (such contracts would continue to be reduced to 0 and receive one star for this measure) and the current CAM deductions. In addition, we propose to modify the BAPP measure cut points as detailed in Table 2.

Table 2: BAPP Measure Cut Points

1 Star	2 Stars	3 Stars	4 Stars	5 Stars
0, 10 or 20	30 or 40	50 or 60	70 or 80	90 or 100

For the 2018 Star Ratings, CMS proposes to modify the BAPP measure with the revisions described above. This is consistent with our policy that when a methodology change does not significantly impact the numerator or denominator of the measure, the measure will continue to be included in the Star Ratings. All elements that have previously been included in the BAPP measure would still be included in the revised measure. The revisions modify how many points are deducted for the size of the CMP (capping the deduction at 40 points versus automatically taking a 40 point deduction for each CMP) and change the data timeframe making the data more recent. We do not view this as a significant revision. The revised BAPP measure would receive

a weight of 1 for the 2018 Star Ratings and would carry a weight of 1.5 for the 2019 Star Ratings to align with other access measures. Alternatively, CMS is considering whether to delay implementation of the revised BAPP measure until the 2019 Star Ratings. Under this option, the current BAPP measure would continue to be included in the 2018 Star Ratings, and the revised BAPP measure would be on the 2018 display page and would then be included in the 2019 Star Ratings with a weight of 1 and in the 2020 Star Ratings with a weight of 1.5. CMS welcomes comments on the timing of the transition of the revised BAPP measure into the Star Ratings Program.

CMS also solicits comments on the various aspects of the proposed revised BAPP measure including: weight, data timeframe, revised methodology for the CMP deduction, retention of the CAM and sanction portions of the measure, and cut points. Contract-level simulations of the revised BAPP measure will be available in HPMS in February 2017.

Data Integrity

Data used for the Part C and D Star Ratings must be accurate and reliable. CMS' longstanding policy has been to reduce a contract's measure rating to 1 star if we determine that incomplete, biased or erroneous data have been submitted. As discussed in previous Call Letters, these reductions would include cases where CMS identifies mishandling of data, inappropriate processing, or implementation of incorrect practices by the organization/sponsor that resulted in incomplete, biased or erroneous data. Examples would include, but are not limited to: a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract's failure to adhere to Plan Finder or PDE data requirements; a contract's errors in processing coverage determinations/exceptions or organization determinations found through program audits or other reviews; compliance actions due to errors in operational areas that would directly impact the data reported or processed for specific measures; or a contract's failure to pass Part C and D Reporting Requirements Data Validation related to organization/sponsor-reported data for specific measures. CMS' modifications to measure-specific ratings due to data integrity issues are separate from and in addition to any CMS compliance or enforcement actions related to a sponsor's deficiencies. Sponsors should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications are posted on: http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx. Information about Data Validation of Reporting Requirements data is posted on https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.

Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from attempts to inflate performance or mask deficiencies. CMS has taken several steps in the past years to protect the integrity of the data we use to calculate Star Ratings; however, we continue to identify new vulnerabilities where

inaccurate or biased data could exist. Therefore, CMS will continue to enhance the data integrity reviews to identify incomplete or biased Star Ratings measure data.

CMS piloted a new program audit protocol in 2016 evaluating Part D sponsors' MTM programs. Findings identified during pilots of the new MTM audit protocols are not currently applied to Star Ratings. After the pilot phase, we will review and apply any relevant MTM program audit findings for data integrity reviews for the MTM Comprehensive Medication Review (CMR) Completion Rate measure that could demonstrate systemic failures by sponsors that resulted in biased MTM data.

All four Star Rating appeals measures use data reported by sponsors to Maximus, the IRE. Information from the Medicare Parts C and D audits on sponsor's processing and operational issues is one means of evaluating the integrity or completeness of the IRE data. Additionally, targeted review of IRE cases and relevant compliance actions may be considered as evidence that the IRE data are incomplete. Sponsors have raised concerns about CMS' use of audit findings to determine the completeness of the IRE data used for Star Ratings, since only a small subset of sponsors are audited each year and the vast majority have audit findings resulting in data integrity reductions.

In the November 28, 2016 HPMS memo titled, "Industry-wide Appeals Timeliness Monitoring," CMS discussed a large-scale monitoring project that will be implemented in 2017 (beginning with 2016 data on Part C organization determinations and reconsiderations (referred to as the ODAG process) and Part D coverage determination and redeterminations (referred to as the CDAG process)). This monitoring effort will provide a way for CMS to assess the completeness of the data at the IRE across all contracts. CMS proposes to review the findings and use them for the Star Ratings data integrity reviews for the four appeals measures as appropriate beginning with the 2018 Star Ratings.

2018 Star Ratings Program and the Categorical Adjustment Index

In the draft and final CY 2017 Call Letters, CMS described extensive research that was conducted to develop an interim analytical adjustment for the average within-contract disparity in performance associated with a contract's percentages of beneficiaries with low income subsidy and/or dual eligible (LIS/DE) and disability status. CMS' interim response to address the LIS/DE and disability effect revealed in our comprehensive research culminated in the creation of the Categorical Adjustment Index (CAI). The details of the methodology and the 2017 CAI values were released in the final CY 2017 Call Letter and detailed in the 2017 Medicare Part C & D Star Rating Technical Notes available on the CMS webpage at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

The application of the CAI for the 2017 Star Ratings resulted in a modest movement of the Star Ratings. Nineteen contracts saw their overall Star Rating increase by a half-star in their overall

rating. Nine contracts moved from an overall rating of 3.5 to 4.0 after the CAI was applied to their unadjusted Star Rating. For MA-only and MA-PDs, seven contracts increased a half-star after the application of the Part C CAI value, and 16 MA-PD contracts increased a half-star in their Part D summary rating. The movement for stand-alone PDPs was bidirectional. Nine PDPs decreased a half-star and three increased a half-star after the application of the PDP-specific CAI values for the Part D summary rating.

For the 2018 Star Ratings Program, CMS is proposing to continue the use of the interim analytical adjustment, the CAI. The overall methodology would remain unchanged for 2018.

As stated in the CY 2017 Call Letter (CY 2017 Rate Announcement, Attachment VII, pages 131-133), the CAI values will be updated annually and published in the final Call Letter. The CAI values will be determined using the previous rating year's measurement period, which allows the CAI release of the values well in advance of the first Star Ratings preview period. Thus, the 2018 CAI values are determined using data from the 2017 Star Ratings which employ performance data from measurement year 2015.

LIS/DE status for the 2018 Star Ratings will be based on the Medicare enrollment data from CY 2016. The disability status of an enrollee will be determined using information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems for CY 2016. Disability status is based on the original reason for entitlement code (OREC). In addition, the Medicare Part C & D Star Rating Technical Notes will provide the CAI values along with the details of the methodology

For the 2018 Star Ratings Program, the analysis and criteria used to select measures for adjustment were the same as those used for the 2017 Star Ratings program. CMS updated its analyses of the measures using the 2015 measurement period data and evaluated the variability of within-contract differences in performance for a similar subset of Star Ratings measures[15] examined last year. A summary of the updated analysis conducted to select the measures including the minimum, median, and maximum values for the within- contract variation for the LIS/DE differences will be posted at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html. The decision criteria used to select measures for adjustment was (1) a median absolute difference between LIS/DE and non-

[15] The 16 clinical quality measures that comprised the subset of the Star Ratings measures examined for the 2017 CAI included: adult BMI assessment, rheumatoid arthritis management, breast cancer screening, controlling blood pressure, diabetes care – blood sugar controlled, diabetes care – eye exam, diabetes care – kidney disease monitoring, colorectal cancer screening, osteoporosis management in women who had a fracture, plan all-cause readmissions, annual flu vaccine, monitoring physical activity, reducing the risk of falling, medication adherence for diabetes medications, medication adherence for hypertension, and medication adherence for cholesterol. For the 2018 CAI analysis, reducing the risk of falling was removed for possible adjustment because it will not be included in the 2018 Star Ratings Program due to a specification change. In addition, plan all-cause readmissions was removed because revisions are under consideration. One new measure was added to the analysis for the 2018 Star Ratings, Medication Therapy Management (MTM) Program Completion Rate for CMR.

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

The measures proposed for adjustment for the 2018 Star Ratings include the following three Part C measures for MA (MA-only, MA-PD) and 1876 contracts: Breast Cancer Screening, Osteoporosis Management in Women Who had a Fracture, and Diabetes Care – Blood Sugar Controlled. As done last year, in order to apply consistent adjustments across MA-PDs and PDPs, the Part D measures were selected by applying the selection criteria to MA-PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. For the 2018 Star Ratings program, the two Part D measures: Medication Adherence for Hypertension (RAS antagonists) and Medication Therapy Management (MTM) Program Completion Rate for CMR are proposed for adjustment for MA-PDs and PDPs.

2018 Categorical Adjustment Index (CAI) Values

MA contracts have up to three mutually exclusive and independent adjustments – one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). PDPs have one adjustment for the Part D summary rating. Tables 3 – 14 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 3 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 twelve equal-sized groups. Table 4 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 8.110160%, the contract's LIS/DE initial category is L3. The exceptions for the upper limit exclusion for a class are the twelfth initial category for LIS/DE and the fifth quintile for disabled.

Table 3: Categorization of MA Contracts into Initial LIS/DE Groups for the Overall Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 6.188617
L2	6.188617 to less than 8.110160
L3	8.110160 to less than 10.344828
L4	10.344828 to less than 12.224661
L5	12.224661 to less than 15.456919
L6	15.456919 to less than 19.752043
L7	19.752043 to less than 24.168883
L8	24.168883 to less than 33.968268
L9	33.968268 to less than 51.805150
L10	51.805150 to less than 76.665433
L11	76.665433 to less than 99.831252
L12	99.831252 to less than or equal to 100.000000

Table 4: Categorization of MA Contracts into Disability Quintiles for the Overall Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
D1	0.000000 to less than 15.160537
D2	15.160537 to less than 19.602284
D3	19.602284 to less than 26.769989
D4	26.769989 to less than 38.698266
D5	38.698266 to less than or equal to 100.000000

Table 5 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 5: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L2	D1	−0.020980
B	L3 - L7 L1 - L2	D1 - D3 D2 - D3	−0.009289
C	L8 - L10	D1 - D3	0.001019
D	L1 - L9	D4 - D5	0.011701
E	L11 - L12 L10	D1 - D4 D4	0.037323
F	L10 - L11	D5	0.060366
G	L12	D5	0.085606

Tables 6 and 7 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.

Table 6: 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 5.983054
L2	5.983054 to less than 8.039216
L3	8.039216 to less than 10.242867
L4	10.242867 to less than 12.184512
L5	12.184512 to less than 15.386761
L6	15.386761 to less than 19.691642
L7	19.691642 to less than 23.623793
L8	23.623793 to less than 33.865945
L9	33.865945 to less than 51.765486
L10	51.765486 to less than 76.665433
L11	76.665433 to less than 99.831252
L12	99.831252 to less than or equal to 100.000000

Table 7: 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 14.987446
D2	14.987446 to less than 19.397330
D3	19.397330 to less than 26.688919
D4	26.688919 to less than 38.496072
D5	38.496072 to less than or equal to 100.000000

Table 8 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 8: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	LIS/DE Initial	Disability Quintile	CAI Value
A	L1 - L2	D1	−0.034597
B	L3 - L5 L1 - L2 L3	D1 - D2 D2 - D3 D3	−0.008463
C	L6 - L12 L6 - L9 L4 - L9 L1 - L9	D1 D2 D3 D 4- D5	0.000971
D	L10 - L11 L12	D2 - D5 D2	0.038593
E	L12	D3 - D5	0.060840

Tables 9 and 10 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 9: Categorization of MA-PD Contracts into Initial LIS/DE Groups for the Part D Summary Rating

LIS/DE Initial Group	Percentage of Contract's LIS/DE Beneficiaries
L1	0.000000 to less than 6.188617
L2	6.188617 to less than 8.189398
L3	8.189398 to less than 10.554205
L4	10.554205 to less than 13.047285
L5	13.047285 to less than 15.695174
L6	15.695174 to less than 20.120593
L7	20.120593 to less than 25.628787
L8	25.628787 to less than 37.247228
L9	37.247228 to less than 57.692308
L10	57.692308 to less than 83.018448
L11	83.018448 to less than 99.905110
L12	99.905110 to less than or equal to 100.000000

Table 10: 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 15.274769
D2	15.274769 to less than 20.230934
D3	20.230934 to less than 27.548509
D4	27.548509 to less than 40.446927
D5	40.446927 to less than or equal to 100.000000

Table 11 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 11: Final Adjustment Categories and CAI Values for the Part D Summary Rating for MA-PDs

Final Adjustment Category	LIS/DE Initial Group	Disability Quintile	CAI Value
A	L1 - L2 L3 - L4	D1 - D3 D1 - D2	−0.013576
B	L5 - L9 L3 - L4	D1 - D3 D3	−0.002877
C	L1 - L7 L8	D4 - D5 D4	0.007977
D	L10 - L12 L9 - L11	D1 - D3 D4	0.037128
E	L8 - L9	D5	0.04875
F	L10	D5	0.080788
G	L11	D5	0.10459
H	L12	D4 - D5	0.123372

Tables 12 and 13 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 12: 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 1.861410
L2	1.861410 to less than 6.885402
L3	6.885402 to less than 29.506059
L4	29.506059 to less than or equal to 100.000000

Table 13: 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 8.159247
D2	8.159247 to less than 14.153052
D3	14.153052 to less than 30.526888
D4	30.526888 to less than or equal to 100.000000

Table 14 provides the description of each of the final adjustment categories for the Part D summary rating for PDPs and the associated value of the CAI per final adjustment category.

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

Table 14: Final Adjustment Categories and CAI Values for the Part D Summary Rating for PDPs

Final Adjustment Category	LIS/DE Quartile	Disability Quartile	CAI Value
A	L1	D1	−0.157338
B	L2 - L4 L1	D1 - D2 D2	−0.108075
C	L1 - L3 L4	D3 - D4 D3	−0.019559
D	L4	D4	0.098544

Additional response to address lack of an LIS indicator for enrollees in Puerto Rico

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

For the 2017 Star Ratings, an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS was applied to make the application of the CAI equitable for contracts in Puerto Rico. The details of the methodology are in the Announcement of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter Attachment VII, Section I, pages 135-136 and in Attachment O in the 2017 Medicare Part C & D Star Rating Technical Notes.

For the 2018 Star Ratings, CMS proposes to continue to employ the methodology developed for the additional adjustment for Puerto Rico using the 2015 data from the American Community Survey and CY 2016 Medicare Enrollment data. CMS continues to explore alternative data sources for Puerto Rico to provide both resource and income information for the determination of the additional adjustment.

CMS recognizes the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of LIS. For the 2017 Star

Ratings, CMS implemented a differentiated weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings for contracts that solely serve the population of beneficiaries in Puerto Rico.

For the 2018 Star Ratings, CMS proposes to continue to reduce the weights for the adherence measures to zero (0) for the summary and overall rating calculations and maintain the weight of three (3) for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico.

Next Steps

CMS is firmly committed to building the foundation for a long-term solution that appropriately addresses the issue at hand and aligns with our policy goals. CMS remains steadfast that any policy response must delineate the two distinct aspects of the LIS/DE and/or disability issue - quality and payment as well as prevent distortion of the quality ratings and their meaning. Further, the long-term solution must recognize the unique challenges of serving vulnerable populations. While the measure stewards continue their work, CMS will continue to consider all feasible options that exist for a long-term response.

We will engage the Star Ratings measure stewards, including the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), to review their measures to determine if any are sensitive to the composition of the enrollees in a plan and whether case-mix adjustment of individual measures would be appropriate. We continue to reach out to stakeholders and other HHS collaborators for feedback.

Our work closely aligns with the research agenda of the Office of the Assistant Secretary for Planning and Evaluation (ASPE), as outlined in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185).[16] In December 2016, ASPE released the first in a two-part series of Reports to Congress (RTC) mandated by the IMPACT Act.[17] In it, ASPE analyzes the effect of social risk factors on health outcomes of Medicare beneficiaries. ASPE reviewed a number of CMS programs, including Medicare Advantage. We are carefully reviewing and considering the feasibility of the considerations presented in ASPE's RTC for MA contracts and sponsors, as well as the impact on our use of the ratings for beneficiaries.

In order to develop and implement a long-term response to the effect LIS/DE and disability status have on Star Ratings, CMS seeks comment on the continued use of the CAI, approaches

[16] ASPE, as instructed the IMPACT ACT, is conducting a study that examines the effect of individuals' socioeconomic status on quality measures, resource use, and other measures for individuals in the Medicare program.

[17] 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.

proposed by ASPE, or other suggestions as well as comments on our specific proposal for CY2018.

2018 CMS Display Measures

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that have been transitioned from the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed solely for informational purposes. Organizations and sponsors will have the opportunity to preview the data for their display measures prior to release on CMS' website. Data for measures moved to the display page will 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. It is expected that all 2017 display measures will continue to be shown as display measures on CMS.gov in 2018.

CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Other display measures may be provided as information only. Below are the revised or new measures for the 2018 display page.

- **CAHPS measures (Part C & D).** Patient experience surveys such as CAHPS focus on how patients experienced or perceived key aspects of their care, not how satisfied they were with their care. CAHPS surveys follow scientific principles in survey design and development. The surveys are designed to reliably assess the experiences of a large sample of patients. They use standardized questions and data collection protocols to ensure that information can be compared across health care settings. CAHPS surveys are developed with broad stakeholder input, including a public solicitation of measures and review by a technical expert panel, and the opportunity for anyone to comment on the surveys through multiple public comment periods through the Federal Register.

  In the 2017 Call Letter, CMS committed to shortening the 2017 MA CAHPS survey by removing some questions that are not used in current Star Ratings measures. We removed items from the CAHPS survey that were previously reported on the display page. Display items related to Reminders for appointments, Reminders for immunizations, Reminders for screening tests, Computer used during office visits, Computer use by provider helpful, Computer use made talking to provider easier, and Getting information from drug plan will not be included on the 2017 MA & PDP CAHPS surveys and will not be reported on the 2018 display page.

- **Pneumococcal Vaccination Status for Older Adults (Part C).** The Pneumococcal Vaccination Status for Older Adults (PNU) measure, currently collected through the Medicare CAHPS survey, assesses the percentage of Medicare members 65 years of age and older who have ever received a pneumococcal vaccination. The 2014 Advisory Committee on Immunization Practices pneumococcal vaccination guideline supports

administration of a sequential series of two vaccines for adults age 65 and older. Recent stakeholder and public comment feedback indicates there is significant interest in finding alternative non-survey based methods to assess pneumococcal vaccination status and guideline adherence. Alternative data sources of interest include claims, case management systems, medical records, registries and electronic health records. CMS is exploring potential non-survey based methods of collecting this information and would welcome feedback.

In the meantime NCQA recommended the following wording changes to the existing CAHPS measure: "Have you ever had one or more pneumonia shots? Two shots are usually given in a person's lifetime and these are different from a flu shot. It is also called the pneumococcal vaccine." As previously announced, the new wording will be utilized for 2017 CAHPS implementation. This measure is on the CMS display page.

- **Hospitalizations for Potentially Preventable Complications (Part C).** This measure is a risk-adjusted measure that assesses the rate of hospitalization for complications of chronic and acute ambulatory care-sensitive conditions. The measure is therefore an important indicator of care coordination. CMS first included this measure on the 2017 display page, with plans to move it into the 2018 Star Ratings. Due to concerns from NCQA, the measure developer, we propose to continue this as a display measure for 2018, and move it to the 2019 Star Ratings. The consensus process used by NCQA raised some concerns which were significant enough to warrant a delay. Among these concerns were a large number of outlier plans—those that performed much better or worse than other plans and for unknown reasons. Also, there was some interest in studying the potential bias that might occur when hospitals use observation stays instead of inpatient admissions. NCQA will be studying and reviewing their findings with stakeholders during the coming year and CMS will follow their activities. Please refer to the NCQA HEDIS 2017 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications.

- **Statin Therapy for Patients with Cardiovascular Disease (Part C).** The Statin Therapy for Patients with Cardiovascular Disease measure was developed by NCQA as part of HEDIS. It focuses on the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year. Since the HEDIS statin measures overlap with the measures developed by the PQA, CMS included only one of the HEDIS measures on the 2017 display page and will retain it on the 2018 display page. After gaining experience with the new treatment guidelines and metric, we plan to include this measure in the 2019 Star Ratings.

- **Asthma Measures (Part C).** The measure, Medication Management for People with Asthma, captures the percentage of members 5 to 85 years of age who were identified as having persistent asthma and were dispensed appropriate medications on which they remained during the treatment period (i.e., first prescription date through end of measurement year). The measure, Asthma Medication Ratio, captures the percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. Stakeholders expressed concerns that asthma and COPD might be difficult to distinguish among those age 65 and older. CMS and measure developers will consider the utility of prescription drug event and encounter data to solve these concerns before moving forward with implementing these measures. For this reason, Medication Management for People with Asthma will not be reported on the 2018 display page, nor on the 2018 Star Ratings.

- **Non-Recommended PSA-Based Screening in Older Men (Part C).** This measure (PSA) reflects the percentage of men age 70 and older who were screened unnecessarily for prostate cancer using the prostate-specific antigen (PSA) based screening. It excludes men in hospice, men with a prostate cancer diagnosis or dysplasia of the prostate. It also excludes those with a prior-year PSA test that was elevated (that is, a PSA in the current year is needed for monitoring) and excludes those who were dispensed prescriptions for 5-alpha reductase inhibitor (5-ARI) during the measurement year. CMS plans to report PSA on the 2018 display page and will consider it for 2019 Star Ratings.

- **Formulary Administration Analysis measure (Part D)**. We propose to adopt a new display measure using the results of the Formulary Administration Analysis (FAA) program by which CMS evaluates whether Part D sponsors are appropriately adjudicating Part D drug claims consistent with Part D requirements and sponsors' CMS-approved benefits. For this study, Part D sponsors submit all point-of-sale rejected claims relating to non-formulary status, Prior Authorization, Step Therapy, and Quantity Limits for a specified time period. CMS then selects a targeted sample of rejected claims for further analysis. Each rejected claim is reviewed by the Part D sponsor to verify whether the rejection is consistent with the approved formulary status. CMS next assigns a pass or fail to each sample claim depending on the appropriateness of the rejection. The percentage of failures will be displayed for each Part D sponsor. Since 2015, CMS has produced two display measures using results of the Transition Monitoring Program Analysis (TMPA). We are considering ways in which to expand TPMA and FAA monitoring to allow the inclusion in the Star Ratings as important beneficiary access measures. At the earliest, these measures may be proposed for the 2020 Star Ratings.

- **High Risk Medication (Part D).** As described earlier, we plan to transition the HRM measure from the Star Ratings to the display page for 2018 (based on 2016 data). The

PQA, the measure steward, revised the criteria to calculate the average dose for doxepin, reserpine, and digoxin. We plan to implement this change for the 2018 display measure based on 2016 data.

The HRM measure drug list was further revised by the PQA to reflect the updated 2015 American Geriatrics Society (AGS) Beers Criteria. The intent of this measure has not changed. The specifications, other than the list of medications, have not changed. Per the PQA, the updated measure is effective for use in performance measurement beginning in January 2017. We propose to implement the updated HRM drug list for the 2019 display measure (using 2017 data).

In summary, the revised PQA HRM drug list excludes three drugs (i.e., thioridazine, trimethobenzamide and chloral hydrate), and adds fourteen new HRM drugs. We evaluated the impact of the revised PQA's HRM NDC list on the HRM rate calculations at the contract-level. We generated HRM rate calculations for the CY 2015 participating contracts, and used the final 2015 HRM rates as a baseline. Using the revised list, the HRM rate increased by 3.3% percentage points (3.5% and 3.3% percentage point increase for MA-PD and PDP contracts, respectively). The estimated revised YOS 2015 HRM rates were 10.9% overall, 8.4% for MA-PD contracts and 12.6% for PDP contracts.

Avoiding potentially inappropriate medications in older adults remains important for Medicare beneficiaries' quality of care. This measure will be reconsidered for the Star Ratings again in the future once analyses and specification changes, if any, are completed by the PQA. Any changes will be proposed or implemented with sufficient lead time.

- **Drug-Drug Interactions (Part D).** The drug-drug interactions (DDI) measure is defined as the percent of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or subsequent to the initial prescription. An expert panel convened by the PQA conducted an extensive review of the drug-drug pairs included in its DDI measure, which resulted in a revised list of approved drug-drug interactions effective for the 2017 measurement year. The intent and specifications of the measure were not changed.

  We performed an evaluation of the PQA's revised drug list on the DDI rate calculations at the contract-level. We generated DDI rate calculations for the CY 2015 participating contracts, using 2015 PDE data as of 6/30/16 for both the revised DDI NDCs and the final 2015 rates. The NDC list used for the final 2015 rates was updated in February 2016. Overall, the DDI rate decreased by 2.1% percentage points (1.9% and 2.1% percentage point decrease for MA-PD and PDP contracts, respectively). The new estimated DDI rates were 3.8% overall, 3.1% for MA-PDs and 4.2% for PDPs. We

propose to implement the PQA's revised DDI measure drug list for the 2019 display measure based on 2017 data.

- **Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes (Part D).** In 2013, CMS began to calculate a general atypical antipsychotic utilization rate in nursing homes for inclusion in the Part D display measures. We propose to remove this measure from the 2018 display measure set and replace with the PQA Antipsychotic Use in Persons with Dementia (APD) measure (discussed below).

- **Antipsychotic Use in Persons with Dementia (APD) (Part D)**. The PQA APD measure is defined as the percentage of Medicare Part D beneficiaries 65 years or older with dementia who received prescription fills for antipsychotics without evidence of a psychotic disorder or related condition.

  Part D sponsors began to receive 2016 APD measure reports on a monthly basis through the Patient Safety Analysis website. In addition to the overall APD rates, sponsors also receive rates across three population breakouts:
  - APD-COMM: Community-only residents (never a nursing home resident)
  - APD-STNH: Short-term nursing home residents (100 cumulative days or less in a nursing home based on the Long Term Care Minimum Data Set (MDS)), and
  - APD-LTNH: Long-term nursing home residents (greater than 100 cumulative days in a nursing home).

  As discussed in the final CY 2017 Call Letter, we proposed to add the APD measure (plus the three population breakout rates) to the 2018 display measures using 2016 data. At this time, we propose to only add the overall APD measure to the 2018 display page. We observed some variability in the population breakouts (APD-COMM, APD-STNH, and APD-LTNH) in the monthly 2016 patient safety reports distributed to date. Currently, a beneficiary is assigned to one of the population breakouts based on the number of days that he or she spent in a nursing home during the measurement period but there is no requirement that he or she meet the measure inclusion criteria while staying in a nursing home. Therefore, we propose to improve the precision of the stratification rate calculations beginning with the 2017 reports; beneficiaries must have an antipsychotic claim (meet the numerator criteria) while residing in the community or nursing home. We also propose to report only two population breakouts: APD-COMM and APD-LTNH. This will be applied to the 2017 data for the 2019 display measures at which time we propose to display the overall APD rate as well as the rates for the two population breakouts. We will assess adding the APD measure to the Star Ratings in the future.

- **Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D).** PQA's opioid measures examine multi-provider and/or high dosage

opioid use among individuals 18 years and older without cancer and not in hospice care. These three measures were included in the Patient Safety reports starting in 2016.

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

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

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

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

Additional changes made by the PQA to these measures include:

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

We propose to implement these changes beginning with the 2017 Patient Safety reports. We also propose to add the three measures to the 2019 Part D display page (using 2017 data), but not to add these measures to the Star Ratings at this time.

- **Statin Use in Persons with Diabetes (SUPD) (Part D).** This PQA measure calculates the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice according to the Enrollment Database (EDB) are excluded from the denominator of the SUPD measure for the entire year. We propose that the SUPD measure remains on the display page for 2018 using 2016 data.

The PQA revised the SUPD measure specifications to exclude beneficiaries with end-stage renal disease (ESRD). Beginning with the 2017 measurement year, we would exclude beneficiaries based on ESRD indicator found in Medicare Enrollment Database (EDB). We plan to add the SUPD measure to the 2019 Star Ratings (using 2017 data).

Forecasting to 2019 and Beyond

The following describes changes to existing measures and potential new measures. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings for 2019 or later. As we add new measures, CMS will consider which measures are topped out or have little variation across contracts to transition them to the display page.

Patient Safety Report Frequency

Currently, Part D contracts are provided both their Star Rating and display patient safety measure rates on a monthly basis through the Patient Safety website. Most of the rates are calculated using PQA measure specifications and national drug code (NDC) lists updated bi-annually, usually in January and July. We observed that the monthly measure rates may be affected by both the time between NDC updates as well as a lag in PDE data submissions. Beginning with the 2017 reports, we propose to generate the patient safety measures reports (and outlier notices) quarterly instead of monthly to reduce the variability due to data lags. CMS seeks input on this proposal from Part D contracts.

Changes to existing measures

- **Colorectal Cancer Screening (Part C).** The Colorectal Cancer Screening (COL) measure assesses the percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer. This measure is based on the U.S. Preventive Services Task Force (USPSTF) guideline on colorectal cancer screening in adults age 50-75. In June 2016 the USPSTF released a new clinical recommendation statement and NCQA updated the measure specifications so that computed tomography colonography and FIT-DNA are recognized as screening test options, as well as screening via fecal occult blood test, flexible sigmoidoscopy and colonoscopy. These changes have been implemented in the HEDIS 2017 measure specification, but as they expand screening options, this measure will not be removed from Star Ratings.

Potential changes to existing measures

- **Initiation and Engagement in AOD Treatment (IET, Part C measure).** The Initiation and Engagement in Alcohol or Other Drug Dependence Treatment (IET) measure assesses the percentage of adolescent and adult members with a new episode of alcohol or other drug dependence (AOD) who 1) initiated AOD treatment within 14 days

of the diagnosis and 2) had two or more additional services for AOD treatment within 30 days of the initiation visit. CMS would welcome feedback on including data on the use of Medication-Assisted Treatment (MAT) in the denominator and numerator components of the measure. These changes are being considered for data collection in 2018, which would lead to reporting of this measure on the display page in 2020.

- **Telehealth and Remote Access Technologies.** CMS welcomes feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare covered telehealth services and/or as a provided by the MAO as a MA supplemental benefit, as eligible encounters in various Part C quality measures.

  For example, some HEDIS measures require a visit for the denominator, numerator, or exclusion, and we seek comment on if telehealth and/or remote access technology encounters should be counted as eligible encounters for the relevant portion of the measure, that is whether for counting as part of a measure, such telehealth and/or remote access technology visits are equivalent (reasonable replacements) for in-person visits for relevant clinical areas. NCQA is interested whether this inclusion might be appropriate, for example, for certain behavioral health services.

  If such encounters were included, data from 2018 would reflect this change and could be included in 2020 display page.

- **Cross-Cutting Exclusions for Advanced Illness.** CMS welcomes feedback on the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected Part C measures. While many Part C measures are designed to compare the quality of care provided to general populations or disease-specific care provided to individuals with a chronic condition, these measures may not be clinically appropriate for certain individuals with advanced illness and may overlook the quality issues that are specific to these patients. NCQA is therefore considering the need for exclusions for selected measures for patients with advanced illness where providing certain treatments and services may not be appropriate. We welcome feedback about whether specific illnesses and health care utilization (e.g., use of palliative care services) may warrant an exclusion, and to which measures the exclusion should be applied. We would be concerned about any changes to measures that result in lessened incentives for providing high-quality care to such beneficiaries.

- **Care Coordination measures (Part C).** A critical reason Medicare Advantage plans exist is to coordinate care and ensure good transitions between care settings. Therefore, CMS proposes to treat measures of such activities as intermediate outcomes since the reflect actions taken which can assist in improving a beneficiary's overall health status. We are proposing to weight care coordination and transition measures as a 3 starting with

the 2019 Star Ratings. This would include the CAHPS Care Coordination measure and Medication Reconciliation measure and additional measures in future years.

- **Center for Medicare and Medicaid Innovation Model Tests.** The MA Value-Based Insurance Design (MA-VBID) model test is an opportunity for MAOs to offer supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. The Part D Enhanced Medication Therapy Management (MTM) model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. We note that some stakeholders have expressed concern regarding the potential for the improvements in quality resulting from the MA-VBID and the Part D Enhanced MTM Model test to adversely influence the Star Ratings of contracts ineligible to participate (or that include some PBPs ineligible to participate). CMS' goal is to not penalize participants or non-participants in either model.
For the MA-VBID Model test, CMS is considering the option of exclusion of VBID-participants' data when calculating the cut points for relevant measures. CMS has waived the MTM requirements under Section 1860D–4(c)(2) and 42 CFR 423.153(d) and the Part D Reporting Requirements for MTM for Part D plans participating in the Part D Enhanced MTM Model. However, Part D sponsors with plans participating in this model must establish MTM programs in compliance with current requirements and reporting data for the remaining plans under each Part D contract. Therefore, the MTM Program CMR Completion Rates will be calculated using available plan-reported data from the remaining plans under the Part D contract. CMS plans to analyze if this approach significantly advantages or disadvantages Enhanced MTM model participants and evaluate potential adjustments as necessary, including the establishment of different cut points for model participants or to case-mix adjust scores for the purpose of determining cut points.

Temporary removal of measures from Star Ratings

- **Reducing the Risk of Falling (Part C).** This measure, collected through the Medicare Health Outcomes Survey (HOS), assesses the percentage of beneficiaries who discussed falls or problems with balance or walking with their provider and received fall risk intervention(s) from their provider. NCQA made two changes to this measure. First, NCQA changed the denominator of both indicators to include all beneficiaries age 65 and older, as opposed to limiting the denominator to those age 75 and older or age 65-74 with a balance or walking problem or fall in the past year. This action removes a potential bias toward sampling only patients who were treated unsuccessfully. Second, NCQA updated the list of example interventions by removing the phrase "Check your blood pressure lying down or standing" and adding "Suggest you take Vitamin D." This aligns the list of

interventions with current USPSTF recommendations. These changes required revising the underlying survey questions in HOS. The measure will remain in the Star Ratings for 2018. The revised questions will be first collected in 2018. As a result of these changes, there will be no data for this measure for the 2019 and 2020 Star Ratings.

NCQA is exploring several revisions to the HEDIS Plan All Cause Readmission measure based on feedback they have received from the field and stakeholders. These revisions may impact the definition of the denominator, numerator and risk adjustment model for data collected in 2018. The specific revisions they are exploring include 1) Inclusion of observation stays in the denominator and numerator; 2) revising the measure denominator to be the overall plan population as opposed to index hospital admissions; and 3) adding death in the measurement year as a possible factor in the risk adjustment model.

Potential new measures for 2019 and beyond

- **Care Coordination Measures (Part C).** Effective care coordination, including care transition, contributes to improved health outcomes (http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Care_Coordination_Measures.aspx). CMS believes that 5-star MA contracts perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plan care coordination activities, however, is based largely on anecdotes and discussions with high performing plans, as well as on data from CAHPS surveys, which reflect enrollees' experiences with the care they receive.

  CMS is working to expand efforts to better evaluate a plan's success at effective care coordination. To identify potential new care coordination measures, CMS has awarded two contracts to conduct targeted research, extensive literature reviews, and data analysis, and to engage in discussions with expert panels and high performing plans. As part of this effort, the contractors are using various data sources such as administrative data, encounter data, Part D data and medical record reviews. We are considering whether the measures should be focused on subgroups of MA enrollees or all MA enrollees. We are also considering the activities that best represent care coordination, such as ensuring seamless transitions across settings, appropriate follow up after inpatient and emergency department visits, utilizing appropriate health IT tools to share information, communication across providers, and comprehensive assessments, as well as the relationship between the plan and provider in care coordination activities. We will provide more details as measures are developed in this area.

- **Transitions of Care (Part C).** CMS welcomes feedback about a new HEDIS *Transitions of Care* measure with four indicators:

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

The intent of the measure is to improve the quality of care transitions from an inpatient setting to home. The measure would be potentially collected in calendar year 2018 for use on the display page in 2020. CMS welcomes feedback about any of the components of the measure, about data collection options, and about the ability of such a measure to contribute to better assessment of care coordination for Medicare Advantage enrollees.

- **Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C).** CMS is considering use of a new HEDIS measure assessing follow-up care provided after 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 following an acute event, like an emergency department visit, can help to prevent the development of more severe complications. The developer, NCQA, is evaluating what timeframe (e.g., 7, 14, or 30 days post-ED visit) and what types of follow-up (e.g., face- to-face office visits, telephone or web interactions, or visits to the home) are appropriate. CMS is interested in feedback on these questions as well as on the utility and importance of this measure as a care transitions measure.

- **Opioid Overuse (Part C).** Additionally, NCQA approved the PQA's three opioid measures (discussed above) in 2016 but is considering two additional measures of opioid overuse including:

  Multiple Prescribers: The percentage of members receiving prescriptions for opioids from four or more prescribers during the measurement year.

  Multiple Pharmacies: The percentage of members receiving prescriptions for opioids from four or more pharmacies during the measurement year.

  Once developed, we will consider future testing or collection which could begin in calendar year 2018 for use on the 2020 display page.

- **Depression Screening and Follow-Up for Adolescents and Adults (Part C).** CMS is exploring with measure developers adapting a provider-level measure for use in

measuring plan performance. The measure assesses the percentage of patients age 12 and older who were screened for depression using a standardized assessment tool, such as the PHQ-9, and if positive, received appropriate follow-up care within 30 days of the positive screen. This measure would potentially be collected in 2018 for use on the display page in 2020. CMS welcomes feedback on the measure, the best range of standardized assessment tools to be used in primary care settings for screening, and the measure's reliance on electronic clinical data systems.

- **Alcohol Screening and Follow-Up (Part C).** CMS aims to adapt a provider-level measure, Unhealthy Alcohol Use: Screening & Brief Counseling (NQF 2152), for health plan reporting. The intent of this measure is to increase the use of alcohol screening and brief intervention, which is recommended by the USPSTF for adults 18 and older. A number of health plans have been helping to test and evaluate performance for the adapted measure and to gather information on feasibility of implementation at the health-plan level. CMS would welcome feedback on the implementation of data collection in 2018 for reporting on the display page in 2020.

- **Appropriate Pain Management (Part C).** CMS continues to welcome feedback on ways to measure appropriate management of chronic and acute pain, especially among patients with particular specific conditions such as chronic medical illnesses, substance abuse, and depression. CMS is interested in feedback about different settings, such as inpatient, emergency department, and primary care settings, and about the value of a wide range of pharmacologic and nonpharmacologic approaches. Finally, CMS is interested in the applicability and feasibility of implementing such measures at the plan level versus at the medical group or individual practitioner level.

- **Plan Makes Timely Decisions about Appeals (Part C).** CMS is considering including dismissals and withdrawn appeals in this measure starting with the 2019 Star Ratings to align with the Part D appeals measure.

- **New PQA-endorsed measures in development for future testing/consideration (Part D).**

    1. Concurrent Use of Opioids and Benzodiazepines: The percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.

    2. Adherence to Non-infused Disease Modifying Agents Used to Treat Multiple Sclerosis: The percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80% during the measurement period for disease-modifying agents treating multiple sclerosis.

Measurement and Methodological Enhancements

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. Feedback or recommendations can help CMS' continuing analyses, as well as our collaboration with measurement development entities such as NCQA and PQA. We are also interested in stakeholder input on measures that should be transitioned to the display page starting with the 2019 Star Ratings due to measure scores being "topped out" or showing high performance across all contracts. For example, overall performance is high on Diabetes Care – Kidney Disease Monitoring. In making decisions to transition measures to the display page, CMS does not have a strict formula. Although some measures may show uniform high performance across contracts and little variation between them, we want to balance how critical the measures are to improving patient care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures. If plans have only recently achieved uniformly high performance, for example, or if no other measures capture a key focus in Star Ratings, a "topped out" measure may be retained in Star Ratings.

- In light of recent USPSTF updates related to breast cancer screening, CMS is interested in feedback about the current evidence for age and appropriate methods for primary screening for breast cancer. CMS and the steward for the Breast Cancer Screening HEDIS measure, NCQA, will be reviewing feedback to assess whether or not changes are needed to the measure.

- Effective processing of Part C organization determinations and reconsiderations and Part D coverage determination and redeterminations by sponsors are critical areas of the Medicare Advantage and Part D program. CMS requirements for these processes provide key beneficiary protections for access to health care and prescription drugs. We have featured appeals measures in the Star Ratings since 2007 because they are such important indicators of beneficiary access. We are interested in developing new or enhanced measures of beneficiary access, especially with the industry-wide collection of data from all sponsors using CMS audit protocols for ODAG and CDAG. In addition to the current measures of sponsors' timeliness and reliable decision-making, we are interested in potentially evaluating sponsors' compliance with effectuating appeals and provider outreach requirements, as well as appropriate clinical-decision making and notification to beneficiaries and their caregivers. We welcome stakeholder feedback on the types of information that would be more important to Medicare beneficiaries when comparing their access to needed medical services and drugs.

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.

Since the 2016 Call Letter, CMS has announced the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) model tests; both began operations on January 1, 2017. Each of these model tests are described below.

Potential means of adjustment to account for the impact of these models on Star Ratings are discussed above under Enhancements to the 2018 Star Ratings and Beyond.

CMS continues to work on the development of potential new innovations in health plan design. We welcome stakeholder suggestions and input.

Medicare Advantage Value-Based Insurance Design Model Test

The MA-VBID model test is an opportunity for MAO's to offer supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. Only those MAOs expressly authorized by CMS to participate in the model may do so, and only within PBPs accepted into the model test. The model will test whether the additional flexibility provided to MAOs to develop and offer interventions can improve health outcomes and lower expenditures for Medicare Advantage enrollees.

CMS is testing the model in Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee. Beginning in CY 2018, CMS will also test the MA-VBID model in Alabama, Michigan, and Texas.

CMS has authorized eleven MAOs from nine parent organizations in Indiana, Massachusetts, and Pennsylvania to participate in the model test in CY 2017, and released a Request for Applications for CY 2018 participation.

For more information, including a description of other changes to the model test's design for CY 2018, please visit: https://innovation.cms.gov/initiatives/vbid/.

Part D Enhanced MTM Model

The Part D Enhanced MTM model tests whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. The model is an opportunity for stand-alone basic Part D plans to right-size their investments in MTM services, identify and implement innovative strategies to optimize medication use, improve coordination of care between plans and providers, and strengthen system linkages.

Six Part D Sponsors encompassing 22 PBPs are participating in the CMS Innovation Center's Part D Enhanced MTM model for 2017. These plans will offer MTM programs subject to the terms and conditions of the model test in the selected regions. All other Part D plans, including any ineligible plans offered by the PDP sponsors of participating plans, will remain subject to the current regulatory requirements for MTM programs. For more information, please visit: https://innovation.cms.gov/initiatives/enhancedmtm/.

Section II – Part C

Overview of CY 2018 Benefits and Bid Review

Portions of this guidance apply to cost-based plans and MA plans (including EGWPs, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs), and Institutional Special Needs Plans (I-SNPs)). CMS does not evaluate whether employer group plans, D-SNPs, and 1876 Cost Plans are duplicative under 42 C.F.R. § 422.256(b)(4) for our "meaningful difference" evaluation. Similarly, employer group plans and 1876 Cost Plans are not evaluated for low enrollment under 42 C.F.R. § 422.506(b)(1)(iv) and (b)(2). CMS reserves the right to review employer group plans for low enrollment and/or meaningful difference in future years.

Medicare-Medicaid Plans in capitated financial alignment model demonstrations are not subject to the review criteria summarized in the table below and benefits and benefit review guidance for these plans will be provided separately.

CMS makes all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expects all MAOs to submit their best, accurate, and complete bid(s) on or before the Monday, June 5, 2017 deadline. Any organization whose bid fails the Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference, Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements at any time prior to final approval will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of error(s).

The following table displays key MA bid review criteria and identifies the criteria that are used to review the bids of the various plan types identified in the column headings.

Table 15: Plan Types and Applicable Bid Review Criteria

Bid Review Criteria	Applies to Non-Employer Plans (Excluding Dual Eligible SNPs)	Applies to Non-Employer Dual Eligible SNPs	Applies to 1876 Cost Plans	Applies to Employer Plans
Low Enrollment 42 C.F.R. §422.506(b)(1)(iv) and (b)(2)	Yes	Yes	No	No
Meaningful Difference 42 C.F.R. § 422.254(a)(4)	Yes	No	No	No
Total Beneficiary Cost section 1854(a)(5)(C)(ii) of the Act 42 C.F.R. § 422.254	Yes	No	No	No
Maximum Out-of – Pocket (MOOP) Limits 42 C.F.R. §422.100(f)(4) and (5) and §422.101(d)(2) and (3)	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing 42 C.F.R. § 422.254(b)(4)	Yes	Yes	No	Yes
Service Category Cost Sharing 42 C.F.R. §§417.454(e), 422.100(f) and 422.100(j)	Yes	Yes	Yes[1]	Yes
Part C Optional Supplemental Benefits 42 C.F.R. §422.100(f)	Yes	Yes	No	No

[1] Section 1876 Cost Plans and MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 C.F.R. §§417.454(e) and 422.100(j)).

CMS has interpreted and applied the regulatory standards for service category cost sharing standards and amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) requirements for CY 2018 and has provided guidance on these requirements in each applicable section below. Consistent with last year, MAOs also must address the requirements

implemented under the Affordable Care Act, such as the medical loss ratio and health insurance providers fee, and are expected to do so independently of our requirements for benefits or bid review. Therefore, CMS is not making specific adjustments or allowances for these changes in the benefits review requirements.

Plans with Low Enrollment

At the end of March, CMS will send affected MAOs a list of non-SNP plans that have fewer than 500 enrollees or fewer than 100 enrollees for SNP plans and that have been in existence for three or more years [as of March 2017 (three annual election periods)]. The notification represents CMS' decision not to renew these plans under 42 C.F.R. §422.506(b)(1)(iv) and (b)(2). Plans with low enrollment located in service areas that do not have a sufficient number of competing options of the same plan type (such that the low enrollment plan still represents a viable plan option for beneficiaries), as determined by CMS, will not receive this notification.

Through return e-mail, MAOs must either (1) confirm each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2018, or (2) provide a justification for renewal. If CMS does not find a unique or compelling reason the low enrollment plan is a viable plan option for beneficiaries, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting justifications will be included with the list of low enrollment plans sent to the MAO. Note: These requirements do not apply to Section 1876 cost plans, employer plans, or MA Medical Savings Account (MSA) plans.

CMS recognizes there may be certain factors, such as the specific populations served and geographic location of the plan that led to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because they focus on a subset of enrollees with certain medical conditions. CMS will consider this information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs should follow CMS renewal/non-renewal guidance (see the Medicare Managed Care Manual: section 150 of Chapter 4, and/or section 60.2 of Chapter 16B) to determine whether a low enrollment plan may be consolidated with another plan(s). CMS will continue to evaluate and implement low enrollment requirements on an annual basis.

Meaningful Difference (Substantially Duplicative Plan Offerings)

Pursuant to 42 C.F.R. § 422.254(a)(4), MAOs offering more than one plan in a given service area must guarantee the plans are substantially different so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs. CMS will continue to use plan-specific per member per month (PMPM) out-of-pocket cost (OOPC) estimates to identify meaningful differences in beneficiary costs among the same plan types. For CY 2018, benefits and the reduction in cost sharing offered as part of the Value-Based Insurance Design (VBID) model test will not be

included in the meaningful difference evaluation as in CY 2017. Documentation and instructions for the OOPC model are available at: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.

CMS will continue to evaluate meaningful differences among CY 2018 non-employer and non-cost contractor plans offered by the same MAO, in the same county and, under the same contract. Consistent with past years, we will consider a difference of at least $20.00 PMPM between the OOPC for each plan offered by the same MAO in the same county to be meaningful for purposes of applying the meaningfully different standard. The evaluation process will be the same as indicated in the final CY 2017 Call Letter. We will provide a detailed explanation of the evaluation process in mid-April 2017 via an HPMS Memorandum titled "CY 2018 MA Bid Review and Operations Guidance."

Plans are reminded that plan characteristics such as premium, variations in provider networks, and/or serving different populations are not considered meaningfully different characteristics. Premium is excluded from the criteria because by regulation, the meaningful difference requirement is intended to be an objective measure of benefits between two plans; the inclusion of premium would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity. Provider network differences also are excluded from our criteria because having a provider in one plan and not the other is not a difference in benefit coverage. In addition, plan providers can change throughout the year (e.g., terminate their provider contract or close their practice to new members), so point-in-time provider network differences are not similarly transparent to a beneficiary when making a plan choice for the year. However, we are interested in how differences in the provider network could constitute a meaningful difference and how plans could work with us to make such network differences both transparent to beneficiaries and consistent throughout the plan year. CMS reserves the right to conduct the meaningful difference evaluation at either the legal entity or parent organization level in future years.

CMS notes meaningful difference will be evaluated based on the "as submitted formulary" prior to rebate reallocation, and "first approved formulary" following rebate reallocation. MAOs must follow the CY 2018 renewal/non-renewal guidance in the final CY 2018 Call Letter to determine if their plans may be consolidated with other plans.

If CMS provides an opportunity to correct CY 2018 meaningful difference issues following the submission deadline, we will not prescribe how the MAOs should redesign benefit packages to achieve the differences. The MAO will not be permitted to change its formulary (e.g., adding drugs, etc.) as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS identified formulary review concerns negatively affects the formulary and bid review process. For example, portions of the annual formulary review process are based on outlier analyses. If an MAO were permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely

impacted. In addition, significant formulary changes will necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor's formulary and could affect approval of its contract. To avoid meaningful difference issues, MAOs are strongly encouraged to make sure all Part C and 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. We make all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expects all MAOs to submit bids that satisfy our requirements.

Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Act to deny MAO bids, on a case-by-case basis, if it determines the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next through the use of the TBC standard. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. By limiting excessive increases in the TBC from one year to the next, CMS is able to make sure enrollees who continue enrollment in the same plan are not exposed to significant cost increases. As in past years, CMS will evaluate TBC for non-employer plans (excluding D-SNPs). For CY 2018, benefits and cost sharing that are offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the TBC evaluation. The MA plans participating in the VBID model test will be evaluated under the TBC calculation, including plan premium and non-VBID benefits and cost sharing.

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.

Detailed TBC requirements and examples will be provided in mid-April 2017 via an HPMS Memorandum titled "CY 2018 MA Bid Review and Operations Guidance". CMS will maintain the TBC requirements and change thresholds communicated in the final CY 2017 Call Letter. However, we are taking this opportunity to refine and clarify previous guidance on the topics below.

Each individual plan being consolidated into another plan must meet the TBC requirement on its own merit. The TBC for each CY 2017 plan will be compared independently to the CY 2018 plan. In this calculation, CY 2017 plans being consolidated into the continuing CY 2018 plan will <u>not</u> have the following adjustments applied to the TBC calculation: (1) county benchmark, (2) quality bonus payment and/or rebate percentages, and (3) annual changes in OOPC model

software. If applicable, the adjustment for the maximum Part B premium buy-down amount change in the bid pricing tool will be applied to the calculation for consolidating plans. The TBC evaluation for the continuing plan (CY 2017 vs. CY 2018) will have all applicable adjustments applied to the TBC calculation.

If CMS provides an opportunity to correct CY 2018 TBC issues following the submission deadline, the MAO will not be permitted to change its formulary (e.g., adding drugs etc.) as a means to satisfy this requirement. The formulary review process has multiple stages and making changes that are unrelated to CMS identified formulary review concerns negatively affects the formulary and bid review process. For example, portions of the annual formulary review process are based on outlier analyses. If an MAO were permitted to make substantial formulary changes after the initial reviews, these analyses could be adversely impacted. In addition, significant formulary changes would necessitate additional CMS review, outside of the normal review stages, and may jeopardize the approval of a sponsor's formulary and contract. To avoid TBC issues, MAOs are strongly encouraged to make sure all Part C and Part D benefit and formulary changes are considered as part of their TBC evaluation prior to submitting their final bids and formularies to CMS. We make all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expect all MAOs to submit bids that satisfy our requirements. Detailed TBC information and examples will be provided in mid-April 2017 via the HPMS Memorandum titled "CY 2018 MA Bid Review and Operations Guidance."

Maximum Out-of-Pocket (MOOP) Limits

As codified at 42 CFR §422.100(f)(4) and (5) and §422.101(d)(2) and (3), all MA plans, including employer group plans and SNPs, must establish limits on enrollee out-of-pocket spending that do not exceed the annual maximum amounts set by CMS. Although the MOOP requirement is for Parts A and B services, an MAO can include supplemental benefits as services subject to the MOOP. MA plans may establish as their MOOP any amount within the ranges shown in the table.

Table 16 below displays the CY 2018 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 the CY 2017 Call Letter, 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 16: CY 2018 Voluntary and Mandatory MOOP Range Amounts by Plan Type (Values may be updated at a later date)

Plan Type	Voluntary	Mandatory
HMO	$0 - $3,400	$3,401 - $6,700
HMO POS	$0 - $3,400 In-network	$3,401 - $6,700 In-network
Local PPO	$0 - $3,400 In-network and $0 -$5,100 Combined	$3,401 - $6,700 In-network and $3,401 - $10,000 Combined
Regional PPO	$0 - $3,400 In-network and $0 - $5,100 Combined	$3,401 - $6,700 In-network and $3,401 - $10,000 Combined
PFFS (full network)	$0 - $3,400 Combined	$3,401 - $6,700 Combined
PFFS (partial network)	$0 - $3,400 Combined	$3,401 - $6,700 Combined
PFFS (non-network)	$0 - $3,400	$3,401 - $6,700

As explained in the CY 2012 Call Letter, MOOP limits are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The mandatory MOOP amount represented approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, five percent of Original Medicare beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments and coinsurance. The voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs.

The Office of the Actuary conducts an annual analysis to help CMS determine the proposed MOOP amount. Since the MOOP requirement was finalized in 42 C.F.R. § 422.100(f)(4) and (5), a strict application of the 95th and 85th percentile would have resulted in MOOP limits fluctuating from year-to-year. CMS has exercised discretion to maintain stable MOOP limits from year-to-year, if the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages, and does not discourage the adoption of the lower voluntary MOOP amount if the limit increases one year and then decreases the next. CMS expects to increase MOOP limits if a consistent pattern of increasing costs emerges over a period of time.

Although it may be rare that a dual-eligible enrollee would be responsible for paying cost sharing (because the State Medicaid program is making those payments on his/her behalf), all MA plans must track enrollees' out-of-pocket spending for covered services in order to make certain an enrollee does not spend more than the MOOP amount limit established by the plan. If the plan charges cost sharing for covered services, certain dual-eligible enrollees for whom cost-sharing is allowed may incur cost sharing and any enrollee losing his/her Medicaid eligibility may be responsible for cost sharing. D-SNPs have the flexibility to establish $0 as the MOOP amount, thereby guaranteeing there is no cost sharing for plan enrollees, including those who are liable for Medicare cost sharing. Otherwise, if the D-SNP does charge cost sharing for Medicare Part A and Part B covered benefits, it must track enrollees' out-of-pocket spending and it is up to the plan to develop the process and vehicle for doing so.

CMS is conducting research and evaluating potential future changes to the MOOP limits, based on Medicare FFS, MA encounter, and general benefit data analyses. CMS will communicate any future changes through the Call Letter or HPMS guidance documents so that plans will have adequate time to comment and prepare. In addition, any significant changes would be transitioned over time to avoid disruption to benefit designs and minimize any potential beneficiary confusion.

Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost Sharing Limits

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 and must not be discriminatory. In order to ensure that cost sharing is consistent with both 42 C.F.R. § 422.254(b)(4) and §422.100(f)(2), CMS will evaluate actuarial equivalent cost sharing limits separately in the following service categories for CY 2018: Inpatient, 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 2018. As indicated in the final CY 2017 Call Letter and described in the Part C Cost Sharing Standards section of this Call Letter, CMS will not permit cost sharing for the first 20 days of the Skilled Nursing Facility (SNF) benefit for CY 2018. Therefore, SNF has been removed from the AE evaluation.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the BPT. Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to Original Medicare Actuarially Equivalent Cost Sharing (BPT Worksheet 4, Section IIA, column n). For Inpatient services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

Once the comparison amounts have been determined, excess cost sharing can be identified. Excess cost sharing is the difference (if positive) between the plan cost sharing amount (column #1) and the comparison amount (column #5). The table below uses illustrative values to demonstrate the mechanics of this determination.

Table 17: 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	1.410	$35.67	$0.00	Pass
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 only reflect Part A fee-for-service actuarial equivalent cost sharing for that service category.

NOTE: In CY 2017, CMS waived the requirement for MA employer plans to submit a Bid Pricing Tool (BPT), which affects our ability to evaluate the PMPM Actuarial Equivalent Cost Sharing discussed in this section. MA employer plans continue to be subject to all unwaived MA regulatory requirements regardless of whether they are affirmatively evaluated as part of bid review or in connection with other oversight.

Part C Cost Sharing Standards

For CY 2018, 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 18 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for MA plans that we will not consider discriminatory or in violation of other applicable standards. CY 2018 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 standards have been updated to reflect estimated changes in Original Medicare cost for CY 2018.

Table 18: CY 2018 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	$4,235
Inpatient Hospital – Acute - 10 days	1a	$2,495	$1,996
Inpatient Hospital – Acute - 6 days	1a	$2,271	$1,817
Inpatient Hospital Psychiatric - 60 days	1b	$2,677	$2,142
Inpatient Hospital Psychiatric - 15 days	1b	$2,025	$1,620
Skilled Nursing Facility – First 20 Days[1]	2	$0/day	$0/day
Skilled Nursing Facility – Days 21 through 100[1]	2	$167.50/day	$167.50/day
Cardiac Rehabilitation Services	3	$50	$50
Intensive Cardiac Rehabilitation Services	3	$100	$100
Pulmonary Rehabilitation Services	3	$30	$30
Emergency Care/Post Stabilization Care[2]	4a	$100	$80
Urgently Needed Services[2]	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%

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
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[1,3]	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, skilled nursing care and renal dialysis services (42 CFR §§417.454(e) and 422.100(j)).

[2] 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).

[3] Part B Drugs - Chemotherapy cost sharing displayed is for services provided on an outpatient basis and includes administration services. MAOs have the option to charge either coinsurance or a copayment for most service category benefits. For example, based on the cost sharing requirements indicated above for Part B Drugs – Chemotherapy, a plan can choose to either assign up to a 20% coinsurance or $75 copayment to that particular benefit.

MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 CFR §422.100(j)). Although CMS has not established a specific service category cost sharing limit for all possible services, MA plans may not pay less than 50% of the contracted (or Medicare allowable) rate and cost sharing for services cannot exceed 50% of the total MA plan financial liability for the benefit. 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 3 includes specific benefits for cardiac rehabilitation, intensive cardiac rehabilitation and pulmonary rehabilitation services), while other categories include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (e.g., category 8b includes outpatient diagnostic radiological services). It is expected that organizations typically have much lower cost sharing for enrollees than our requirements due to effective managed care principles, effective negotiations between organizations and providers, and competition.

MAOs with benefit designs using a coinsurance or copayment amount for which CMS does not have an established amount (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 CMS service category requirements 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 2018 > 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.

The following summarizes the changes in cost sharing requirements for CY 2018:

- As indicated in the final CY 2017 Call Letter, CMS will not permit cost sharing for the first 20 days of the SNF benefit for CY 2018. Please note plans are not permitted to apply a service category deductible or a per stay amount to the SNF benefit. In CY 2017, MA plans with a voluntary MOOP were able to have limited cost sharing for the first 20 days of the SNF benefit. However, total cost sharing for the overall SNF benefit (days 1-100) was not permitted to be higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).

- Three additional cost sharing thresholds have been added for cardiac rehabilitation services, intensive cardiac rehabilitation services, and pulmonary rehabilitation services. As indicated in the final CY 2017 Call Letter, these services have been an area of concern for CMS based on research conducted with organizations having higher than expected cost sharing amounts or benefits designs that were not fully transparent to beneficiaries.

- Per our authority at 42 C.F.R. §422.113(b)(2) (v), the Emergency Care/Post Stabilization Care limit for plans has been increased for CY 2018 to better align cost sharing with actual costs and as an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services. The voluntary MOOP amount has been increased from $75 to $100, while the mandatory MOOP amount has been increased from $75 to $80. CMS expects having different limits based on the plan’s MOOP amount will encourage organizations to offer benefit packages with a lower voluntary MOOP amount, while maintaining beneficiary protection.

  As part of the CY 2017 Call Letter process, CMS requested and received helpful comments about cost sharing flexibility for voluntary MOOP plans and suggestions and incentives to

encourage MAOs to offer plans with a lower voluntary MOOP for enrollees. CMS is continuing to evaluate available data (e.g., Medicare FFS and MA encounter data) and explore alternatives that would encourage effective benefit designs for beneficiaries and expect to make refinements in future years.

CMS is continuing to conduct research and evaluate additional changes to the service category cost sharing limits and we expect to add other limits for inpatient acute and inpatient psychiatric days in future years. For example, CMS is considering additional limits for shorter stays for both inpatient acute and inpatient psychiatric applicable in CY 2019 and encourage organizations to take this into consideration as they design their benefit packages for CY 2018.

Part C Optional Supplemental Benefits

As part of our evaluation whether the bid and benefits are not discriminatory against enrollees with specific (or high cost) health needs, CMS will continue to review non-employer bid submissions to verify enrollees electing optional supplemental benefits are receiving reasonable value. CMS will continue to consider a plan to be non-discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following thresholds: (a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15% and (b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by a percent of premium, is no greater than 30%.

CMS understands some supplemental benefits are based on a multi-year basis, but the plan bids submitted each year are evaluated based on that particular plan year.

Employer Group Waiver Plans

In CY 2017, CMS waived the requirement for MA employer plans to submit a MA or Part D Bid Pricing Tool (BPT), but employer plans must complete and submit the MA portion of the Plan Benefit Package (PBP) in accordance with CMS requirements. Organizations should make a good faith effort in projecting CY 2018 member months for each plan and place the amount in Section A-2 of the PBP. The following question must be completed for all MA and 1876 Cost Plan organizations: "Indicate CY 2018 total projected member months for this plan."

Medical Services Performed in Multiple Health Care Settings

CMS will continue its efforts to avoid duplication of medical services categories in the PBP and provide guidance on how to properly place services that can be performed in different health care settings (e.g., physician office, outpatient hospital, and free standing facility) in the appropriate service category to correctly complete data entry within the PBP.

CMS aims to improve transparency and streamline data entry so cost sharing associated with those PBP service categories reflects the services provided across a variety of healthcare settings.

CMS is concerned that including the same service in multiple locations throughout the PBP may result in confusing marketing materials and that CMS cost sharing requirements may be compromised. Based on the out-of-pocket cost (OOPC) model methodology, including services with zero cost sharing for the minimum amount in a multiple service category will artificially reduce the estimated out-of-pocket costs used by beneficiaries in comparing plans on Medicare Plan Finder and adversely affect CMS bid review for meaningful difference and Total Beneficiary Cost (TBC).

Most individual PBP service categories reflect cost sharing for services provided in different places of service. The two service categories below generated the most questions because they reflect a specific place of service. Based on bid review activities, MAOs requested examples of services that may be included by plans:

- Outpatient Hospital (9a): Some examples include, outpatient surgery, observation services, and palliative care services.

- Outpatient Diagnostic/Therapeutic Radiological Services (8b): Some examples include, magnetic resonance imaging (MRI), positron emission tomography (PET) and single-photon emission computed tomography (SPECT) services.

These examples are provided in the service category descriptions in HPMS documentation and the PBP screens.

Tiered Cost Sharing of Medical Benefits

For CY 2018, MAOs will continue to submit tiering requests through an electronic mailbox. Organizations must submit the benefit design to CMS prior to bid submission to help make sure benefits are acceptable and communications are transparent for beneficiaries. Organizations also are permitted to modify proposed cost sharing amounts in their actual bid submission. Further details regarding the process will be provided in an HPMS memorandum in mid-April.

CMS Monitoring and Compliance Activities Regarding Encounter Data

Under 42 C.F.R. § 422.310 MAOs are required to submit encounter data for each item and service provided to an MA plan enrollee. The Medicare Advantage Encounter Data System (EDS) was implemented to receive encounter data beginning in 2012 and has collected over 2 billion encounter data records to date. PACE organizations are also required to submit encounter data.

Pursuant to 42 C.F.R. § 422.310(d), for PY 2015 CMS initiated the transition to Encounter Data based risk scores for MA and PACE enrollees by using diagnoses from encounter data records as an extra source of data when calculating beneficiary risk scores. For PY 2016, CMS blended two risk scores, one calculated using diagnoses from the RAPS, and the other risk score calculated using diagnoses from encounter data records; the RAPS and ED-based risk scores are weighted

90 percent and 10 percent, respectively. For PY 2017, the RAPS and ED-based risk scores will be weighted 75 percent and 25 percent, respectively. See Attachment III of this CY 2018 Advance Notice.

Additionally, as a prudent purchaser of medical care for Medicare enrollees, CMS has a need to ensure the collection of complete and accurate encounter data for a range of program purposes beyond risk adjustment, such as analysis of service utilization in the MA program. For example, a recent CMS analysis of encounter data was used by the Department of Health and Human Services to locate and assist MA enrollees requiring respiratory services during the disaster relief efforts in Louisiana this summer. Ensuring the completeness and accuracy of encounter data is also important as a growing community of analysts starts to use these data for a range of research projects.

As required under § 422.310(b) and (d), MAOs must submit risk adjustment data that characterize the context and purpose of each item and service provided to a Medicare enrollee, and must also conform to CMS' requirements for submitting this data and to all relevant national standards. In addition, at § 422.504(l), CMS requires MAOs to certify to the accuracy, completeness, and truthfulness of their encounter data (based on best knowledge, information, and belief). Thus, CMS expects that MAOs are conducting self-assessments regarding the accuracy and completeness of their encounter data submissions for each contract they have with CMS, and that each year MAOs apply the findings from their self-assessments to improve the accuracy and completeness of their encounter data submissions. We also note that CMS is conducting site visits with a sample of MAOs to understand different approaches to and issues with encounter data processing and to identify areas where CMS can improve technical assistance and guidance.

These proposed monitoring measures will be used to review and evaluate whether an MAO's encounter data submissions meet the regulatory standards applicable to CMS-specified abbreviated formats (also known as RAPS data) and data that is equivalent to FFS data (also known as encounter data).

CMS has been conducting basic monitoring of MAOs' encounter data submissions since 2012 and will now be using performance measures related to encounter data submission to guide oversight and enforcement in this area, with the goal of further ensuring complete and accurate submissions. CMS is implementing compliance actions for some failures to comply with the regulatory submission standards set forth at § 422.310(b) and (d) and at § 422.504(l). CMS will include MMPs in these efforts as appropriate.

CMS is focusing monitoring and compliance activity in these areas:

- Operational Performance: Refers to submitters' performance related to encounter data submission requirements such as certification to submit, non-submission, and frequency of submission.

- Completeness Performance: Refers to both the overall volume of encounter data records (e.g., whether encounter data records are being submitted for all services rendered) as well as to the completeness of data within an encounter data record (e.g., whether key fields are populated as expected).

- Accuracy Performance: Refers to the reasonableness of ED patterns. Measures addressing the reasonableness of specific data elements or reasonable patterns in submitted data would be considered under the area of accuracy (e.g., reasonable patterns of HCPCs and diagnosis codes).

CMS will communicate its measures and acceptable performance thresholds (benchmarks) via the Call Letter, HPMS memos, or other guidance communications.

CMS has identified the following seven measures (4 operational and 3 completeness) to use to guide its evaluation and oversight of MAO data submission under 42 C.F.R. §422.310:

- (Operational Performance O1) **Failure to complete end-to-end certification**

  CMS will assess certification status to identify contracts that have failed to complete end-to-end certification.

- (Operational Performance O2) **Failure to submit any encounter data records**

  CMS will assess failure to submit any encounter data records for a given calendar year.

- (Operational Performance O3) **Failure to submit encounter data records on a timely basis**

  CMS' encounter data systems must accommodate submissions from all MAOs of data on each item and service provided to each enrollee. To handle submissions for millions of enrollees each year, CMS and MAOs need to manage system loads in an efficient and cost-effective manner. To this end CMS has communicated to submitters the need for routine, timely submissions of encounter data records (EDRs) since 2012, expressed as the standards described in Table 19.

  Therefore, CMS will assess the frequency of submitters' file submissions each quarter, based on the most recently completed three quarters. CMS will count whether an MAO has submitted files on a timely basis and as frequently as necessary. The frequency standards are based on the enrollment size of a contract as shown in the table below.

Table 19: Plan Size Submission Frequency Requirements

Number of Medicare Enrollees in the Contract	EDR Minimum Submission Frequency
Greater than 100,000	Weekly
50,000 – 100,000	Bi-Weekly (every 2 weeks)
Less than 50,000	Monthly

- (Operational Performance O4) **Excessive encounter data submission at the end of the risk adjustment data submission window**

  Submission of an excessive number of records at the end of the submission window indicates that encounter data records have not been submitted timely throughout the year. The denominator of the measure will be the total number of encounter data records submitted with dates of service in the calendar year for which the most recent risk adjustment submission window has passed, and the numerator of the measure will be the subset of encounter data records for the applicable calendar year submitted in the last two months of the submission window.

- (Completeness Performance C1) **Extremely low volume of overall encounter data record submissions.**

  The regulation at §422.310(b) requires submission of encounter data for all items and services provided to an MA enrollee; a low volume of submissions indicates that encounter data is not being submitted for all items and services on a timely basis. CMS will assess submitters' overall volume of encounter data records (those records making it through the front-end of the EDS) each quarter, based on the most recently completed three quarters. CMS will use as a guide whether a submitter's overall volume of encounter data records is at or below a percentage of the benchmark for two consecutive quarters within a rolling three quarter period. The benchmark for comparison will be the average overall front-end volume of encounter data records for all MA contracts within the enrollment size category (small contracts are those under 50,000 enrollees, medium contracts are those with enrollment between 50,000 and 100,000, and large contracts are those with greater than 100,000 enrollees).

- (Completeness Performance C2) **Extremely low volume of accepted encounter data records by service type.**

  The regulation §422.310(b) requires submission of encounter data for all items and services provided to an MA enrollee; a low volume of submissions indicates that encounter data is not being submitted for all items and services on a timely basis in the required format. CMS will assess submitters' volume of accepted encounter data records

in the aggregate as well as by service type (inpatient, outpatient, professional, DME). CMS will assess whether a submitter's aggregate or service level volume of encounter data records is at or below a region-specific percentage of the benchmark for two consecutive quarters. The benchmark for comparison will be the aggregate and service level volume of encounter data records for all MA contracts within a region.

- (Completeness Performance C3) **Low matching rate of inpatient encounter data records to inpatient no-pay records.**

  The regulation §422.310(b) requires submission of encounter data for all items and services provided to an MA enrollee; a low matching rate to inpatient no-pay records received from hospitals by CMS indicates that encounter data is not being submitted for all items and services. Certain inpatient hospitals must submit "informational-only" bills (also known as "No Pay" claims) for MA enrollee discharges, under FFS payment policies. These bills are submitted to CMS in order to capture the number of MA inpatient days, which are utilized in calculations of medical education and disproportionate share (DSH) payments to the hospitals. For information on requirements for informational-only bills, see Chapter 3 of the Medicare Claims Processing Manual (e.g., Sections 20.3 and 140.2.5.3) on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.

  CMS assumes that the number of hospital inpatient No Pay claims for enrollees under an MA contract serves as a comparison "floor" for assessing the minimum level of inpatient encounter data records (EDRs) that CMS would expect to receive from each contract. .

  CMS will assess the ratio of total matched No Pay claims to total No Pay claims**.** The measure is calculated as the contract-level count of No Pay claims that match[18] inpatient encounter data records divided by the total number of No Pay claims for a contract year. The measure will be used to assess encounter data records submitted with dates of service in the calendar year for which the most recent risk adjustment submission window has passed.

CMS will communicate a contract's performance on these measures to the appropriate contacts. Currently, CMS uses the Encounter Data Report Cards, which are distributed to MAOs, cost plans, and PACE organizations via HPMS to provide information on some of the existing performance measures (e.g. frequency of file submission and volume of submissions).

In future years, CMS expects to revise existing performance measures or include additional measures as they are developed as part of CMS' on-going evaluation and oversight of MAO

[18] The EDR-No Pay match is determined based on the following four fields: beneficiary ID, claim from date, claim through date, and contract ID.

compliance with the standards set forth at § 422.310(b) and (d) and at § 422.504(l). The measures and benchmarks discussed here will be used to evaluate MAO compliance with the regulatory and statutory requirements related to risk adjustment data submission. Each performance measure will be calculated independently. These evaluations will inform and provide direction for CMS oversight and compliance actions with regard to the applicable regulations. Each performance measure will be calculated independently.

CMS will continue monitoring and assessment of contractor performance, using these measures. CMS will identify contracts failing to meet the performance thresholds for follow up communication and tracking, and will conduct compliance activity, including but not limited to notices of non-compliance, warning letters, and corrective actions plans as needed to improve performance.

Clarifications and Updates

Benefit Period Clarification for PBP

An organization may structure its hospital and skilled nursing facility (SNF) benefits to define 'benefit periods' differently than in Original Medicare. Such a benefit period typically starts the day inpatient care begins and ends when an enrollee has not received any inpatient care for a defined period of time. For example, in Original Medicare, the beneficiary must have 60 days without inpatient care to begin a new benefit period for inpatient care. CMS provides organizations with the four options listed below when choosing a benefit period for inpatient hospital acute, inpatient hospital psychiatric and SNF (referred to as inpatient facility hereinafter) benefits in the PBP. All benefit periods (including "Other") must not limit the number of inpatient days it covers to less than the number that would be covered by Original Medicare during a contract year and must be actuarially equivalent to Original Medicare's benefit and should be easily understood by the enrollee.

PBP Options:

(1) Original Medicare's benefit period for inpatient facilities, begins the day an enrollee is admitted to the inpatient facility. The benefit period ends when the enrollee has not received any inpatient care, for 60 days in a row. If the enrollee goes into a hospital or a SNF after one benefit period has ended, a new benefit period begins. The enrollee must pay cost sharing for each benefit period. There's no limit to the number of benefit periods.

(2) Annual benefit period begins the day an enrollee is admitted to an inpatient facility but there is no end of the period. The enrollee is charged cost sharing only once a year, no matter how many times the enrollee is admitted or discharged from an inpatient facility throughout the year.

(3) Per Admission benefit period (also may be referred to as "per stay") begins the day an enrollee is admitted to an inpatient facility and ends when the enrollee is discharged. The enrollee is charged the cost sharing each time he/she is admitted to an inpatient facility.

(4) "Other" benefit period is an option for plans to select if the Original Medicare, Annual or Per Admission alternatives do not describe the benefit period the organization is providing. The organization must provide a description of the benefit period in the notes section of the PBP so CMS can review and understand how their benefit period is being provided to their enrollees.

Based on previous bid review activities, CMS discovered some plans have chosen "Other" for the benefit period and the description used by the plan to describe the benefit period more appropriately fell into the a "Per Admission" or "Per Stay" benefit period category. It is important plans select the appropriate benefit period and only select "Other" for the benefit period if no other options provided in the PBP appropriately characterize the benefit period.

Reinsurance

CMS is reminding MAOs that Part C reinsurance arrangements must comply with the statutory requirements in Section 1855 of the Act (42 U.S.C. 1395w-25). Please note this does not apply to Part D plans, including the Part D portion of an MA-PD plan. Section 1855(b) provides four categories of permissible reinsurance arrangements and the types of risk for which an MAO may seek reinsurance. These are:

(1) insurance or other arrangements for the cost of providing to any enrollee such services the aggregate value of which exceeds such aggregate level as CMS specifies;

(2) insurance or other arrangements for the cost of such services provided to its enrolled members other than through the organization because medical necessity required their provision before they could be secured through the MAO;

(3) insurance or other arrangements for not more than 90 percent of the amount by which the MAO's costs for any of its fiscal years exceed 115 percent of its income for such fiscal year; and

(4) arrangements with physicians or other health care professionals, health care institutions, or any combination of them to assume all or part of the financial risk on a prospective basis for the provision of basic health services by such physicians or other health professionals or through such institutions.

By completing the Attestation of Benefit Plan in HPMS as part of the contracting process with CMS, MAOs attest that benefits will be offered in accordance with all applicable Medicare

program authorizing statutes and regulations and program guidance that CMS has issued, which includes the aforementioned Section of the Act.

CMS has received questions from MAOs about the permissibility of specific types of reinsurance. As an example, quota share arrangements, a pro rata reinsurance where the insurer and the reinsurer share risk (possibly from the first dollar of coverage) based upon an agreed percentage, do not fall within the four categories of reinsurance arrangements permitted by the statute. Accordingly, this type of reinsurance arrangement is not permissible.

Regarding category (1) above, the Act also provides us with the authority to establish an aggregate limit applicable to when an organization "may obtain insurance or make other arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds such aggregate level as [specified] from time to time." CMS, based on an analysis performed by the Office of the Actuary, may establish an aggregate limit for reinsurance in future rulemaking. We request comments on the aggregate threshold for category (1) to assist in developing a proposal for potential future rulemaking.

SNP-Specific Networks

CMS has increasingly taken steps to make certain that Medicare Advantage (MA) networks provide adequate access to covered services to meet enrollees' healthcare needs in accordance with 42 C.F.R. § 422.112(a)(1)(i). We currently assess MA network adequacy at the contract level; however, many Medicare Advantage organizations (MAOs) offer a variety of plans under a contract. These include special needs plans (SNPs), which are MA coordinated care plans specifically designed to provide targeted care to special needs individuals who are either (1) institutionalized (I-SNPs), (2) dually eligible for both Medicare and Medicaid (D-SNPs), or (3) have a specific severe or disabling chronic condition (C-SNPs). All SNPs are required to limit enrollment to beneficiaries who meet the eligibility criteria for the type of SNP and to follow the same rules as non-SNP MA plans, but the key difference is that SNPs provide focused care to special target populations based on their unique health care needs. Given the different needs of SNP populations, CMS is interested in exploring the potential benefits of establishing separate network adequacy evaluations of SNP-specific networks.

We seek comment from SNP enrollee advocates, professional organizations, and sponsors on how and whether SNP-specific networks do and should differ from non-SNP MA plan networks in order to provide adequate access to covered services in light of the needs of the SNP covered population. For example, C-SNP networks might have or need more providers in certain specialties related to the chronic condition(s) of the given C-SNP. CMS asks commenters to consider what SNP-specific networks currently look like, how they are different from other MA networks, what would be desirable in SNP-specific network adequacy evaluation, and any suggested modifications to our current network adequacy evaluation and oversight relative to SNP-specific networks. We are also interested in how SNP specific network adequacy

evaluation would improve patient health or the quality of care. Our goal is to better understand current SNP-specific networks and to make appropriate changes to ensure adequate access for some of our most vulnerable MA enrollees in need of enhanced care coordination. Based on the feedback from SNP stakeholders, CMS may consider future guidance and development of SNP-specific network adequacy evaluations.

Decreasing Health Disparities in the Quality of Care that Vulnerable Populations Receive

A high priority for CMS is addressing disparities in health and health care between the population groups our agency serves. Furthermore, this supports the Health and Human Services (HHS) Strategic Goals for ensuring access to quality, culturally competent care for vulnerable populations. HHS Strategic Goal 1 (Strengthen Health Care) aims to reduce racial and ethnic disparities by providing culturally and linguistically appropriate health information, empowering individuals and their families through education and outreach strategies, and targeting environmental health initiatives in lower-income and minority communities. [19]

We are taking this opportunity to reinforce the importance of providing health care to enrollees in a nondiscriminatory way and to clarify our policies to assist MAOs in identifying ways to eliminate disparities. 42 C.F.R. §422.110 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in health programs and activities that receive Federal financial assistance provided or made available by the Department. CMS reminds MAOs of their obligation to ensure that all enrollees receive high quality and necessary care without discrimination.

To improve health equity among vulnerable populations – racial and ethnic minorities, people with disabilities, sexual and gender minorities, and rural populations – MAOs are expected to promote access to high-quality and culturally competent health care services. CMS believes that some MAOs have interpreted the regulations at 42 C.F.R. § 422.110, which prohibits discrimination, to preclude the MAO from conducting outreach that targets a portion of the population or providing targeted interventions to a specific subset of enrollees. In fact, MAOs may target groups of enrollees for specialized services based on the enrollees' health conditions, as illustrated by the Enhanced Disease Management supplemental benefit described in Chapter 4 of the Medicare Managed Care Manual. CMS also expects MAOs to analyze enrollee data to identify disparities among their enrollees and undertake quality improvement and outreach activities to increase enrollee engagement so that appropriate care, including preventive services, can be provided to enrollees that have been identified as having worse health outcomes. To assist in the identification and prioritization of disparities, in 2016 CMS launched Part C and D Performance Data Stratified by Race and Ethnicity for HEDIS and CAHPS measures at the

[19] https://www.hhs.gov/about/strategic-plan/

contract and national level, which can be found at this link: https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.html.

In alignment with the above-referenced law and HHS strategic goals, CMS seeks comment from the industry regarding their experiences related to identifying and engaging enrollees in order to provide appropriate services, especially to vulnerable enrollees. CMS is particularly interested in learning about MAOs' collection of information about enrollees' race, gender, ethnicity and languages and how that information is used to eliminate disparities through quality improvement and outreach activities.

Section III – Part D

Formulary Submissions

CY 2018 Formulary Submission Window

The CY 2018 HPMS formulary submission window will open this year on May 15, 2017 and close at 11:59 PM PDT on June 5, 2017. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 5, 2017 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 5th deadline will result in denial of that bid submission.

CY 2018 Formulary Reference File

CMS will release the first CY 2018 Formulary Reference File (FRF) in March 2017. 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 2017, 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.

In May 2017, CMS is planning to provide a subsequent release of the 2018 FRF prior to the June 5th formulary submission deadline. The May FRF will be released in mid to late May in order to allow for sufficient time to evaluate and add new Part D drugs that become available in our datasets. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2011 and 2012, 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 2018 FRF and the June 5th deadline, CMS is unable to accommodate an updated version of the 2018 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2018 FRF will not be included in the 2018 OOPC model.

CMS will offer a summer formulary update window that will allow for the following formulary changes: 1) the addition of drugs that are new to the summer release of the FRF, and 2) the submission of negative changes on brand drugs, only if an equivalent generic or therapeutically similar drug is added to the summer FRF and corresponding formulary file within the same category and class, at the same tier or lower, and with no more restrictive utilization management than what was applied to the existing brand. Thus, plan sponsors need to carefully consider any newly added drugs to the May release of the 2018 FRF, since additional restrictions will be imposed on the summer formulary update window.

Part D sponsors are reminded that they may enhance their formularies by adding Part D drugs (with or without utilization management restrictions), reducing beneficiary cost-sharing, or removing utilization management edits between the summer update window and the first HPMS submission of the upcoming plan year. These enhancements must be included in the Part D sponsor's marketing materials and must be submitted during the next available HPMS formulary submission window. Sponsors are encouraged to notify beneficiaries of formulary additions in a timely manner since in some cases, such as new generics, an earlier conversion could lead to better value for the beneficiary and potentially reduce program costs.

Changes for CY 2018 Formulary Submissions

Historically, CMS has collected the drug type label for each RxCUI on the formulary file submission. Similarly, this information is collected on the PBP to indicate which types of drug will be placed on each tier. For CY 2018, we have proposed that the formulary file submission format will no longer contain a field for drug type label, and the options on the PBP will be streamlined to two options: brand and generic. To see our proposal, which is pending OMB approval (OMB control number 0938-0763), please refer to the Paperwork Reduction Act (PRA) listing CMS-R-262, titled "CY 2018 Plan Benefit Package (PBP) Software and Formulary Submission" for complete file layouts and PBP screenshots, available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html.

United States Pharmacopeia (USP) Convention Medicare Model Guidelines

Version 7.0 of the USP Medicare Model Guidelines is currently under development. It is anticipated that the final version of 7.0 will be available on usp.org in February 2017. Upon CMS' acceptance of the revision, Part D sponsors that utilize the Model Guidelines for their formulary classification will be expected to use this version in their formulary development and submission processes. In addition, CMS intends to utilize this version in its review process.

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 2017 MTM program annual cost threshold is $3,919. The 2018 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2018 Call Letter.

Tiering Exceptions: Policy Clarifications, Additional Operational Guidance, and Solicitation for Stakeholder Feedback

Consistent with §1860D-4(g)(2) of the Social Security Act and CMS, regulations at 42 C.F.R. § 423.578(a), plan sponsors offering prescription drug benefits for Part D drugs through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures. These procedures must permit enrollees to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement.

Changes in the prescription drug landscape, including the considerable impact of high-cost drugs on the Part D program, have resulted in increasingly complex plan benefit packages and more variation in type and level of cost-sharing. In response, CMS has made a number of changes to Part D formulary tier models for non-defined standard plans, including changes to tier labeling, which has resulted in brand and generic drugs being placed on the same tiers more frequently. However, some of these changes, along with the prevalence of multiple brand and generic drug tiers on formularies, have resulted in confusion about CMS policies related to tiering exceptions.

While tiering exceptions are not unlimited, we believe that plan sponsors are being more restrictive in their application of these exceptions than the statute and regulations contemplate, in part because current tier models that are widely used across the industry are not explicitly referenced in regulations. Through audit findings, independent review entity (IRE) reversals of denied tiering exception requests, and numerous inquiries from plan sponsors and PBMs, we have repeatedly seen plan sponsors incorrectly deny tiering exception requests. For example, we have seen plan sponsors do the following:

- incorrectly deny requests based solely upon a tier being labeled "generic" without taking into consideration that the tier also includes brand drugs, and therefore is not "generic" for purposes of 42 C.F.R. §423.578(a)(6);

- fail to consider tiering exception requests for any drug on a tier that is labeled as "preferred," solely because that tier is labeled as "preferred," even when there are alternative drugs in a lower-cost tier on the plan sponsor's formulary; and

- fail to consider tiering exceptions into lower cost-sharing tiers when those lower tiers contain alternatives to the requested drug, including situations where there are alternatives on multiple lower-cost tiers.

CMS anticipates that the following policy clarifications related to tiering exceptions will make the process more accessible for enrollees and less cumbersome for plan sponsors to administer. By helping plan sponsors ensure that their tiering exceptions process complies with CMS requirements, we also hope that it will help reduce IRE overturns for these cases.

Preferred and Non-Preferred Drugs

When plans design their tiering exceptions criteria and adjudicate requests for tiering exceptions, CMS expects these sponsors to apply the correct definitions for preferred and non-preferred drugs. Pursuant to 42 C.F.R. §423.100, a preferred drug is "a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary." Sponsors should not base tiering exception eligibility on the tier label of the tier on which the alternative drug(s) are placed, but rather whether the tier has lower cost-sharing than the requested drug, thereby making it preferred. For example, if the plan sponsor's formulary includes Tier 2 – Generic ($15 copay) and Tier 3 – Preferred Brand ($45 copay), Tier 2 is preferred relative to Tier 3. In this example, Tier 2 is a mixed tier containing both brand and generic drugs. Outside of the allowable limitations established by CMS (e.g., the requested drug is on the specialty tier, there are no alternatives contained on any lower tier), plan sponsors should not restrict their consideration of a tiering exception request based on the tier label, and should not limit their consideration to a single lower tier if there are multiple lower tiers containing alternative drugs.

Approval of Tiering Exception Requests

Chapter 18, §30.2.1.4 states that, "When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier." CMS is clarifying that, in situations where the requested drug has alternatives in multiple lower tiers and the plan sponsor has approved the request for a tiering exception, the plan must apply the cost-sharing for the *lowest* applicable cost-sharing tier that contains alternatives for the requested drug because, consistent with the manual provision, the lowest cost-sharing tier is the "applicable lower cost-sharing tier." For example, if the requested drug is a generic drug on Tier 4 – Non-Preferred Drug, and there are alternative drugs on multiple lower tiers, e.g. both Tier 3 – Preferred Brand and Tier 2 –Generic that the plan or a higher level adjudicator has determined would be less effective or have adverse effects for the enrollee, the appropriate cost-sharing for the approved request would be the lowest tier, i.e., Tier 2. We would expect the prescriber's supporting statement to say that those multiple alternatives are or would be less effective or have adverse effects to approve the Tier 4 drug at the Tier 2 price. Consistent with 42 C.F.R. §423.578(a), a tiering exception is granted when the Part D plan sponsor determines that the requested drug is medically necessary.

Therefore, it is incumbent upon the plan to determine, in light of the supporting statement, whether there is another alternative to the prescribed drug that is in a lower tier than the preferred drug addressed in the prescriber's supporting statement. As stated in §§30.2.1.3 and 40.2 of Chapter 18, and in the clarifying guidance issued through an October 18, 2016, HPMS memorandum "Guidance on Outreach for Information to Support Coverage Decisions," if the plan sponsor believes it needs additional information to support the medical necessity of the requested drug, it must make reasonable and diligent efforts to obtain the additional information from the prescriber. In the example above, Tiers 3 and 2 are mixed tiers containing both brand and generic drugs. Current tier labels for non-defined standard Part D plans allow plans to label a tier as "generic" even when that tier contains multiple brand drugs, as long as the majority of the drugs on that tier are generic. As described in §30.2.1.4 of Chapter 18, the limitation on approval of tiering exceptions at the cost-sharing that applies to generic drugs set forth at 42 CFR §423.578(a)(6) refers to tiers that *only include* generic drugs, not mixed tiers that are labeled generic.

Request for Information on Tiering Exceptions

Through the CY 2018 Call Letter, CMS is soliciting information, on a voluntary basis, related to tiering exceptions from plan sponsors, PBMs, and other interested stakeholders. While tiering exception requests constitute a small percentage of overall case volume at all levels of the coverage and appeals process, they are consistently associated with significantly lower approval rates than all other types of coverage and exception requests. Additional information that stakeholders elect to provide to CMS will help close information gaps for tiering exception cases, particularly at the plan sponsor level, and inform potential future rulemaking in this area. Specifically, we are requesting the following aggregated at the PBP level:

- At both the coverage determination and redetermination levels, information related to tiering exceptions request volume, approval/denial and appeal rates, compared to other types of cases;
- At both the coverage determination and redetermination levels, data related to the reasons that tiering exception requests are approved or denied, for example:
    - Categorical denials, such as requests for drugs contained on the specialty tier, approved non-formulary drugs, or drugs for which there are no lower-cost alternatives on the plan's formulary
    - Medical necessity denials, such as requests where the plan sponsor is not able to obtain sufficient information to approve (a missing or incomplete supporting statement), or where the plan sponsor has determined the medical necessity criteria is not met

- Data related to volume of requests for tiering exceptions to a $0 copay tier, and rates/rationale for approval and denial;
- Information about enrollee complaints related to tiering exceptions and ways CMS could improve beneficiary experiences with the tiering exceptions process; and
- Specific areas of concern or confusion related to CMS policy for tiering exceptions encountered by plan sponsors, PBMs, beneficiaries, or other stakeholders, including areas identified through plan analysis of IRE overturns.

Access to Preferred Cost-Sharing Pharmacies

In the CY 2016 Call Letter, CMS announced the policies we would implement during 2016 to address low access to preferred cost-sharing pharmacies (PCSPs). CMS then stated in the CY 2017 Call Letter that we would continue to implement policies for that year. Because we believe that the policies first announced for CY 2016 have afforded beneficiaries improved beneficiary access to PCSPs and clearer information about PCSP networks offered by Part D plans, we will continue to apply them in CY 2018 and in succeeding plan years.

For each plan year, CMS will take the following steps related to PCSP access for beneficiaries. First, we will post information about the current year's PCSP access levels on the CMS website. Second, we will require plans who were outliers with respect to access to PCSPs to disclose that their plan's PCSP network offered lower access than other plans. Finally, we will work with plans that are extreme outliers to address concerns about beneficiary access and marketing representations relating to preferred cost-sharing. We will work with extreme outlier plans to either improve access or develop targeted marketing strategies to ensure that beneficiaries selecting these plans are aware of their status as extreme outliers.

The current policy has improved access to PCSPs since it was first implemented, and we will continue to apply the same outlier thresholds that have been in place since CY 2016. Therefore, plans that provide PCSP pharmacy access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas will be identified as outliers in 2018 and succeeding years, unless CMS notifies sponsors of a change in the thresholds in a future Call Letter. Outlier plans will be required to disclose in marketing materials, including websites, that their plans' PCSP networks offer lower access. The required disclaimer language was first announced in the June 24, 2015, HPMS memo "Marketing Disclaimer Language for Plans with Limited Access to Preferred Cost-Sharing Pharmacies" and was reissued in an August 16, 2016, HPMS memorandum. CMS continues to expect that plans will analyze their own 2017 and 2018 networks to determine whether they are below outlier thresholds. CMS will analyze preferred cost-sharing pharmacy access on a quarterly basis and will remind plans of their outlier status periodically.

CMS will also continue to work with extreme outliers to address concerns about beneficiary access and marketing representations related to preferred cost-sharing. CMS will notify these plans in or around April of each year that we intend to address with them during bid negotiations PCSP access issues for the upcoming plan year. In 2016 and 2017, most plans identified as extreme outliers opted to improve access rather than develop marketing plans to better inform beneficiaries of low PCSP access. We anticipate plans will take similar steps during negotiations for 2018 and future plan years.

We will continue to publish information about PCSP access levels annually on the CMS website at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html. We will also explore the feasibility of incorporating this information into the Medicare Plan Finder in the future.

Sponsors that fail to include required marketing disclosure language and/or do not meet the terms of bid negotiation agreements will be subject to compliance and/or enforcement actions.

Part D Benefit Parameters for Non-Defined Standard Plans

Each year, in order to implement certain regulations, we set forth certain benefit parameters, which are based on updated data analysis, and therefore, are subject to change from year to year. Specifically, pursuant to § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package (other than defined standard) or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered; and, pursuant to 42 C.F.R. § 423.104(d)(2)(iii), tiered cost-sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. The benefit parameters for CY 2018 are set forth in Table 20 below.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 20 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 55% 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 24% applies. We remind sponsors that when cost-sharing reductions beyond the standard benefit are offered through a supplemental Part D benefit, the plan liability is applied to applicable drugs for applicable beneficiaries before the manufacturer discount.

Benefit Review

We will continue to scrutinize the expected cost-sharing amounts incurred by beneficiaries under coinsurance tiers in order to more consistently compare copay and coinsurance cost-sharing impacts. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty tiers that are greater than the standard benefit of 25%, we will compare the average

expected cost-sharing amounts submitted by sponsors in the PBP to the established copay thresholds, as noted in Table 20 below, to determine whether the coinsurance values are discriminatory. We will also continue to disallow incentives such as $0 or very low cost-sharing for 30 day supplies at mail service, unless offering the same cost-sharing at the retail network.

We remind sponsors that we expect Drug Tier Labels to be representative of the drugs that make up that tier. Sponsors will continue to have the option of selecting a non-preferred *brand* tier or non-preferred *drug* tier, but not both. CMS will continue to evaluate the brand/generic composition of the non-preferred *brand* tier as part of the bid review process and communicate concerns based on an outlier analysis. While we continue to believe a coinsurance structure is preferable for the non-preferred *drug* tier, CMS will continue to afford Part D sponsors the flexibility to determine what cost-sharing structure is most appropriate for their benefit design, with the goal of maintaining transparency and a meaningful benefit offering for beneficiaries who enroll in a plan with non-preferred drug tiers that also balances a sponsor's ability to mix brand and generic drugs within the tier. We intend to conduct outlier tests for those Part D sponsors who choose a copay structure for the non-preferred drug tier. In order to demonstrate that the cost-sharing structure chosen provides a value for beneficiaries, we expect sponsors to evaluate and be prepared to provide written justification upon request. Sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.

Please note that the PBP tool has been modified for CY 2018 with respect to Drug Type Labels. The options have been simplified to include either "brand" or "generic." Please refer to "Changes for CY 2018 Formulary Submissions," of this Call Letter for additional information.

Consistent with CY 2017, the meaningful difference threshold for CY 2018 will be based on the 50^{th} percentile of the November CY 2017 Bid Data run through the new CY 2017 OOPC MPF model that incorporates CY 2017 Formulary Data, 2010/11 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates. The 50^{th} percentile continues to identify a value that can be considered to be a substantial difference in out-of-pocket costs between bids. While we have noted a trend towards decreasing differentials between basic and EA plan drug benefits, we continue to see an increased differential between EA plans offered by the same organization potentially making it more challenging for plan sponsors to offer second EA plans. We will continue to monitor these differences for CY 2019 to ensure that there is a meaningful difference between basic and EA plans.

Therefore, in 2018 the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $20 and the minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $37. As in the past, meaningful difference requirements apply to all stand-alone PDPs. We also continue to expect that the additional EA

PDPs within a service area will have a higher value than the first EA plan and will include additional gap cost-sharing reductions for at least 10 percent of their formulary brand drugs**.**

CMS makes all of the necessary tools and information available to sponsors in advance of the bid submission deadline, and therefore expects all PDPs to submit bids that satisfy our requirements. If CMS provides an opportunity to correct CY 2018 meaningful difference requirements following the submission deadline, the PDP will not be permitted to 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 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.

In the CY 2012 Call Letter, CMS explained that it does not believe that sponsors can demonstrate meaningful differences based on expected OOPCs between two stand-alone basic Part D benefit designs while maintaining both the statutory actuarial equivalence requirements and fulfilling the requirement to maintain cost effective drug utilization review programs. As we approach CY 2020 and the closure of the coverage gap, CMS believes that Part D sponsors will find it difficult to maintain three plans (a basic and at most two EA plans) that will meet the meaningful difference test between all plans once the coverage gap is closed. Therefore, CMS encourages plan sponsors to consider this in their current and future plan offerings to minimize future beneficiary disruption. We expect that, for CY 2018, our application of the meaningful difference standard will still allow us to approve up to 3 plan benefit packages (1 basic, and at most, two enhanced plans).

The methodology for developing the CY 2018 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 22, 2016 titled "Medicare Plan Finder (MPF) Plan Version of Out-of-Pocket Cost (OOPC) Model for CY." Customary updates for utilization data, as well as PBP and formulary data used for CY 2018 bid submissions, are also included in the 2018 model.

Table 20: Benefit Parameters for CY 2018

	CY 2018 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$ 20
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$ 37
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
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%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)[6]	S[3]
Preferred Generic Tier	24%
Generic Tier	24%
Preferred Brand/Brand Tier	55%
Non-Preferred Drug Tier	55%
Non-Preferred Brand Tier	55%
Injectable Tier	55%
Select Care/Diabetic Tiers[5]	55%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$670

[1] The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 50th percentile of the November CY 2017 Bid Data run through the CY 2017 OOPC MPF model which incorporates CY 2017 Formulary Data, 2011/12 MCBS Data, and FDA Application Type for applicable/non-applicable determinations related to coverage gap cost-sharing estimates. This threshold excludes plans that were waived of the meaningful difference requirements due to the transition period afforded during consolidation. For each parent organization, any cost-sharing OOPC comparison between a basic plan and EA plan in the same region must meet the minimum Enhanced Alternative Plan vs. Basic Plan threshold. For each parent organization, any cost-sharing OOPC comparison between two EA plans in the same region must meet the threshold established annually by CMS.

[2] These thresholds are based on the 95th percentile of the CY 2017 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). The coinsurance threshold for these tiers is derived from an average expected copayment amount using PDE data for drugs submitted on preferred cost-sharing tiers. As noted earlier in this section, we continue to expect cost-sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be $0.

[6] Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this gap benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier (partial tier coverage). If the additional gap cost- sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 24% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 50% manufacturer discount for applicable drugs.

Specialty Tiers

Per 42 C.F.R. § 423.578 (a)(7), if a Part D plan sponsor maintains a formulary tier (the specialty tier) in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception. Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement. The current cost threshold of $670 was established for CY 2017 as a result of applying the annual percentage increase used in the Part D benefit parameter updates to the previous threshold of $600.

In the final CY 2017 Call Letter, we noted that the cost threshold may or may not be increased on an annual basis moving forward, and that we would test increased thresholds and continue to perform other analyses to assess whether threshold adjustments are necessary. Further, we stated that a series of analyses would be performed to investigate whether the inclusion of Part D drugs on a specialty tier adversely affects drug utilization or enrollment decisions by certain types of beneficiaries, and the impact of tiering exceptions for specialty tier drugs.

Given that CY 2017 is the first year for the increased specialty tier threshold, CMS is continuing to collect data to support future policy making. Initial analyses have been performed utilizing CY 2016 prescription drug event (PDE) data and the drugs identified as generally being eligible for specialty tier inclusion based on the $670 threshold. The vast majority of 30-day equivalent PDE – nearly 99% – are for drugs that are below the threshold. However, we are concerned that the percentage of FRF drugs eligible for the specialty tier continues to increase, and is now near 20%, in spite of the increased cost threshold. The proportion of Part D expenditures that are for specialty tier eligible drugs is also increasing and is now near 20%. CMS will maintain the $670 threshold for CY 2018, but we will continue to investigate these and other trends in order to shape future analyses involving the specialty tier.

Improving Drug Utilization Review Controls in Medicare Part D

In the CY 2013 Call Letter and supplemental guidance, CMS described an opioid overutilization policy, which takes a medication safety approach by which sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications.[20] In July 2013, CMS launched the Overutilization Monitoring System (OMS) to help oversee sponsors' compliance with this CMS overutilization guidance.

CMS has continued to focus and refine its opioid overutilization policy and expects sponsors to further reduce opioid overutilization in the Part D program. In this section, we solicit comments and suggestions about new proposals described below to reduce the unsafe overutilization of medications by Part D beneficiaries.

- Changes to the retrospective OMS opioid overutilization methodology;
- Additional guidance about prospective formulary-level cumulative morphine equivalent dose (MED) point of sale (POS) edits;
- Addressing chronic use of benzodiazepine sedative-hypnotics in the Medicare Part D population.

Changes to the OMS Opioid Overutilization Methodology

Under the Part D opioid overutilization policy, sponsors are expected to implement appropriate plan-level claim controls at POS for opioids, use improved retrospective drug utilization review to identify beneficiaries at high risk for an adverse event due to opioids, and perform case management with the identified beneficiaries' prescribers followed by beneficiary-specific POS edits to prevent Part D coverage of opioid overutilization, if necessary.

Review of Current Methodology

Since the OMS was launched in July 2013 to oversee sponsors' compliance with the opioid overutilization policy, CMS has used the following criteria to retrospectively identify beneficiaries who may potentially be overutilizing opioids:

> Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

[20] An excerpt from the Final 2013 Call Letter, the supplemental guidance and additional information about the OMS are available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

Review of Final CY 2017 Call Letter

In the final CY 2017 Call Letter, CMS announced its intention to modify the OMS opioid overutilization criteria based on experience from compliance activities, additional analyses, and updates to the CDC guideline for prescribing opioids for chronic pain.

In response to the CY 2017 Call Letter, we received support for the proposed changes, and thus in this proposed Call Letter, we are pursuing these modifications. Our policy goals are to:

- Improve the identification of inappropriate opioid use (i.e., reduce "false positives" related to overutilization that resolved recently and to better identify the most egregious cases of overuse),
- Align with the CDC guideline on opioid prescribing if applicable (available on the CDC website at http://www.cdc.gov/drugoverdose/prescribing/guideline.html).
- Define a target population for which the caseload would be manageable for Part D sponsors.

Post-Final CY 2017 Call Letter Analysis

With respect to additional analyses we referred to in the final CY 2017 Call Letter, we completed an analysis to assess the impact and validity of the following modifications to the OMS opioid overutilization criteria on identifying beneficiaries whose opioid use may require focused case management:

Modification	**Rationale**
Shorten the measurement period from 12 months to 6 months	A shortened measurement period better identifies current potential overutilization and reduces the number of repeat cases reported by the OMS.
Use average MED rather than a count of 90 consecutive days of high MED	By allowing gaps between prescription fills and days' supply in the calculation, the average MED methodology better identifies beneficiaries who are chronic users of high opioid doses than the consecutive days method.
Lower the MED mg threshold (90 mg)	A lower MED threshold is in line with the newly published CDC guideline for recommended maximum dose and captures additional beneficiaries with egregious patterns of overutilization.
Group providers, such as physicians, within the same practice	Grouping providers reduces false positives by eliminating beneficiaries managed in the group practice setting.

A full description of the analysis including the methodology, findings, and summary is available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

Specific Proposed Changes to the OMS Opioid Overutilization Methodology

Based on this analysis, CMS suggests modifying the OMS 'Overutilization of Opioids' criteria beginning in 2018 to be:

- During the most recent 6 months,
    - Use of opioids with an average daily MED exceeding 90 mg for any duration; and
    - Received opioids from more than 3 prescribers and more than 3 pharmacies, OR from more than 4 prescribers regardless of the number of opioid dispensing pharmacies.
- Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded.
- Prescribers associated with the same single TIN will be counted as a single prescriber.

We note that in 2012, we estimated that 22,222 beneficiaries (or 0.07% of all Part D enrollees) would meet the initial opioid overutilization criteria based on 2011 data. During the first year of the policy in 2013, 25,347 beneficiaries were identified as potential opioid overutilizers, which represented 0.21% of all opioid users. The number of potential opioid overutilizers was reduced to 15,651 beneficiaries by 2015 (0.13% of Part D opioid users).

The estimated number of beneficiaries in Part D that would meet the proposed revised criteria using 2015 data is 33,223, or 0.27% of all Part D opioid users. This represents 0.08% of all Part D enrollees, similar to our initial estimates in 2012 (0.07%). About 35% or 11,675 of the overutilizers were identified based on the additional criterion of 'OR more than 4 opioid prescribers regardless of the number of opioid dispensing pharmacies'.

After three years' experience, we believe that the revised criteria will more effectively identify opioid overuse that places a beneficiary at increased risk for an adverse event, will better align with the CDC guideline, and will still be manageable for sponsors to use to trigger additional patient-specific utilization review and case management. We will continue to monitor the number and percent of potential opioid overutilizers based on the revised OMS criteria and the initial criteria (for historical purposes). Our goal was and continues to be a continued reduction in opioid overuse in the Medicare Part D program.

While we are proposing the above changes for 2018, we also seek stakeholder input on a more significant revision to target beneficiaries with more than 3 prescribers regardless of the number of opioid dispensing pharmacies. Based on 2015 data, we estimate that over 114,000 beneficiaries would be identified. We seek comment on whether this additional workload for Part D sponsors would be manageable or effective.

Proposed Changes to Part D Sponsors' Internal Opioid Criteria for Retrospective Identification of Opioid Overutilization and Subsequent Case Management

In light of our proposed changes to the OMS 'Overutilization of Opioids' criteria, we also propose that Part D sponsors should lower their internal opioid criteria for retrospective identification of opioid overutilization and subsequent case management to be no less restrictive than use of opioids with an average daily MED exceeding 90 mg for any duration during the measurement period as proposed for use by CMS in the OMS. Sponsors may use a lower MED threshold and may vary other criteria including the number of prescribers and pharmacies.

A Note about the Comprehensive Addiction and Recovery Act of 2016

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) includes provisions that permit Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries' access to frequently abused drugs to certain prescribers and pharmacies. CMS' implementation of Section 704 for plan year 2019 in accordance with the statutory provisions is underway. The effect of implementation on the Part D opioid overutilization policy will be addressed as soon as possible as we continue with the rulemaking process.

CMS' Expectation for Hard Formulary-Level Cumulative Opioid MED POS Safety Edits in CY 2018

Part D sponsors were expected to implement hard and/or soft formulary-level safety edits based on a cumulative MED approach at POS at the pharmacy to prospectively prevent opioid overutilization, beginning in 2017, as described in the final CY 2017 Call Letter. We also stated in the final 2017 Call Letter that we expect all sponsors to implement a hard edit, at a minimum in 2018, using reasonable controls to limit false positives. In addition to a hard edit, sponsors may also choose to continue to implement soft edits in 2018. Note that PACE organizations are expected to comply with these expectations unless they do not adjudicate claims at POS.

In implementing this hard cumulative MED safety edit, CMS expects sponsors' Pharmacy and Therapeutics (P&T) committees to develop the edit specifications based on the observed opioid overutilization in their Part D plans, and the reasonableness of the numbers of targeted beneficiaries for plan oversight. We recommend that this hard edit threshold be set no lower than 200 mg MED. We also expect sponsors to apply specifications to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through case management or the coverage determination and appeals process. We also expect sponsors to set criteria for the hard edit that are not so overly permissive that beneficiaries who are potentially at high risk for opioid overutilization would not be identified. We do not

recommend that the MED calculation be based on a consecutive high-MED days' method but rather an average MED method to better capture high opioid dose episodes.

Sponsors may choose to include a prescriber count criterion in the edit specifications to enhance the safety aspect of the edit. A prescriber count can assist sponsors in specifically identifying and addressing cases with multiple prescribers of opioids for the same beneficiary, where these prescribers may not know about each other's prescribing.

We solicit feedback from sponsors on their experience with these edits to date, including pharmacist overrides / responses, if available, and setting the threshold at or above 200 mg MED.

Part D sponsors will continue to submit information on their CY 2018 cumulative opioid MED POS edits using a template through HPMS. Additional information will be provided in an HPMS memo describing the submission process and due dates for submission.

Addressing Chronic Use of Benzodiazepine Sedative-Hypnotics in the Medicare Part D Population

There continue to be concerns regarding the risks and benefits of benzodiazepine use, especially in the elderly due to an increased risk of falling.[21]

Therefore, we analyzed and tested the PQA measure, *Use of Benzodiazepine Sedative-Hypnotic Medications in the Elderly (BSH),* to assess the chronic use of these medications in the elderly enrolled in Part D.

The BSH rate measures the percent of Part D enrollees 65 years of age and older who received two or more prescription fills for any BSH medication for a cumulative period of more than 90 days. We calculated BSH rates across all Part D contracts using 2014 PDE data, adjusted for member-years.

We found that the average BSH measure rate across all Part D contracts was low (~1%) during 2014. The number of elderly Part D beneficiaries with chronic BSH use was about 300,000. Overall, 73% of Part D contracts' BSH rates did not exceed 0.97%, the aggregate average rate, and 10% had rates more than double the average, from 2% to more than 17%. BSH rates were lowest for community-only beneficiaries compared to long-term nursing home (NH) residents, 0.93% and 1.27%, respectively.

We do not propose to add the measure to the Star Ratings or display measures at this time since the overall use of BSH medications in the elderly is not an absolute contraindication per the Beers Criteria and the BSH rates were low for most Part D contracts. We will continue to monitor BSH rates, and we will consider outreach to outlier contracts in the future if necessary.

[21] Cumming RG, Miller JP, and Kelsey JL. et al. Medications and multiple falls in elderly people: the St. Louis OASIS study. Age Ageing. 1991 20:455–461.

We strongly encourage Part D sponsors to evaluate their claims data and use drug utilization management tools to monitor beneficiaries' BSH use before it becomes chronic. We also recommend that sponsors assess prescriber rates to identify outliers for educational or administrative interventions.

Clarification of Part D "Reference-Based Pricing" Policy

In the CY 2010 Call Letter, CMS explained that reference-based pricing cost-sharing designs would no longer be permitted in Medicare Part D beginning in 2010. These cost-sharing designs require enrollees to pay a differential (i.e. penalty) based upon the difference between the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. We explained that this prohibition was necessary to improve transparency with regard to expected enrollee cost-sharing. Since that time, we have learned that the term "reference-based pricing" or "reference pricing" is also used to describe payment arrangements between payers and pharmacies that do not involve enrollees paying a penalty based upon the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. Such payment arrangements include maximum allowable cost (MAC) pricing of generic drugs and possibly other reference-based pricing of brand drugs by drug class. The Part D prohibition announced in the CY 2010 Call Letter applies only to the cost-sharing designs that require enrollees to pay a differential (i.e. penalty) based upon the difference between the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. This policy does not otherwise prohibit reference-based payment arrangements negotiated between pharmacies and Part D sponsors (or their Pharmacy Benefit Managers) that establish the negotiated price.

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 2018 COB user fee will be collected at a monthly rate of $0.116 for the first 9 months of the coverage year (for an annual rate of $0.087 per enrollee per month) 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 2018 bids.

In contract year 2018, 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 System (MARx) management of COB data; and
- Review of Workers' Compensation settlement set-aside funds, which verify that medical services are paid for by the appropriate party

Social Security Number Removal Initiative (SSNRI)

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (PL 114-10 s.501) included a mandate to remove the current Health Insurance Claim Number (HICN) from Medicare cards. This is a reminder that beginning in 2018 the current Social Security based HICN will be replaced with a Medicare Beneficiary Identification number (MBI). MBIs will be assigned to all Medicare recipients, and cards will be mailed to beneficiaries beginning no earlier than April 2018.

CMS is aware that plans are preparing to modify applicable systems, processes, and relevant forms to account for use of either a HICN or MBI. This includes being able to accept and process enrollment requests which include either the HICN or the MBI via all CMS-approved enrollment mechanisms, as well as planning for potential impacts on appeals-related and Part D Coordination of Benefits-related functions. Additional policy and operational information for these business processes as well as for other business processes and systems will be issued in the future to assist plans with making these changes.

SSNRI-related information for Medicare health and drug plans will be disseminated in the same manner that all other policy and system updates are distributed. The information will also be posted to a Social Security Number Removal Initiative (SSNRI) webpage, https://www.cms.gov/Medicare/SSNRI/Index.html. CMS posts updates as they become available, and plans can use that site as an additional resource. For questions about how SSNRI will impact various systems, please refer to the contact list provided in the HPMS memorandum released on November 18, 2016, titled "Social Security Number Removal Initiative (SSNRI) Selected Updates for Medicare Advantage and Part D Plans."

Part D Low Enrollment

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. While we are particularly concerned with plans that have fewer than 500 enrollees, we urge sponsors to voluntarily withdraw or consolidate any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html to determine if any of their plans meet this criterion. By April 2017, we will notify plans with less than 1,000 enrollees of available options for consolidation/withdrawal options. We reserve the right to require low enrollment plans to

consolidate/withdraw in the future based on the marketplace at that time to ensure that all Part D plans offered in the marketplace are attractive to beneficiaries and do not add to their confusion in selecting a plan best suited to their prescription drug coverage needs.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2018

Contract Year (CY) 2018 will be the fifth contract year since the implementation of the first capitated model under the Medicare-Medicaid Financial Alignment Initiative. Since that time, CMS – in collaboration with our state partners – has implemented eleven capitated model demonstrations in ten states. While most initial implementation challenges and opportunities have been addressed, we hope to continue to build on the strong partnerships both CMS and the states have developed with participating Medicare-Medicaid Plans (MMPs) to provide high-quality, seamless and integrated care to individuals dually eligible for Medicare and Medicaid in CY 2018 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, as well as the policy regarding the use of past performance information for determining plan eligibility to receive passive enrollment. We will also provide guidance shortly after the issuance of the CY 2018 Final Call Letter about the applicability of the provisions in other sections of the Call Letter to MMPs.

As is the case for other Medicare Advantage (MA) and Part D plans, MMPs must submit a formulary, medication therapy management (MTM) program, and plan benefit package (PBP) each contract year, and annual submission timelines for MMPs are aligned with the standard MA and Part D schedule.

In addition to the requirements for MA and Part D plans, MMPs must also submit:

- On an annual basis, information to ensure the plan has a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid service providers, including long-term supports and services.

- If applicable based on the approval period given to the most recent model of care (MOC) submission, a MOC that meets CMS's requirements for D-SNPs, as well as any applicable state requirements.

- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 21 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 21: Previously Released Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPEnrollmentManual090216.pdf
Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
State-specific Marketing Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
Waiver of Part D LIS Cost-Sharing Amounts	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf
Past Performance Review Methodology Updates for CY 2018	TBD

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 2017. This submission will ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. MMPs may assess the Medicare portion of their networks at any time using the organization initiated upload functionality in the HPMS Network Management Module (NMM). The current reference file, as referenced in the three-way contracts, that provides the MMP standards is available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html as well as on the reference page within the NMM. CMS

will release additional guidance on the submission process, including how MMPs will be able to submit exception requests, in the summer of 2017. The Medicare pharmacy portion of the network will be checked per the Part D reporting requirements.

Model of Care (MOC)

MMPs with a model of care (MOC) expiring on December 31, 2017 were notified in the fall of 2016 regarding the need to submit a MOC for review and approval by February 17, 2017, for contract years beginning on or after January 1, 2018. MMPs with MOCs that are still within their period of approval in CY 2018 may make substantive changes to those MOCs through the off-cycle update process, as discussed in more detail in the January 14, 2016 HPMS memorandum, "Changes to Special Needs Plans and Medicare-Medicaid Plan Model of Care Submissions and Updates in the Health Plan Management System for CY 2017."

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 2018 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 5, 2017. Supplemental formulary files are due in HPMS on June 9, 2017 at 11:59 a.m. EDT.

MMPs must also submit an ADD file that includes non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. CMS will work with states to provide ADD file guidance to MMPs by May 2017. State guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). It is at the states' discretion whether to require MMPs to include one proxy NDC or multiple NDCs on the ADD file for each covered product.

State reviewers are solely responsible for reviewing and approving the ADD file. CMS will approve all other submitted formulary files. Reviews will begin immediately after the submission deadlines and will continue until all deficiencies have been resolved.

We clarify that mid-year ADD file change submissions – that is, changes to the ADD file after the contract year has begun – are at the discretion of each state. CMS will work with states to open HPMS gates for ad hoc and/or regular ADD file resubmissions as necessary.

CMS will release a CY 2018 formulary training video for plans in mid-to-late March, 2017.

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 7, 2017, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2018. In addition, CMS will release an online training module on the CY 2018 PBP software for plans on April 7, 2017.

MMPs must submit their integrated PBPs to CMS no later than June 5, 2017 (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 2018)
- 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 2017. The PBP review will be 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 corrections 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 2017 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 2017 (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 2017 (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 2017 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.

Past Performance Information and Eligibility for Passive and Opt-in Enrollment

Our policy regarding the use of past performance information is articulated in previous guidance memoranda, including section 30.2.5 of the "Medicare-Medicaid Plan Enrollment and Disenrollment Guidance" (see https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MMPEnrollmentManual090216.pdf for more information). MMPs should refer to that guidance for additional information regarding the impact of sanctions, treatment of new legal entities, and eligibility for passive enrollment after effectuation of the three-way contract.

Appendix 1 – Improvement Measures (Part C & D)

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Breast Cancer Screening	Process Measure	1	Yes
C	Colorectal Cancer Screening	Process Measure	1	Yes
C	Annual Flu Vaccine	Process Measure	1	Yes
C	Improving or Maintaining Physical Health	Outcome Measure	3	No
C	Improving or Maintaining Mental Health	Outcome Measure	3	No
C	Monitoring Physical Activity	Process Measure	1	Yes
C	Adult BMI Assessment	Process Measure	1	Yes
C	Special Needs Plan (SNP) Care Management	Process Measure	1	Yes
C	Care for Older Adults – Medication Review	Process Measure	1	Yes
C	Care for Older Adults – Functional Status Assessment	Process Measure	1	Yes
C	Care for Older Adults – Pain Assessment	Process Measure	1	Yes
C	Osteoporosis Management in Women who had a Fracture	Process Measure	1	Yes
C	Diabetes Care – Eye Exam	Process Measure	1	Yes
C	Diabetes Care – Kidney Disease Monitoring	Process Measure	1	Yes
C	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	Yes
C	Controlling Blood Pressure	Intermediate Outcome Measure	3	Yes
C	Rheumatoid Arthritis Management	Process Measure	1	Yes
C	Improving Bladder Control	Process Measure	1	No
C	Medication Reconciliation Post-Discharge	Intermediate Outcome Measure	1	No
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

Part C or D	Measure	Measure Type	Weight	Improvement Measure
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	Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	No
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
C	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	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	Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	No
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

Part C or D	Measure	Measure Type	Weight	Improvement Measure
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	Yes
D	MTM Program Completion Rate for CMR	Process Measure	1	Yes