February 20, 2015

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

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 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 2016. Also included with this notice are proposed changes in the payment methodology for CY 2016 for Part D benefits and annual adjustments for CY 2016 to the Medicare Part D benefit parameters for the defined standard benefit. For 2016, CMS will announce the MA capitation rates and final payment policies on Monday, April 6, 2015, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

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 2016. Attachment III sets forth the changes in payment methodology for CY 2016 for Part D benefits. Attachment IV presents the annual adjustments for CY 2016 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 2016 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; and employer and union-sponsored group plans, including both employer/union-only group health plans (EGWPs) and direct contract plans. The Call Letter contains 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: AdvanceNotice2016@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 6, 2015 release of the final Announcement of Calendar Year 2016 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 6, 2015.

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Attachments

2016 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 2016

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"). For 2016, most counties will be fully transitioned to the new rate methodology, while others will continue to be based on a blended rate. Section 1853(n)(4) of the Social Security Act requires that the blended benchmark (which is increased by quality bonus payment percentages where applicable) be capped at the level of the 1853(k)(1) applicable amount.

The MA county rates are based on two trend factors (the MA Growth Percentage and FFS Growth Percentage).[1] For 2016, the rate established under section 1853(k)(1) is the greater of: 1) the county's 2016 FFS rate or 2) the 2015 applicable amount increased by the CY 2016 national per capita MA growth percentage. For 2016, the specified amount will be based on a percentage of the 2016 FFS rate. The 2016 FFS rate is calculated, in part, using the FFS growth percentage. CMS plans to rebase the county FFS rates for 2016 as part of the calculation of the rates for 2016.

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 2016 is 2.68 percent. This estimate reflects an underlying trend change for CY 2016 in per capita cost of 1.14 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. Consistent with the 2015 Final Announcement, the basis for the preliminary MA growth percentage reflects an assumption that Congress will act to

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[1] The national per capita MA growth percentage is described in section 1853(c)(6)(C) and includes projected expenditures for MA enrollees and FFS enrollees. OACT estimates an MA growth percentage for aged and disabled Medicare beneficiaries, and separately for ESRD beneficiaries. In contrast, the FFS growth percentage reflects projected expenditures for FFS beneficiaries only, also estimated separately for aged and disabled beneficiaries versus ESRD beneficiaries.

prevent the projected cumulative 21.2 percent reduction in Medicare physician payment rates from occurring in 2016. The Office of the Actuary has been directed by the Secretary to use this assumption, on the grounds that it is a more reasonable expectation than the reduction required under the statutory "sustainable growth rate" formula.

Table I-1. National Per Capita MA Growth Percentage for 2016

	Prior Increases	Current Increases			NPCMAGP for 2016 With §1853(c)(6)(C) adjustment[1]
	2003 to 2015	2003 to 2015	2015 to 2016	2003 to 2016	
Aged+Disabled	43.00%	45.18%	1.14%	46.84%	2.68%

[1]Current increases for 2003-2016 divided by the prior increases for 2003-2015

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 for the county FFS portion of the benchmark. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2016 divided by the prior projected FFS USPCC for 2015.

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 FFS USPCC Growth Percentage for CY 2016 – non-ESRD

	Total USPCC	FFS USPCC
Current projected 2016 USPCC	$797.59	$780.12
Prior projected 2015 USPCC	$776.75	$768.84
Percent increase	2.68%	1.47%

Table I-3 compares last year's estimate of the total non-ESRD USPCC with current estimates for 2004 to 2017, 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 2018. 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	$295.77	$295.77	$247.41	$247.41	$543.18	$543.18	1.000
2004	$313.80	$313.80	$270.70	$270.70	$584.50	$584.50	1.000
2005	$334.52	$334.52	$292.49	$292.49	$627.01	$627.01	1.000
2006	$344.97	$344.97	$313.33	$313.33	$658.30	$658.30	1.000
2007	$355.58	$355.59	$330.32	$330.32	$685.90	$685.91	1.000
2008	$371.88	$371.88	$350.66	$350.66	$722.54	$722.54	1.000
2009	$383.67	$385.42	$367.50	$367.56	$751.17	$752.98	0.998
2010	$385.11	$384.96	$376.26	$376.37	$761.37	$761.33	1.000
2011	$389.47	$387.89	$385.95	$385.86	$775.42	$773.75	1.002
2012	$378.65	$375.27	$392.55	$392.69	$771.20	$767.96	1.004
2013	$380.40	$376.48	$399.90	$397.25	$780.30	$773.73	1.008
2014	$369.75	$366.12	$415.25	$411.17	$785.00	$777.29	1.010
2015	$364.81	$360.16	$423.76	$416.59	$788.57	$776.75	1.015
2016	$367.26	$366.13	$430.33	$428.68	$797.59	$794.81	1.003
2017	$376.12	$377.41	$445.62	$447.97	$821.74	$825.38	0.996
2018	$393.02		$466.46		$859.48		

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	$372.65	$372.39	$374.10	$374.18	$746.75	$746.57	1.000
2011	$373.33	$371.16	$383.94	$383.77	$757.27	$754.93	1.003
2012	$358.65	$353.75	$391.55	$391.46	$750.20	$745.21	1.007
2013	$363.98	$359.28	$395.93	$393.53	$759.91	$752.81	1.009
2014	$361.47	$358.09	$402.75	$399.37	$764.22	$757.46	1.009
2015	$357.62	$358.67	$413.09	$410.17	$770.71	$768.84	1.002
2016	$360.31	$363.95	$419.81	$421.63	$780.12	$785.58	0.993
2017	$369.30	$374.25	$435.15	$439.41	$804.45	$813.66	0.989
2018	$385.50		$454.99		$840.49		

These estimates are preliminary and could change when the final rates are announced on April 6, 2015 in the Announcement of CY 2016 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 fee-for-service growth percentage will also be presented in the April 6, 2015 Announcement.

Attachment II. Changes in the Part C Payment Methodology for CY 2016

Section A. MA Benchmark, Quality Bonus Payments and Rebate

As noted in Attachment I, the Affordable Care Act establishes a new methodology for calculating each MA county rate as a percentage of FFS spending in each 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"). (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 a plan.)

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 plans to rebase the county FFS rates for 2016.

The Program for All Inclusive Care for the Elderly is exempt from the MA blended benchmark provisions, 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 2016, for 2016, the applicable amount is the greater of: 1) the county's 2016 FFS rate or 2) the 2015 applicable amount increased by the CY 2016 National Per Capita Medicare Advantage Growth Percentage.

A2. Specified Amount

The specified amount is based upon the following formula.

(2016 FFS rate 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);

Applicable percentage is a statutory percentage applied to the county's base payment amount, as described at Sec. 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 2016 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2015 average per capita FFS costs, because 2015 is the most recent FFS rate rebasing year prior to 2016. 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. CMS is publishing the 2016 applicable percentages by county with the Advance Notice at http://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*

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

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 2016 payments. For CY 2016 payments, plans with less 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 A8 for rebate percentages for CY 2016.

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

Star Rating	2016 QBP Percentage*
Less 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 each county rate in the service area. For 2016, MA plans with a Star Rating less 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 rates are capped at the Section 1853(k)(1) amount – that is, what the benchmark would have been under the pre-ACA rules, as per Section 1853(n)(4) of the Act.

New MA Plans

The method for determining the QBP percentage for a new MA plan is different from the method described above. For the purposes of determining a QBP percentage, at § 422.252 a new MA plan is defined as an MA contract offered by a parent organization that has not had another MA contract in the previous three years.[3] These new MA plans are treated as qualifying plans (meaning 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,

[3] All regulatory cites are to Title 42 of the Code of Federal Regulations unless otherwise noted. *See also §1853(o)(3)(iii)(II).*

this type of new MA plan will bid against a service area benchmark that reflects a 3.5 percentage point increase to each county rate in the plan's service area. As discussed below, all rates are capped at the Section 1853(k)(1) amount – that is, what the benchmark would have been under the pre-ACA rules, as per Section 1853(n)(4) of the Act.

Note that for a parent organization that has had a contract with CMS in the previous three years, 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. CMS finalized this policy in the 2012 Announcement (page 2), found on the CMS website at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

Low Enrollment Plans

Sec. 1853(o)(3)(A)(ii)(II) of the Act, as implemented at § 422.258(d)(7)(iv)(B), 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 a contract level, and thus determine whether a contract (meaning all plans under that contract) is a qualifying contract. Pursuant to § 422.252, a low enrollment contract is one that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan. Note that the standards for statistical reliability of performance measures, including HEDIS and HOS, are addressed in the Call Letter discussion of Star Ratings.

While section 1853(o)(3)(A)(ii) requires that low enrollment plans "not able to have a quality rating" due to insufficient data be treated as qualifying plans entitled to an increase in payment under section 1853(o), it does not address the amount of this required increase. As in 2015, for 2016 payments, we propose to treat low enrollment contracts that meet the standard to be qualifying contracts, which means they will receive the QBP percentage of 3.5 percentage points that is paid with respect to new MA plans. We interpret § 1853(o)(3) 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 basis for assigning 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. This is consistent with our treatment of low enrollment contracts for purposes of determining the rebate available to the plan, and with our treatment of low enrollment plans for CY2015.

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 2016 that is less than the national monthly per capita cost for FFS for 2016.

For example, a 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. 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 rates are capped at the Section 1853(k)(1) amount – 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 2016 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 2015 Rate Calculation Data file (columns W and X) on the CMS website at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The 2016 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 2016 Announcement.

A5. Affordable Care Act County Rates Transitional Phase-In

The blend of the specified amount and applicable amount used to create the county rates, as discussed above, is being phased in on a transitional basis. This transition began in 2012 and will be completed by 2017. In 2012, each county was assigned to one of three transition periods - two, four, or six years. CMS determined a county's specific transition period by calculating the difference between the county's Projected 2010 benchmark amount and 2010 applicable amount. The county transition period assigned is based on the size of the difference between these two amounts, with six year counties having the largest differential (at least $50). The projected 2010 benchmark amount was a one-time only calculation, which has been employed solely for the purpose of assigning each county its appropriate transition period, in accordance with the Affordable Care Act.

The transition periods for each county (2, 4, or 6 years) were published with the 2012 Advance Notice and can be found at the CMS website at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

A6. Blended Benchmark Calculations.

Section 1853(n)(1) and (3) of the Act sets forth the rules for calculating the blended benchmark, depending on the assigned transition period.

Table II-3. Blended Benchmark Calculations

Year	Two Year County Blend		Four Year County Blend		Six Year County Blend	
	Pre-ACA	ACA	Pre-ACA	ACA	Pre-ACA	ACA
2012	1/2	1/2	3/4	1/4	5/6	1/6
2013	0	100%	1/2	1/2	2/3	1/3
2014	0	100%	1/4	3/4	1/2	1/2
2015	0	100%	0	100%	1/3	2/3
2016	0	100%	0	100%	1/6	5/6
2017	0	100%	0	100%	0	100%

A7. Cap on Blended Benchmarks.

Section 1853(n)(4) of the Act requires that the blended benchmark for a county must be capped at the level of the county's applicable amount at section 1853(k)(1) of the Act. This provision specifies that the QBP increase must be included in the blended benchmark before the comparison is made to determine if the cap is required. Thus, for all counties, rates are capped at the section 1853(k)(1) amount – that is, what the benchmark would have been under the pre-ACA rules.

A8. Rebate

Under section 1854(b)(1)(C) of the Act, except for MSA plans, the level of rebate is tied to the plan's Star Rating. Rebates are calculated, for each plan, as a percentage of the difference between the risk-adjusted service area benchmark and the risk-adjusted bid. Plans use rebates to fund supplemental benefits and/or to buy down beneficiary premiums. 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	2016
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 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, for purposes of determining the rebate percentage. The statute is silent on the rebate percentage to assign to low enrollment plans in years after 2012. As we did for 2015, CMS is proposing to use its discretion and treat low enrollment plans as having a Star Rating of 3.5 stars for purposes of determining the rebate percentage for 2016.

Section B. Calculation of Fee for Service Rates

The FFS rate 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 2015 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.

Also in 2015, 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.

For 2016, 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 2016, ensures that the 2016 FFS county rates reflect the most current FFS fee schedules and payment rules.

B1. AGA Methodology for 2016

In the first step, CMS is proposing to add the 2013 cost and enrollment data, and drop the 2008 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 claims data from 2009-2013.

In the second step, CMS will exclude hospice expenditures and FFS claims paid on behalf of cost plan enrollees from the 2013 claims. Comparable adjustments were previously made to 2009-2012 claims data.

For Puerto Rico, CMS will only include claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment for all five years (2009 to 2013).

In the third step, CMS will re-price the historical inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2009 – 2013 to reflect the most current (i.e., FY 2015) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2015) Geographic Practice Cost Index. For 2016, CMS will also continue to adjust historical FFS claims to account for Section 3133 of the Affordable Care Act (ACA), which replaced 75 percent of hospital Medicare Disproportional Share Hospital (DSH) Payments with uncompensated care payments (UCP) beginning on October 1, 2013. Consistent with the methodology implemented for 2015, CMS would adjust 2009 - 2013 claims 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 2015 Inpatient Prospective Payment System (IPPS) rule (79 FR 50014). Also for 2016, we will continue re-pricing Durable Medical Equipment (DME) claims from 2009-2013 to reflect the most current DME prices associated with the competitive bid program, and will continue using the Round 1 Recompete and Round 2 prices in making these adjustments.

As in prior years, CMS will, (1) make additional adjustments to the FFS rates for those items detailed in this Section 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 2016 risk model in order to develop the AGA for that county.

Additional Adjustments

As in prior years, CMS will also make additional adjustments to the FFS rates for certain items.

These adjustments are made after the AGA is calculated:

- Direct Graduate Medical Education: removed from FFS county rates (section 1853(c)(1)(D)(i) of the Act)
- Exclusions for Electronic Health Record incentives for doctors and hospitals (section 1853(c)(1)(D)(i) of the Act)
- Indirect Medical Education: removed from FFS county rates, as per phase-out schedule in MIPPA (section 1853(k)(4) of the Act)
- Credibility: for counties with less than 1,000 members, blend county experience with that of others in the market area
- VA-DOD: apply a cost ratio (an increase to claim costs) to counties with significant Tricare enrollment in the Uniformed Services Family Health Plan (section 1853(c)(1)(D)(iii) of the Act).

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

Since CY 2012, a VA-DoD adjustment has been applied based on analysis using FFS data from calendar years 2004-2006. This analysis was performed separately for all DoD and USFHP-only enrollees to compare the average FFS costs to determine if there were significant differences between the DoD groups and the total Medicare population. To approximate an adjustment to the county fee for service (FFS) payment rates, we analyzed the cost impact of removing the dual-eligibles from the Medicare claims and enrollment. For this analysis, dual-eligibles were defined as those Medicare beneficiaries who are also eligible to receive care through the Department of Defense. We calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding dual-eligibles (DoD) to all Medicare beneficiaries (or all beneficiaries) for each county.

For CY 2012, we analyzed the ratios in counties with at least 10 members in the respective groups and found that there was no statistical significance of the DoD ratios, but did find that the Uniformed Services Family Health Plan (USFHP)-only ratios were significant. Accordingly, adjustments were made to counties with at least 10 USFHP members and CMS then adjusted the FFS rates by the ratios calculated.

For CY 2016, we are proposing to update the VA-DoD adjustment using the same methodology first implemented in CY 2012, based on an analysis of more recent Medicare claims for DoD dual enrollees for calendar years 2008-2012. CMS will adjust the FFS rates by the ratios calculated. Based on applying the adjustments to the 2016 FFS rates, the average FFS rate will change in 179 affected counties by an average of $1.16, with a range of a decrease of $0.08 to an increase of $20.74; 165 counties will experience increases in FFS rates of $0.01 or more.

Section C. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 amended section 1853(k)(4) of the Act to require CMS to phase out indirect medical education (IME) amounts from MA capitation 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 2016, we will first calculate the 2016 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 2016 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), the maximum reduction for any specific county in 2016 is 4.2 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 2016 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section D. ESRD Rates

In developing the 2016 ESRD Medicare Advantage rates, we obtain the FFS dialysis reimbursement and enrollment data by each state for the years 2009 – 2013. 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 2013 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2013 data above, and using trend factors, develop the prospective 2016 FFS ESRD dialysis USPCC. The 2016 ESRD dialysis rates by state are determined by multiplying the 2016 FFS ESRD dialysis USPCC by the state AGA. The 2016 ESRD dialysis rate is adjusted by removing the direct graduate medical education (GME) expenses and gradually removing the indirect medical education (IME) expenses.

Section E. Clinical Trials

In 2016, we will continue the policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Section F. Location of Network Areas for PFFS Plans in Plan Year 2017

Section 1852(d) of the Act requires MA organizations 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) of the Act through signed 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 risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as having at least 2 network-based plans (as defined in section 1852(d)(5)(C) of the Act) 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 2017 in the final Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. We will also include the list on the CMS website at http://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html. We will use January 1, 2015 enrollment data to identify the location of network areas for plan year 2017.

Section G. CMS-HCC Risk Adjustment Model for CY 2016

We introduced an updated, clinically revised CMS-HCC model for payment year 2014. As discussed in the 2014 Advance Notice and Final Announcement, the updated model included both recalibrating the model on more current data and incorporating the clinical update. This updated model resulted in more appropriate relative weights for the HCCs found in the model because they reflect more recent coding and expenditure patterns in FFS Medicare, as well as newly constructed hierarchical condition categories (HCCs) that were possible as a result of ICD-9 codes introduced since the creation of the original CMS-HCC model. For payment years 2014 and 2015, risk scores used in Part C payment were a blend of the risk scores from this clinically-revised model and the 2013 model.

For payment year 2016, we propose to transition entirely to using risk scores calculated from the community, institutional, new enrollee, and C-SNP new enrollee segments of the clinically-revised CMS-HCC model in Part C payment for aged/disabled beneficiaries.

We will continue to use the same risk adjustment model for PACE payments that we have used from 2012 through 2015. This model is described in the 2012 Final Announcement in Tables 9 through 11 http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

Section H. Medicare Advantage Coding Pattern Adjustment

For 2016, CMS proposes to update the MA coding adjustment factor to the statutory minimum of 5.41 percent.

Given the range of possible methods for calculating the MA coding differences factor, we do recognize that there may be alternative methods that appear to be more accurate. We discuss below another approach to determining this factor, and are asking for comment regarding this methodology.

Below we offer three analyses that strongly suggest that the health status of MA enrollees is no worse, and more likely is better, than the health status of FFS beneficiaries of similar age, gender, Medicaid, and institutional status. These include analyses of self-reported health status and mortality rates,[4] as well as Part D drug information.

Self-Reported Health Status. Analysis of self-reported data on health status and on whether the respondent has ever been diagnosed with one of a variety of conditions from the 2006-2011 Medicare Current Beneficiary Survey (MCBS) suggests that the average risk for MA enrollees is approximately 96% of the average risk for FFS beneficiaries.

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[4] R Kronick and WP Welch, "Measuring Coding Intensity in the Medicare Advantage Program," Medicare & Medicaid Research Review, June 2014. http://www.cms.gov/mmrr/Downloads/MMRR2014_004_02_a06.pdf

Mortality Rates. Mortality rates for MA beneficiaries are significantly lower than mortality rates for FFS enrollees. For example, in 2012, the mortality rate in MA was 81% of the mortality rate in FFS. (It is possible that lower mortality rates result from better quality of care in MA, but it seems more likely, given the size of the difference, that this reflects, at least in part, relative health status.)

Part D Drug Information. MA enrollees are significantly less likely than FFS beneficiaries to be prescribed drugs that are predictive of high expenditures. HHS has used information from Part D data to construct risk scores for MA and FFS enrollees, and has found that MA enrollees are at significantly lower risk than demographically similar FFS beneficiaries.

The first step in the HHS analysis of Part D data used information on FFS beneficiaries who were enrolled in Part D in 2011. HHS used the Rx-Defined Morbidity Groups (or "Rx-MGs") of the Johns Hopkins Adjusted Clinical Groups System (ACG) to classify Part D drugs. The result of applying the ACG pharmaceutical grouper to Part D data is a series of 0-1 indicator variables for drug classes, where the variable has a value of 1 if the beneficiary filled a prescription for one of the drugs included in that class, and a 0 otherwise.

The second step was to estimate the parameters of a prospective multivariate regression, in which the dependent variable was the sum of 2012 Part A and Part B expenditures for the subset of FFS beneficiaries in the first step who remained in FFS in 2012. The regression included 0-1 indicator variables for each of the drug classes, as well as demographic variables for age, gender, Medicaid status, and institutional status.

The third step used the parameter estimates from the regression to compute a pharmacy-based risk score for each MA and FFS beneficiary enrolled in Part D. (This risk score, it should be clear, is quite different from the risk score used in adjusting payments to Part D plans. The risk score used for Part D plans uses diagnostic information to predict Part D spending. The risk score we computed in this analysis uses prescription drug information to predict Part A and Part B spending.) Based on this analysis, we found that the average pharmacy-based risk score for MA enrollees was significantly lower than the average pharmacy-based risk score for FFS beneficiaries.

Of the three sources of information that are independent of the diagnoses reported by MA plans, each suggests that MA enrollees are at similar or lower risk than demographically similar FFS beneficiaries. We are aware of no independent data source that suggests that MA enrollees are at greater risk than demographically similar FFS beneficiaries.

<u>Alternate Methodology for Coding Pattern Adjustment</u>. Given the likelihood that MA enrollees are, on average, at similar (or better) risk than demographically similar FFS beneficiaries, we are considering an alternative approach to calculating the coding pattern adjustment for 2017 or future years. Under this approach, the MA coding pattern adjustment would be calibrated to produce the result that payments to MA plans, in the aggregate, would be no greater than the

level of payment that would have been made if we were still using the variables in the adjusted average per capita cost (AAPCC) payment system that was in effect prior to 2000 – that is, if we adjusted payment for age, gender, Medicaid, and institutional status.[5] Using such a model, we would first estimate the risk of MA-enrolled beneficiaries relative to the risk of beneficiaries in FFS. Next, we would calculate the ratio of MA-to-FFS risk using the CMS-HCC model. Using the difference between the two ratios, we would calculate the MA coding adjustment factor.

CMS requests comment on this alternate methodology.

Risk Adjustment Data Validation (RADV). Results from the pilot and targeted RADV activities indicate that some diagnoses submitted by MA organizations are not supported by medical record documentation. Thus, CMS is conducting RADV contract-level audits to recover overpayments in Medicare Advantage. RADV audits verify, through medical record review, the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. RADV audits are CMS's primary corrective action to recoup Part C improper payments. CMS expects that payment recovery will have a sentinel effect on the quality of risk adjustment data submitted by plans for payment.

Section I. Normalization Factors

When we calibrate a risk adjustment model, we produce a fixed set of dollar coefficients appropriate to the population and data for that calibration year. We set the average risk score to 1.0 in the denominator year. When the model with fixed coefficients is used to predict expenditures for other years, risk scores are no longer 1.0. Historically, predictions for prior years have been lower and predictions for succeeding years have been higher than for the calibration year. Because average predicted expenditures change after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score in FFS is held to 1.0 in subsequent years.

The normalization factor is derived by first using the risk model to be used in the payment year to predict risk scores over a number of years. We then fit a trend line to the risk scores. For the 2015 payment year, CMS applied a quadratic functional form to risk scores from 2010 through 2013; this functional form better reflected more recent changes in the population trends. For the 2016 payment year, we propose to again use a quadratic functional form and to apply that functional form to 2011 through 2014 risk scores 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 a quadratic functional form and apply that functional form to 2010 through 2013 risk scores for the RxHCC

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[5] Report to Congress: Proposed Method of Incorporating Health Status Risk Adjusters into Medicare+Choice Payments, HCFA Office of Strategic Planning, Research and Evaluation Group, Division of Payment Research, March 1, 1999.
http://www.cms.gov/Medicare/Health-PlansMedicareAdvtgSpecRateStats/Downloads/RTC_RiskAdjusters1999.pdf

model; these factors and annual trends are shown in I5. Note that the factors may not be exact due to rounding. The final normalization factors will be published in the final 2016 Announcement, to be released April 6, 2015.

I1. Normalization for the CMS-HCC Model

The preliminary 2016 normalization factor for the model implemented in 2014 (V22) is: 0.992.

The Part C normalization factors for the CMS-HCC risk adjustment models are applied to the following risk scores: aged/disabled community, aged/disabled institutional, aged/disabled new enrollee, and C-SNP new enrollee. The trend is calculated on the population of FFS beneficiaries.

The risk scores used to calculate the preliminary annual trend for the CMS-HCC model are:

2011: 0.988
2012: 0.997
2013: 0.996
2014: 1.000

I2. Normalization Factor for the PACE Model

The preliminary 2016 normalization factor for the CMS-HCC risk adjustment model used for the PACE program is 1.042.

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 trend is calculated on the population of FFS beneficiaries.

The risk scores used to calculate the preliminary annual trend for the PACE model are:

2011: 1.031
2012: 1.042
2013: 1.043
2014: 1.048

I3. Normalization Factor for the ESRD Dialysis Model

The preliminary 2016 normalization factor for the ESRD dialysis model is 0.990.

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

The risk scores used to calculate the annual trend for the ESRD Dialysis model are:

2011: 0.956
2012: 0.972
2013: 0.974
2014: 0.985

I4. Normalization Factor for Functioning Graft Model

The preliminary 2016 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.042.

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 risk scores used to calculate the annual trend for the CMS-HCC model are:

2011: 1.031
2012: 1.042
2013: 1.043
2014: 1.048

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

The preliminary 2016 normalization factor for the RxHCC model is 0.939. The normalization factor for the RxHCC model is applied to all Part D risk scores for beneficiaries enrolled in a Part D plan. The trend is calculated on the population of both FFS and MA beneficiaries.

The risk scores used to calculate the annual trend for the RxHCC model are:

2010: 0.993
2011: 1.001
2012: 1.007
2013: 1.000

Section J. Frailty Adjustment for PACE organizations and FIDE SNPs

Section 1853(a)(1)(B)(iv) of the Social Security Act requires CMS to take into account the frailty of the PACE population when making payments to PACE organizations, and allows CMS to pay a frailty adjustment to Fully Integrated Dual Eligible (FIDE) Special Needs Plans (SNPs) if the SNP has similar average levels of frailty to the PACE program. The frailty model is used to explain costs that are not explained by diagnoses in the CMS-HCC model.

The frailty factors for PACE organizations will not change for FY 2016; the same frailty factors used in 2015 for PACE organizations will be used. These can be found in the 2012 Announcement in Attachment VI, Table 13, at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html. Frailty for FIDE SNPs will be based on frailty factors associated with the 2014 risk adjustment model. The factors are replicated below.

Table II-5. FIDE SNP Frailty Factors for CY 2016

ADL	Non-Medicaid	Medicaid
0	-0.074	-0.156
1-2	0.143	0.000
3-4	0.278	0.195
5-6	0.278	0.446

Section K. Medical Loss Ratio Credibility Adjustment

In the May 23, 2013 Medical Loss Ratio (MLR) final rule (CMS–4173–F), 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 Section II.F of the preamble to the final rule, we published two tables of credibility factors: Table 1a—MLR Credibility Adjustments for MA–PD Contracts and Table 1b—Proposed MLR Credibility Adjustments for Part D Stand-Alone Contracts.

For CY 2016, we are not proposing any changes to the credibility adjustments published in the final rule. The factors are presented in Tables II-6 and II-7 below.

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	Full-credible

*MA-PD combined with MA-only

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	Full-credible

Section L. International Classification of Diseases-10 (ICD-10) Code Set

The transition from the ICD-9 code set to the ICD-10 code set is scheduled to take place by October 1, 2015. Consistent with previous payment years, we propose that the data collection year for risk scores used for 2016 payment would use diagnoses from the prior calendar year (CY2015). Thus, both ICD-9 codes (from dates of service January 1, 2015 – September 30, 2015) and ICD-10 codes (from dates of service October 1, 2015 – December 31, 2015) would be used in calculating 2016 risk scores.

Section M. Encounter Data as a Diagnosis Source for 2016

We propose to calculate the 2016 risk score by blending two risk scores calculated as follows: one risk score calculated using diagnoses with dates of service of 2015 from RAPS and FFS and another separate risk score using diagnoses with dates of service 2015 from EDS and FFS. We will blend the two risk scores, weighting the risk score from RAPS and FFS by 90% and the risk score from EDS and FFS by 10%. For PACE organizations, we propose to continue the same method of calculating risk scores as used for the 2015 payment year, which is to use diagnoses from the following sources in equal measure (with no weighting): (1) Encounter Data System (EDS) data valid for risk adjustment with 2015 dates of service; (2) Risk Adjustment Processing System (RAPS) data valid for risk adjustment with 2015 dates of service; and (3) Diagnoses from FFS claims valid for risk adjustment.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2016

Section A. Update of the RxHCC Model

For 2016, 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 2016 model will encompass the following changes:

1) Update to reflect the 2016 benefit structure;
2) Updates to the data years used to calibrate the model;
3) Clinical update to the diagnoses included in some prescription drug hierarchical condition categories (RxHCCs);
4) Inclusion of MA-PD data in the model calibration; and
5) An actuarial adjustment to the Chronic Viral Hepatitis C RxHCC.

A1. Update to reflect the 2016 benefit structure

CMS recalibrated the RxHCC risk adjustment model to reflect the 2016 benefit structure. This update involves making adjustments to the Prescription Drug Event (PDE) data from the prediction year to approximate the 2016 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 plan liability in the coverage gap. For 2016, plan liability for non-LIS beneficiaries in the coverage gap will be 42 percent for non-applicable (generic) drugs and 5 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 as a result of the cost sharing reduction 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 current model is calibrated on 2010 diagnoses and 2011 expenditure data from the PDE records. As part of this recalibration for 2016, we updated the underlying data, using diagnosis data from 2012 fee-for-service (FFS) claims and MA-PD RAPS files, along with 2013 expenditure data from PDE records.

A3. Clinical update to the diagnoses included in some prescription drug hierarchical condition categories (RxHCCs)

CMS has made some clinical updates to the RxHCC risk adjustment model to better predict plan liability for prescription drugs. These changes improve the predictive power of some RxHCCs, and also reflect the impact on Part D costs for certain diseases of changes in the prescription drug market. Clinical changes to HCC-based models are made both with clinician input regarding the clinically-appropriate composition of each RxHCC, and with a consideration of each RxHCC's contribution to total plan liability for prescription drug costs. As a result of the clinical revisions, the 2016 model has 76 payment RxHCCs, compared with the 78 RxHCCs for the model used from 2011-2014. The decrease in number of RxHCCs is a net result of the addition of two new RxHCCs and the removal of four RxHCCs.

One of the newly added RxHCCs was created for high cost, secondary metastatic cancers and liver cancer (often secondary). The second new RxHCC is for chronic Hepatitis C and was split from the chronic viral hepatitis RxHCC. The new RxHCCs are:

- Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer; and
- Chronic Viral Hepatitis C.

The four RxHCCs that have been removed are:

- Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections
- Chronic Kidney Disease Stage 3
- Chronic Kidney Disease Stage 1, 2, or Unspecified
- Nephritis

In addition, CMS made changes to some of the RxHCCs in order to reflect recent drug expenditure patterns related to the continual introduction of new drugs, the diffusion of use of recently approved drugs, and the approval of generic drugs. Changes were made to the underlying diagnostic groupings within RxHCCs to improve predictive accuracy when spending for that condition was underpredicted (actual expenditures are more than predicted) or overpredicted (predicted expenditures are more than actual). The updates to the RxHCCs improve the model's ability to predict drug spending.

Preliminary 2016 payment year diagnosis code to 2016 RxHCC model mappings will be posted on the CMS Risk Adjustment Webpage, http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html?DLSort=0&DLPage=1&DLSortDir=descending.

Renumbering of RxHCCs

As part of our revision of some of the RxHCCs in the Part D risk adjustment model, we needed to renumber the RxHCCs. We understand that renumbering the RxHCCs entails the need for system changes and creates challenges in tracking over time. In order to avoid having to undertake a comprehensive renumbering as the result of any future model changes, we incorporated a series of gaps in the numbering of the RxHCCs between disease groups. These gaps will allow future changes in the classifications without requiring the renumbering of the entire set of RxHCCs. Specifically, at least five RxHCC numbers were skipped between each disease group and rounded up to the nearest multiple of five to start the next disease group.

For a list of RxHCCs in the proposed model, please see Table 6 in Attachment V.

A4. Inclusion of MA-PD data in the model calibration

The Part D model is similar to the Part C model, in that it includes demographic and diagnosis information clustered into hierarchical condition categories from one year to predict plan liability in the following year. The current version of the RxHCC model incorporates diagnosis data from FFS and prescription drug costs from Part D stand-alone plans (PDPs). In the past, to be included in the model estimation sample, beneficiaries were (1) FFS beneficiaries who were both entitled to Part A and enrolled in Part B in the base year, and (2) enrolled in a PDP for at least one month in the prediction year.

We have not historically used data for beneficiaries enrolled in MA-PD plans because, prior to 2011, many plans were submitting diagnostic data limited to the diagnoses in the model at that time. Without the additional diagnoses, these beneficiaries' data were not comprehensive enough to include in the RxHCC model.

Since the updated RxHCC model has been in place for a number of years, and MA-PDs are submitting more complete diagnostic data, we can recalibrate the RxHCC model using both FFS and MA-PD diagnoses. Therefore, in 2016, the updated version of the RxHCC model would include data for beneficiaries enrolled in MA-PD plans. To recalibrate the model for payment year 2016, diagnoses from FFS and MA-PD beneficiaries enrolled in a Part D plan were used; 2012 diagnoses were used to predict 2013 expenditures. To be included in the model estimation sample, beneficiaries must be: (1) FFS or Medicare Advantage (MA-PD or MA-only) for all 12 months of the base year (2012); and (2) enrolled in a PDP or an MA-PD for at least one month in the payment year (2013).

MA-PDs account for almost 40 percent of Part D enrollment and have different cost, coding, and utilization patterns than PDPs. Incorporating both FFS and MA-PD data into the Part D model allows MA-PD coding and utilization patterns to be accurately reflected in the Part D relative costs and improves the predictive accuracy of the RxHCC model.

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.

A5. Actuarial adjustment to the Chronic Viral Hepatitis C RxHCC

Over the last year, several medications to treat chronic Hepatitis C entered the market. These newly approved medications have high cure rates and are substantially more costly than previously approved therapies. Due to the effectiveness of these new agents and the prevalence of chronic Hepatitis C, the cost of these medications is having a significant impact in Medicare Part D.

The CY 2016 Part D model was calibrated using diagnosis data from 2012 and expenditure data from 2013. Therefore, the projected coefficient for the RxHCC for chronic Hepatitis C did not account for expenditures associated with treating patients with Hepatitis C with the new medications. To capture the substantial cost of these medications that are expected in the payment year, CMS applied an actuarial adjustment to the coefficient of the new chronic Hepatitis C RxHCC. To calculate the adjustment, CMS utilized diagnostic data and PDE expenditures from 2014 to estimate the total drug costs for beneficiaries on a treatment regimen including the new drug(s). We then calculated the amount of these costs that would map to plan liability. We made further adjustments to estimate the average costs in the 2016 payment year for beneficiaries who had Hepatitis C in 2015. In other words, we modeled the costs that our prospective model would predict in the payment year for beneficiaries with Hepatitis C in the base year, if these new Hepatitis C drugs had existed in 2012-2013. As a result of these analyses, CMS increased the coefficient of the Chronic Viral Hepatitis C RxHCC.

Similar to other CMS-HCC risk adjustment models, the RxHCC model is prospective; in other words, we use historical data to predict future costs. Our objective using a prospective model is to identify chronic, predictable conditions, not acute events. Thus, the Part D model is not designed to predict the costs of a disease that is primarily diagnosed, treated and cured in the same year.

CMS recognizes that Hepatitis C treatment over the next few years presents a unique situation. Given the clinical ramifications, as well as the uncertainty regarding the future pattern of Hepatitis C among Medicare beneficiaries and the patterns of expenditures to treat these beneficiaries, including the impact of new drugs coming on the market and possible market competition, CMS considers this actuarial adjustment to be a temporary measure. CMS will continue to closely observe the pattern of the diagnosis and treatment of Hepatitis C and revisit this adjustment for the 2017 RxHCC model.

In the future, when we update the model using 2013 diagnostic data to project 2014 costs, our prospective model will likely estimate higher costs than will occur in the future payment years, when beneficiaries with Hepatitis C in the base year will largely be treated in the base year. Because of the influx of these new medications in 2014, we anticipate needing to apply a downward adjustment to the overestimated Hepatitis C coefficient in a 2013-2014 model (which would be used for the 2017 payment year), in order to estimate a more accurate relative factor.

A6. Recalibration

Coefficients for condition categories were estimated by regressing the plan liability, adjusted as discussed above, for the Part D basic benefit for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (for example, age/sex group, low income subsidy status, disability status). Changes in the coefficients for each condition category are the result of the extent to which each category predicts plan liability for Medicare Part D benefits. Condition categories that do not predict costs well – because the t-value is low, the number of beneficiaries with a certain condition is small so the coefficient is unstable, the condition does not have well specified diagnostic coding, or the condition is predictive of low marginal costs – are not included in the model.

In order to use the risk adjustment model to calculate risk scores for payment, we created relative factors for each demographic factor and RxHCC in the model. The relative factors were used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year.

We created relative factors by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year. The denominator for the revised RxHCC risk adjustment model was again developed by using data from Medicare beneficiaries enrolled in both MA-PDs and PDPs. We do this in order to set the average RxHCC risk score to 1.0 for the enrolled population. We used a denominator of average per capita cost for 2013 to create the relative factors for the model. The denominator, which is used to create relative factors for all segments of the model, is $1,002.93.

In a final step, hierarchies were imposed 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 marginal cost attributable to an RxHCC, relative to changes in the average cost, can alter the relative factor associated with that RxHCC. In addition, changes in the relative factors will result from the other changes discussed above, including the clinical update, the addition of MA-PD data, and the actuarial adjustment to the Hepatitis C RxHCC.

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

Section B. International Classification of Diseases-10 (ICD-10) Code Set and Diagnosis Data Sources for 2016 Risk Scores

The transition from the ICD-9 code set to the ICD-10 code set is scheduled to take place by October 1, 2015. Consistent with previous payment years, we propose that the data collection year for risk scores used for 2016 payment would use diagnoses from the prior calendar year (CY2015). Thus, both ICD-9 codes (from dates of service January 1, 2015 – September 30, 2015) and ICD-10 codes (from dates of service October 1, 2015 – December 31, 2015) would be used in calculating 2016 risk scores.

Section C. Encounter Data as a Diagnosis Source for 2016

We propose to calculate the 2016 risk score by blending two risk scores calculated as follows: one risk score calculated using diagnoses with dates of service of 2015 from RAPS and FFS and another separate risk score using diagnoses with dates of service 2015 from EDS and FFS. We will blend the two risk scores, weighting the risk score from RAPS and FFS by 90% and the risk score from EDS and FFS by 10%. For PACE organizations, we propose to continue the same method of calculating risk scores as used for the 2015 payment year, which is to use diagnoses from the following sources in equal measure (with no weighting): (1) Encounter Data System (EDS) data valid for risk adjustment with 2015 dates of service; (2) Risk Adjustment Processing System (RAPS) data valid for risk adjustment with 2015 dates of service; and (3) Diagnoses from FFS claims valid for risk adjustment.

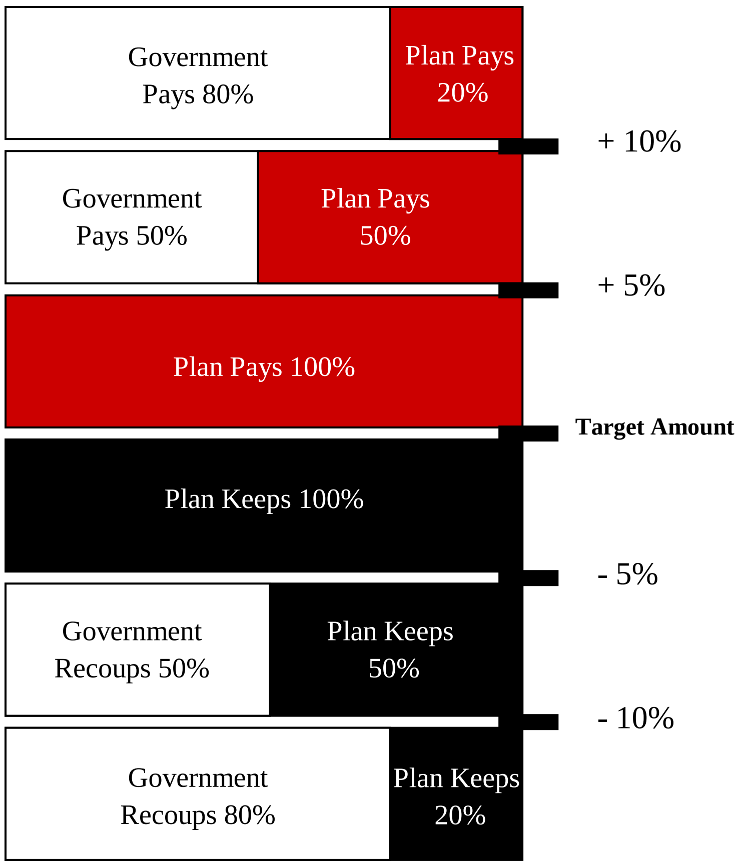
Section D. Payment Reconciliation

Pursuant to section 1860D-15(e)(3)(C) of the Act and the regulations at 42 CFR 423.336 (a)(2)(ii), CMS may establish higher risk percentages for Part D risk sharing beginning in contract year 2012. The risk sharing payments provided by CMS limit Part D sponsors' exposure to unexpected drug expenses. Establishing higher Part D risk percentages would increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS.

CMS has evaluated the risk sharing amounts for 2006 – 2011 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 for Part D sponsors. In addition, the aggregate risk sharing amount paid by CMS varies significantly from year to 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 risk percentages for contract year 2016. We will continue to evaluate the risk sharing amounts each year to determine if higher risk percentages 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 2015. The risk percentages for the first and second thresholds remain at 5 percent and 10 percent of the target amount, respectively, for 2016. The payment adjustments for the first and second corridors are 50 percent and 80 percent, respectively. Please see Figure 1 below which illustrates the risk corridors for 2016.

Figure 1. Part D Risk Corridors for 2016



D1. 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.

D2. 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.

Section E. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2016

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. These parameters include the annual deductible, initial coverage limit (ICL), annual out-of-pocket (OOP) threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries.

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. The Part D benefit parameters are updated using two indexing methods specified by statute: (1) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase," and (2) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

As required by statute, the first indexing method, the "annual percentage increase," is used to update the following Part D benefit parameters:

- the deductible, initial coverage limit, and out-of-pocket threshold 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
- maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

E.1 Updates to Part D benefit parameters

The benefit parameters listed above will be increased by 11.76% for 2016 as summarized by Table III-1 below. This increase reflects the 2015 annual percentage trend of 6.37% as well as a multiplicative update of 5.07% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 11.76% from their 2015 values.

E.2 Updates to co-payments for certain full benefit dual eligible individuals

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100 percent of the Federal poverty line. These maximum copayments will be increased by 1.62% for 2016 as summarized in Table III-1 below.

This increase reflects the 2015 annual percentage trend in CPI of 1.45%, as well as a multiplicative update of 0.17% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase in the CPI.

E.3 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 required to attain 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, 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:

- <u>Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries</u>. This is the amount of total drug spending for a non-applicable (i.e., LIS) beneficiary to attain 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% cost sharing in the deductible and coverage gap phases and 25% in the initial coverage phase.

- <u>Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries</u>. This is an *estimate* of the average amount of total drug spending for an applicable (i.e., non-LIS) beneficiary to attain 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% beneficiary cost sharing in the deductible phase, 25% in the initial coverage phase, and in the coverage gap, 58% cost sharing for non-applicable (generic) drugs and 95% 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.

Enhanced alternative coverage plans must use these values when mapping enhanced alternative coverage plans to the defined standard benefit, as the Total Covered Part D Spending at the Out-of-pocket Threshold is necessary to calculate the covered plan paid (CPP) amounts reported on the prescription drug event (PDE) records.

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

Annual Percentage Increases

	Annual percentage trend for 2015	Prior year revisions	Annual percentage increase for 2015
Applied to all parameters but (1)	6.37%	5.07%	11.76%
CPI (all items, U.S. city average): Applied to (1)	1.45%	0.17%	1.62%

Part D Benefit Parameters

	2015	2016
Standard Benefit		
Deductible	$320	$360
Initial Coverage Limit	$2,960	$3,310
Out-of-Pocket Threshold	$4,700	$4,850
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,680.00	$7,062.50
Estimated Total Covered Part D Spending for Applicable Beneficiaries (3)	$7,061.76	$7,515.22
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (5)		
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 (4) (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 (4)	$1.20	$1.20
Other (4)	$3.60	$3.60
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	$2.65	$2.95
Other	$6.60	$7.40
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $8,780 (individuals) or ≤ $13,930 (couples) (6) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00

	2015	2016
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,640 (individual) or $27,250 (couples) (6)		
Deductible	$66.00	$74.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.95
Other	$6.60	$7.40
Retiree Drug Subsidy Amounts		
Cost Threshold	$320	$360
Cost Limit	$6,600	$7,400

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

(2) For beneficiaries who are not considered an “applicable beneficiary” as defined at section 1860D-14A(g)(1) and are not eligible for the coverage gap program, this is the amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.

(3) For beneficiaries who are considered an “applicable beneficiary” as defined at section 1860D-14A(g)(1) and are 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. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.

(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (couple) was not receiving home and community-based services qualify for zero cost-sharing as of January 1, 2015, as specified by the Secretary.

(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2015 values of $66.03, $1.20, and $3.59, respectively.

(6) The actual amount of resources allowable will be updated for contract year 2016.

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

The Affordable Care Act phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit by reducing beneficiary coinsurance for drugs in the gap for applicable beneficiaries. This reduction in cost sharing began in CY 2011 and continues through CY 2020, ultimately resulting in 75% cost sharing for applicable drugs, prior to the application of any manufacturer discounts, and 25% cost sharing for other covered Part D drugs (non-applicable drugs). Applicable drugs are defined at section 1860D-14A(g)(2) of the statute and are generally brand covered Part D 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 product, licensed under section 351 of the Public Health Service Act (BLA). Non-applicable drugs are covered Part D drugs that do not meet the definition of an applicable drug (i.e., generic drugs). 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 2016, the coinsurance under basic prescription drug coverage for certain beneficiaries is further reduced from 2015 for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. The coinsurance charged to eligible beneficiaries will be equal to 58%. Also in 2016, the coinsurance under basic prescription drug coverage for certain beneficiaries is reduced for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit.

The coinsurance charged to eligible beneficiaries will be equal to 45% of the negotiated price, as a result of the application of 95% coinsurance and a 50% manufacturer discount. To be eligible for reduced cost sharing for non-applicable and applicable drugs, a Part D enrollee must have gross covered drug costs above the initial coverage limit and true out-of-pocket costs (TrOOP) below the out-of-pocket threshold. Medicare beneficiaries will not be eligible for this reduced cost sharing if they are enrolled in a qualified retiree prescription drug plan or are entitled to the low-income subsidy.

The 58% coinsurance for non-applicable drugs and 45% coinsurance for applicable drugs in the coverage gap represent an increase in plan liability and a reduction in beneficiary cost sharing. Therefore, we further specify that these 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 2016.

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

As discussed in previous notices, the Affordable Care Act phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit. By 2020, beneficiary cost sharing for all covered brand and generic drugs and biological products will equal to 25 percent until the beneficiary reaches catastrophic coverage. The cost sharing reductions, in conjunction with the coverage gap discount program, will serve to effectively close the coverage gap for applicable (i.e., non-low-income) beneficiaries by CY 2020. 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 2016, applicable beneficiaries will pay 45 percent and plans will pay 55 percent of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2016

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) 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, and 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 2016, and (3) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

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), and (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

Section 1860D-2(b)(6) of the Social Security Act defines the "annual percentage increase" 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 $320 in 2015 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,960 in 2015 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,700 in 2015 and rounded to the nearest multiple of $50. The "annual percentage increase" applied to the out-of-pocket threshold is CPI+2% which is the lesser of API and CPI+2% as required by the ACA.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2015, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2015, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $66[6] in 2015 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2015, and rounded to the nearest multiple of $0.05.

Section B. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security 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 below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 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 $3.60 for all other drugs in 2015[7], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

Section C. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security 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 the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2016 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

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[6] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2015 value of $66.03.

[7] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2015 values of $1.20 per generic or preferred drug that is a multi-source drug, and $3.59 for all other drugs.

$$\frac{August\ 2014\text{–}July\ 2015}{August\ 2013\text{–}July\ 2014} = \frac{\$3{,}263.64}{\$3{,}068.21} = 1.0637$$

In the formula, the average per capita cost for August 2013 – July 2014 ($3,068.21) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2014 – July 2015 ($3,263.64) is calculated based on actual Part D PDE data incurred from August – December, 2014 and projected through July, 2015.

The 2016 benefit parameters reflect the 2015 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. 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	4.17%	4.17%
2010	3.02%	3.07%
2011	2.44%	2.48%
2012	2.44%	2.45%
2013	2.01%	1.95%
2014	−2.82%	−2.72%
2015	4.07%	9.18%

Accordingly, the 2016 benefit parameters reflect a multiplicative update of 5.07 percent for prior year revisions. In summary, the 2015 parameters outlined in Section A are updated by 11.76 percent for 2016 as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2015	6.37%
Prior year revisions	5.07%
Annual percentage increase for 2016	11.76%

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, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2016, the September 2015 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2015 CPI based on the projected amount included in the President's FY2016 Budget.

The September 2014 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2016 is calculated as follows:

$$\frac{\text{Projected September 2015 CPI}}{\text{Actuarl September 2014 CPI}} \; or \; \frac{241.481}{238.031} = 1.0145$$

(Source: President's FY2016 Budget and Bureau of Labor Statistics, Department of Labor)

The 2016 benefit parameters reflect the 2015 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2014 annual percentage increase. The 2015 parameter update reflected an annual percentage trend in CPI of 1.48 percent. Based on the actual reported CPI for September 2014, the September 2014 CPI increase is now estimated to be 1.66 percent. Accordingly, the 2016 update reflects a multiplicative 0.17 percent correction for prior year revisions. In summary, the cost sharing items outlined in Section B are updated by 1.62 percent for 2016 as summarized by Table IV-3.

Table IV-3. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2015	1.45%
Prior year revisions	0.17%
Annual percentage increase for 2015	1.62%

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

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $310 and $6,350, respectively, for plans that end in 2014, and, as $320 and $6,660, respectively, for plans that end in 2015. For 2016, the cost threshold is $360 and the cost limit is $7,400.

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

For 2016, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $7,515.22. It is calculated as the ICL plus 100 percent beneficiary cost sharing divided by the weighted gap coinsurance factor. The factor is calculated assuming 100 percent cost sharing in the deductible phase, 25 percent in the initial coverage phase and in the coverage gap, 58 percent for non-applicable (generic) drugs and 95 percent of the ingredient cost and sales tax for applicable (brand) drugs and 45 percent of the dispensing and vaccine administration fees for applicable (brand) drugs. In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.15 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 55 percent reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.08 percent to 94.92 percent in cost sharing for applicable (brand) drugs in the coverage gap.

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

$$\text{ICL}+\frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad or \quad \$3{,}310+\frac{\$3{,}752.50}{89.234\%}=\$7{,}515.22$$

One hundred percent beneficiary cost sharing in the gap is the estimated total drug spending in the gap assuming 100 percent coinsurance.

One hundred percent beneficiary cost sharing in the gap is calculated as follows:

OOP threshold − OOP costs up to the ICL *or* $4,850 − $1,097.50 = $3,752.50

- Weighted gap coinsurance factor is calculated as follows:

  (Brand GDCB % for non-LIS × 94.92% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 58% cost sharing for non-applicable drugs)

  or

  (84.6% × 94.92%) + (15.4% × 58%) = 89.234%

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to applicable (brand) drugs as reported on the 2014 PDEs.

- Gap cost sharing for applicable drugs is the coinsurance incurred by applicable beneficiaries for applicable (brand) drugs in the coverage gap, where:

  Coinsurance for applicable drugs = [(percentage of gross covered brand drug costs attributable to ingredient cost + sales tax) × (cost sharing percentage) + (percentage of gross covered brand drug costs attributable to dispensing + vaccine administration fees) × (cost sharing coinsurance percentage)]

  or

  94.92% = [(99.85% × 95%) + (0.15% × 45%)]

- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to non-applicable (generic) drugs as reported on the 2014 PDEs.

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

Attachment V. Preliminary RxHCC Risk Adjustment Factors

Table 1. Preliminary RxHCC Model Relative Factors for Continuing Enrollees

		Continuing Enrollee (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		-	0.255	-	0.403	1.784
35-44 Years		-	0.426	-	0.617	1.840
45-54 Years		-	0.522	-	0.708	1.646
55-59 Years		-	0.507	-	0.681	1.534
60-64 Years		-	0.468	-	0.624	1.439
65-69 Years		0.270	-	0.398	-	1.520
70-74 Years		0.270	-	0.402	-	1.431
75-79 Years		0.258	-	0.393	-	1.341
80-84 Years		0.248	-	0.369	-	1.263
85-89 Years		0.233	-	0.340	-	1.183
90-94 Years		0.204	-	0.279	-	1.072
95 Years or Over		0.149	-	0.195	-	0.880
Male						
0-34 Years		-	0.213	-	0.438	1.733
35-44 Years		-	0.345	-	0.570	1.736
45-54 Years		-	0.433	-	0.618	1.583
55-59 Years		-	0.448	-	0.592	1.450
60-64 Years		-	0.419	-	0.541	1.337
65-69 Years		0.275	-	0.331	-	1.395
70-74 Years		0.275	-	0.346	-	1.330
75-79 Years		0.235	-	0.337	-	1.283
80-84 Years		0.184	-	0.325	-	1.225
85-89 Years		0.143	-	0.289	-	1.164
90-94 Years		0.105	-	0.256	-	1.084
95 Years or Over		0.085	-	0.216	-	0.945
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.084	-	0.170	-	0.050
Originally Disabled_Male		-	-	0.114	-	0.050
Variable	**Description Label**					
RXHCC1	HIV/AIDS	2.431	2.844	3.139	3.594	1.802
RXHCC5	Opportunistic Infections	0.205	0.122	0.128	0.175	0.104

Continuing Enrollee (CE) RxHCC Model Segments

Variable	**Disease Group**	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC15	Chronic Myeloid Leukemia	5.276	5.842	6.032	7.795	3.566
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	2.873	3.191	2.404	2.870	0.942
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.040	0.916	1.137	1.058	0.320
RXHCC18	Lung, Kidney, and Other Cancers	0.219	0.239	0.275	0.271	0.051
RXHCC19	Breast and Other Cancers and Tumors	0.081	0.040	0.074	0.081	0.042
RXHCC30	Diabetes with Complications	0.379	0.418	0.446	0.545	0.381
RXHCC31	Diabetes without Complication	0.249	0.229	0.298	0.323	0.268
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.151	7.700	2.644	8.226	0.477
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.114	0.168	0.057	0.172	0.060
RXHCC42	Thyroid Disorders	0.078	0.146	0.076	0.145	0.053
RXHCC43	Morbid Obesity	0.084	0.030	0.065	0.065	0.138
RXHCC45	Disorders of Lipoid Metabolism	0.067	0.079	0.116	0.167	0.076
RXHCC54	Chronic Viral Hepatitis C	4.273	4.273	4.231	4.231	4.231
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.289	0.420	0.835	0.568	0.281
RXHCC65	Chronic Pancreatitis	0.202	0.160	0.112	0.109	0.120
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.091	0.160	0.076	0.109	0.050
RXHCC67	Inflammatory Bowel Disease	0.419	0.330	0.344	0.600	0.152
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.111	0.081	0.156	0.171	0.075
RXHCC80	Aseptic Necrosis of Bone	0.117	0.173	0.123	0.190	0.108
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.627	0.646	0.963	1.496	0.429
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.277	0.319	0.354	0.612	0.148

Variable	Disease Group	Continuing Enrollee (CE) RxHCC Model Segments: Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.186	0.283	0.213	0.312	0.121
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.051	0.138	0.130	0.191	-
RXHCC95	Sickle Cell Anemia	0.090	0.211	0.086	0.622	0.358
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.555	0.793	0.547	0.646	0.477
RXHCC97	Immune Disorders	0.305	0.284	0.312	0.358	0.247
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.090	0.106	0.058	0.209	0.056
RXHCC111	Alzheimer's Disease	0.471	0.273	0.209	0.130	-
RXHCC112	Dementia, Except Alzheimer's Disease	0.207	0.102	0.054	-	-
RXHCC130	Schizophrenia	0.286	0.385	0.470	0.778	0.212
RXHCC131	Bipolar Disorders	0.286	0.348	0.331	0.533	0.212
RXHCC132	Major Depression	0.171	0.303	0.220	0.392	0.198
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.171	0.230	0.184	0.389	0.117
RXHCC134	Depression	0.148	0.177	0.145	0.241	0.117
RXHCC135	Anxiety Disorders	0.064	0.115	0.098	0.187	0.099
RXHCC145	Autism	0.171	0.230	0.396	0.437	0.117
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	0.060	0.099	0.396	0.323	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	0.060	-	0.245	0.185	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.115	0.050	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.304	0.501	0.336	0.573	0.143
RXHCC157	Spinal Cord Disorders	0.134	0.149	0.104	0.080	0.079

Continuing Enrollee (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
RXHCC159	Inflammatory and Toxic Neuropathy	0.216	0.456	0.224	0.358	0.084
RXHCC160	Multiple Sclerosis	1.470	2.464	1.558	3.345	0.722
RXHCC161	Parkinson's and Huntington's Diseases	0.502	0.729	0.321	0.422	0.193
RXHCC163	Intractable Epilepsy	0.291	0.461	0.261	0.828	0.047
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.114	0.066	0.047	0.155	-
RXHCC165	Convulsions	0.058	0.044	0.035	0.096	-
RXHCC166	Migraine Headaches	0.135	0.221	0.140	0.162	0.121
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.116	0.280	0.144	0.212	0.188
RXHCC185	Primary Pulmonary Hypertension	0.543	1.488	0.544	1.264	0.235
RXHCC186	Congestive Heart Failure	0.178	0.130	0.248	0.140	0.142
RXHCC187	Hypertension	0.152	0.079	0.221	0.111	0.074
RXHCC188	Coronary Artery Disease	0.143	0.061	0.157	0.033	0.021
RXHCC193	Atrial Arrhythmias	0.173	0.096	0.062	0.019	0.049
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.058	-	0.045	-	-
RXHCC207	Spastic Hemiplegia	0.159	0.268	0.053	0.151	-
RXHCC215	Venous Thromboembolism	0.074	0.127	0.032	0.120	0.028
RXHCC216	Peripheral Vascular Disease	-	-	0.058	0.023	-
RXHCC225	Cystic Fibrosis	0.311	3.162	0.359	3.216	0.218
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.311	0.158	0.359	0.265	0.191
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.157	0.158	0.136	0.248	0.089
RXHCC241	Diabetic Retinopathy	0.229	0.174	0.164	0.095	0.118
RXHCC243	Glaucoma	0.256	0.186	0.296	0.244	0.222
RXHCC260	Kidney Transplant Status	0.329	0.164	0.384	0.350	0.213
RXHCC261	Dialysis Status	0.180	0.295	0.352	0.752	0.231
RXHCC262	Chronic Kidney Disease Stage 5	0.100	0.085	0.107	0.092	0.068
RXHCC263	Chronic Kidney Disease Stage 4	0.100	0.085	0.098	0.092	0.068

Variable	Disease Group	Continuing Enrollee (CE) RxHCC Model Segments: Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.124	0.150	0.060	0.085	0.048
RXHCC314	Pemphigus	0.299	0.574	0.197	0.309	0.085
RXHCC316	Psoriasis, Except with Arthropathy	0.164	0.206	0.297	0.521	0.199
RXHCC355	Narcolepsy and Cataplexy	0.653	1.030	0.664	1.215	0.252
RXHCC395	Lung Transplant Status	1.173	0.481	0.962	0.928	0.592
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.804	0.381	0.585	0.395	0.273
RXHCC397	Pancreas Transplant Status	0.284	0.164	0.384	0.320	0.213
Non-Aged Disease Interactions						
Variable	**Disease Group**					
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	1.279
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.268
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.268
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.179
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.157
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.111
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.115
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.146
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.174

Note: The 2013 denominator of $1002.93 used to calculate the proposed RxHCC model factors is the national predicted annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. 'Originally Disabled' is defined as originally entitled to Medicare by disability only and are now entitled due to age.

Source: RTI Analysis of 100% 2013 PDE, 2012 Carrier NCH, 2012 Inpatient SAF, 2012 Outpatient SAF, 2013 HPMS, 2013 CME, 2012-2013 Denominator, Part D Intermediate File, and 2012 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD Only – Not Originally Disabled	Originally Disabled Only – Not Concurrently ESRD	Originally Disabled and Concurrently ESRD
Female				
0-34 Years	0.648	0.648	-	-
35-44 Years	1.034	1.056	-	-
45-54 Years	1.219	1.314	-	-
55-59 Years	1.162	1.563	-	-
60-64 Years	1.162	1.726	-	-
65 Years	0.577	1.778	1.079	1.778
66 Years	0.626	1.778	1.081	1.778
67 Years	0.633	1.778	1.081	1.778
68 Years	0.663	1.778	1.081	1.778
69 Years	0.672	1.778	1.081	1.778
70-74 Years	0.674	1.778	0.896	1.778
75-79 Years	0.658	1.778	0.658	1.778
80-84 Years	0.600	1.778	0.600	1.778
85-89 Years	0.461	1.778	0.461	1.778
90-94 Years	0.219	1.778	0.219	1.778
95 Years or Over	0.219	1.778	0.219	1.778
Male				
0-34 Years	0.353	0.641	-	-
35-44 Years	0.741	0.741	-	-
45-54 Years	0.976	1.208	-	-
55-59 Years	0.999	1.379	-	-
60-64 Years	0.983	1.548	-	-
65 Years	0.584	1.751	0.898	1.751
66 Years	0.649	1.751	0.852	1.751
67 Years	0.666	1.751	0.835	1.751
68 Years	0.684	1.751	0.800	1.751
69 Years	0.718	1.751	0.800	1.751
70-74 Years	0.723	1.751	0.774	1.751
75-79 Years	0.696	1.751	0.696	1.751
80-84 Years	0.575	1.751	0.575	1.751
85-89 Years	0.457	1.751	0.457	1.751
90-94 Years	0.343	1.751	0.343	1.751
95 Years or Over	0.343	1.751	0.343	1.751

Notes: The 2013 denominator of $1002.93 used to calculate the proposed RxHCC model factors is the national predicted annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. ‘Originally Disabled’ is defined as originally entitled to Medicare by disability only and are now entitled due to age. 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% 2013 PDE, 2012 NCH, 2013 HPMS, 2013 CME, 2012-2013 Denominator, and Part D Intermediate File.

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

Variable	Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD Only – Not Originally Disabled	Originally Disabled Only – Not Concurrently ESRD	Originally Disabled and Concurrently ESRD
Female				
0-34 Years	0.999	1.890	-	-
35-44 Years	1.444	1.894	-	-
45-54 Years	1.470	2.010	-	-
55-59 Years	1.337	2.053	-	-
60-64 Years	1.264	1.974	-	-
65 Years	0.931	2.102	1.138	2.102
66 Years	0.622	2.102	0.892	2.102
67 Years	0.622	2.102	0.892	2.102
68 Years	0.622	2.102	0.892	2.102
69 Years	0.622	2.102	0.742	2.102
70-74 Years	0.644	2.102	0.742	2.102
75-79 Years	0.706	2.102	0.706	2.102
80-84 Years	0.706	2.102	0.706	2.102
85-89 Years	0.706	2.102	0.706	2.102
90-94 Years	0.559	2.102	0.559	2.102
95 Years or Over	0.559	2.102	0.559	2.102
Male				
0-34 Years	0.867	2.016	-	-
35-44 Years	1.228	1.925	-	-
45-54 Years	1.255	2.022	-	-
55-59 Years	1.103	1.836	-	-
60-64 Years	1.038	1.691	-	-
65 Years	0.775	1.711	0.941	1.711
66 Years	0.481	1.711	0.515	1.711
67 Years	0.481	1.711	0.515	1.711
68 Years	0.481	1.711	0.515	1.711
69 Years	0.481	1.711	0.515	1.711
70-74 Years	0.523	1.711	0.555	1.711
75-79 Years	0.557	1.711	0.557	1.711
80-84 Years	0.546	1.711	0.546	1.711
85-89 Years	0.527	1.711	0.527	1.711
90-94 Years	0.441	1.711	0.441	1.711
95 Years or Over	0.441	1.711	0.441	1.711

Notes: The 2013 denominator of $1002.93 used to calculate the proposed RxHCC model factors is the national predicted annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. ‘Originally Disabled’ is defined as originally entitled to Medicare by disability only and are now entitled due to age. 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% 2013 PDE, 2012 NCH, 2013 HPMS, 2013 CME, 2012-2013 Denominator, and Part D Intermediate File.

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

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.452	2.738
35-44 Years	2.452	2.738
45-54 Years	2.423	2.738
55-59 Years	2.423	2.738
60-64 Years	2.227	2.738
65 Years	2.267	2.738
66 Years	2.022	2.738
67 Years	2.022	2.738
68 Years	2.022	2.738
69 Years	2.022	2.738
70-74 Years	1.842	2.738
75-79 Years	1.648	2.738
80-84 Years	1.564	2.738
85-89 Years	1.304	2.738
90-94 Years	1.304	2.738
95 Years or Over	1.304	2.738
Male		
0-34 Years	2.179	2.644
35-44 Years	2.530	2.644
45-54 Years	2.319	2.644
55-59 Years	2.112	2.644
60-64 Years	2.017	2.644
65 Years	2.025	2.644
66 Years	1.804	2.644
67 Years	1.804	2.644
68 Years	1.804	2.644
69 Years	1.804	2.644
70-74 Years	1.794	2.644
75-79 Years	1.700	2.644
80-84 Years	1.560	2.644
85-89 Years	1.445	2.644
90-94 Years	1.445	2.644
95 Years or Over	1.445	2.644

Notes: The 2013 denominator of $1002.93 used to calculate the proposed RxHCC model factors is the national predicted annual cost under the model. This Part D denominator is based on the combined PDP and MA-PD populations. 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% 2013 PDE, 2012 NCH, 2013 HPMS, 2013 CME, 2012-2013 Denominator, and Part D Intermediate File.

Table 5. Preliminary List of Disease Hierarchies for the Proposed RxHCC Model

Prescription Drug Hierarchical Condition Category (RxHCC)	If the Disease Group is Listed in this column…	…Then drop the Disease Group(s) listed in this column
	Prescription Drug Hierarchical Condition Category (RxHCC) LABEL	
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.

Table 6. Comparison of Current and Proposed RxHCC Risk Adjustment Model RxHCCs

Current RxHCC Risk Adjustment Model RxHCCs		Proposed RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
1	HIV/AIDS	1	HIV/AIDS	Infection
5	Opportunistic Infections	5	Opportunistic Infections	
8	Chronic Myeloid Leukemia	*15*	*Chronic Myeloid Leukemia*	Neoplasm
9	Multiple Myeloma and Other Neoplastic Disorders	*16*	*Multiple Myeloma and Other Neoplastic Disorders*	
		17	**Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer**	
10	Breast, Lung, and Other Cancers and Tumors	*18*	*Lung, Kidney, and Other Cancers*	
11	Prostate and Other Cancers and Tumors	*19*	*Breast and Other Cancers and Tumors*	
14	Diabetes with Complications	30	Diabetes with Complications	Diabetes
15	Diabetes without Complication	31	Diabetes without Complication	
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	*40*	*Specified Hereditary Metabolic/Immune Disorders*	Metabolic
19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	*41*	*Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders*	
20	Thyroid Disorders	42	Thyroid Disorders	
21	Morbid Obesity	43	Morbid Obesity	
23	Disorders of Lipoid Metabolism	45	Disorders of Lipoid Metabolism	
		54	**Chronic Viral Hepatitis C**	Liver
25	Chronic Viral Hepatitis	*55*	*Chronic Viral Hepatitis, Except Hepatitis C*	
30	Chronic Pancreatitis	65	Chronic Pancreatitis	Gastrointestinal
31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	
32	Inflammatory Bowel Disease	67	Inflammatory Bowel Disease	
33	Esophageal Reflux and Other Disorders of Esophagus	68	Esophageal Reflux and Other Disorders of Esophagus	
38	Aseptic Necrosis of Bone	80	Aseptic Necrosis of Bone	Musculoskeletal
40	Psoriatic Arthropathy	*82*	*Psoriatic Arthropathy and Systemic Sclerosis*	
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	
42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	
45	Osteoporosis, Vertebral and Pathological Fractures	87	Osteoporosis, Vertebral and Pathological Fractures	
47	Sickle Cell Anemia	95	Sickle Cell Anemia	Blood
48	Myelodysplastic Syndromes, Except High-Grade	*96*	*Myelodysplastic Syndromes and Myelofibrosis*	
49	Immune Disorders	97	Immune Disorders	
50	Aplastic Anemia and Other Significant Blood Disorders	*98*	*Aplastic Anemia and Other Significant Blood Disorders*	

Current RxHCC Risk Adjustment Model RxHCCs		Proposed RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
54	Alzheimer's Disease	111	Alzheimer's Disease	Cognitive
55	Dementia, Except Alzheimer's Disease	112	Dementia, Except Alzheimer's Disease	
58	Schizophrenia	130	Schizophrenia	Psychiatric
59	Bipolar Disorders	131	Bipolar Disorders	
60	Major Depression	132	Major Depression	
61	Specified Anxiety, Personality, and Behavior Disorders	133	Specified Anxiety, Personality, and Behavior Disorders	
62	Depression	134	Depression	
63	Anxiety Disorders	135	Anxiety Disorders	
65	Autism	145	Autism	Developmental Disorder
66	Profound or Severe Mental Retardation/Developmental Disability	146	Profound or Severe Intellectual Disability/Developmental Disorder	
67	Moderate Mental Retardation/Developmental Disability	147	Moderate Intellectual Disability/Developmental Disorder	
68	Mild or Unspecified Mental Retardation/Developmental Disability	148	Mild or Unspecified Intellectual Disability/Developmental Disorder	
71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	Neurological
72	Spinal Cord Disorders	*157*	*Spinal Cord Disorders*	
74	Polyneuropathy	*159*	*Inflammatory and Toxic Neuropathy*	
75	Multiple Sclerosis	160	Multiple Sclerosis	
76	Parkinson's Disease	*161*	*Parkinson's and Huntington's Diseases*	
78	Intractable Epilepsy	163	Intractable Epilepsy	
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	
80	Convulsions	165	Convulsions	
81	Migraine Headaches	166	Migraine Headaches	
83	Trigeminal and Postherpetic Neuralgia	168	Trigeminal and Postherpetic Neuralgia	
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	*185*	*Primary Pulmonary Hypertension*	Heart
87	Congestive Heart Failure	*186*	*Congestive Heart Failure*	
88	Hypertension	187	Hypertension	
89	Coronary Artery Disease	188	Coronary Artery Disease	
93	Atrial Arrhythmias	193	Atrial Arrhythmias	
97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	Cerebrovascular Disease
98	Spastic Hemiplegia	207	Spastic Hemiplegia	
100	Venous Thromboembolism	215	Venous Thromboembolism	Vascular
101	Peripheral Vascular Disease	216	Peripheral Vascular Disease	

Current RxHCC Risk Adjustment Model RxHCCs		Proposed RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
103	Cystic Fibrosis	225	Cystic Fibrosis	Lung
104	Chronic Obstructive Pulmonary Disease and Asthma	226	Chronic Obstructive Pulmonary Disease and Asthma	
105	Pulmonary Fibrosis and Other Chronic Lung Disorders	227	Pulmonary Fibrosis and Other Chronic Lung Disorders	
106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections			
111	Diabetic Retinopathy	241	Diabetic Retinopathy	Eye
113	Open-Angle Glaucoma	243	Open-Angle Glaucoma	
120	Kidney Transplant Status	260	Kidney Transplant Status	Kidney
121	Dialysis Status	261	Dialysis Status	
122	Chronic Kidney Disease Stage 5	262	Chronic Kidney Disease Stage 5	
123	Chronic Kidney Disease Stage 4	263	Chronic Kidney Disease Stage 4	
124	Chronic Kidney Disease Stage 3			
125	Chronic Kidney Disease Stage 1, 2, or Unspecified			
126	Nephritis			
142	Chronic Ulcer of Skin, Except Pressure	311	Chronic Ulcer of Skin, Except Pressure	Skin
145	Pemphigus	314	Pemphigus	
147	Psoriasis, Except with Arthropathy	316	Psoriasis, Except with Arthropathy	
156	Narcolepsy and Cataplexy	355	Narcolepsy and Cataplexy	Sleep
166	Lung Transplant Status	395	Lung Transplant Status	Transplant
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	*396*	*Major Organ Transplant Status, Except Lung, Kidney, and Pancreas*	
168	Pancreas Transplant Status	397	Pancreas Transplant Status	

Note: RxHCCs were re-numbered to leave spaces of RxHCC numbers between disease groups (category short names). This will allow for future changes to the classification without requiring the entire set of RxHCCs to be re-numbered.

Source: RTI International

Attachment VI: 2016 Draft Call Letter

2016 Announcement
Table of Contents

How to Use This Draft Call Letter

The 2016 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs) and Part D sponsors need to take into consideration in preparing their 2016 bids. Guidance on Medicare-Medicaid Plan (MMP)-specific requirements will be released in early 2015.

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) continued program vibrancy and stability, 2) value for beneficiaries and tax-payers, 3) better quality care for beneficiaries, and 4) improved compliance for plans and sponsors. This year, to achieve these outcomes, CMS' 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 Draft Call Letter, please contact: Nishamarie Sherry at Nishamarie.Sherry@cms.hhs.gov (Part C issues) and Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues).

Section I – Parts C and D

Annual Calendar

Below is a combined calendar listing of side-by-side 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.

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
January 13, 2015	Release of the Contract Year (CY) 2016 MA/MA-PD/PDP and 1876 Cost Plan Expansion Applications	✓	✓	✓	
January 13 & 15, 2014	Industry Training and Technical Assistance for CY 2016 Model of Care (MOC) Submissions	✓			
January 14 & 21, 2015	Industry training on 2016 Applications	✓	✓	✓	
January 30, 2015	Deadline for D-SNPs meeting a high level of integration, as determined by CMS, to submit a request to CMS to offer additional supplemental benefits	✓			
February 18, 2015	2016 Expansion Applications are due to CMS by 8 PM EST	✓	✓	✓	
February 18, 2015	Renewing Dual Eligible Special Needs Plans (D-SNPs) required to complete attestations in HPMS	✓			
February 18, 2015	Special Needs Plans (SNPs), whose MOC approval expires at the end of CY 2015, are required to resubmit their MOCs for NCQA review.	✓			
Late February, 2015	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals	✓			
Late February, 2015	D-SNPs that requested to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications				
March 2, 2015	CMS releases guidance concerning updates to Parent Organization designations in HPMS	✓	✓	✓	✓
March 17, 2015	Parent Organization Update requests from sponsors due to CMS (instructional memo released in February 2015)	✓	✓		✓
Mid-Late March, 2015	Release of CY 2016 Formulary Training Video and 2016 Formulary Reference File (FRF)	✓	✓	✓	✓
March 27, 2015	Release of the Fiscal Soundness Module in HPMS	✓	✓		✓
March/April, 2015	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2016	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
Early April, 2015	CY 2016 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs and Part D sponsors for download from the CMS website. Information will assist plans in meeting meaningful difference and MA Total Beneficiary Cost (TBC) requirements prior to bid submission	✓	✓		
Early April, 2015	Information about renewal options for contract year 2016 (including HPMS crosswalk charts) provided to plans	✓	✓		
April 2015	Conference call with industry to discuss the 2016 Call Letter	✓	✓	✓	✓
April 6, 2015	2016 Final Call Letter released 2016 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released	✓	✓	✓	✓
April 8, 2015	Industry training on CY 2016 Formulary Submission	✓	✓	✓	✓
April 10, 2015	Release of the 2016 Plan Benefit Package (PBP) online training module	✓	✓	✓	✓
April 10, 2015	Release of the 2016 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS	✓	✓	✓	✓
April 15, 2015	Deadline for MAOs to submit requests for full contract consolidations for CY 2016	✓		✓	
Mid-April, 2015	Release of HPMS Memo: Contract Year 2016 Medicare Advantage Bid Review and Operations Guidance	✓			
April 20, 2015	Release of the 2016 Medication Therapy Management (MTM) Program Submission in HPMS		✓		✓
April 22, 2015	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	✓	✓
Mid/Late April, 2015	Plan submit requests for tiering of medical benefits and justifications to CMS for review and consideration	✓			
Late April, 2015	Total Beneficiary Cost data for CY 2016 Bid Preparation Release	✓			
May, 2015	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2016 available for all organizations	✓	✓	✓	✓
May 1, 2015	MA, MA-PD and PDP plans to notify CMS of intention to non-renew a county (ies) for individuals, but continue the county (ies) 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 4, 2015	Deadline for submission of CY 2016 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (11:59pm PDT)		✓		✓
May 8, 2015	Release of the 2016 Bid Upload Functionality in HPMS	✓	✓	✓	✓
May 8, 2015	Release of 2016 Actuarial Certification Module in HPMS	✓	✓	✓	
May 8, 2015	Release of 2016 Formulary Submission Module in HPMS	✓	✓	✓	✓

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
Mid-Late May 2015	Release of CY 2016 Formulary Reference File Update	✓	✓	✓	✓
May 29, 2015	Plans/Part D Sponsors begin to upload agent/broker compensation information in HPMS	✓	✓	✓	✓
May 29, 2015	Release of the 2016 Marketing Module in HPMS. Plans/Part D Sponsors begin to submit 2016 marketing materials	✓	✓	✓	✓
May 31, 2015	Release of the 2013 DIR Submission Module in HPMS	✓	✓		
Late May/Early June, 2015	Release of the 2016 Medicare Marketing Guidelines in HPMS (Chapter 3 of the Medicare Managed Care Manual/Chapter 2 of the Prescription Drug Benefit Manual)	✓	✓	✓	✓
Late May/June, 2015	CMS sends qualification determinations to applicants based on review of the 2016 applications for new contracts or service area expansions	✓	✓		
June 1, 2015	Deadline for submission of CY 2016 bids 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 2016 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT) Deadline for submission of CY 2016 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 2016 contract non-renewal, service area reduction notice to CMS from MA plans, MA-PD plans, 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 2016	✓	✓	✓	✓ *Bid related items only*
Early June to Early September, 2015	CMS completes review and approval of 2016 bid data. Submit attestations, contracts, initial actuarial certifications, and final actuarial certifications	✓	✓	✓	
June 2, 2015 - June 5, 2015	Window for submitting first round of crosswalk exception requests through HPMS	✓	✓	✓	
June 5, 2015	Deadline for submission of CY 2016 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS (12 p.m. EDT)	✓	✓	✓	✓
June 5, 2015	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)*(12 p.m. EDT)				✓
Late June, 2015	Release of the CY 2016 Summary of Benefits (SB) hard copy change request module in HPMS	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D	Cost	MMP
Late June, 2015	CMS sends an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that are non-renewing or reducing their service area	✓	✓	✓	
June 30, 2015	Final date to submit CY 2015 marketing materials to guarantee timely CMS review and approval. Plans/Part D Sponsors may continue to submit CY 2015 file and use materials as these may be filed in HPMS five calendar days prior to their use	✓	✓	✓	
Early July, 2015	2016 Plan Finder pricing test submissions begin	✓	✓	✓	✓
July 1, 2015	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS	✓	✓	✓	
July 1, 2015	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, 2015	Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓			
Mid July 2015	Release of CY 2016 FRF Update in advance of the Limited Formulary Update Window	✓	✓	✓	✓
Mid-Late July, 2015	CY 2016 Limited Formulary Update Window	✓	✓	✓	✓
Late July, 2015	Submission deadline for agent/broker compensation information via HPMS	✓	✓	✓	✓
Late July 2015	Second window for submitting HPMS crosswalk exceptions	✓	✓	✓	
Late July / Early August, 2015	CMS releases the 2016 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, 2015	Rebate reallocation period begins after release of the above bid amounts	✓	✓	✓	
No Later Than July 31, 2015	CMS informs currently contracted organizations of its decision to not renew a contract for 2016	✓	✓	✓	
August 1, 2015	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS	✓	✓	✓	
August 21-25, 2015	First CY 2016 preview of the 2016 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs)	✓	✓		✓
August 26 – August 28, 2015	First CY 2016 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS	✓	✓	✓	✓ *MPF only*
August 31, 2015	2016 MTM Program Annual Review completed		✓		✓
Late August 2015	Contracting Materials submitted to CMS	✓	✓	✓	
End of August/Early September 2015	Plan preview periods of Star Ratings in HPMS	✓	✓	✓	

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early September 2015	CMS begins accepting plan correction requests upon contract approval	✓	✓	✓	
Mid- September 2015	All 2016 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS)	✓	✓	✓	
September 9 - 11, 2015	Second CY 2016 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS	✓	✓	✓	✓ *MPF only*
September 16 -30, 2015	CMS mails the 2016 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓	✓
Late September, 2015	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications	✓			
September 23, 2015	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. Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request any SB hard copy change	✓	✓	✓	
September 30, 2015	The following documents are due to current enrollees by September 30, 2015: • Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans offering Part D. • 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 multi-language insert should be sent with the ANOC/EOC and the SB. The documents identified above are the only documents permitted to be sent prior to October 1, 2015	✓	✓	✓	✓
Mid October, 2015	Release of the online CY 2017 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, PDPs, and “800 series” EGWPs and Direct Contract EGWPs)	✓	✓	✓	✓
October 1, 2015	Organizations may begin marketing their CY 2016 plan benefits. Note: Once an organization begins marketing CY 2016 plans, the organization must cease marketing CY 2015 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2015 materials upon request, conduct one-on-one sales appointments, and process enrollment applications	✓	✓	✓	✓
October 1, 2015	Tentative date for 2016 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs)	✓	✓	✓	✓

2016*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
October 2, 2015	The final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, and cost-based plan enrollees PDPs, MA plans, MA-PD plans, and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2015	✓	✓	✓	
October 8, 2015	Star Ratings go live on medicare.gov on or around October 8, 2015	✓	✓	✓	
October 15, 2015	Part D sponsors must post PA and ST criteria on their websites for the 2016 contract year		✓		✓
October 15, 2015	2016 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)	✓	✓		✓
November 13, 2015	Notices of Intent to Apply (NOIA) for CY 2017 due for MA and MA-PD plans, PDPs, and “800 series” EGWPs and Direct Contract EGWPs.	✓	✓		
Early November, 2015	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval	✓	✓	✓	✓
Late November, 2015	Display measures data are posted in HPMS for plan preview	✓	✓	✓	
November – December, 2015	CMS issues “close out” information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas	✓	✓		
December 1, 2015	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC			✓	
December 1, 2015	Cost-based plans must publish notice of non-renewal			✓	
December 7, 2015	End of the Annual Election Period	✓	✓		✓
Mid December, 2015	Display measures data on cms.gov updated	✓	✓	✓	
December 31, 2015	Deadline for D-SNPs and MMPs that separated the ANOC from the EOC to provide the EOC to enrollees	✓			✓
2016					
January 1, 2016	Plan Benefit Period Begins	✓	✓	✓	✓
January 1 – February 14, 2016	Annual 45-Day Medicare Advantage Disenrollment Period (MADP)	✓			
Early January 2016	Release of CY 2017 MAO/MA-PD/PDP/SAE/EGWP applications	✓	✓		
Mid-January, 2016	Industry training on CY 2017 applications	✓	✓	✓	
Late February 2016	Applications due for CY 2017	✓	✓	✓	

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 2016, the bid submission deadline is June 1, 2015 at 11:59 PM Pacific Daylight Time.

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

- Plan Benefit Package (PBP) and Bid Pricing Tool (BPT)
- Service Area Verification (SAV)
- Plan Crosswalk (if applicable)
- Formulary Submission (if offering a Part D plan with a formulary)
- Formulary Crosswalk (if offering a Part D plan with a formulary)
- Substantiation (supporting documentation for bid pricing)

MA, MA-PD, PDP, and cost-based plans are responsible for ensuring 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 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) 2015 Bid Upload Functionality in HPMS," dated May 9, 2014).

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. CMS expects organizations to 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 CMS about any technical upload or validation errors well in advance of the bid submission deadline. CMS will not accept late submissions unless they are the result of a technical issue beyond the organization's control. All organizations should ensure 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 CFR §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' time and resources and call into question an organization'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 this Call Letter, or
- A Part D bid that includes an incorrect PBP-to-formulary crosswalk.

This year, CMS reminds organizations that submit clearly inaccurate bids that fail to meet Part C and D requirements and established thresholds will receive a compliance notice in the form of a letter and/or a corrective action plan. In addition, organizations and sponsors that submit inaccurate bids might not be allowed to revise their bids to correct inaccuracies, and the bids will 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 CFR §§422.254, 423.265(c)(3) and 423.505(k)(4), submission of the final actuarial certification serves as documentation that the final bid submission has been verified and is complete and accurate at the time of submission. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization'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 until the plan correction window in September. The plan correction window will be open from early September to late September 2015. 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 corrective action plans to organizations/sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice for CY 2015.

Formulary Submissions

CY 2016 Formulary Submission Window

The CY 2016 HPMS formulary submission window will open this year on May 8, 2015 and close at 11:59 pm PDT on June 1, 2015. CMS must be in receipt of a <u>successfully submitted and validated</u> formulary submission by the deadline of June 1, 2015 in order for the formulary to be considered for review. The formulary used in a Part D plan 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 1st deadline will result in denial of that bid submission.

CY 2016 Formulary Reference File

CMS will release the first CY 2016 Formulary Reference File (FRF) in March 2015. 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 2015, 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 <u>not</u> be modified to incorporate any subsequent FRF updates, as described below.

In May 2015, CMS is planning to provide a release of the 2016 FRF just prior to the June 1st formulary submission deadline. Given the limited timeframe between the May release of the 2016 FRF and the June 1st deadline, CMS is unable to accommodate an updated version of the 2016 OOPC model to incorporate the May FRF changes. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2016 FRF will not be included in the 2016 OOPC model.

CMS will continue to offer a summer formulary update; however, formulary changes during this particular update submission will be limited to: 1) the addition of drugs that are new to the summer release of the FRF (historically posted in July); and 2) the submission of negative changes on brand drugs, only if the equivalent generic is added to the summer FRF and corresponding formulary file. Thus, plan sponsors need to carefully consider any newly added drugs on the May release of the 2016 FRF, since additional limitations will be imposed on the summer formulary update window.

Submission of Formulary Quantity Limits

In an effort to improve the preciseness of formulary quantity limit (QL) submission and review, as well as the transparency of these limits to Part D enrollees and their prescribers, CMS is enhancing the QL submission process for CY 2016. CMS understands that there are generally two types of QLs: daily QLs and quantity over time restrictions. Since these two types of QLs are not differentiated on the HPMS formulary file submitted for review, CMS must interpret sponsors' submissions with respect to how the QL will be implemented. Through Part D audits and other interactions with plan sponsors, we have become aware of differences between how CMS and plans have interpreted certain QL submissions. As a result, the HPMS formulary file field descriptors and allowable values will be changed for CY 2016. The Quantity_Limit_YN field will be changed to a Quantity_Limit_Type field. Sponsors will designate each formulary drug with a "0" (No QL), "1" (Daily QL), or "2" (QL over time). The respective QL amount and QL days will continue to be submitted as they were for CY 2015. For example, if the QL for a given drug is 1 tablet per day, and the drug may be dispensed in days supplies consistent with the approved plan benefit package (e.g., 30 days per month), the QL type field value would be "1", and the corresponding amount and days fields could be "30" and "30", respectively. However, if the amount allowed per 30 days is 5 tablets, the QL type field would be "2" and the amount and days fields would be "5" and "30", respectively. Additional submission instructions will be provided with the CY 2016 formulary submission training and technical manual.

Midyear Formulary Changes

CMS continues to gain experience with midyear formulary changes submitted by Part D sponsors. Both maintenance (e.g., generic substitution) and non-maintenance changes (e.g., therapeutic substitution) must be submitted to and approved by CMS (our longstanding midyear formulary change policy is outlined in detail in Chapter 6 of the Prescription Drug Benefit Manual, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf). However, the submission deadline and notification timeframes currently differ between the two types of changes. Consistent with the date first set forth the June 20, 2007 HPMS memo outlining formulary change operational guidance, maintenance changes may be submitted to CMS through July 31 of the plan year. In contrast, the operational deadline for non-maintenance changes is April 30th, as established in the January 7, 2010 HPMS memo pertaining to CY 2010 formulary change operational guidance.

Submission deadlines are necessary so that CMS has sufficient time to review proposed changes and in order for Part D sponsors to provide notices to effectuate changes. Further, as outlined in section 30.3.4 of Chapter 6, sponsors may elect to provide notice to all required parties prior to receiving CMS approval of a maintenance change, although in doing so they risk having to rescind the notice should the change not be approved by CMS. However, sponsors are currently prohibited from sending notice for non-maintenance changes until CMS has explicitly approved the change.

For CY 2016, we are proposing to better align maintenance and non-maintenance changes with respect to submission timeframes and notification requirements. First, given the later initial formulary submission deadline for the upcoming plan year that was established for CY 2015, P&T committees may not be meeting until just before this deadline. Thus, the evaluation and decisions regarding the current year's formulary may be occurring later than what CMS envisioned when establishing the April 30 non-maintenance deadline. As a result, we implemented a July 31 deadline for the submission of both maintenance and non-maintenance changes for CY 2015 and will maintain this deadline for CY 2016.

With respect to non-maintenance changes, we propose eliminating the current prohibition on sponsors of providing advanced notice to required parties until CMS explicitly approves the change. Beneficiaries that are taking the drug affected by a change are exempt from that change for the remainder of the plan year, and thus there are no "affected enrollees" that must receive notice. In addition, CMS' approval rates for maintenance and non-maintenance changes are similar. If sponsors do opt to notify the required parties at the same time as CMS, they should make certain that they only submit changes to CMS that would be approvable, in accordance with the annual formulary update operational guidance, in order to reduce the risk of needing to rescind change notices.

While we do not anticipate that these proposed changes will result in significant increases in non-maintenance formulary change requests, we remind sponsors that substantial changes to the formulary that was initially approved will not be permitted. Non-LIS beneficiaries generally may make only one plan election per year, usually during the annual election period, so CMS must verify that beneficiaries' drug benefits do not materially change mid-year. Also, formularies must remain consistent with the plan pricing CMS approved during the annual bid review cycle. Therefore, CMS will continue to monitor the number of changes submitted per each formulary and retains the right to reject changes if they appear to result in a "bait and switch" or significant deviation from the formulary content that was approved.

Revisions to Good Cause Processes

In April 2011, we published final regulations to allow reinstatement into an MA, MA-PD, or PDP plan when an individual is disenrolled for failure to pay premiums or the Part D income related monthly adjustment amount (Part D-IRMAA), but is determined to have good cause (76

FR 21456, 21511). We published coordinating regulations in April 2012, extending the same rights to beneficiaries enrolled in cost-based plans (77 FR 22096). These good cause provisions authorize CMS to reinstate a disenrolled individual's enrollment without an interruption in coverage in certain circumstances where the non-payment was due to circumstances that the individual could not reasonably have been expected to foresee or could not control, such as an unexpected hospitalization.

On February 12 2015, we published final regulations providing CMS with the authority to designate an entity to act on behalf of CMS to effectuate reinstatements when good cause criteria are met (80 FR 7912). These regulations allow CMS to assign an entity other than CMS, such as a plan (e.g., MA organization, Part D plan sponsor, or entity offering a cost plan) to carry out portions or all of the good cause process.

CMS intends to assign the responsibility to conduct good cause reviews to MAOs and Part D plan sponsors for CY 2016 and will expect that they perform the work from start to finish (that is, intake, research, decision, notification, and effectuation). We will provide guidance regarding the application of the good cause criteria and related activities in our enrollment manuals (Chapter 2 and Chapter 17, Subchapter D, of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual). Our expectation is that plans will develop their own internal processes for reviews, based on our guidance, and carry out the majority of this workload without involving CMS. CMS will develop an oversight protocol for any activities assigned to plans that are currently carried out by CMS to verify that plans appropriately apply the regulatory standards associated with the good cause process. As part of this oversight, CMS will retain the authority to review both favorable and unfavorable decisions to make certain that results are fair and sound applications of the regulatory standard for reinstatement.

We believe that with proper guidelines, instructions and oversight, organizations and sponsors are well positioned to efficiently resolve good cause reinstatement requests under the applicable regulations, since most individuals will contact the plan as the first entity regarding their disenrollment. Also, plans can readily access a former enrollee's premium billing and payment history and can address possible allegations of plan error without having a complaint entered into CMS' Complaint Tracking Module.

CMS will transfer this responsibility to plans starting January 1, 2016, such that plans will be responsible for the intake and processing of good cause reinstatement requests for individuals disenrolled effective December 31, 2015, and later. We are requesting comments from MAOs, Part D sponsors and entities offering cost plans on ways in which this responsibility can be transitioned from CMS to plans in the most effective and least disruptive manner.

Enrollment Eligibility for Individuals Not Lawfully Present in the United States

On February 12, 2015, we published final regulations to establish U.S. citizenship or lawful presence as a requirement to be eligible to enroll in or remain enrolled in an MA, MA-PD, PDP, and cost-based plans (80 FR 7912). This criteria is part of our compliance with Section 401 of the Personal Responsibility and Work opportunity Act of 1996 (PRWORA), amended by section 5561 of the Balanced Budget Act, which generally prohibits providing Medicare benefits to individuals who are not U.S. citizens or nationals, or lawfully present. 8 U.S.C. 1611 and 1641. Individuals who are determined by the Social Security Administration, based on information from Department of Homeland Security (DHS) and other sources, to be not lawfully present will not be eligible for enrollment. This data will be provided to CMS by the Social Security Administration (SSA) after individuals are notified and have the opportunity to be heard about their lawful presence status. CMS will provide this information to plans; plans should not request evidence of citizenship or lawful presence status at the time of enrollment. Plans will be expected to check an individual's eligibility via CMS systems when processing enrollment requests following normal processes. Enrollment requests for ineligible individuals will be denied and, as required by regulation, individuals must receive written notice of the enrollment denial.

Further, CMS will involuntarily disenroll any current plan members for which we receive data of their unlawful presence status. Plans will be notified of such disenrollments via the Daily Transaction Reply Report (DTRR). The effective date of the involuntary disenrollments will be the first of the month following notice by CMS that the individual is ineligible. Disenrolling such beneficiaries in the month following when CMS notifies the plan of the individual's ineligibility allows plans to terminate such enrollments quickly and prevents future improper payments, as recommended by the OIG in its January 2013 report regarding improper Medicare payments for services rendered to unlawfully present beneficiaries. Plans are strongly encouraged to notify individuals who are involuntarily disenrolled for this reason.

We will be releasing subregulatory guidance (Chapter 2 and Chapter 17d of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual) to provide updated model notices and additional details on processing such cases.

Making the Exceptions and Appeals Processes More Accessible for Beneficiaries

CMS continues to explore avenues to make the MAO determination, appeal, and grievance (ODAG) and the Part D coverage determination, appeal and grievance (CDAG) processes more understandable and accessible for Medicare beneficiaries and verify plan compliance with established requirements. To that end, we have identified certain areas where operational processes may be adjusted which should lead to improved outcomes for all stakeholders.

<u>Coverage Denial Notices and Requests for Clinical Documentation</u>

MA organizations and Part D plan sponsors continue to have unacceptably high rates of non-compliance in ODAG and CDAG. For additional details on related audit results, please refer to the HPMS memorandum issued August 27, 2014 entitled "Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews." Two areas of persistent non-compliance that are of particular concern to CMS are:

1. Plan denial notices that fail to provide the required level of specificity for the enrollee and provider (as applicable) to understand the plan's rationale for denying the requested item, service or drug and what information is needed by the plan to approve coverage; and
2. Plan deficiencies related to documenting sufficient outreach to providers to obtain information necessary to make an appropriate clinical decision.

Denial Notices

Guidance on the information that must be provided in the standardized denial notices is set forth in the instructions for CMS-10003 (Part C standardized denial notice) and CMS-10146 (Part D standardized denial notice), as well as in Chapter 13 of the Medicare Managed Care Manual (section 40.2.1) and Chapter 18 of the Medicare Prescription Drug Benefit Manual (section 40.3.4). These requirements have also been addressed in multiple versions of the annual common findings and best practices HPMS memoranda.

MAOs and Part D plan sponsors must make certain that enrollees and providers receive accurate, clear and detailed information related to the specific reason(s) for denial (e.g., not a covered benefit, did not meet specified clinical/medical criteria). In addition, the applicable Medicare coverage rule or plan policy (e.g., EOC provision) must be described in the denial notice, including any specific coverage requirement that must be met to obtain the item or service. In the Part D context, the denial notice should reference specific formulary requirements related to the requested drug (e.g., non-formulary, prior authorization, step therapy, safety edits). Information on formulary requirements must comport with the CMS-approved formulary.

Requesting Clinical Documentation

If an MA organization or Part D plan sponsor needs clinical information in order to make a substantive and thorough clinical decision on a coverage request, the MA organization or plan sponsor should request necessary documentation from the provider and document the outreach efforts. CMS recognizes that there may be instances where requested documentation is not received from a provider, so it is critical for the plan to accurately document in the record attempts at obtaining necessary clinical information from providers. MA organizations and Part D plan sponsors should have a policy and internal controls (to detect potential non-compliance) in place related to: (1) making reasonable attempts, based on the facts and circumstances of the case, to request needed clinical information prior to making a coverage decision; and (2) documenting requests for clinical information, including the date, time, and method (e.g., telephone call).

Future Improvements

To improve Part D plan sponsor compliance with the above requirements, CMS will be revising the Part D denial notice (Notice of Denial of Medicare Prescription Drug Coverage - Form CMS-10146) to include:

- A new section of the standard denial notice that plans will populate with detailed clinical information about the basis for the denial, relevant coverage policy and, if applicable, the information/documentation that is needed to cover the item, service or prescription drug.

- Plans would be required to, wherever possible, include extracted language from the relevant sections of the CMS approved plan formulary in this new section of the denial notice. The detailed clinical information that will be required in this new section will primarily be for the benefit of the physician or other prescriber (in contrast to the enrollee-friendly denial rationale that will continue to be provided in the existing free-text field of the denial notice). If there are circumstances where it is not possible to use the extracted language from the approved plan formulary, please provide examples.

As these changes are implemented for the Part D notice, we will also be exploring how these changes should be applied to the Part C standardized denial notice. It is our belief that these revisions to the Part C and Part D notices will enable plans to provide clearer information about their coverage/payment denials and information that is needed to produce a favorable coverage/payment decision. In addition, we expect plans that follow these new guidelines to more easily and frequently meet CMS' requirements for these notices, and notices that adhere to this format and guidelines to pass our review on audits. Thus, we encourage plans to start implementing these changes as soon as possible so that they begin seeing improvements to their decision letters and audit results in calendar year 2015. We expect to have these changes fully incorporated in our manual guidance in calendar year 2016. However, CMS welcomes comments on these proposals, including input on what the required minimal standard should be when it comes to attempting to contact providers to request clinical documentation. We also welcome suggestions on other strategies to help plans to address the issues outlined above and improve overall performance in ODAG and CDAG processes.

<u>Improved Information at the Point of Sale</u>

Under current requirements at 42 CFR § 423.562(a)(3), Part D plan sponsors must arrange with network pharmacies to provide enrollees with a written copy of the standardized pharmacy notice (Prescription Drug Coverage and Your Rights - Form CMS-10147) when the enrollees' prescriptions cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. The notice instructs enrollees on how to contact their plans and explains an enrollee's right to receive, upon request, a coverage determination (including a detailed written decision) from the Part D plan sponsor regarding his or her Part D prescription drug benefits, including information about the exceptions process.

The pharmacy notice, as it exists now, does not include any personalized information. Pharmacies have the discretion to include the enrollee’s name and the drug or prescription number, but these fields are not required. We have received feedback from beneficiary advocacy groups that it would be more helpful if the notice provided personalized information, specifically the reason for the POS rejection. This could, in theory, save the enrollee time and effort in reaching out to the plan separately to understand why a prescription could not be filled at POS and help an enrollee determine next steps if s/he wants to request a coverage determination. Alternatively, advocacy groups suggest that a rejection at the pharmacy counter should be treated as an adverse coverage determination and immediately trigger the processing of an appeal by the plan. They suggest that this would eliminate the need for enrollees to request a coverage determination and an appeal for certain POS rejections. CMS intends to work with stakeholders to further explore whether such an approach is feasible for certain types of POS rejections, such as those based on PA criteria, step therapy requirements and quantity limits so long as proper transaction codes are in place.

As CMS has previously stated, collaboration with the National Council of Prescription Drug Programs (NCPDP) would be necessary to develop and standardize codes that would assist Part D sponsors, processors and pharmacies with generating information on certain POS transactions, such as specific reasons for the rejection of a claim. As we explore how best to approach any potential changes, we ask for comments from our partners on the benefits and costs of implementing these potential changes and developing new standardized codes, suggestions about reasonable timeframes for implementing such standards and other considerations that we should keep in mind as we pursue potential refinements to our programs.

Expanded Data Collection for Part D Appeals

An important aspect of improving plan compliance with our established CDAG and ODAG requirements and ensuring beneficiary access both to the appeals process and to medically necessary drugs is obtaining more accurate and complete information that will allow us to monitor plan compliance with CMS’ requirements and identify any barriers to accessing covered Part D drugs. Currently, CMS uses aggregate data reported by plans, and data collected by the Independent Review Entity (IRE), to identify and monitor trends in the Part D coverage determinations, exceptions and appeals processes. CMS program audits allow us to review coverage determination and appeal cases in detail for a limited number of plans, and these audits have consistently demonstrated that plans have difficulty following certain coverage determinations and appeals requirements, as detailed above.

The data currently available to CMS (aggregate quarterly data submitted by plans via annual reporting) do not provide sufficient information to allow us to determine whether plans are providing appropriate access to Part D drugs through their coverage determination process. For example, according to plan-reported data for CY2013, less than 17% of all Part D denied coverage determinations were appealed to the plans for redeterminations. Of those cases submitted for redeterminations, Part D sponsors reversed their initial denials to the beneficiaries, by subsequently approving nearly 80% of redeterminations. These data indicate that the majority of denials by plans at the coverage determination stage are not appealed, but those that are appealed are largely favorable for beneficiaries. What is unclear from these data is why most denials by plans at the coverage determination stage are not appealed, why plans reverse their initial denials so often, and whether beneficiaries who do not appeal a plan denial are obtaining on-formulary drugs or simply going without prescribed drugs.

We propose exploring the development of an appeals tracking system to receive regular data feeds for all coverage requests received and processed by plans in order to obtain a full data-stream of information from beginning (coverage determination) to end (IRE). These data feeds could provide case-level data, including the beneficiary, drug, and dosage in order to allow CMS to link to PDE, IRE and other program data. We are considering mirroring many of the data elements included in the universes for CMS program audits: since sponsors are already familiar with and may have designed systems functionality to respond to those data layouts, this approach should be less burdensome for plans. We are also expecting to be able to obtain these data on a more contemporary basis than we currently obtain plan reported data (e.g., daily, monthly or quarterly).

CMS' main objectives for the expanded data reporting would be to:

- Assist plans in their compliance efforts by identifying improvements we can make to CMS coverage determination and appeals requirements and subregulatory guidance.
- Reduce or eliminate information gaps in current appeals data.
- Obtain more accurate and detailed information about overall volumes of coverage determinations and redeterminations, as well as drug utilization data for beneficiaries who receive denials at the coverage determination or redetermination levels.
- Perform more detailed data analysis to understand trends seen in aggregate data (e.g., is the low redetermination rate caused by enrollees being able to obtain a formulary alternative or because they do not have adequate information to request an appeal?).
- Strengthen CMS' oversight of beneficiary access to covered prescription drugs and more accurately identify and evaluate beneficiary harm.

We are seeking feedback from our partners on the following:

- Potential vehicles and methodologies by which these data could be collected by CMS,
- Specific data elements necessary to meet the stated objectives, and

- Potential challenges we may face with our proposal to collect expanded appeals data, as well as possible solutions to those challenges.

Feedback received during the 2016 Call Letter process will better inform us of the feasibility of collecting case-level data, including necessary system requirements. We expect to begin discussing and evaluating feedback received on the proposals in 2015 with potential Part D program implementation in 2017. Due to program and data collection differences, CMS is not specifically soliciting feedback on Part C expanded appeals data collection, but we are considering exploring a similar expansion for Part C in the future.

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years – Timeline for Application of Termination Authority

CMS reminds MAOs and PDP sponsors that we may, under our regulatory authority at 42 C.F.R. §§ 422.510(a)(4)(xi) and 423.509(a)(4)(x), terminate the contracts of organizations that, upon the release of the 2016 star ratings in October 2015, have failed in three consecutive years (i.e., the 2014, 2015, and 2016 sets of ratings) to achieve at least three stars on their Part C or Part D performance. This authority only recently became applicable, and our policies for carrying out star rating-based terminations continue to evolve as we evaluate the effect of such terminations on the Part C and Part D programs, including the impact on beneficiaries of the timing of the issuance of notices to affected beneficiaries. As a result of our ongoing analysis, CMS has modified our timeline for conducting star rating-based terminations for contracts that meet the regulatory criteria for termination for the first time with the release of the CY 2016 star ratings (i.e., contracts rated at or above 3 stars for CY 2013, but below 3 stars for CY 2014, CY 2015, and CY 2016). After the 2016 ratings are released in late 2015, these contracts will receive non-renewal notices from CMS in February 2016 with an effective date of December 31, 2016 at 11:59 PM EST (under 42 C.F.R. §§ 422.506(b)(1)(ii) and 423.507(b)(1), CMS may non-renew a contract for any of the reasons for which it may terminate a contract). In March 2016, CMS will issue notices to beneficiaries enrolled in plans offered under the non-renewed contracts advising them that they will need to choose a new plan during the Fall 2016 annual election period to continue their Part C and Part D plan enrollment without interruption in 2017. CMS will not calculate or publish 2017 star ratings associated with the non-renewed contracts, so affected organizations should not expect that an improved 2017 star rating performance would cause CMS to reverse its non-renewal determination.

Enhancements to the 2016 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 2016 Star Ratings, CMS is continuing to make enhancements to the current methodology to further align it with our policy goals. Our priorities include enhancing the measures and methodology to reflect the true performance of organizations and sponsors, maintaining stability because of the link to payment, and providing advance notice of future changes. Unless noted below, we do not anticipate methodology changing from the 2015 Star Ratings.

For reference, the list of measures and methodology included in the 2015 Star Ratings is described in the Technical Notes: http://go.cms.gov/partcanddstarratings. The star cut points 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 2016 with the most current data available.

As announced in previous years, we will annually 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.

CMS is exploring the development of an integrated Star Rating system for Medicare-Medicaid Plans (MMPs) participating in the capitated Financial Alignment Initiative. Although all CMS quality measurement programs are studying if and how socioeconomic status affects the ability of plans and providers to provide high-quality care to low-income beneficiaries, this exploration is not derived from those concerns. The purpose of this effort is to develop a rating system that acknowledges the additional needs of Medicare-Medicaid enrollees and measure the performance of the MMPs in integrating the Medicare and Medicaid benefits. More information will be provided during the first quarter of 2015.

We appreciate the feedback we received from approximately 100 organizations to the November 21, 2014 HPMS memo, *Request for Comments: Enhancements to the Star Ratings for 2016 and Beyond.* The proposals below reflect the comments where appropriate. Also, CMS will post a summary of the comments on CMS.gov at: http://go.cms.gov/partcanddstarratings.

A. *Changes to the Calculation of the Overall Rating and the Part C and D Summary Ratings*

- *Background*

  CMS is interested in improving the accuracy of the assignment of overall and Part C and D summary Star Ratings and ensuring the system creates incentives for quality improvement. In constructing Star Ratings, a key concern is the potential for generating Star Ratings that do not reflect a contract's "true" performance, otherwise referred to as the risk of "misclassification." For example a "true" 4-star could be scored as a 3-star contract, or vice versa. Misclassification occurs in any measurement system because all measurement is a mixture of *signal* (true performance) and *noise* (random measurement error due to rounding, sampling variation and similar factors). In recent years several features have been implemented in the quality rating system to simplify information for consumers, as well as to make the information more transparent for organizations and sponsors. For example, we group the measure scores into star categories and round the measure data to whole numbers to make it easier for consumers to understand what a particular score means. Since the 2011 Star Ratings, we have also implemented pre-determined 4-star thresholds for some measures to increase transparency for organizations and sponsors and set expectations for high performance. However, all of these features create more “noise” or measurement error in the system. As the uses of a quality rating system expand (e.g., from being a basis for a beneficiary to select a plan, to the basis for a plan to be rewarded for the quality of services provided to its enrollees), the impacts of misclassification grow as well.

- *Current Scoring Method*

  The 2015 overall Star Rating is a composite measure constructed from 33 measures for Part C and 13 measures for Part D. The measures are numeric scores such as counts and percentages of screening and testing, chronic care, patient experience, customer service, and patient safety measures. Currently, each measure is assigned a rating from 1-5 stars. Scores are grouped using statistical techniques to minimize the distance between scores within a grouping (or “cluster”) and to maximize the distance between scores in different groupings.

  There are two methods for calculating the measure stars:

  - Clustering. Clusters are defined as contracts with similar distances between their data values and the center data value. The measure scores are inputs for a clustering algorithm, which determines break points in the distribution and groups the scores into star categories.
  - Significance testing. The measure scores are assigned stars with a combination of percentile-based categories and whether the score is significantly different from the mean of all contracts.

For the 2015 Star Ratings, 22 Part C and 5 Part D measures have pre-determined 4-star thresholds (67% of Part C measures, and 39% of Part D measures). We did not introduce any new 4-star thresholds for the 2015 Star Ratings. For those measures with pre-determined 4-star thresholds, any contract with a measure score above the threshold receives 4 or 5 stars, and any contract with a score below the threshold receives 1, 2, or 3 stars. The pre-determined 4-star threshold is applied before the clustering or significance testing. For example, for clustered measures, first the contracts that score above the pre-determined threshold are selected, and then this subset is clustered into two categories to determine which contracts receive 4 stars and which receive 5 stars.

Performance consistency across measures is considered an important indicator for the reliability of quality measurement. The individual measures selected by CMS for Star Ratings are proxies for the underlying central concept of high quality care. As such, consistently high performance across all measures is an indication that we can be more confident that an organization or sponsor’s underlying operations and clinical services reflect the high quality of care they provide. In contrast, an organization or sponsor that demonstrates more inconsistent behavior in measures may not offer the same stable quality, due to non-aligned operations or clinical services. An organization or sponsor's inconsistent performance—high on some measures, low on others—could also mean mismanagement of some areas by internal staff or subcontractors.

To incorporate this consistency indicator into the rating process, CMS has applied a "Reward Factor", previously called an i-Factor, to the mean overall and Part C and D summary ratings since 2009 in order to reward contracts if they have both consistently high and stable relative performance. Specifically, the Reward Factor calculation adds a value of 0, 0.1, 0.2, 0.3, or 0.4 to each contract's overall and summary ratings according to the variability and mean performance of its measure stars, and in doing so it increases the number of contracts at the high end of the rating scale that have low variation and high mean performance in their individual measure scores. The 2015 Part C & D Star Rating Technical Notes provides more information about the calculations.

- *Pre-determined Thresholds*

Some sponsors and stakeholders are concerned that it is difficult to improve without published targets for achieving 4 or more stars on a measure. While we understand the perceptions that pre-determined 4-star thresholds provide stability by setting performance expectations, in reality the use of pre-determined thresholds violates our principle of assigning stars that maximize the difference between star categories. Pre-determined 4-star thresholds can thus cause contracts to receive different ratings when there is no significant difference in their scores (e.g., if a 4-star threshold is 80%, a contract that scores 79.4% would receive 3 stars while a contract that scores 80.1% would receive 4 stars when there may be no meaningful difference between a score of 79.4 and a score of 80.1). The use of pre-determined 4-star thresholds is also problematic when there is general improvement in measure performance over time or when there are changes to a measure's specifications and predetermined thresholds remain constant. It is also problematic when there are large distributional changes in the scores across contracts. In this case, there may not be any contracts with 4 or 5 stars, or any contracts with 1, 2, or 3 stars, for a particular measure. These examples illustrate how pre-determined thresholds increase noise in the Star Ratings and are counter to industry feedback that thresholds assist sponsors in targeting their improvement efforts.

CMS' analyses of past Star Ratings found that sponsors on average have more significant levels of improvements in Part C and D measures **without** pre-determined thresholds, as compared to measures where there are pre-set thresholds. Using the 2015 Star Ratings, our analysis showed that on average only 28% of contracts improved significantly across the 20 Part C measures with 4-star thresholds included in the improvement measure, compared to 51% of contracts that improved significantly across the nine Part C measures without 4-star thresholds. We found similar findings for Part D, where on average, only 24% of contracts showed significant improvement across the five measures with 4-star thresholds included in the improvement measure, while 63% of contracts showed significant improvement across the five Part D measures without 4-star thresholds. Although some of this difference in improvement in measures without pre-determined thresholds may be due to the measures with pre-determined thresholds being older, some of the measures without pre-determined thresholds such as adherence have been collected and reported for at least five years. These findings continue to suggest that pre-set thresholds hamper continuous quality improvement in MA and Part D contracts.

As announced in the 2015 Call Letter (See Section 1, “Enhancements to the 2015 Star Ratings and Beyond”, H. “Forecasting to 2016 and Beyond”, 1 (d) “Changes to Thresholds for 2016”), based on CMS’ analyses, we propose removing the pre-determined measure thresholds for the 2016 Star Ratings. The cut points would be determined using the same methodology used in the past (e.g., relative distribution and clustering of the data), and we would continue to use the “Reward Factor” for contracts with consistently high performance.

We understand that some sponsors are concerned that eliminating pre-determined 4-star thresholds will make it more difficult to set targets for performance. Currently, 33% of the Part C measures and 61% of the Part D measures do not have pre-determined 4-star thresholds. As described earlier, sponsors achieve more significant improvements in measures without pre-determined 4-star thresholds. In response to our 2016 Request for Comments, more commenters were in support of eliminating the pre-determined thresholds all at once versus gradually phasing them out of the program. Although there was some support for adding the annual improvement percentage increase (IPI) to the thresholds, the majority of commenters were not in favor of implementing the IPI and we are dropping this alternative proposal.

We will proceed as originally planned and as announced in prior Call Letters and eliminate all pre-determined 4-star thresholds for the 2016 Star Ratings. Our primary goal in eliminating the thresholds is to improve the accuracy of the assignment of overall and Part C and D summary Star Ratings and make certain the system creates incentives for quality improvement. Based on the 2015 simulations of the impact of eliminating pre-determined 4-star thresholds, most contracts (83%) would have no change in their overall rating. Approximately 7% of contracts would go up 0.5 stars and 10% would go down by 0.5 stars. Simulations found that for contracts with no SNPs and for SNP-only contracts, 82% of contracts would not change their overall rating. For contracts with some SNPs as plan benefit packages, 87% of contracts would not change their overall rating.

Some commenters to the Request for Comments expressed concern that all thresholds would go up with this change. For the Part C measures with pre-determined 4-star thresholds in

2015, close to half of the 4-star cut points would remain the same or go down, while the remaining would go up. For the Part D measures for MA-PDs, 60% or 3 measures would remain the same or go down and 40% or 2 measures would go up. For the PDPs, 20% or 1 measure would have a lower 4-star cut point and 80% or 4 measures would go up. This simulation does not show significant increases in thresholds across all measures.

In 2014, we provided contract-specific information on the impact of removing pre-determined 4-star thresholds, as well as results of our analyses of performance trends in Star Rating measures, and as applicable, pre-determined 4-star thresholds. In January 2015, through HPMS, we provided contracts with these simulations using the 2015 Star Ratings data. A document showing trends overtime in cut points is available at http://go.cms.gov/partcanddstarratings. We will continue to update this document to help sponsors target their quality improvement efforts. We believe that sponsors can use these data as a substitute for pre-determined 4-star thresholds to help set benchmarks for performance.

- *New 2016 Measure:*

CMS intends to add the following measure to the 2016 Star Ratings.

1. *Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).* This measure is based on the PQA-endorsed measure, Completion Rate for Comprehensive Medication Review (CMR), which is used to calculate the percentage of beneficiaries who met eligibility criteria for the Medication Therapy Management (MTM) program and who received a CMR with a written summary in CMS standardized format. Since this is a new measure, it will be assigned a weight of "1"; in future years it will continue to receive a weight of "1" as a process measure. The specifications from the 2015 Display Measure will continue to be used for the 2016 Star Rating. The denominator is the number of beneficiaries who were at least 18 years or older as of the beginning of the reporting period and who were enrolled in the MTM program for at least 60 days during the reporting period. Only those beneficiaries that meet the contracts' specified targeting criteria per CMS – Part D requirements pursuant to §423.153(d) of the regulations at any time in the reporting period are included in this measure. Sponsors are statutorily required to offer a CMR to all beneficiaries enrolled in their MTM program at least annually, and this includes enrollees who are in LTC settings. Therefore, LTC beneficiaries are included in the measure calculation. However, beneficiaries that were in hospice at any point during the reporting period are excluded from this measure because the beneficiary's drugs may be covered under the hospice benefit or waived through the beneficiary's hospice election and sponsors may not be fully responsible for the management of the beneficiary's medication use during this time. The numerator is the number of beneficiaries included in the denominator who received a CMR at any time during the

reporting period. Sponsors are reminded that they should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs and to whom they must offer a CMR. Some stakeholders are concerned that the variability in MTM program eligibility criteria may bias the measure calculation. As stated in the 2015 Call Letter, analyses have not found a correlation between a sponsor's rate of MTM program eligibility and the CMR completion rate.

- *Additional 2016 Star Ratings Measures:*

CMS intends to return these measures to the 2016 Star Ratings.

1. *Breast Cancer Screening (Part C)*. The HEDIS specification for 2014 changed the age range from 40 to 69 years old to 50 to 74 years old and increased the numerator time frame for documentation of a mammogram from 24 months to 27 months. These changes were a result of NCQA's measure re-evaluation process that included: a scan of clinical guidelines and evidence; feedback from variety of stakeholders, including women's health experts, clinicians, consumer advocates, and health plans; and a public comment period. The revised age range aligns with current recommendations from the U.S. Preventive Services Task Force (Grade B recommendation, with additional research underway), American Academy of Family Physicians, and others. The increased numerator time frame from 24 to 27 months provides a 3-month grace period to account for logistics of obtaining a mammogram and is in response to concerns that the lack of a grace period results in women being screened more often than every two years. We are returning this measure to the 2016 Star Ratings, after moving it to the 2015 Display Page for one year since the measure specification changed during the 2013 measurement year (i.e., it expanded the members included in the denominator). Since this is a process measure, it will continue to be assigned a weight of "1."
2. *Call Center – Foreign Language Interpreter and TTY Availability measures (Part C & D)*. These measures were excluded from the 2015 Star Ratings due to concerns about data quality. For the 2016 Star Ratings, we plan to use a similar data collection timeframe as past years – February through June 2015. All contracts would be monitored using the same timeframe. CMS will provide further information about the quality issues identified with the 2014 data, and the steps taken to correct them, as well as prevent other issues in the future. Since this is an access measure and there is no change in methodology, it will be assigned a weight of "1.5."
3. *Beneficiary Access and Performance Problems (Part C & D)*. This measure had moved out of the 2015 Star Ratings and into the Display Measures since there were significant methodological changes to the 2013 audit process and scoring. Based on feedback from plans and CMS' expectations of regular methodology updates for calculating audit results, we have removed audit results from this measure for stability in the

specifications and will include it in the 2016 Star Ratings. The data currently displayed on the 2015 Display Page use this revised methodology. Appendix 3 includes the detailed specifications. For the 2016 Star Ratings, we will assign this measure a weight of "1" as the methodology change causes this to be considered a "new" measure for weighting purposes. For the 2017 Star Ratings, it will revert to the weight of "1.5" as it had in 2014, as an access measure.

- *Changes to Measures for 2016*

CMS' general policies regarding specification changes to measures for 2016 Star Ratings:

- If a specification change to an existing measure is announced in advance of the measurement period, the measure remains in the Star Ratings; it will not be moved to the Display Page.
- If the change is announced during the measurement period that 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 is announced during the measurement period that does not significantly impact the numerator or denominator of the measure, the measure will continue 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).

The methodology for the following measures is being modified:

1. *Controlling Blood Pressure (Part C).* In December 2013, the eighth Joint National Committee (JNC 8) released updated guidance for the treatment of hypertension. These recommendations set the treatment goal for patients 60 years of age and older to <150/90 mm Hg and keep the treatment goal for patients ages 18-59 years at <140/90 mm Hg. This guideline also recommended that all diabetic patients age 18 and older should be treated to a goal of <140/90 mm Hg and questioned the use of other targets. NCQA staff worked with the NCQA advisory committees, including the Cardiovascular Measurement Advisory Panels, Technical Measurement Advisory Panel, and additional stakeholders. The revised measure went to public comment in February-March 2014 and was approved by the Committee on Performance Measurement and Board of Directors in June 2014. We propose to use the updated measure for the 2016 Star Ratings, and this measure will not be transitioned to the Display Page because beneficiaries that meet the old guidelines will automatically meet the newer more lenient guidelines.

2. *Plan Makes Timely Decisions about Appeals (Part C).* Effective January 2014, organizations are responsible for reviewing requests for dismissal from an enrollee and making the decision; MAOs should not be forwarding requests for dismissal to the Independent Review Entity (IRE) for the dismissal decision. (MAOs should be forwarding to the IRE any reconsideration if the MAO upholds any part of an adverse

organization determination under §422.590.) Therefore, the IRE no longer captures data around the timeliness of dismissal cases, and consequently, we propose to exclude dismissals from this measure for the 2016 Star Ratings. If CMS collects information about Part C dismissals in the future, we may modify this measure to account for these cases.

3. *Plan All-Cause Readmissions (Part C)*. This is a measure of the percentage of hospital discharges that result in a readmission for any cause within 30 days of discharge. This measure is reported as a ratio of a health plan's observed rate of readmission compared to an expected rate of readmission based on a case mix adjusted model (the model takes into account how sick patients were when they went into the hospital the first time.). As discussed in last year's Request for Comments, NCQA has made two changes to this measure which we propose to use for the 2016 Star Ratings: 1) excluding planned readmissions from the measure and 2) removing the current exclusion from the denominator for hospitalizations with a discharge date in the 30 days prior to the Index Admission Date.

   As commenters to our Request for Comments noted, observation stays present challenges for health systems, payers, consumers and measure developers. Currently, observation stays are not included in this measure; however, NCQA is exploring this. In terms of risk adjustment, we are not aware of a valid scale or other measure that defines the appropriateness of a discharge across all clinical conditions. Therefore, the risk adjustment model used by NCQA for this measure cannot take this into account.

4. *Osteoporosis Management in Women who had a Fracture (Part C)*. It is essential for older women to have adequate assessment for osteoporosis following a fragility fracture and/or to be provided treatment to prevent future fractures if indicated. This measure assesses the percentage of women who had a fracture and received either screening or treatment for osteoporosis. NCQA has added an upper age limit, extended the look back period for exclusions due to prior bone mineral testing, removed estrogens from this measure, and removed single-photon absorptiometry and dual-photon absorptiometry tests from the list of eligible bone-density tests. We propose using the modified measure for the 2016 Star Ratings. For this measure, the denominator changes make the measure specifications easier to meet, while the numerator changes should have very little impact on the measure. Estrogens are in the Part D High Risk Medication measure as drugs to be avoided so they are not commonly being used for treating osteoporosis.

   We received some comments on exclusion criteria for this measure. NCQA has considered exclusions for members in long term care facilities or those that are nursing home certifiable living in the community, but its advisory panels have suggested this blanket exclusion is not appropriate. Members in these types of facilities are often frail and may be particularly susceptible to fragility fractures. Individuals who have a fragility fracture would benefit from screening and/or treatment for osteoporosis to reduce risk of future fractures. Additionally, the measure allows for bone mineral density tests that are portable and can be brought to patients who are in long term care facilities.

For dementia, current coding cannot distinguish between women who have mild vs. severe dementia using claims data. Women with mild dementia and those with chronic or severe and persistent mental illness may still benefit from screening and treatment of osteoporosis following a fragility fracture. NCQA will continue to explore this as a potential exclusion in the future. Further, the measure allows for numerous bone mineral density tests and pharmacologic therapies, which gives providers and patients flexibility in determining the best course of intervention.

5. *Complaints about the Health/Drug Plan (CTM) (Part C & D)*. As announced in the 2015 Call Letter, CMS proposes to modify the measurement period from 6 months of the current contract year to 12 months of the prior contract year. For example, 12 months of 2014 complaints data will be used for the 2016 measures. Expansion of the data used for this measure will provide a more comprehensive evaluation of the plan. Currently complaints filed in the second half of a year are not accounted for in a contract's performance rating when only the 6-month period is used. Also, this change addresses some contracts' concerns and allows for an approximately 6-month "wash out" period to account for any adjustments per CMS' CTM Standard Operating Procedures. CMS' simulation of contracts' complaint rates using the full CY2013 complaints data was similar to rates based on the first 6 months of CY2013. There were also instances where contracts' complaint rates improved when using the full 12 month set of complaints, due to the "wash-out period" noted above. Due to this change, the complaints measures will not be used in the calculation of the Improvement measures.

6. *Improvement measures (Part C & D).* Please refer to Appendix 4 for the measures to be used to calculate the 2016 improvement measures. Revisions have been made as a result of feedback received during the Request for Comments.

7. *Appeals Auto-forward and Upheld measures (Part D).* As we first announced in the CY 2015 Call Letter, we propose to modify the Part D Upheld measure to use the same 12-month measurement period as the Part D Appeals Auto-forward measure. For the 2016 Star Ratings Upheld measure, we will use the full 12 months of 2014 data. This change will allow consistency across all four Part C and Part D appeals measures as well as provide a more comprehensive evaluation of plans' decisions. Additionally, this change will allow CMS to include cases reopened by the IRE. Consistent with the Part C measure, if a reopened case is decided prior to April 1 of the following year, the decision for the reopened case is used in place of the reconsideration decision. Previously,

contracts with fewer than 5 total cases were not rated in the Part D Upheld measure. We will re-evaluate and adjust the minimum number of cases as necessary.

We also propose to modify the Part D Auto-Forward measure to exclude cases the independent review entity (IRE) remands to the plan. Based on sponsor feedback and discussions with the IRE, plans may occasionally auto-forward cases to the IRE in error, when the plan hasn't exceeded the applicable coverage determination/redetermination timeframe. As described above, CMS' policy is to continue a measure in the Star Ratings if a specification change announced during the measurement year does not significantly impact the numerator or denominator. Exclusion of remanded cases will not significantly impact the numerator for this measure; therefore we propose to implement this change for the 2016 Star Ratings.

8. *Medication Adherence (for Diabetes Medications and Hypertension (RAS antagonists)) and Diabetes Treatment (Part D)*. PQA updated their 2014 specifications for these three measures to exclude End-Stage Renal Disease (ESRD) patients from the denominator of these measures based on the ICD-9 code 585.6 and/or by the RxHCC 121. As stated in the 2015 Call Letter, CMS proposes to use the beneficiary ESRD coverage start and termination dates reported in the Medicare Enrollment Database (EDB) rather than the ICD-9 code or RxHCC, to identify beneficiaries for exclusion for the 2016 Star Ratings. Beneficiaries with ESRD will be excluded from the denominators of these measures for the entire calendar year, not limited to the ESRD coverage period in the EDB.

   EDB data are available for all Part D beneficiaries, and are also current (after considering data lag), whereas RxHCCs do not necessarily reflect current diagnoses. CMS' testing of these indicators found a very high level of overlap between the ESRD indicators in the EDB and ICD-9 codes in in-patient and out-patient claims when calculating the final rates for these measures. While there is some lag in data updates, we found the overlap between the two data sources was greater than 95%. Issues of data lag should be resolved by the time the final 2016 Star Ratings are calculated in July 2015.

   The Pharmacy Quality Alliance (PQA) is retiring its current, PQA endorsed measure, Diabetes: Appropriate Treatment of Hypertension due to revised Eighth Joint National Committee (JNC 8) Guidelines for the treatment of hypertension. CMS will also retire the Part D Diabetes Treatment measure for CY2017 Star Ratings. However, since the measure was endorsed through 2014, CMS will include the Diabetes Treatment measure in the 2016 Star Ratings (based on 2014 data), and will continue to provide updated monthly Diabetes Treatment measure reports of 2014 PDE through June 2015 only via the Patient Safety Analysis website.

9. *Medication Adherence (Diabetes Medications, Hypertension (RAS antagonists), and for Cholesterol (Statins)) (Part D).* Currently, when calculating the Proportion of Days Covered (PDC) for the three Adherence measures, if a beneficiary disenrolls from his/her contract in the middle of the calendar year due to death or disenrollment, CMS uses the Common Medicare Environment (CME) enrollment table to obtain the beneficiary's disenrollment date and identify the end of the beneficiary's measurement period. The disenrollment date in the CME is always the last day of the month of disenrollment, regardless of the date of death or actual disenrollment. For example, if a beneficiary is enrolled in a contract starting January 1, 2013 and has a death date of May 10, 2013, CMS uses the May 31, 2013 CME disenrollment date as the end of the beneficiary's measurement period. In response to sponsor feedback, we investigated the feasibility and impact of using the exact death date when available in CME instead of the CME disenrollment date as the end of the beneficiary's measurement period.

   This change affects two aspects of the Adherence rate calculation. First, it may reduce the number of beneficiaries eligible for inclusion in the denominator due to the 91 days restriction. To be included in the denominator of the Adherence rate per the PQA specifications, the beneficiary must have at least two fills of the relevant medication(s) and the first fill must occur at least 91 days before the end of the beneficiary's measurement period. By using the death date instead of the month-end date as the end of the beneficiary's measurement period, some beneficiaries may no longer be eligible for the denominator.

   Secondly, for beneficiaries who have death dates that occur before the end of the month, the methodology change shortens the beneficiary measurement period in the PDC calculation. The PDC represents the proportion of days covered by the relevant medication(s) between the date of the beneficiary's first fill and the last day of the measurement period.

   Based on simulations with the data used for the 2015 Star Ratings, we found replacing the month-end date with the death date to generally have no effect on the majority of contracts' Adherence rates. This change could have an impact on a small number of individual beneficiaries' PDCs within a contract; therefore, some contracts may observe a small positive or negative impact on their Adherence rates. Simulations of this change using data from the 2015 Star Ratings found that a small number of contracts (less than 5%) may have small increases or decreases in their highest Star Rating (i.e., overall rating for MA-PDs and Part D rating for PDPs). We propose using the exact death date (when available in CME) instead of the CME disenrollment date as the end of the beneficiary's measurement period beginning with the 2016 Star Ratings to improve the specificity of the PDC calculation. Comments from sponsors strongly supported this change to improve the accuracy of the measure. We also plan to implement this change in the Patient Safety monthly reports of 2014 PDE in early 2015. We note that there can be up to a three month delay for a beneficiary's death date to populate in the CME; therefore the data may change by the time data are finalized for the 2016 Star Ratings in July 2015.

10. *Obsolete NDCs (Part D).* For the 2016 Star Ratings and display measures (using 2014 PDE data), we propose to implement PQA's 2014 obsolete date methodology.

    Specifically, the obsolete date methodology includes the following steps:

    - Query the MediSpan and First DataBank databases to develop an NDC list.
    - Cross-check the NDC list developed at step 1 against the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE) and its effective dates.
    - Include the NDC in the file if:
      - There is no obsolete date noted by MediSpan or First DataBank or NSDE; or
      - The obsolete date in any of the databases is within the measurement year; or
      - The obsolete date is within six months prior to the beginning of the measurement year.

    While most commenters supported the implementation of the PQA's updated obsolete NDC methodology for the 2016 Star Ratings, CMS received some suggestions for additional methodology changes (including increasing the frequency of updates to the NDC list and increasing the look back period). The PQA maintains the NDC lists and methodology; we will share these comments with the PQA.

11. *CAHPS (Part C & D).* As announced in the 2015 Call Letter, we will make minor modifications to the CAHPS methodology to permit imprecisely measured low-reliability contracts to receive 5 stars or 1 star, if evidence warrants such a designation. In the past we have not assigned contracts that had a score with low reliability 1 or 5 stars given the imprecision around the score. However, CMS has conducted additional analyses and some contracts with scores that have low reliability nonetheless have good evidence of performance that is well above the 4-star cut point or below the 2-star cut point. We will modify the CAHPS methodology to permit low-reliability contracts to be assigned 5 stars if the measure score exceeds the 5-star cut point and also exceeds the 4-star cut point by 1 standard error. Similarly, low-reliability contracts can be assigned 1 star if their score is below the 1-star cut point and also falls below the 2-star cut point by 1 standard error.

- *Retirement of Measures*

  Due to the release of the new American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines on the Treatment of Blood Cholesterol, NCQA convened its Cardiovascular Measurement Advisory panel in order to address the question of whether changes were needed in their HEDIS measures related to LDL-C control.

For HEDIS 2015, NCQA retired the following measures so they will no longer be included in the Star Ratings:

- Cardiovascular Care: Cholesterol Screening
- Diabetes Care: Cholesterol Screening
- Diabetes Care: Cholesterol Controlled

Guidelines from the eighth Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-8) support several therapeutic categories, in addition to Angiotensin Converting Enzyme (ACE) Inhibitors and Angiotensin Receptor Blockers (ARBs), as first line treatment of hypertension for persons with diabetes (*JAMA. 2014; 311(5):507-520)*. As a result, the PQA has elected to retire the measure Appropriate Treatment of Hypertension in Diabetes. CMS proposes to retain the measure for the 2016 Star Ratings, which is based on 2014 data, and then remove it from the 2017 Star Ratings.

- *Temporary Removal of Measures from Star Ratings*

1. *Improving Bladder Control (Part C)*. This measure, collected through the Health Outcomes Survey (HOS), assesses the percentage of beneficiaries with a urine leakage problem who discussed this problem with their provider and received treatment for the problem. NCQA is making 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 an issue. This will remove 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 will change 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 how much urinary incontinence impacts quality of life for beneficiaries. This outcome indicator will not be part of the Star Rating system until additional analyses have been done. These changes required revising the underlying survey questions in HOS. The revised questions will be first collected in 2015. As a result of these changes, there will be no data for this measure for the 2016 and 2017 Star Ratings. We will address the use of data from the revised measures for the 2018 Star Ratings in a subsequent Call Letter.

- *Contracts with Low Enrollment*

  Low enrollment contracts, as defined in §422.252, are those where enrollment is such that HEDIS and HOS data collections cannot be used to reliably measure the performance of the health plan. In the past, we have believed that contracts with less than 1,000 enrollees would meet that definition, but we have reevaluated whether that threshold is an appropriate implementation of the regulatory standard. Contracts with less than 1,000 enrollees first submitted HEDIS data to CMS in the summer of 2013. As a precursor to including low-enrollment contracts in the Star Ratings, CMS included HEDIS scores for low-enrollment contracts as part of the 2014 display measures. For the 2014 Star Ratings, 27 additional contracts would have received an overall rating if we used these data rather than merely posting the data as part of the display measures. Based on the data we received, CMS has determined that there are sufficient data to reliably measure and report on contracts in the Star Ratings with 500 or more enrollees in July of the HEDIS measurement year. (William T. Hoyt. 2010. Interrater Reliability and Agreement in Gregory R. Hancock and Ralph O. Mueller, The Review's Guide to Quantitative Methods in the Social Sciences. NY: Routledge.)

  Last year CMS delayed including contracts with enrollment from 500 to 999 enrollees into the Star Ratings on Medicare Plan Finder to gain an additional year of experience with collecting and analyzing these data and to evaluate the reliability of the data. Beginning with the 2016 Star Ratings, contracts with 500 or more enrollees as of July 2014 will not be considered low enrollment contracts; they will be included for Quality Bonus Payments to be made in CY 2017. Contracts with 500 or more enrollees in most cases will have sufficient data to produce both overall and Part C and D ratings. The HEDIS data for contracts with less than 500 enrollees will continue to be posted on the Display Page as these will continue to be considered low enrollment contracts.

  In the fall of 2014, CMS provided low enrollment contracts (i.e., less than 500 enrollees) their simulated 2014 Star Ratings data and will provide it again in January 2015 with simulated 2015 Ratings. It is important to note that only the measures where the contract meets the minimum denominator requirements are included in the Star Ratings. Thus, if a contract with 500 to 999 enrollees does not meet the minimum denominator requirements for a measure, the particular measure will not be included in its overall rating calculation. Contracts between 500 to 999 enrollees have always been included in the Star Ratings for all non-HEDIS measures when the contract met the measure denominator requirements. However, without the HEDIS data, the contracts did not have enough measures to obtain an overall rating. Starting with HEDIS 2013 contracts with less than 1,000 enrollees began submitting HEDIS data. For the HEDIS measures, we plan to exclude from the cut point determinations and the overall rating calculations any contract-specific measure scores that have low reliability. Specifically, any contracts with 500-999 enrollees that have a contract-level reliability of less than 0.7 for a measure will be excluded. The contract-level reliability measures the signal-to-noise ratio which is how much of what is being measured is “signal” (true variation in performance), rather than “noise” (measurement error). Reliability levels of 0.7 or greater are acceptaby reliable.

- *Data Integrity*

CMS’ Star Ratings data must be accurate and reliable. CMS’ policy is to reduce a contract’s measure rating to 1 star if it is identified that biased or erroneous data have been submitted. This exclusion would include cases where CMS finds mishandling of data, inappropriate processing, or implementation of incorrect practices by the organization/sponsor have resulted in 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; 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 may perform additional audits or reviews to assure the validity of data for specific contracts. Without independent validation of these data, CMS could reward contracts with falsely high ratings in these areas.

CMS has taken several steps in the past years to protect the integrity of the data; however, we continue to identify new vulnerabilities where inaccurate or biased data could exist. We are interested in developing more comprehensive quality checks for measures using organization or sponsor-reported data, for example, the Part C and D appeals measures which use data that sponsors report to the IRE. Sponsors have commented in the past that they too are supportive of a comprehensive review of their processes, in lieu of focused or targeted sampling to determine if errors have been made, but at no additional costs to sponsors.

CMS began using validated Part C and D plan reported data for the 2015 Star Ratings with the introduction of the SNP Care Management measure. In order to be evaluated in this measure, contracts must score at least 95% for the SNP Care Management reporting section, and also be found by the data validator to be compliant with data validation standards/sub-standards for the specific data elements used for the measure.

We propose to expand our use of the Part C and D data validation results as a new method of comprehensively reviewing sponsors’ operational systems, and verify the validity of some data used for Star Ratings. Per the Part C and D reporting requirements, contracts submit various data related to their processing of organization determinations, coverage determinations, and appeals, including the timeliness of their processing, data related to the delivery of their MTM programs, etc. Independent data validators assess if these data were accurately reported.

For example, contracts that fail data validation for specific data elements related to organization determination, coverage determination or redetermination timeliness (e.g., For the CY2014 Coverage Determinations and Redeterminations reporting section, elements 1.N – coverage determinations processed timely and 2.C – redeterminations processed timely) would be found to have biased the data reported to the IRE, and therefore should be reduced in the respective Part C or D appeals Star Rating measures. Similar applications could be determined for other reporting areas directly relevant to Star Rating measures. CMS would not apply data validation results to measurement areas where other validation or audit activities exist, such as HEDIS measures.

We performed an analysis of Part D data reported by sponsors for CY 2013 which were independently validated in April-June 2014. A total of 62 contracts failed to meet CMS' passing thresholds for accurately reporting coverage determinations/exceptions or redeterminations data for CY2013 (4 of these 62 contracts failed to pass data validation in both sections' data) as outlined in the Part C and D Data Validation Standards. Of these 62, 8 contracts were also found by CMS 2014 program audits to have serious CDAG deficiencies and already reduced in the corresponding 2015 Star Ratings appeals measure. Therefore, if we had expanded the use of CMS' data validation results for the 2015 Star Ratings, approximately 50 additional contracts would have reduced Part D appeals Star Ratings. Since not all sponsors are audited by CMS each year, this method may more comprehensively capture evidence of biased data. In response to the November Request for Comments, organizations submitted technical comments and questions regarding the data validation standards and inter-rater reliability. CMS will provide additional guidance in response to these issues. We continue to consider expanding the data integrity checks to use the Part C and D Data Validation results for associated measures as a viable option in the future. However, we would not consider applying the data validation results until the CY2017 Star Ratings, at the earliest, until the concerns raised are explored and additional guidance is issued.

The High Risk Medication (HRM) measure calculates the percent of Medicare Part D beneficiaries 65 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. The measure is endorsed by the PQA and NQF, and the HRM rate is calculated using the PQA specifications and medication list based on American Geriatrics Society (AGS) recommendations.

We have received comments regarding the measure specifications with respect to Part D formulary and utilization management requirements. Sponsors may be required to include certain HRM medications on their formularies to meet certain formulary review requirements. The goal of this measure is to reduce potentially inappropriate use of these medications when there may be safer drug choices. We understand that the use of these medications may be medically necessary for some beneficiaries 65 and older, and the goal is not to achieve a zero percent HRM rate. Also, Part D sponsors generally serve some enrollees under age 65.

Sponsors may apply utilization management edits to reduce the inappropriate use of these medications. However, in the absence of specific age-related contraindications in the FDA-approved labeling, these edits must be submitted and approved by CMS through HPMS. Sponsors who implement unapproved edits for these medications may be found to have data integrity issues. CMS' policy is to reduce a contract's measure rating to 1 star if it is identified that biased or erroneous data have been submitted. Implementation of unapproved edits for HRM medications would be subject to this policy.

- *Duals/LIS*

CMS is proud of the Star Ratings Program and the quality improvements it has generated. We believe MAOs have responded to this program because it employs a solid, reliable methodology. CMS continuously reviews the methodology and seeks to enhance the methodology to improve the Star Ratings process, incentivize plans, and provide information that is a true reflection of the performance and experience of the enrollees.

Multiple MA organizations and PDP Sponsors believe that plans with a high percentage of dual eligible (Dual) and/or LIS enrollees are disadvantaged in the current Star Ratings Program. Similar claims have been made about other Medicare quality measurement programs such as readmission rates, Hospital Quality Reporting, Home Health Quality Initiative, ESRD Quality Incentive Program, and the Outpatient Quality Reporting Program. CMS is committed to exploring and examining whether the Star Ratings are sensitive to the percentage of Dual/LIS enrollees in the plan. Extensive internal and contract-supported research has been commissioned and continues to date. The IMPACT Act (P.L. 113-185) instructs ASPE (Assistant Secretary for Planning and Evaluation) to conduct a study that examines the effect of individuals' socio-economic status (SES) on quality measures and resource use and other measures for individuals under the Medicare program. All CMS components are in the process of coordinating their research with ASPE. The Star Ratings team has already begun discussions with ASPE and will continue to work collaboratively to examine the issue and its impact on ratings. CMS will continue to work diligently to explore this issue with the goal that MA and Part D beneficiaries receive the highest quality care possible.

In addition, CMS issued a Request for Information (RFI) that provided the opportunity for the public and plans to submit their analyses and research that demonstrated that dual status causes lower MA and Part D quality measure scores. In the RFI, we also solicited examples of any research that demonstrated that high quality performance in MA or Part D plans can be achieved in plans serving Dual beneficiaries. The research conducted and information collected related to Dual/LIS status and Star Ratings measures will be publically available the week of February 25th at http;//go.cms.gov/partcanddstarratings. Prior to posting the submissions, they are being reviewed to verify there is no proprietary information or information that could potentially identify individuals. This information will be redacted prior to posting the submissions.

There are a total of 46 Part C and D Star Rating measures for 2015. The current research conducted by CMS, both internally and in conjunction with our contractors, excluded measures that were already case-mix adjusted for SES, not a beneficiary-level issue but rather a plan-level issue, were being retired/revised, or restricted to SNP only. After applying these exclusions, CMS' extensive review focused on 19 of the 46 individual Star Rating measures.

The CMS research had the advantages of access to Star Ratings data across contracts and at different levels of measurement (e.g., beneficiary, plan-level, contract-level, and the ability to link beneficiary-level datasets). Numerous advanced statistical methodologies were employed for the research. Regardless of the statistical methodology employed, statistically significant results do not necessarily imply practical significance. Given the large quantity of data available for internal research, the practical significance (i.e., the size of the effects) was evaluated in addition to the statistical significance.

CMS' research examined a number of issues including, but not limited, to the following: modelling the effect of Dual/LIS status on the measure outcomes of interest using contract effects both with and without controlling for individual characteristics of age, sex and race/ethnicity; examining the effect of controlling for self-reported health status, education and age; and exploring the possible existence of differences in performance of Dual/ LIS and non-Dual/LIS in terms of the percent of Dual/LIS enrollees in the contract.

Our research has found some differences in measure-level performance for LIS/Dual beneficiaries, although for the majority of measures the differences are small. Even for measures with larger observed differences, evidence of an association between higher Dual enrollment (and higher LIS beneficiary enrollment) and lower Star Ratings does not prove causality. For some measures, scores were higher for plans with higher Dual enrollment. Additionally, in some cases, the association between Dual/LIS dissipated or reversed once the models included additional individual characteristics. For some Part D measures, the differential between LIS and non-LIS results was specific to whether the plan was an MA-PD or PDP. Further, findings suggest that certain beneficiary characteristics—namely, educational attainment, Dual eligibility, self-rated general health status, and age—are strongly associated with better rates for several HEDIS measures within contracts. In addition, the preliminary analysis revealed that in general, contracts that have a high percentage of LIS enrollees have LIS group means on par with the non-LIS enrollees in the contract.

In response to the RFI, CMS received over sixty-five submissions. The majority of the submissions were from sponsors and plans or organizations representing them. The submissions varied in terms of content, evidence, and data source. Over half of the submissions employed quantitative methodologies and of those, approximately half included statistical significance testing. A number of the submissions used a mixed methodology. CMS is grateful for the time and effort put forth by the commenters to aid in the examination of the Dual/LIS concerns.

Some of the quantitative research used rich, detailed patient-level data that was readily available to plans employing a variety of methodologies. Other submissions relied on publically available data as the primary source for information. The unit of analysis varied based on the data employed. The definition of Dual and LIS varied across submissions. A number of the studies included Duals in Dual SNPs only, some analyzed Duals and excluded all beneficiaries enrolled in Dual SNPs, and others used a broader view and included all Duals, regardless if the enrollee was enrolled in a Dual SNP, MA-PD or PDP. A number of the submissions used a standard for evidence as association and not causation. Some of the research conducted reflected limited regional effects and thus, lacked generalizability of the results to the Star Ratings Program; nonetheless, it was valuable in its own right.

A comparison of the RFI quantitative, statistically-based submissions demonstrated varied results. Some research indicated that Duals (as a group) realized lower performance outcomes on measures, while other research on the same measure using a different subgroup of beneficiaries found no difference in performance outcomes for Duals or that Duals experienced better outcomes as compared to a non-Dual comparison group. Many of the studies found an association between performance rates and Dual status but did not control for demographic characteristics.

The qualitative submissions provided the opportunity for submitters to share their best practices. Many of the submissions referenced other studies and provided responses that reflected a strong commitment to continuous improvement in providing quality care. A number of plans provided insight to the challenges of addressing the needs of the Dual/LIS population and innovative ways to provide outstanding care to all of their beneficiaries. There were some sponsors that focus on Duals and LIS that were proud of their high quality performance in MA or Part D plans and provided proof that such results can be achieved.

The National Committee for Quality Assurance (NCQA) responded to CMS' Request for Information with concerns that we may risk lowering the standard on measurement by applying case-mix adjustment to performance measures since this can mask disparities in care for lower SES patients. NCQA recommended working with providers to ensure they have the resources and skills to meet the patients' needs. In their communications to CMS, NCQA cites other work that demonstrates that good outcomes can be achieved despite challenges that may be present for subgroups of beneficiaries.

CMS believes additional research into what is driving the differential performance on a subset of measures is necessary before any permanent changes in the Star Ratings measurements can be considered. However, our preliminary analyses have revealed both practical and statistically significant evidence of differential outcomes for Dual/LIS beneficiaries for the following six Part C Measures: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, and Reducing the Risk of Falling. Additionally, our analyses have revealed some evidence of differential outcomes for Dual/LIS beneficiaries for the following Part D Measure which was specific to PDPs (a similar effect was not observed for MA-PDs for this measure): Medication Adherence for Hypertension (RAS antagonists).

In the long-term, it may be appropriate to adjust the Star Ratings in cases where there is scientific evidence that performance on certain measures is impacted by patient factors such as comorbidities, disability, or Dual/LIS status. Additionally, such adjustments may particularly be warranted when these unadjusted patient factors may influence patient ability to meet recommended clinical guidelines. These factors could include, for example, health literacy issues, transportation issues, comorbidities, and disabilities. Any changes would be proposed through the Star Ratings Request for Comments and future Call Letters.

We propose, therefore, to take the interim step of reducing the weights on this subset of Part C measures for MA and 1876 contracts and one Part D measure for PDP contracts for the 2016 Star Ratings. The subset of measures was selected on the basis of both statistical and practical significance and includes the following six Part C measures: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, and Reducing the Risk of Falling. The weight of one measure for PDPs, Medication Adherence for Hypertension (RAS antagonists), would also be modified under this proposal for the 2016 Star Ratings Program. The weight of this measure would remain unchanged for MA-PDs. CMS would reduce the weights of the aforementioned subset of measures by half – thus, these Part C measures listed above except Diabetes Care – Blood Sugar Controlled, would have a modified weight of 0.5 for the Star Ratings for 2016 (instead of 1) for MA and 1876 contracts, and the Part C measure Diabetes Care – Blood Sugar Controlled for MA and 1876 contracts and the Part D measure listed for PDPs would have a modified weight of 1.5 (instead of 3) for PDPs. This adjustment is proposed regardless of a contract's percentage of Dual and/or LIS enrollees. The modified weights would just be applied to the individual measure stars for the subset of measures and would not be incorporated into the measure weights used for the improvement measures. CMS wants to continue to incentivize and reward improvements to these measures. Poor performing contracts overall can show significant improvement on individual measures.

The reduced weights will target immediate relief to plans with significant Duals/LIS enrollment while maintaining incentives for all plans to improve on these important measures. Given the uncertainty about what is driving the association, long-term adjustments should be based on further in-depth examination of the issue by CMS and its HHS partners in quality measurement, as well as external measure developers, to determine the driving factors for the difference that has been observed in the preliminary research and the RFI submissions. The research will extend beyond the subset of measures for which the weights would be modified in 2016. The additional research and examination of the issue will be used as the basis for any long term revisions to the methodology. However, if the research in the coming months provides definitive, actionable results demonstrating that sponsors that enroll a disproportionate number of Dual/LIS beneficiaries are systematically disadvantaged by the Star Ratings, CMS could propose additional interim methods to mitigate the effects. For example, our Request for Comments for the 2017 Star Ratings and beyond released in Fall 2015 could contain additional approaches if warranted. CMS continues to encourage true quality improvement by all plans and cannot risk masking disparities in care or the integrity of the Star Ratings Program by implementing long term changes that are not grounded in scientific evidence.

- *Measures Posted on the CMS Display Page*

Display measures on www.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 tested before inclusion into the Star Ratings, or measures displayed for informational purposes. Similar to the 2015 Display Page, organizations and sponsors have the opportunity to preview their data on the display measures prior to release on CMS' website in Fall 2015. Data on measures moved to the Display Page will continue to be collected and monitored, and poor scores on display measures are subject to compliance actions by CMS. During the Request for Comments, some commenters voiced concerns about CMS issuing compliance actions for display measures. We remind sponsors that many display measures evaluate compliance with contractual requirements, and that overall performance trends are considered when identifying poorly performing contracts. It is expected that all 2015 display measures will continue to be used for 2016, and remain posted on www.cms.gov. CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings. Other display measures may be provided as information only.

Regarding the Pharmacotherapy Management of COPD Exacerbation (PCE) display measures, NCQA staff has determined that changes to the PCE measure to incorporate intravenous corticosteroids administered during inpatient or ED visits is not possible at this time due to the significant technical challenges of capturing this information through a measure limited to administrative claims. The administration of these medications during treatment of the exacerbation is clinically appropriate to include in the measure numerator, and NCQA will continue to examine methods to re-specify the measure accordingly as data sources are made available for measurement.

- *Forecasting to 2017 and Beyond*

  The following describes potential changes to existing measures and potential new measures. All of the HEDIS changes and additions are tentative pending a final decision by the NCQA Committee on Performance Measurement and the Board of Directors in June 2015. We also describe potential changes to CAHPS measures to reflect AHRQ's CAHPS 5.0 Health Plan Survey.

  - Potential changes to existing measures:

    1. *Medication Reconciliation Post Discharge*: 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. NCQA is proposing two changes: 1) expand the coverage on this measure from Medicare Special Needs Plans only to all of MA; and 2) expand the age range from adults 65 years and older to adults 18 years and older. Both of these proposed changes for HEDIS 2016 are seen as an important step to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. If this measure is implemented for HEDIS 2016, CMS will include in the 2017 Display Page and will consider for the 2018 Star Ratings.

    2. CAHPS 5.0 changes: The current MA & PDP CAHPS Survey includes the core CAHPS 4.0 Health Plan Survey. CMS is interested in potentially updating the survey for future years to reflect AHRQ's CAHPS 5.0 Health Plan Survey. We will conduct an experiment in 2015 to understand if/how performance on CAHPS measures differs between 4.0 and 5.0. Based on these results we will consider whether changes or adjustments should be made to the MA & PDP CAHPS Surveys in the future. We will provide details on results as soon as they are available.

       CMS reminds contracts that MA & PDP CAHPS Surveys are currently translated into Spanish and Chinese (Cantonese and Mandarin). We welcome suggestions for translations into additional languages.

    3. MPF Price Accuracy: CMS is considering updating the MPF Price Accuracy measure in the future. The first proposed change is related to the method in which claims are excluded from the measure. Currently, the measure is limited to 30-day claims filled

at pharmacies reported by sponsors as retail only or retail and limited access only in their Medicare Plan Finder (MPF) Pharmacy Cost files. That is, claims filled for near 30 days supplies, or claims filled for 60 and 90 days supplies are excluded. Additionally, claims filled by retail pharmacies who are also long term care, mail order, or home infusion pharmacies are excluded. These restrictions result in the exclusion of many PDEs, thus potentially biasing the reliability of the measure.

We propose to include claims with 28-34 days supplies, as we believe it would be appropriate to compare their PDE costs to MPF's fixed display of 1 month pricing. We also propose to include 60 and 90 day supply claims. Beginning with CY2015 MPF submissions, plans must provide brand and generic dispensing fees for 60 and 90 day supply claims in the Pharmacy Cost file. CMS can use these data, along with 60 and 90 day supply Pricing File data, to compare MPF and PDE costs. While the majority of claims are for a 30 day supply, we found that claims with a 90 day supply account for almost one-fifth of available PDE data, thus allowing for a more comprehensive evaluation of PDE claims.

Additionally, we propose to use the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims. Prior to the availability of this PDE field, there was no way to determine whether a given claim was priced under the retail setting of the dispensing pharmacy when a pharmacy had multiple types. There may be incentives for sponsors to misreport pharmacy types in the MPF Pharmacy Cost files to reduce the number of claims eligible for inclusion in the Price Accuracy Score. CMS began requiring pharmacies to populate the Pharmacy Service Type field on all PDEs at the end of February 2013. As of June 2014, the Pharmacy Service Type field was populated for 99.9 percent of CY2014 PDEs submitted. We recommend expanding the retail claims identification process to include all PDEs that are from at least retail pharmacies according to the Pharmacy Cost data and have a Pharmacy Service Type of either Community/Retail or Managed Care Organization (MCO). Although some sponsors cited concern about the accuracy of these data as reported by pharmacists, Part D sponsors are ultimately responsible for the accuracy of their submitted PDE to CMS. According to PDE requirements, CMS expects, "…sponsors and their network pharmacies to develop and implement controls to improve the accuracy of this information during 2013…" This methodology change would increase the number of PDEs eligible for inclusion in the Price Accuracy Scores while continuing to identify only retail claims.

These proposed changes can also be applied to mail order claims. Including mail order claims with 28-34, 60, and 90 days supplies would add another dimension to the Price Accuracy Scores and further increase the number of PDEs eligible for inclusion. CMS could take the following steps to include mail order pharmacy claims: 1) CMS uses the MPF Pharmacy Cost data to identify mail order pharmacies; 2) CMS identifies PDEs filled at those pharmacies, with the Pharmacy Service Type field reported as Mail Order; 3) CMS uses MPF Pricing File data for 30, 60, and 90 day supply mail order claims, and MPF Pharmacy Cost data for brand and generic dispensing fees to compare MPF and PDE costs for mail order claims.

We are also considering changes to the methodology by which price accuracy is calculated. Because the current methodology measures the magnitude of a contract's overpricing relative to its overall PDE costs, the Price Accuracy Scores do not reflect the frequency of accurate price reporting, and can be significantly impacted by high cost PDEs. As a result, contracts with divergent accurate price reporting and/or consistency can receive the same Price Accuracy Score. CMS is interested in modifying the methodology to also factor in how often PDE costs exceeded MPF costs. The frequency of inaccuracy by a contract would be the percent of claims where PDE cost is greater than MPF cost. The numerator is the number of claims where PDE cost is greater than MPF cost, and the denominator is the total number of claims. This ratio is then subtracted from 1 and multiplied by 100 to calculate the Claim Percentage Score, with 100 as the best possible score and 0 as the worst possible score. The contract's accuracy score would be a composite of the Price Accuracy Score and the Claim Percentage Score.

By capturing the frequency of inaccuracy as well as the magnitude, the measure would better depict the reliability of a contract's MPF advertised prices. CMS is aware that while the Medicare Plan Finder 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 the Price Accuracy measure, there is the potential to harm beneficiaries by not changing the prices at the point of sale to lower prices, where warranted. We would note that PDEs priced lower to MPF displayed pricing does not lower a plan's score in this measure. CMS' simulation of this proposal found little change in the range of contracts' accuracy scores. Other options we explored included measuring the magnitude of inaccuracy as a percentage cost difference, instead of the current measure's use of absolute cost difference. Testing however found this method may overstate small differences between PDE and MPF costs for low-cost claims. For example, when using percentage cost differences, a claim with a $2.00 PDE cost and a $1.00 MPF cost would be considered equally overpriced as a claim with a $200.00 PDE cost and a $100.00 MPF cost.

We propose these changes are implemented for the 2017 Star Ratings (using 2015 PDE and MPF data). The current methodology will remain for 2016 Stars, and we do not anticipate testing these changes first as a 2017 Display measure. We believe the proposed changes will greatly improve the Price Accuracy Scores, making them a more comprehensive assessment of contracts' price reporting for Part D beneficiaries.

- Potential new measures:

  1. Care Coordination Measures: Effective care coordination contributes to improved health outcomes. CMS believes that 5-star plans perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plans, however, is based largely on anecdote and discussions with high-performing plans, as we currently lack the tools to accurately capture and measure how well plans are coordinating care.

     To date, our ability to measure plans' care coordination efforts has largely been limited to data we collect from CAHPS surveys, which reflect enrollees' experience with the care they receive. CMS is working to expand efforts in this area to measure the plans' coordination approaches. These efforts will focus on developing measures related to the patient assessment of their plans' care coordination, encounter data-based measures, and medical records-based measures. CMS is particularly interested in comments on measures that could be developed using MA encounter data. For example, measures that identify post-discharge utilization by plan enrollees in order to identify plans in which an unusually high number (proportion) of enrollees do not obtain expected follow-up care (follow-up physician visit within first week), enrollees receiving Part A-covered skilled nursing facility care who do not receive information about receiving long-term services and supports in a community settling, or, if appropriate, for whom there are no changes to prescribed medications following discharge. In addition, CMS is interested in measuring the effectiveness, timeliness and clinical relevance of information shared electronically during transitions and referrals, and is seeking to identify measures of electronic exchange of health information that reflect improved care coordination. As measures are developed and tested, they will be added to the Display Page and Star Ratings.

     CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings. Comments and suggestions received to the Request for Comments have been shared with measure developers for their consideration.

  2. Asthma Measure Suite: NCQA tested three asthma measures in the fall of 2014 to evaluate the effects of expanding the measure to include older adults. The age range for these measures is currently members 5 – 64 years of age. The three measures under consideration for inclusion of older adults include:

     - Use of Appropriate Medications for People with Asthma: The percentage of members during the measurement year who were identified as having persistent asthma and who were appropriately prescribed medication during the measurement year.

- Medication Management for People with Asthma: The percentage of who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period (i.e., first prescription date through end of measurement year).
- Asthma Medication Ratio: 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.

Testing results will be reviewed with NCQA’s measurement advisory panels, including the Geriatric Measurement Advisory Panel. These panels will help NCQA determine whether expanding the age range of these measures to include the 65+ population is appropriate. The proposed changes, if approved, would be published in HEDIS 2016.

3. Depression: NCQA is developing a new set of HEDIS measures that would assess depression care along the continuum of care. These measures are intended for all individuals age 12 and older but may be particularly relevant to the population age 65 and older. The measures currently in testing include:

- Depression Screening and Follow-up: The percentage of individuals who were screened for depression using a standardized tool and received appropriate follow-up for a positive screen.
- Utilization of the PHQ-9 for Monitoring of Depressive Symptoms: The percentage of individuals with a diagnosis of major depression or dysthymia who were monitored using the Patient Health Questionnaire (PHQ-9).
- Depression Remission, Response or Treatment Adjustment at 6 Months: The percentage of individuals with a diagnosis of major depression or dysthymia and symptomatic depression at baseline who achieved either remission of depression symptoms, response (i.e., reduction) in symptoms or an adjustment in treatment at six months.

4. Hospitalizations for Potentially Preventable Complications: NCQA is finalizing testing of a risk-adjusted measure of hospitalization for ambulatory care sensitive conditions based on the NQF endorsed Prevention Quality Indicators (PQI), developed by AHRQ. This measure will assess the rate of hospitalization for complications of chronic and acute ambulatory care sensitive conditions. The intent of the measure is to assess the quality of ambulatory care to prevent the complications of chronic and acute conditions that result in hospitalization. The new measure, if approved, would be published in HEDIS 2016.

5. Statin Therapy: NCQA is currently developing two statin therapy measures aligned with the 2013 ACC/AHA blood cholesterol guidelines. The measures are focused on two of the major statin benefit groups described in the guidelines: patients with clinical atherosclerotic cardiovascular disease and patients with diabetes. Measure development and field-testing are expected to continue through the fall and winter. The new measures if approved would be published in HEDIS 2016.

   The PQA has developed a new measure to support ACC/AHA guidelines which recommend moderate- to high- intensity statin therapy for primary prevention for patients aged 40-75 years of age with diabetes. The measure calculates the percentage of patients in this age group who received a medication for diabetes that also received a statin medication during the measurement period. This measure was endorsed by the PQA in November 2014, and CMS will continue to test this measure, explore developing new reports to Part D sponsors via the Patient Safety Analysis website, and evaluate adding this measure as a future Part D Star Rating. For example, with PQA endorsement of this measure in 2014, this measure could be considered as a new 2017 Display Measure (using 2015 data) and a 2018 Star Rating (using 2016 data). Patient safety reports to sponsors may be released as early as spring 2015.

6. High Risk Medication (HRM): The American Geriatric Society (AGS) is currently considering revisions to the Beer's criteria which may precipitate future changes to the PQA measure specifications and medication list. CMS is closely following these activities. If changes are published by the AGS and measure updates endorsed by the PQA prior to the 2016 formulary and bid deadlines in May and June 2015, CMS may consider adoption for the 2018 Star Ratings (using 2016 data), or 2019 Star Ratings (using 2017 data). Additionally, CMS will consider other stakeholder's suggestions for future measure specification changes.

7. Opioid Overutilization: PQA is currently developing three measures that examine multi-provider, high dosage opioid use among individuals 18 years and older without cancer. Patients enrolled in hospice are also excluded. The measures currently in development include:

   - Measure 1 (Opioid High Dosage): The proportion (XX out of 1,000) of individuals without cancer or enrolled in hospice receiving a daily dosage of opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer.
   - Measure 2 (Multiple Prescribers and Multiple Pharmacies): The proportion (XX out of 1,000) of individuals without cancer or enrolled in hospice

receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

- Measure 3 (Multi-Provider, High Dosage): The proportion (XX out of 1,000) of individuals without cancer or enrolled in hospice receiving prescriptions for opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

If these measures are endorsed by the PQA prior to the 2016 bid deadline in June 2015, CMS may adopt them as display measures beginning in CY 2017 (using 2015 data) or alternatively to use in the Overutilization Monitoring System (OMS). Due to concerns about the lack of consensus clinical guidelines for the use of opioids to treat chronic, non-cancer pain and potential exceptions due to medical necessity, CMS is not considering these measures for Star Ratings at this time.

- Measurement Concepts

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 welcome comments and input on alternative levels of evaluation (e.g., PBP or parent organization). We are specifically interested in understanding how physician and provider networks may differ across PBPs and whether this would result in differences in quality across PBPs.

- We also welcome comments on additional measures (e.g., care transitions, including transitions from nursing facilities, and other institutions to community settings, patient-reported outcomes/intermediate outcomes collected through enrollee surveys, condition-specific measures, SNP-specific measures, measures for people with disabilities, mental health measures related to substance abuse and suicide, and outcomes based measures for MTM).

- We have also heard concerns from organizations and sponsors with low enrollment that certain measures (such as complaints and appeals) and associated star assignments may be sensitive to small measure denominator size. For the 2016 Star Ratings, we proposed to expand the measurement period for the Complaints about the Health Plan/Drug Plan measures and the Appeals Upheld (Part D) measure to 12 months to increase the number of enrollees included in these measures. This should help minimize any potential concerns, but we welcome feedback from sponsors on this matter, including analysis reflecting any sensitivity issues and potential solutions.

In addition, we are interested in feedback to whether organization-specific cut points are relevant for some Part D measures, when organization type should not result in performance differences. For example, the MPF price accuracy measure evaluates differences in a Part D Sponsors' submitted MPF price files and PDE files, and CMS questions if MA-PDs and PDPs are comparable for this process measure and could be measured together.

Audit & Oversight

Program & Compliance Plan Audit Performance

Since the fall of 2014, CMS has released four HPMS memos regarding best practices, improvement strategies and common findings from program audits, which are meant to be educational for plan sponsors. These memos discuss CMS audit findings related to common compliance violations that resulted in the improper denial of access to care for beneficiaries. Despite our release of these memos and various other outreach efforts, CMS has not found that program audit performance has improved. We strongly encourage plan sponsors to utilize the evaluation tools and information that we have made available to proactively verify that their organizations are compliant with CMS requirements. Organizations must confirm that necessary access to drugs and health services remains uninterrupted for beneficiaries. As a reminder, CMS can pursue enforcement actions including sanctions or civil money penalties for plan sponsors that substantially fail to meet this requirement.

New Program Audit Modules

As announced earlier this year via HPMS memo, CMS will pilot two new audit modules during 2015. These modules will test compliance with Medication Therapy Management (MTM) and Provider Network Adequacy requirements. Organizations are on notice that the two modules will be revised based on our experience in 2015 and made permanent for contract year 2016, consistent with past similarly piloted audit modules.

Integrated Dual-Eligible Special Needs Plans

As first articulated in the 2012 Draft Call Letter, we are working to promote integrated care for Medicare-Medicaid enrollees. We would like to streamline administrative requirements in order to offer Medicare-Medicaid enrollees a more seamlessly integrated benefit, facilitate state efforts to use D-SNPs as a vehicle for delivery of coordinated Medicare and Medicaid benefits, and ease the regulatory burden on MAOs that contract to offer highly integrated D-SNPs with both states and CMS. Through a Memorandum of Understanding reached with the state of Minnesota http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/

Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MNMOU.pdf, we use administrative flexibilities in a number of areas, including marketing and regulatory oversight, to further these goals.

We are interested in extending these flexibilities to D-SNPs that meet the high standard for integration of Medicare and Medicaid benefits articulated in the CY 2013 Call Letter and section 40.4.4 of Chapter 16b of the Medicare Managed Care Manual. Below we reiterate existing administrative mechanisms for promoting that alignment. In order to inform our ongoing efforts, we also seek comment on additional administrative flexibilities that may further these goals, including the:

- Development of materials that better communicate the integrated benefit to the Medicare-Medicaid enrollee population, including materials in alternative formats and languages other than English for Medicare-Medicaid enrollees who require such materials;
- Enhanced coordination of state and CMS regulatory oversight; and
- Integration of state quality-of-care priorities into the care delivery provided by highly integrated D-SNPs.

Seamless Conversion Enrollment Option

Entities that offer Medicaid Managed Care Organizations (MCO) and also offer integrated D-SNPs can promote coverage of an integrated Medicare and Medicaid benefit through seamless conversion enrollment of Medicaid MCO members as they become eligible for Medicare. In Chapter 2 of the Medicare Advantage Manual, we provide guidance for how MAOs may request CMS approval to offer the seamless conversion option for newly Medicare eligible individuals allowed under Sec. 1851(c)(3)(ii). In order to access information on Medicare eligibility dates for individuals who will become eligible for Medicare because of disability, plans may work with the state Medicaid agency, which receives advanced notice of individuals' eligibility via their "State MMA" file exchange with CMS.

MAOs interested in exercising this option must send proposals to the appropriate Regional Office account manager in order for CMS to review the proposal and approve its use. Criteria for CMS approval are outlined in section 40.1.4 of Chapter 2 and include the requirement that the MAO have a process for identifying individuals currently enrolled in the Medicaid Managed Care Organization no later than 90 days prior to the date of initial Medicare eligibility, including individuals whose eligibility is based on disability or age. We are also interested in comments on MAOs' experience seeking approval for this option and any suggestions for improving the approval process.

Promoting Integrated D-SNPs

Both states and their contracted D-SNPs have the ability to reach out to and inform Medicare-Medicaid enrollees of their option to enroll in D-SNPs that provide integrated Medicare and

Medicaid benefits. As explained in section 70.6 of the Medicare Marketing Guidelines, health plans may contact current Medicare Advantage, Prescription Drug Plan, and Medicaid managed care members to promote other Medicare products they offer, including their integrated D-SNPs and their MMPs.

We also note that the CY 2013 Final Call Letter explained that states may use outreach and education or provide information to current or prospective Medicare beneficiaries in order to make beneficiaries aware of D-SNP products that integrate Medicare and Medicaid benefits.

Benefit Flexibility for Highly Integrated, High Performing D-SNPs

In our final rule issued April 2, 2012, we amended our regulations at 422.102(e) to allow certain D-SNPs that meet high integration and performance standards to offer supplemental benefits beyond those permitted for MA plans, such as non-skilled in-home support services, caregiver supports, assistive devices for home safety and the other benefits described in the CY 2013 Final Call Letter. (77 FR 22117). In the CY 2013 Final Call Letter we described the contract design requirements, qualifying criteria and conditions for DSNPs seeking this benefits flexibility, and the types of benefits we would approve under this initiative. We are interested in expanding the number of D-SNP enrollees who could benefit from this flexibility and are using this draft Call Letter to remind D-SNPs, as well as the states that contract with D-SNPs for delivery of Medicaid benefits, of the availability of this flexibility. In the past, we have requested that D-SNPs intending to offer supplemental benefits submit a request to CMS by early March, so that CMS may review and determine if these plans meet required qualifications to do so by early May. Our past experience suggests that notifying D-SNPs in May about whether we will permit them to offer supplemental benefits is too late for them to structure their benefit package to take advantage of this flexibility for the upcoming contract year. To provide D-SNPs with more lead time to be able to take advantage of this flexibility, this year we required that plans submit a request to offer supplemental benefits to CMS no later than January 30, 2015 for CY 2016. CMS will notify those D-SNPs that requested to offer additional supplemental benefits for CY 2016 as to whether they meet required qualifications in late February 2015. Information about the process to request to offer additional supplemental benefits and how to qualify to do so was provided to the industry via a HPMS memo released on January 20, 2015. For CY 2017, we are planning to start this process even earlier. We will provide more details as to any changes in the process for CY 2017 via HPMS memo.

We also seek recommendations on whether updating the contract design requirements, qualifying criteria, or other conditions could increase the number of highly integrated, high performing D-SNPs that take advantage of this flexibility to provide beneficiaries with supplemental benefits.

State Access to D-SNP CAHPS Data

Certain states that contract with D-SNPs for delivery of Medicaid benefits to Medicare-Medicaid enrollees have expressed interested in receiving beneficiary-level data on CAHPS survey for D-SNPs with which they contract in order for the state to obtain a more granular picture of plan performance and assess disparities in care. States may obtain this beneficiary-level data for their use by entering a data use agreement with CMS. More information is available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/States.html or through contacting CMS at DataUseAgreement@cms.hhs.gov.

Value-Based Contracting to Reduce Costs and Improve Health Outcomes

Commercial organizations as well as CMS have increasingly taken steps to make certain that health care providers operate most efficiently, reduce costs, and improve the health outcomes of patients. Such programs often involve physician incentive programs and frequently include financial incentives paid to providers. The Affordable Care Act provides primary care incentive payments, for example, to physicians meeting specific qualifications designed to improve and encourage primary care and the Medicare Shared Savings Program, a new way for Medicare to support high quality, efficient care over time. Through the Innovation Center, CMS is testing on a large scale a wide variety of new payment models including different type of accountable care organizations, bundled payments for episodes of care or related health care services, and primary care medical homes. The overall goal of these payment models is to improve quality of care and reduce its cost. More specific goals include reducing hospital readmissions and improving performance on specific health care measures.

In order for these models to succeed in the long term, health care providers must make operational changes within their organizations. These changes will only be attractive if a critical mass of payers, including CMS, supports these new financial models for health care payment. Therefore, in order to test and evaluate new payment models effectively, CMS will be reaching out to and having conversations with MA organizations regarding how they are using physician incentive payments (e.g. payments based on quality of care, patient satisfaction) and value-based contracting of provider services to achieve these goals. Based on this input, we will also, this year, ask MAOs to share data regarding their adoption of alternative payment models. In the context of value-based contracting we are also interested in comments from MAOs regarding issues or concerns they may have regarding compliance with the physician incentive regulations at 422.208. We note that, under this regulation, MAOs must guarantee that stop-loss insurance is in place if their physicians are at risk for more than 25 percent of their potential income based on the use or cost of referrals they make. MAOs have great flexibility to include incentives in their physician contracts and many are employing methods to reduce costs, better coordinate care and promote better health outcomes. CMS wants to work with organizations and other key stakeholders, including hospitals and other providers, to explore and better understand possible means for achieving those goals with the idea of incorporating the most successful of these methods, more fundamentally, into MA program policies. In addition, CMS may consider future rulemaking to require MAOs to report plans' use of alternative payment models to CMS.

Section II – Part C

Overview of CY 2016 Benefits and Bid Review

Portions of this guidance apply to cost-based plans and MA plans (including EGWPs, D-SNPs, Chronic Care Special Needs Plans (C-SNPs), and Institutional Special Needs Plans (I-SNPs)). We currently do not evaluate whether employer group plans, D-SNPs, and cost-based plans are duplicative under §422.256(b)(4), also referred to as the "meaningful difference" evaluation. Similarly, employer group plans and cost-based plans are not evaluated for low enrollment under § 422.506(b)(1)(iv) and (b)(2). Please note: 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 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 1, 2015 deadline. Any organization whose bid fails the published Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference, Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may be dependent on the type and/or severity of errors.

The following chart displays key MA bid review criteria and identifies which criteria apply to the plan types identified in the column headings.

Table 1. 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	Yes	Yes	No	No
Meaningful Difference	Yes	No	No	No
Total Beneficiary Cost	Yes	No	No	No
Maximum Out-of –Pocket (MOOP) Limits	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing	Yes	Yes	No	Yes
Service Category Cost Sharing	Yes	Yes	Yes[1]	Yes
Part C Optional Supplemental Benefits	Yes	Yes	No	No

[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)).

We have made changes to service category cost sharing amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) limits for CY 2016 and have provided these changes in each applicable section below. Consistent with past years, MAOs must also address 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, we are not making specific adjustments or allowances for these changes in our benefits review requirements.

Plans with Low Enrollment

Under 42 CFR §422.506(b)(1)(iv) and (b)(2), CMS will send affected MAOs a list of plans that have fewer than 500 enrollees for non-SNP plans or fewer than 100 enrollees for SNP plans and have been in existence for three or more years as of March 2015 (three annual election periods). The notice will serve as CMS’ decision not to renew such plans. The list will not include plans with low enrollment that CMS determined were 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 establishes a viable plan option for enrollees).

MAOs must either confirm, through return email, that each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization’s plans for CY 2016, or they must provide a justification for renewal. If CMS does not find a unique or compelling reason that the plan is a viable independent option for enrollees in order to maintain the plan with low enrollment, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting business cases and the information required in those submissions 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 lead 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 the CY 2016 renewal/non-renewal guidance (see the Medicare Managed Care Manual: section 150 of Chapter 4 per HPMS memo released November 7, 2014, and/or section 60.3 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 §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. For CY 2016, CMS will 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. Documentation and instructions for the OOPC model are available at: [http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html)

Last year in evaluating meaningful difference, CMS considered HMO and HMO-POS as one plan type, unless the HMO-POS plan covered all Parts A and B services outside the network, in which case the HMO-POS plan was considered meaningfully different from the HMO plan. This standard for evaluating meaningful difference will remain for CY 2016.

In the 2015 Draft Call Letter (page 101), CMS proposed to consider HMO-POS plans meaningfully different only if the plans do not place geographic or provider limitations on the out-of-network benefits. CMS is not implementing this proposed approach for CY 2016, but may in future years. For CY 2017, CMS will also consider applying the meaningful difference evaluation at the "legal entity"/MAO level rather than the "contract" level as the evaluation is currently performed. In addition we are considering future rulemaking to ultimately broaden our authority to the "parent organization level" to make certain that plans offered by the same parent organization in the same county are meaningfully different. However, we would continue to apply the current plan type and SNP flexibilities discussed in the methodology below. We invite MAOs to provide comments to CMS regarding this potential change in policy for CY 2017 and beyond.

CMS will evaluate meaningful differences among CY 2016 non-employer and non-cost contractor plans offered by the same MAO, in the same county and, under the same contract, as follows:

1. The MAO's plan offerings will be separated into five plan type groups on a county basis: (1) HMO and HMO-POS not offering all Parts A and B services out-of-network; (2) HMO POS offering all Parts A and B services out-of-network; (3) Local PPO; (4) Regional PPO; and (5) PFFS.

2. SNP plan offerings will be further separated into groups representing the specific target populations served by the SNP. Chronic Care SNPs will be separated by the chronic disease served and Institutional SNPs will be separated into the following three categories: Institutional (Facility); Institutional Equivalent (Living in the Community); and a combination of Institutional (Facility) and Institutional Equivalent (Living in the Community). We currently do not apply the meaningful difference evaluation to D-SNPs.

3. Plans within each plan type group will be further divided into MA-only and MA-PD sub-groups for evaluation. That is, the presence or absence of a Part D benefit is considered a meaningful difference.

4. The OOPC (Part C and Part D) PMPM estimate will be calculated for each plan. CMS considers 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.

Please note that plan characteristics, such as premium, variations in provider networks, and/or serving different populations are not considered meaningfully different characteristics. CMS has received requests to change its meaningful difference interpretation and analysis to allow provider network and/or premium differences to constitute a meaningful difference between similar plan offerings. While we considered these requests, CMS is maintaining its current interpretation that excludes premium differences from the criteria since the regulatory meaningful difference requirement is intended to be an objective measure of benefits between two plans and the inclusion of premium would introduce risk selection, costs, and margin into the evaluation and negate the evaluation's objectivity. Network differences have also been excluded from our criteria because having a provider in one plan and not the other is not a change in benefit coverage. We note that MAOs are permitted to tier medical benefits within limits and provide lower cost sharing to enrollees that use more effective providers within an individual plan.

CMS expects MAOs to submit CY 2016 plan bids that meet the meaningful difference standards, but will not prescribe how the MAOs should redesign benefit packages to achieve the differences. Furthermore, MAOs will have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission and CMS will not approve plan bids that do not meet these standards. MAOs must follow the CY 2016 renewal/non-renewal guidance in the final Call Letter to determine if their plans may be consolidated with other plans.

NOTE: Please see policy updates below for changes to PBP that will impact the OOPC model and may potentially affect the meaningful difference evaluation for certain plans.

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 confirm 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).

MAOs have described potential challenges in complying with the TBC standard, in light of other payment-related changes. CMS has focused on sharing information and providing transparency as it relates to the TBC year-to-year evaluation. As such, plans are expected to anticipate and manage changes in quality compensation, county benchmark, coding intensity, and other environmental factors to minimize changes in benefit and cost sharing over time.

Consistent with past years, in mid-April CMS will provide plan specific CY 2015 TBC values and the following adjustments that are incorporated in the TBC calculation to account for changes from one year to the next:

- Technical Adjustments: (1) annual changes in OOPC model software and (2) maximum Part B premium buy-down amount change in the bid pricing tool (no change for CY 2016).
- Payment Adjustments: (1) county benchmark, (2) coding intensity, and (3) quality bonus payment and/or rebate percentages.

CMS will continue to use a TBC threshold at $32.00 PMPM for CY 2016. A plan experiencing a net increase in adjustments must have an effective TBC change amount below the $32.00 PMPM requirement to avoid denial of the bid under section 1854(a)(5)(C)(ii). Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the

$32.00 PMPM requirement. In an effort to support plans that improve quality compensation and experience large payment adjustments, along with holding plans accountable for lower quality, we are considering modifications to TBC evaluation. For CY 2016 we are proposing the TBC change amount to be treated differently for the following specific situations:

- Plans with an increase in quality bonus payment and/or rebate percentage, and an overall payment adjustment amount greater than $32.00 PMPM would have a deemed TBC change amount of $0.00 PMPM (i.e., -1 times the TBC change limit of $32 PMPM) plus applicable technical adjustments.
- Plans with a decrease in quality bonus payments and/or rebate percentage, and an overall payment adjustment amount less than -$32.00 PMPM would have a TBC change amount of $64.00 PMPM (i.e., 2 times TBC change limit of $32.00 PMPM) plus applicable technical adjustments. That is, plans would not be allowed to make changes that result in greater than $64.00 worth of decreased benefits or increased premiums.
- Plans with a star rating below 3.0 and an overall payment adjustment amount less than -$32.00 PMPM would have TBC change amount of $64.00 PMPM (i.e., 2 times TBC change limit of $32.00) plus applicable technical adjustments.

Plans with a 3.0 or higher star rating that experience no change in quality bonus payment and/or rebate percentages from CY 2015 to CY 2016 are not affected by this modification to the TBC evaluation. We remind MAOs that the Office of the Actuary extends flexibility on margin requirements so MAOs can meet the TBC standard. CMS will provide detailed operational guidance via an HPMS memo and will post TBC adjustment factors in HPMS in April.

Under §422.254, CMS will reserve 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. For organizations consolidating multiple CY 2015 plans into a single CY 2016 plan, CMS will use the enrollment-weighted average of the CY 2015 plan values to calculate the TBC. Otherwise, these plans will be treated as any other plan for the purpose of enforcing the TBC requirement. CMS had contemplated requiring each individual plan to be "crosswalked" into another plan to meet the TBC threshold on its own merit and discontinue the use of the enrollment-weighted average for multiple plans "crosswalked" into one plan to determine TBC for CY 2016. We will not move forward with this requirement for CY 2016, but will consider it in future years.

For CY 2017, CMS is considering an additional modification to the TBC evaluation and welcomes comments on this additional modification prior to preparing proposals for CY 2017. We intend to "discount" the plan-specific payment adjustment for both increases and decreases in payments. For example, if CMS set the "discount" at ten percent (10%), each plan's net payment adjustment would be multiplied by 0.90 to establish the discounted adjustment factor. This modification would be applied to all plans subject to the TBC evaluation. Since the ACA benchmark transition nears completion, it is our expectation that MAOs are better positioned to share payment changes and provide affordable and effective benefits for beneficiaries.

NOTE: Please see policy updates below for changes to PBP that will impact the OOPC model and may potentially affect the TBC evaluation for certain plans.

Maximum Out-of-Pocket (MOOP) Limits

Table 2 below displays the CY 2016 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to LPPOs and RPPOs. 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.

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. We chose to display the ranges of cost sharing within which plans may establish their MOOPs 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.

Table 2. CY 2016 Voluntary and Mandatory MOOP Range Amounts By Plan Type

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

Although it may be rare that a dual-eligible enrollee would be responsible for paying any cost sharing because the State Medicaid program is making those payments on his/her behalf, all MA plans must track enrollees' actual 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, some dual-eligible enrollees may incur cost sharing and any enrollee losing his/her Medicaid eligibility would be responsible for cost sharing. Currently, SNPs have the flexibility to establish $0 as the MOOP amount, thereby guaranteeing there is no cost sharing for plan enrollees. Otherwise, if the SNP does charge cost sharing for covered services, it must track enrollees' out-of-pocket spending. The plan must develop its own process and vehicle for tracking this spending.

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. CMS will also apply this requirement separately to the following service categories for CY 2016: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. Please note that factors for Inpatient and SNF in Column 4 of the table below (Part B Adjustment Factor to Incorporate Part B Cost Sharing) have been updated for CY 2016.

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 Bid Pricing Tool (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 facility and SNF 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 chart below uses illustrative values to demonstrate the mechanics of this determination.

Table 3. 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	1.397	$35.34	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.068	$10.56	$0.27	Fail
DME	$3.00	$11.37	$2.65	1.000	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1.000	$0.33	$0.00	Pass

[1] PMPM values in column 3 for Inpatient and Skilled Nursing Facility only reflect Part A fee-for-service actuarial equivalent cost sharing for that service category.

Part C Cost Sharing Standards

We will continue our 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 a higher, mandatory MOOP limit. Table 4 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans that we will not consider discriminatory or in violation of the applicable standards. CY 2016 bids must reflect enrollee cost sharing for in-network services no greater than the amounts displayed below. For LPPOs and RPPOs, these standards will be applied only to in-network services. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. Inpatient and Emergency standards have been updated to reflect estimated changes in Original Medicare cost for CY 2016.

Table 4. CY 2016 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient - 60 days	1a	N/A	$4,209
Inpatient - 10 days	1a	$2,444	$1,955
Inpatient - 6 days	1a	$2,218	$1,774
Mental Health Inpatient - 60 days	1b	$2,599	$2,079

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Mental Health Inpatient - 15 days	1b	$1,953	$1,562
Skilled Nursing Facility – First 20 Days[1]	2a	$40/day	$0/day
Skilled Nursing Facility – Days 21 through 100[2]	2a	$160.00/day	$160.00/day
Emergency Care/Post Stabilization Care	4a	$75	$75
Urgently Needed Services[3]	4b	$65	$65
Partial Hospitalization	5	$55/day	$55/day
Home Health	6a	20% or $35	$0
Primary Care Physician	7a	$35	$35
Chiropractic Care	7b	$20	$20
Occupational Therapy	7c	$40	$40
Physician Specialist	7d	$50	$50
Psychiatric and Mental Health Specialty Services	7e and 7h	$40	$40
Physical Therapy and Speech-language Pathology	7i	$40	$40
Therapeutic Radiological Services	8b	20% or $60	20% or $60
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10
Renal Dialysis	12	20% or $30	20% or $30
Part B Drugs-Chemotherapy[4]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

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

[2] MA plans may have cost sharing for the first 20 days of a SNF stay. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost

sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).
[3] Emergency Care and Urgently Needed Care benefits are not subject to a service category and/or plan level deductible amount and/or out-of-network providers.
[4] Part B Drugs - Chemotherapy cost sharing displayed is for services provided on an outpatient basis and includes administration services.

MAOs have the option to charge either coinsurance or a copayment for most service category benefits. For example, based on the cost sharing requirements indicated above for Part B Drugs – Chemotherapy, a plan can choose to either assign up to a 20% coinsurance or $75 copayment to that particular benefit. Please note that MAOs with benefit designs which use 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. This documentation must be submitted as part of supporting documentation for the Bid Pricing Tool as described in the Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2016, Appendix B-Supporting Documentation.

CMS annually evaluates available Medicare data to establish our requirements in accordance with applicable law. We remind organizations that MA plan offerings are not required to have the same cost sharing amounts for both emergency care and urgently needed services. Organizations are afforded the flexibility to design their benefits as they see fit as long as they satisfy Medicare coverage requirements.

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. As in CY 2015, we consider a plan to be not 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%.

We understand 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.

PBP Updates and Guidance

Medical Services Performed in Multiple Health Care Settings

Currently, the same medical service may be entered in multiple PBP service categories, since a single service can be performed in different health care settings (e.g., physician office, outpatient hospital, and free standing facility). CMS is taking this opportunity to clarify our expectations with regard to placing these services in the appropriate service category and correctly completing data entry within the PBP.

Outpatient service categories in the PBP have historically included a variety of services that may have their own dedicated PBP category. By including the same service in multiple locations throughout the PBP, we are concerned that marketing materials may be confusing and that CMS cost sharing requirements could 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 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).

Our goal is to ultimately adjust selected PBP service categories to reflect the services provided across a variety of different places of service. For example, Cardiac and Pulmonary Rehabilitation Services can be administered in a variety of settings including outpatient hospitals, free- standing facilities, or a physician’s office. Instead of having these services appear in multiple PBP service categories, we will expect cost sharing for these services to appear only in PBP Service Category 3 (Cardiac and Pulmonary Rehabilitation Services). The minimum/maximum data fields will reflect the varying cost sharing associated with different places of service. The note for this service category will describe the cost sharing associated with the various places of service and must be consistent with the data entry. Cardiac and Pulmonary Rehabilitation Services in any other section of the PBP will not satisfy CMS requirements and the organization will be asked to correct its bid submission.

This is a change from what we have allowed in the past and may impact benefit design and estimated OOPC. Further, these changes may have an impact on the TBC and meaningful difference evaluation for some plans. As a result, we intend to implement these changes over the next two years and here provide organizations with our expected changes for both CY 2016 and CY 2017 for bid planning purposes. For CY 2016, we expect the service categories listed in the table below to reflect cost sharing for services provided in all outpatient settings.

PBP Sec. B	**Service Category**
3	Cardiac and Pulmonary Rehabilitation Services
7a	Primary Care Physician Services
7d	Physician Specialist Services excluding Psychiatric Services
7f	Podiatry Services
9d	Outpatient Blood Services
11b	Prosthetics/Medical Supplies
12	End-Stage Renal Disease
14a	Medicare-Covered Zero Cost-Sharing Preventive Services
15	Medicare Part B Rx Drugs and Home Infusion Drugs

One area of particular concern is Medicare-covered preventive services. All Medicare-covered zero cost sharing preventive services must be included in PBP Service Category 14a and must not be included in any other service category. For plans choosing to provide preventive services that do not have zero cost sharing under Original Medicare, these services must be included in PBP Service Category 13d, 13e, or 13f (Other) with the exception of glaucoma screening. Glaucoma screening must be included under PBP Service Category 17a (Eye Exams) and included in the cost sharing as any other service.

For CY 2017, we intend to expand our requirement to the service categories listed in the table below to reflect cost sharing for services provided in all outpatient settings. We are also considering making changes to the service categories for PBP Section B-8a, 8b, 9a, and 9b because we have found these sections to reflect duplicative information which have created confusion. We are proposing to change the title of B-8a from “Outpatient Diagnostic Procedures and Tests and Lab Services” to “Diagnostic Procedures and Tests and Lab Services” and 8b from “Outpatient Diagnostic and Therapeutic Radiological Services” to “Diagnostic and Therapeutic Radiological Services,” remove or disable 9a entirely, and rename 9b from “Ambulatory Surgical Center Services” to “Outpatient Surgeries.”

PBP Sec. B	2016 Service Category Titles	Proposed 2017 Service Category Titles
7c	Occupational Therapy Services	No change
7g	Other Health Care Professional Services	No change
7i	Physical therapy and Speech Language Pathology Services	No change
8a	Outpatient Diagnostic Procedures and Tests and Lab Services	Diagnostic Procedures and Tests and Lab Services
8b	Outpatient Diagnostic and Therapeutic Radiological Services	Diagnostic and Therapeutic Radiological Services
9a	Outpatient Hospital Services	Remove/disable
9b	Ambulatory Surgical Center Services (ASC)	Outpatient Surgeries

Organizations are invited to provide comments on our proposed changes and/or provide feedback on how these service categories may be changed in order to more accurately reflect benefits being provided to enrollees.

Service Category Titles

The following Plan Benefit package (PBP) service category titles and data entry guidance will be changed for CY 2016 to align with Medicare Managed Care Manual, Chapter 4 terminology and to further refine benefit descriptions:

- “Web/Phone Technology” name has been changed to “Remote Access Technologies”
- “Membership in Health Club/Fitness Classes” has been changed to “Fitness Benefit”
- “Weight Management Programs and Alternative Therapies” will be listed with the other defined supplemental benefits in 14C.
- “Readmission Prevention” will have a drop down of the services that are included within the benefit, such as medication reconciliation, bathroom safety and meals (this is separate from the 13c meals service category)
- “Worldwide Emergency/Urgent Coverage” in 4c will specify the benefit covers both emergent and urgent care.
- “Nursing Hotline” will be removed and will now be considered “Remote Access Technologies”

Tiered Cost Sharing of Medical Benefits

MAOs may choose to tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data. In addition to other standards for this plan design that are provided in the Medicare Managed Care Manual, Chapter 4, the tiered cost sharing must be applied so that all plan enrollees are charged the same cost sharing amount for any specific provider and all providers are available and accessible to all enrollees in the plan.

We are revising the PBP so that MAOs can more clearly describe their tiered benefit structure using data entry. The PBP will incorporate a new screen that includes a pick list of service categories that may have tiered cost sharing. The MAO must indicate which medical benefit service categories are subject to tiered cost sharing on this screen. The MAO must then complete the minimum and maximum data entry fields in each service category selected along with providing a note describing the tiering structure within that benefit.

Consistent with past years, CMS expects MAOs to submit a proposal summarizing their intent to tier medical benefits prior to bid submission. For CY 2016, MAOs will be submitting tiering requests to CMS through an electronic mailbox and will no longer need to contact the Regional Office Account Manager. Details regarding the process will be provided in an HPMS memo in April.

Policy Updates

Part C Emergency/Urgently Needed Services Deductible Guidance

In the CY 2015 Final Call Letter, CMS stated enrollees utilizing the Emergency Care/Urgently Needed Service benefits are not subject to a service category or plan level deductible amount; however, enrollee cost sharing associated with Emergency and Urgently Needed Service visits always applies toward a plan level deductible. However, beginning in CY 2016, in an effort to separate the Emergency Care/Urgent Needed Services from the plan level deductible in its entirety, CMS is proposing to eliminate the stipulation that all cost sharing associated with Emergency/Urgently Needed Services apply toward any plan-level deductible. We are inviting comments on this proposal.

Annual Physical Exam Supplemental Benefit

Under our current rules, MA plans may choose to offer benefits to enrollees in addition to the covered Medicare Parts A, B, or D benefits as supplemental benefits. Guidance on the criteria CMS applies in determining whether or not specific additional items and services qualify for inclusion in a plan's benefit package are described in Chapter 4 of the Medicare Managed Care Manual, titled "Benefits and Beneficiary Protections." Subject to CMS approval under 42 CFR § 422.102(a)(3), MA plans may offer Annual Physical Exams as mandatory supplemental benefits for all enrollees in the plan. (SNPs are expected to provide higher levels of enrollee assessment than non-SNP MA plans and therefore, may not offer Annual Physical Exams as supplemental benefits (Final Call Letter, April 2, 2012).)

Currently, about 65 percent of MA plans choose to provide an Annual Physical Exam as a supplemental benefit to their enrollees; however, the components of the exam benefit offered vary across plans. We believe that an Annual Physical Exam could be useful to MA enrollees because it engages them with their providers, helps screen for diseases, promotes preventative care, including vaccination(s), encourages a healthy lifestyle and assesses risk for future medical problems. We believe that providing clarification regarding the Annual Physical Exam, will improve MAOs understanding of what comprises an Annual Physical Exam and help differentiate the from Medicare Annual Wellness Visits (AWV).

Beginning for CY 2016, an Annual Physical Exam will qualify as a supplemental benefit if it is provided by a qualified physician or qualified non-physician practitioner, hereafter referred to as a practitioner. At a minimum, the exam must include a detailed medical/family history and the performance of a detailed head to toe assessment with hands-on examination of all the body systems. For example, the practitioner must use visual inspection, palpation, auscultation and manual examination in his/her full examination of the enrollee to assess overall general health and detect abnormalities or signs that could indicate a disease process that should be addressed.

Other aspects of the Annual Physical Exam may include, as appropriate, follow-up orders for referral to other practitioners, lab tests, clinical screenings, EKG, etc. The Annual Physical Exam also should emphasize prevention, i.e., the recommendations for preventive screenings, vaccination(s), and counseling about healthy behaviors.

We seek comments on our description of the Annual Physical Exam that qualify as supplemental benefits.

Exceptions to Policies Permitting Plans to Limit Durable Medical Equipment (DME) to Certain Brands and Manufacturers

As codified at 42 CFR §422.100(l)(2), MA organizations may, within specific categories of durable medical equipment (DME), limit coverage of DME to certain brands or manufacturers. The categories of DME that may be limited are those that are essentially interchangeable. DME items that are specifically tailored to individual needs may not be limited to certain brands or manufacturers. Section 42 CFR §422.100(l)(2)(vii) codifies the requirement that MA plans provide full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories determined annually by CMS to require full coverage. Details regarding applicable items for CY 2016 are provided below; the items identified remain unchanged from CY 2015.

We have identified one category of DME that may not be subject to full limitation based on brand/manufacturer for CY 2016: Speech-Generating Devices. People who require speech-generating devices frequently have other disabilities; the speech-generating device is generally tailored to meet the individual's needs. For example, a child with cerebral palsy (CP) could accidentally change a setting on some devices and therefore, should be furnished with a device that is sensitive to the movements of a child with CP. Consequently, MA plans may not limit coverage to a specific brand or type of device; rather, they must furnish any medically-necessary speech-generating device purchased by an enrollee.

The following four categories of DME may be subject to partial limitation based on brand or manufacturer. Partial limitation means that plans may limit coverage based on brand or manufacturer, provided that the plan covers all items in the subcategories below:

(1) Oxygen: Plans may limit oxygen by brand and manufacturer provided that all modalities – concentrator, liquid and gaseous – are made available.

(2) Wheelchairs: Plans may limit brands and manufacturers of standard manual and power wheelchairs within HCPCS codes, but must provide all categories (i.e., HCPCS codes) of Group I and II wheelchairs.

(3) Powered Mattress Systems (HCPCS code E0277): There is no medical evidence that one type of powered mattress system is more effective than others in preventing pressure ulcers. However, for this code, there are two major, distinct technologies: alternating pressure, and low air loss. Consequently, MA plans may limit brands and manufacturers of these items, but must furnish at least one product from each of the two distinct technologies.

(4) Diabetic supplies: We allow plans to limit diabetic supplies by brand and manufacturer provided that both large-font monitors for the visually impaired and large-button monitors for individuals with arthritis are furnished.

Contract Consolidations

CMS encourages MAOs operating more than one MA-PD contract of the same product type under the same legal entity to consolidate these contracts under a single contract ID for contract year CY 2016. Please note this is separate from an MAO's request to consolidate individual plans, leaving one plan under a single contract ID. MAOs are not permitted to consolidate contracts of different product types.

MAOs can offer the following product types:

- MA-PD Health Maintenance Organization (HMO)/Health Maintenance Organization Point of Service (HMOPOS)
- MA-PD Local Preferred Provider Organization (PPO)
- MA-PD Regional PPO
- MA-PD Provider Sponsored Organization (PSO)
- MA-PD Private Fee-For-Service (PFFS) (with Part D)

- Medicare Advantage (MA) Only – PFFS
- MA Only – Medical Savings Account (MSA)
- Prescription Drug Plan (PDP)
- Employer/Union Direct Contract PFFS no Part D
- Employer/Union Direct Contract PFFS with Part D
- Employer/Union Direct Contract MA-PD Local Preferred Provider Organization (LPPO)
- Employer/Union Direct Contract PDP

CMS requests that an MAO seeking to consolidate multiple contracts under the same legal entity submit a formal request to CMS on plan letterhead in PDF format which includes the following:

- How the MAO came to operate more than one contract of the same plan type (e.g. different service areas, acquisitions, etc.);
- The contract(s) to be consolidated, and the contract ID into which the MAO wishes to consolidate the contract(s);
- The service area covered by the contracts;
- The plan types under the contracts (e.g. employer group waiver plans, SNP plans); and
- Any pending applications under the contracts.

CMS provided specific guidance on the content of consolidation requests via an HPMS memo dated February 6, 2015. CMS requires that all contract consolidation requests be submitted by **April 15, 2015** at https://dmao.lmi.org. CMS will notify MAOs regarding the approval or denial of their request by May 2015.

Limiting Applications

CMS has received inquiries from organizations wishing to apply for a separate contract for the same product type that they are already operating under an existing contract. Organizations can request a new contract ID for the following product types that they do not already operate:

- MA-PD Health Maintenance Organization (HMO)/Health Maintenance Organization Point of Service (HMOPOS)
- MA-PD Local Preferred Provider Organization (PPO)
- MA-PD Regional PPO
- MA-PD Provider Sponsored Organization (PSO)
- MA-PD Private Fee-For-Service (PFFS) (with Part D)
- Medicare Advantage (MA) Only – PFFS
- MA Only – Medical Savings Account (MSA)
- Prescription Drug Plan (PDP)
- Employer/Union Direct Contract PFFS no Part D
- Employer/Union Direct Contract PFFS with Part D
- Employer/Union Direct Contract MA-PD Local Preferred Provider Organization (LPPO)
- Employer/Union Direct Contract PDP

CMS would like to remind existing organizations that CMS will not assign a new contract ID to existing legal entities for product types they currently contract with CMS. If a legal entity would like to broaden its service area (or add Employer Group Waiver Plans or individual plans), that legal entity should complete a Service Area Expansion (SAE) request for its existing contract ID. Please note that Non-network PFFS products transitioning to a full network are exempt from this requirement. If a legal entity would like to offer a SNP as one of their HMO offerings and the entity already holds an HMO/HMOPOS contract, the entity will need to submit a SNP Proposal in order to offer that plan type under their existing HMO contract. CMS will not permit the organization to operate a SNP as a separate HMO contract from their existing HMO contract.

MA/MA-PD Application Change

An organization must meet certain requirements in order to hold an MA contract with CMS (see 42 CFR §422.503) and meet minimum enrollment thresholds (see § 422.514). For example, the organization applying for an MA contract should be able to handle risk and capitated payments. In addition, CMS expects that an organization is able to effectively manage a health care delivery system, including:

- The enrollment and disenrollment of members,
- Timely payment of claims,
- Providing quality assurances, and
- Having systems to handle grievances and appeals.

CMS recognizes that new applicants may believe they are capable of administering and managing an MA contract even when they do not meet the minimum enrollment requirement. CMS also recognizes that there may be reasonable factors, such as specific populations served or geographic location, which might result in a plan having low enrollment. For example, SNPs may legitimately have low enrollment because they focus on a subset of enrollees with certain medical conditions. Such organizations and new applicants may submit a request to waive the enrollment requirement. CMS regulations at 42 CFR §422.514(b) provide for a transition period allowing CMS to waive the minimum enrollment requirement during an organization's first three years of operation.

CMS has developed a minimum enrollment waiver request attestation and a minimum enrollment waiver request template as a part of the CY 2016 Part C (Medicare Advantage) and 1876 Cost Plan Expansion Application under the regulations of 42 CFR §422.502(b), §422.503(b)(1), and §422.514. CMS will require applicants to complete and upload into HPMS the minimum enrollment waiver request attestations and template. Applicants should complete these attestations and the template with detailed explanations (and supporting documentation, as necessary) of the applicant's previous experiences, including that of the parent organization and management, in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in 42 CFR §422.514.

The attestations, template, and supporting documentation must demonstrate to CMS' satisfaction that the organization is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. Please see 42 CFR §422.514(b) for factors that CMS may consider in evaluating any waiver request. If CMS determines the applicant is not able to meet the minimum enrollment requirements to be an MA organization, CMS will notify the applicant of these deficiencies only in a Notice of Intent to Deny (NOID). Applicants that receive the NOID are allowed ten (10) days from the date of the notice to respond in writing to CMS' preliminary findings and to revise their application remedying any defects that CMS has identified. If an applicant fails to submit a revised application within ten (10) days from the date of the notice, or a revised application fails to meet the necessary requirements, CMS will deny the application.

Two-Year Prohibition

Section 1857(c)(4)(A) of the Act prohibits organizations from re-entering the MA program in the event that a previous contract with the organization was terminated at the request of the organization within the preceding two-year period. Under section 1857(c)(4) and various regulations, CMS may provide an exception to this prohibition where circumstances warrant special consideration as determined by CMS. In the Contract Year (CY) 2016 Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Program Final Rule, 80 2911, 7945 CMS adopted a final rule to amend the regulations, expanding application of the two-year prohibition (found at 42 CFR §§422.502, 422.503, 422.506, 422.508, and 422.512) to avoid (1) unnecessarily narrowing the scope of the two-year prohibition, or (2) precluding CMS from preventing poor performing MA organizations from reentering the MA program.

Once the new regulation is effective in CY 2015 and moving forward, CMS interprets §§ 422.503(b)(6) and 422.503(b)(7) as authorizing denials of new contracts and service area expansions, consistent with the proposed text for §§ 422.503, 422.506 and 422.512, regardless of the contract type, product type, or service area of the previous nonrenewal. CMS will apply this new interpretation to all organizations that mutually terminate or non-renew a contract starting April 2015, and moving forward.

In the preamble to the Final Rule, CMS also clarified that (1) the two-year prohibition, for purposes of §§ 422.502, 422.506, 422.507, 422.508, and 422.512, is applied at the legal entity level, and that (2) the two-year ban is applicable for the two (2) contract years following the year in which the non-renewal or termination of an organization's contract is effective. For example, if an organization does not renew its contract for an effective date of January 1, 2016, CMS would not enter into a contract with the organization for CYs 2016 and 2017, unless there are circumstances that warrant special consideration, as determined by CMS. The organization can apply to contract with CMS in 2017 to operate in CY 2018. Likewise, if an organization enters a mutual termination for a contract with CMS midyear during 2015, then CMS will not enter into a contract with the organization for CYs 2016 and 2017 absent circumstances warranting special consideration. An organization can, however, apply to contract with CMS in 2017 to operate in CY 2018. CMS understands that there are a variety of reasons that an organization may decide to terminate or to non-renew a contract, and subsequently want to re-enter the program. CMS will consider when circumstances warrant special consideration on a case-by-case basis.

CMS encourages organizations with questions about the applicability of the two-year prohibition to submit them to CMS's Non-Renew/Terminations mailbox located at: https://dmao.lmi.org.

Guidance to Verify that Networks are Adequate and Provider Directories are Current

Regulations at Section 422.111(b)(3)(i) require MAOs, in what CMS considers to be the provider directory, to disclose "the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services…" and Section 422.112 (a)(1) requires that the MAO "maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served." Providers whose practices are closed or who are otherwise unavailable cannot be used to successfully meet our network adequacy standards. CMS has become aware of a range of issues with online provider directories. Recent provider and beneficiary complaints have highlighted problems with the accuracy of some MAO online provider directory information. For example, there have been complaints of directories including providers who are no longer contracting with the MAO, have retired from practice, have moved locations, or are deceased. Additionally, some provider directories contain the names of providers who, while still in the MAO's network, are not open and available to new patients, but are not indicated in that way. Therefore, CMS may view inaccurate provider directories as an indication that the MAO may be failing established CMS standards.

To ameliorate these issues, we are providing additional guidance on our regulatory requirements. MAOs are expected to establish and maintain a proactive, structured process that enables them to assess, on a timely basis, the true availability of contracted providers which includes, as needed, an analysis to verify continued compliance with applicable network access requirements. An effective process will include:

- Regular (at least quarterly) communications/contacts with providers to ascertain their availability and, specifically, whether they are accepting new patients, in addition to requiring contracted providers to inform the plan of any changes to street address, phone number, and office hours or other changes that affect availability; and

- Developing and implementing a protocol to effectively address inquiries/complaints related to enrollees being denied access to a contracted provider with follow through to make corrections to the online directory.

For online directories, MAOs are expected to update information in real-time, and provide complete information regarding providers who are available to new patients/enrollees. We are reinforcing that, in order for us to consider the MAO compliant with § 422.111, MAOs must include in their online provider directories all active contracted providers, with specific notations to highlight those providers who are closed or not accepting new patients.

We will initiate a three-pronged approach to monitor compliance with the regulations, including:

1) Direct monitoring. We have secured additional contractor funding to verify the accuracy of MAOs' online provider directories.
2) Development of a new audit protocol. A new audit protocol will be tested in CY 2015 to further enhance our oversight of the validity and accuracy of MAOs' online directories as well as the availability and accessibility of network providers and whether the lack of availability and accessibility may impact a plan's ability to meet provider network adequacy standards.
3) Compliance and/or enforcement actions. MAOs that fail to maintain complete and accurate directories may be subject to compliance and/or enforcement actions, including civil money penalties or enrollment sanctions. MAOs whose network adequacy is not met because of failure to have a sufficient number of providers open and accepting new patients may also be subject to such actions.

In addition, CMS is considering, beginning on or after CY 2017, instituting a requirement for MAOs to provide, and regularly update, network information in a standardized, electronic format for eventual inclusion in a nationwide provider database. This approach builds upon other Departmental efforts, including pursuit of similar requirements for Qualified Health Plans in the Health Insurance Marketplace. CMS's goal in this effort is to make provider network data readily available to beneficiaries, stakeholders, and the public and in a uniform format, based on the best available, consensus based standards that would be required by CMS. CMS anticipates that a common format and standard will enable greater interoperability across provider directories and more up-to-date information in provider directories maintained by health plans, at a state level, and in national databases such as the National Plan and Provider Enumeration System. Standardized provider directories will serve as a useful tool to search for individual providers and determine, on a readily-accessible, provider-specific basis, every MA plan for which a specific provider is currently contracted. We believe this approach could also be leveraged by application developers to create user-friendly search applications that will be more accessible, up-to-date, and useful for consumers than the current, non-standardized websites or printed provider directories. This approach will enhance the transparency of provider networks, and enable beneficiaries to make informed decisions about their health care coverage. We invite comments on this proposed strategy, particularly with respect to how frequently provider information should be submitted and whether additional types of information (e.g., National Provider Identifiers) should be required for inclusion in the database.

Guidance for Off-cycle Submission of Summaries of MOC Changes

CMS continues to emphasize the importance of the SNP MOC as a fundamental component of the SNP quality improvement framework. See §§ 422.101 and 422.152(g). In order to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and strategies for providing care during the course of its MOC approval timeframe. CMS indicated in the CY 2015 Call Letter that it would establish a mechanism by which SNPs could notify CMS when they make revisions to their approved MOC.

Based on our experience, we expect that such submissions will be relatively rare. During each of the past few years, very few SNPs have contacted CMS about the need to make MOC changes during an approval cycle and we do not anticipate this new process will result in a higher incidence of such MOC changes. Only relatively unusual circumstances require SNPs to make changes to their MOCs that are so significant that notification of CMS is warranted.

Below, we describe MOC changes requiring CMS notification and how SNPs should submit their MOC changes to CMS.

SNPs that make significant changes to their MOCs must submit a summary of the pertinent modifications to the approved MOC in HPMS. The SNP must also submit a redlined version of the approved MOC with the revisions highlighted.

The HPMS module for submitting the MOC changes will be available later in 2015. Additional details and guidance regarding the new module will be provided via an HPMS memo. Until the module is live in HPMS, SNPs should document any changes to their MOCs and notify CMS of those revisions as they do now.

NCQA will review the summary of changes submitted in HPMS to verify that the revisions are consistent with acceptable, high-quality standards, as included in the original, approved MOC. The revised MOCs will not be rescored and the MOC's original approval period (i.e., 1-year or multi-year) will not change as a result of NCQA's review of the changes. Therefore, changes made to MOC cannot be used to improve a low score.

SNPs should only notify CMS of substantive modifications, particularly those that include fundamental organizational changes and changes that are essential to MOC processes and functions. Examples of process changes that need to be submitted include, but are not limited to:

- Changes in legal entity, parent organization, and oversight (novation/mergers, changes to corporate structure);
- Target population changes;

- New benefit inclusion or benefit exclusions, especially for a SNP's most vulnerable members;
- Changes in level of authority/oversight (medical provider to non-medical provider/clinical vs. non-clinical personnel conducting care coordination activities);
- Changes to delegated providers and agreements; and
- Changes in policies and/or procedures pertinent to: the health risk assessment process, development and ongoing updates to the individualized care plan, changes to risk stratification methodology, care transitions protocols, communication and frequency of meetings with ICT members, beneficiaries, and caregivers.

Changes that do **not** need to be submitted include:

- Changes in administrative staff, types/level of staff;
- Updates on demographic data about the target population;
- Updates to quality improvement metric results;
- Additions/deletions of specific named providers; and
- Grammatical and/or non-substantive language changes;

NCQA reviewers will designate the summary as "***Acceptable"*** or **"*Non-Acceptable"*** and will enter the findings in the HPMS character text box. A system-generated email will be sent to the designated SNP Application Contact, the MA Quality Contact, as well as the individual who submitted the revised MOC summary.

SNPs have one opportunity to correct ("cure") deficiencies to confirm that the revised MOC is consistent with the standards outlined in the original MOC. If NCQA determines that revisions to the MOC, as delineated in the MOC summary, do not reflect the quality standards as demonstrated by the original MOC and its associated score/approval period, the SNP will be notified via email with a "***Non-Acceptable"*** determination and a list of all deficiencies. If the summary and redlined version is non-acceptable after the second review, the SNP must continue implementing its approved MOC (without any revisions) for the remainder of its MOC approval period.

We believe that these proposed processes and procedures will: make certain that CMS and NCQA are apprised of up-to–date information regarding the MOC; strengthen our ability to adequately monitor the approved MOCs; and guarantee that SNPs continue to provide high quality care to enrollees.

Waiver of the Three Day Qualifying Inpatient Hospital Stay

Consistent with the current regulation at 42 CFR 409.30(b)(2), MAOs may cover SNF care that is not preceded by a three day inpatient hospital stay. Waiver of the qualifying hospital stay is based on CMS' determination that SNF stays provided by MAOs without a three day inpatient hospital stay meets the two tests in section 1812(f) of the Act, namely that the inclusion of such services will not result in any increase in the total of payments made under this title and will not alter the acute care nature of the benefit. Currently, ninety-five percent of non-employer MA plans have elected to waive the three day inpatient stay as a condition for SNF coverage. Although longstanding practice has been to allow MA organizations to price the waiver of the three day hospital stay as either a mandatory supplemental or as a basic benefit in the BPT, consistent with current regulation at 42 CFR 422.101(c), we are clarifying that the waiver of the three day hospital stay and the associated SNF stay are basic benefits and must be entered as such in both the PBP and BPT.

Our clarification makes certain that our terminology related to an MA plan's waiver of the three day inpatient stay and bid pricing guidelines are consistent with our regulations and has no effect on how plans present the waived days to enrollees and potential enrollees in marketing material.

Standardizing the Health Risk Assessment (HRA)

All MAOs are to make a best effort to conduct an initial assessment of each enrollee's health care needs within 90 days of the effective date of enrollment (§422.112(b)(4)(i)). SNPs are required to perform a comprehensive initial HRA that includes assessment of each enrollee's physical, psychosocial, and functional needs within the first 90 days of enrollment and conduct reassessments annually thereafter (§422.101(f)(1)(i)). Beginning in CY 2014, CMS included SNPs' timeliness and completion rates as factors in the Star Ratings methodology.

To date, CMS has not required MAOs to use a standardized set of basic components for those assessments. In 2012, we reviewed the HRAs in use by SNPs, as submitted in the Health Plan Management System, and found more than 300 different versions were in use at that time. We found that the most common questions addressed chronic conditions, health care utilization, and activities of daily living and that that the Center for Disease Control and Preventions' (CDC) Model HRA presented in the appendix to "A Framework for Patient-Centered Risk Assessments, Providing Health Promotion and Disease Prevention Services to Medicare Beneficiaries" (http://www.cdc.gov/policy/ohsc/HRA/FrameworkForHRA.pdf), in combination with the other elements of the AWV captured all of the most common components of the HRAs that were in use at the time of review.

We believe the CDC Model HRA and the other components of the AWV are sufficiently comprehensive to identify the medical, functional, cognitive, psychosocial and mental health care needs of enrollees, including those in SNPs. CMS believes that adoption of a standardized framework would provide consistency in CMS' and MAOs' data collection across all plans, provide uniform and comprehensive information to support care planning, health promotion and promote a proactive approach for initiating preventive and other appropriate care.

CMS strongly encourages MAOs to adopt the components in the CDC Model HRA beginning in CY 2016. In addition to those components, MA plans are free to include other components or elements that may appropriately assess the needs of enrollees. CMS may consider developing and requiring a standardized HRA for use by all SNPs in the future through the notice and comment rulemaking process.

We seek comment regarding the adoption of these components by MAOs as minimum elements for HRAs beginning in CY 2016.

Guidance for In-Home Enrollee Risk Assessments

Annual health risk assessments under MA are usually questionnaires sent to enrollees for self-completion and ask for basic information about physical, psychosocial, and functional needs. Special needs plans are required to verify all enrollees are assessed within 90 days of enrolling and annually thereafter whereas other MA plans need only make a "best effort" to assess their enrollees.

Over the past few years, CMS has observed an increase in in-home visits to assess MA enrollees.

These in-home assessment visits are usually performed by non-physician practitioners employed by downstream contractors and the comprehensiveness of the assessments and resulting care planning and care coordination appear to vary across plans.

For CY 2014, CMS proposed in the Advance Notice to exclude, for payment purposes, diagnoses collected from enrollee risk assessments that were not confirmed by a subsequent clinical encounter. For CY 2015, CMS again proposed to exclude, for payment purposes, diagnoses that were not confirmed by a subsequent clinical encounter but modified the proposal to include all home visits, not just in-home enrollee risk assessments. Neither of these proposals was finalized; however, beginning CY 2014, MAOs are required to flag diagnoses resulting from in-home assessments when reporting diagnoses to CMS for risk adjusted payments.

Our concerns related to the in-home enrollees risk assessments were two-fold. First, we were concerned that in-home assessments were merely a strategy by MA plans to find and report more diagnosis codes to CMS, generating higher levels of coding and, therefore, payment than assumed under our risk adjustment methodologies. Second, we were concerned that, while there is potential for the home assessments to improve care, we want to be sure that providers who regularly care for these enrollees actually receive and use the information collected in these assessments and that the care subsequently provided to enrollees is substantially changed or improved as a result of the assessments.

The coverage criteria for home health visits and physician in-home visits are established under original Medicare. (MA plans may have less restrictive coverage terms for covering home health and/or in-home visits as a supplemental benefit.) Medicare coverage for home health visits require, among other things, that the enrollee be homebound and require skilled nursing and/or rehabilitation services in the home. Physician or non-physician practitioners may furnish the visits, depending on the treatment program set out in the plan of care. Original Medicare also covers in-home visits by a physician or non-physician practitioner when care is medically reasonable and necessary.

We believe that in-home assessments can have significant value as care planning and care coordination tools. In the home setting, the provider has access to more information than is available in a clinical setting. For example, the provider is able to evaluate the enrollee's home for potential risks, the need for supports to enable an enrollee to continue living in the community, and other relevant aspects of the enrollee's living situation. We expect plans to take advantage of the opportunities afforded by performance of in-home assessments to obtain and use that full spectrum of information to revise, develop, or implement comprehensive care plans for affected enrollees.

In support of that goal, we are strongly encouraging plans to adopt, as a best practice, a core set of components for the in-home assessments they perform. Our intention in providing guidance on best practices related to in-home assessments is promote their primary use as tools for improving care for MA enrollees and not just as a process to collect diagnoses that increase risk adjusted payments. In-home assessments that incorporate the components listed below, could have significant value as care planning and care coordination tools. At the same time, we remain concerned that in-home risk assessments may continue to be used as a tool to identify diagnoses primarily for reimbursement purposes.

We also will, in CY 2015, track and analyze care provision following in-home visits. We believe this two-pronged approach—providing guidance on best practices for conducting in-home assessments and tracking subsequently provided care—will provide CMS with some evidence that in-home assessments are a means to provide enrollees with all appropriate care and not solely for purposes of collecting diagnoses without providing follow-up care. We also think this approach will provide plans an incentive to adopt comprehensive in-home assessments consistent with the components we have identified as best practices.

As a best practice, we propose that in-home assessments be performed by physicians, or qualified non-physician practitioners[8], specifically advanced practice registered nurses, nurse practitioners, physician assistants or certified clinical nurse specialists. Other best practices as part of the in-home assessments and the MAO's program for such assessments include:

- All components of the annual wellness visit, including a health risk assessment such as the model health risk assessment developed by the;
- Medication review and reconciliation;
- Scheduling appointments with appropriate providers and making referrals and/or connections for the enrollee to appropriate community resources;

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[8] Note that only diagnoses from risk adjustment acceptable physician specialty types may be submitted for payment purposes.

- Conducting an environmental scan of the enrollee's home for safety risks, and need for adaptive equipment ;
- A process to verify that needed follow-up care is provided;
- A process to verify that information obtained during the assessment is provided to the appropriate plan provider(s);
- Provision to the enrollee of a summary of the information, including diagnoses, medications, scheduled follow-up appointments, plan for care coordination, and contact information for appropriate community resources; and
- Enrollment of assessed enrollees into the plan's disease management/case management programs, as appropriate.

Plans' adoption of such comprehensive in-home assessments should provide additional information to support care planning and care coordination; and could lead to improved enrollee health outcomes.

Section 1876 Cost Contract Provisions

Cost Plan Application

We want to remind organizations that CMS will not accept any new cost plan applications but will continue to accept applications to modify cost plan contracts in order to expand service areas in accordance with 42 CFR §417.402. In addition, for CY 2016, CMS will apply the cost plan competition requirements in the review and evaluation of any applications to expand a cost plan's existing service area. CMS will deny any cost plan's application for a service area expansion to the extent that the application is for a service area or portions of service areas in which two or more competing MA local or regional coordinated care plans that meet specified enrollment thresholds are available.

Closing Cost Plans to New Enrollment when a Related Entity is Operating in the Same Service Area

CMS wants to remind MAOs that we revised the cost plan enrollment requirements at 42 CFR §422.503(b)(vi)(G)(5) so that the regulation now says that MA organizations "[n]ot accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan," and that they "[n]ot accept, as either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan." We revised the requirements because, contrary to our intent, they previously permitted legal entities that are related to each other under a common parent organization to offer a cost contract and MA plan in the same service area, creating the same potential for the entities to move higher risk enrollees from one plan to another in order to take advantage of the differing Medicare payment rules for the two plan types or for other reasons that are not related to the enrollees' best interests.

Cost Contract Plan Competition Requirements

In accordance with the Protecting Access to Medicare Act of 2014, beginning CY 2016, CMS will non-renew cost plans in service areas or portions of service areas in which at least two competing MA local or two MA regional coordinated care plans that meet specified enrollment thresholds are available. Affected cost contractors will not be able to operate in impacted service areas in 2017.

We will non-renew any portion of a cost plan's service area if there are also two or more MA local or regional coordinated care plans with a minimum of 5,000 enrollees (urban areas) or 1,500 enrollees (non-urban) for the entire year prior to the non-renewal, operating in the same service area. In CY 2016, we will use 2015 enrollment data to identify the cost plans that are subject to non-renewal and will notify them in time to make necessary arrangements, that they will be non-renewed for CY 2017.

For purposes of plan renewal, the MA local and/or regional coordinated care plans must meet minimum enrollment requirements for the entire year prior to the non-renewal year in order to trigger mandatory cost plan non-renewal or service area reduction. (See 42 CFR §417.402 and 76 FR 21448 (April 15, 2011) for additional information on minimum enrollment and other requirements related to the cost plan competition provisions).

Cost plans that offer Part D as cost-PD plans also may not expand into service areas served by at least two competing MA local or two MA regional coordinated care plans.

Section III – Part D

Improving Drug Utilization Review Controls in Medicare Part D

In this section, we describe the results of sponsors' implementation of improved drug utilization controls to prevent overutilization of medications in Part D, and our additional expectations for further reductions of opioid overutilization in the Medicare Part D program. We solicit comments and suggestions about the proposals described below to strengthen the policy and expand the use of the Overutilization Monitoring System (OMS) in order to reduce the unsafe overutilization of medications by Part D beneficiaries.

Background

In the Final 2013 Call Letter, published April 2012, and supplemental guidance, published September 2012, CMS described several methods for Part D sponsors to prevent overutilization of prescribed medications.[9] CMS' expectations beginning January 1, 2013 generally were outlined as follows: 1) Sponsors were to improve their safety controls at the point-of-sale (POS), in particular with respect to acetaminophen (APAP), and their formulary utilization management designs; 2) Sponsors were to implement improved retrospective drug utilization review to detect egregious cases of opioid overutilization and apply case management principles to targeted cases in accordance with CMS guidance. After case management, sponsors would implement beneficiary-level POS claim edits if necessary to prevent continued overutilization of opioids. Lastly, sponsors that implemented such POS claim edits would share certain data with a new sponsor when the beneficiary moves to another plan in accordance with applicable law.

Since the general overutilization policy was announced, CMS has taken several steps to make sure that sponsors were implementing it effectively and appropriately, beginning with the launch of the OMS. The OMS provides quarterly reports to sponsors on beneficiaries with potential opioid or APAP overutilization issues identified through analyses of PDE data from the previous 12 months and through CMS program integrity investigations; sponsors should respond to the OMS within 30 days on the status of their review for each beneficiary case. In January 2014, the OMS was enhanced to collect potential opioid overutilization issues and the status of each beneficiary case that was identified through Part D sponsors' own internal criteria and reviewed by the sponsors, but not previously identified by CMS. In February 2014, CMS enhanced the MARx system to accept beneficiary-level opioid POS edit data and to alert sponsors when a newly-enrolled beneficiary was subject to a beneficiary-level opioid POS edit in their prior plan.[10] For CY 2015, CMS announced its expectation that sponsors use the CMS 120 mg morphine equivalent dose (MED) and 90 consecutive day threshold as their maximum internal opioid criteria for improved drug utilization review and case management.[11]

Results

We believe the Part D overutilization policy has played a key role in reducing opioid and APAP overutilization in the program. Of the over 80,000 potential overutilization cases identified by the OMS in 2013, 69 percent of the cases involved APAP and 31 percent of cases involved opioids. Through the 3rd quarter of 2014, there was a notable reduction in the number of new

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[9] 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 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

[10] The Medicare Advantage and Prescription Drug Plan Communications User Guide (PCUG): http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-technology/mapdhelpdesk/Plan_Communications_User_Guide.html

[11] Sponsors may lower the MED or number of consecutive days threshold and may vary other factors, such as the number of prescribers and pharmacies as described in the CY 2015 Call Letter.

cases of potential APAP and opioid overutilization. Specifically, in the 4th quarter of 2013, the OMS identified 9,758 new cases (i.e., first time the beneficiary exceeded the OMS overutilization targeting threshold) of potential APAP overutilization (see Table 1) and 13,393 new cases of potential opioid overutilization (see Table 2); whereas, in the 3rd quarter of 2014, these figures dropped to 2,343 and 9,002, respectively. The number of repeat cases of potential APAP overutilization also decreased from 21,629 to 6,770, and repeat cases of potential opioid overutilization increased from 10,201 to 12,875 during the same period.

Table 1: Potential APAP Overutilizers, 12-Month OMS Cycles

OMS Cycle	New Outliers	Repeat Outliers	Total Outliers
2013 Quarter 4 (1/1/13-12/31/13)	9,758	21,629	31,387
2014 Quarter 3 (10/1/13-9/30/14)	2,343	6,770	9,113

Table 2: Potential Opioid Overutilizers, 12-Month OMS Cycles

OMS Cycle	New Outliers	Repeat Outliers	Total Outliers
2013 Quarter 4 (1/1/13-12/31/13)	13,393	10,201	23,594
2014 Quarter 3 (10/1/13-9/30/14)	9,002	12,875	21,877

From January 1, 2013 through December 31, 2014, sponsors notified CMS of 1,162 opioid POS edits for specific beneficiaries.

Acetaminophen (APAP)

As described in the 2015 Call Letter, sponsors are expected to implement soft formulary-level edits in 2015 to reduce overutilization of APAP. However, we stated that if the soft formulary-level POS edits did not significantly reduce overutilization of APAP, we would consider announcing an expectation that Part D sponsors use hard edits for contract year 2016. We are pleased that there has been a significant reduction in APAP overutilization observed through 2014 in the Part D program, as noted above. Therefore, CMS is not expecting sponsors to implement hard APAP formulary edits in CY 2016, but we still encourage sponsors to implement hard APAP formulary edits to prevent doses at egregious levels for which there would be no reasonable medical or dispensing explanation.[12]

Opioids

Although the use of improved drug utilization review, case management, and beneficiary-level POS edits have reduced overutilization of opioids in the Part D program, CMS believes that Part D sponsors should implement soft formulary-level POS edits based on cumulative daily morphine equivalent dose (MED) to further reduce opioid overutilization, especially before it develops, as described in prior Call Letters. For CY 2016, we expect sponsors' Pharmacy and Therapeutics (P&T) committees to develop the specifications for a cumulative MED soft POS edit to prevent opioid overutilization while minimizing false positives. Sponsors can 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 prior authorization, case management or appeals processes.

In 2013, approximately 775,000 beneficiaries (2% of Part D enrollees) met or exceeded 200 mg MED for at least one day, excluding those with cancer or hospice care. The number of these beneficiaries who would have been affected in 2013 by a formulary-level MED edit varies significantly based on the edit specifications, as presented in Table 3 below. CMS recommends a POS edit threshold of 200 mg cumulative MED when ordered by 2 or more prescribers of the overlapping opioid prescriptions, which would apply to approximately 400,000 beneficiaries (about 1% of Part D enrollees) in 2013. By applying the known exceptions described above, sponsors will significantly reduce the number and frequency of these POS edits.

Table 3: Soft Formulary-Level POS Edit Variations

Soft Formulary-Level POS Edit Criteria, Excluding Cancer and Hospice; No Adjustments for Other Known Exceptions								
≥ 200 mg MED, ≥ 2 prescribers			≥ 200 mg MED, ≥ 3 prescribers			≥ 200 mg MED, ≥ 4 prescribers		
Beneficiary Count	Number of POS Edits	Mean # of POS Edits	Beneficiary Count	Number of POS Edits	Mean # of POS Edits	Beneficiary Count	Number of POS Edits	Mean # of POS Edits
401,744	1,369,161	3.41	62,760	124,247	1.98	5,303	9,158	1.73

If the MED threshold for the POS edit is increased to 300 mg MED or 400 mg MED, the number of beneficiaries affected and the number of POS edits are reduced by approximately 40% or 63%, respectively. The projected impact of the POS edits at the pharmacy level is small; a POS edit based on 200 mg MED and at least 2 prescribers would trigger about 23 POS edits for 7

[12] More information about soft and hard rejects and edits is available from the National Council for Prescription Drug Programs: "Telecommunication Version D and Above Questions, Answers and Editorial Updates," *NCPDP*, February 2014, http://www.ncpdp.org/NCPDP/media/pdf/VersionD-Editorial.pdf (accessed 1/22/2015).

beneficiaries on average per pharmacy annually, excluding only beneficiaries with cancer or hospice care.

CMS requests comments from sponsors on whether or not they support and can implement the 200 mg MED and 2 or more prescriber threshold for the soft formulary-level POS edit with the recommended known exceptions, and the number of beneficiaries who would be impacted in their plans. If a sponsor recommends alternative thresholds, such as higher MED levels or number of prescribers, please provide the specifications, rationale, and impact of the recommendations.

Prior to implementing cumulative formulary MED thresholds at POS, the CY 2016 formulary submission must reflect these edits. Each formulary opioid RxNorm concept unique identifier (RxCUI[13]) should be submitted with the lesser of either the quantity limit (QL) that reflects either the cumulative MED level for that individual product or the formulary QL for the product. When a sponsor proposes a cumulative MED edit, all unique opioid RxCUIs must be submitted with a QL on the formulary file. In addition to the HPMS formulary submission reflecting these MED edits, plan sponsors must submit detailed operational information by the CY 2016 formulary submission deadline. The documentation must contain at a minimum the MED level being utilized and a written description of the mechanics of the programs, such as the days in excess of a cumulative level that would trigger the edit and the mechanism in which the edits would be resolved. This information must be submitted via e-mail to partdformularies@cms.hhs.gov with a subject line of "Cumulative MED – [applicable FID number]."

Revisions to the Overutilization Monitoring System Methodology

The OMS has proven to be a valuable tool to make certain that sponsors have established reasonable and appropriate drug utilization management programs to monitor beneficiaries who are at-risk for adverse events due to potential overutilization of opioids and APAP as described above. With input from Part D sponsors and other stakeholders, CMS has revised the OMS and related systems (e.g., MARx). CMS is considering additional enhancements to the OMS for 2016:

1) In order to better measure and compare the use of high-dose opioids and APAP across Part D contracts, CMS proposes two new measures. Contract-level rates and contract-type average rates would be reported to individual sponsors through the OMS to help monitor performance.

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[13] RXCUIs are available in the Formulary Reference Files located in the Related Links section of the CMS Formulary Guidance webpage (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html).

- Opioid Daily Dose rate: # opioid days > 120mg MED/1000 Opioid utilization days
- APAP Daily Dose rate: # APAP days > 4g/1000 APAP utilization days

2) CMS is also considering new opioid-related OMS measures based on the following potentially unsafe use of opioids:
    - High-dose opioids in opioid naïve patients
    - More than 90mg cumulative MED daily of short-acting opioids for greater than 90 consecutive days
    - Concurrent buprenorphine and opioid use for more than 90 consecutive days
    - Concurrent opioid and other CNS depressant use from multiple prescribers

We solicit suggestions on the usefulness of these proposed OMS measures and additional ideas for new measures.

Improved Drug Utilization Controls for Other Drug Classes

CMS has received suggestions to expand the Part D overutilization policy to other therapeutic drug categories and has requested comments in the past, but a consensus has not developed on which drugs or classes of drugs would be appropriate or inappropriate to target. Now that sponsors have more experience in implementing the overutilization policy, and CMS has more experience in overseeing compliance with the policy, we are interested in revisiting the idea to expand the Part D overutilization policy to other drugs or classes of drugs (e.g., benzodiazepines, antipsychotic drugs, skeletal muscle relaxants, amphetamine derivatives) and clinical treatment issues (e.g., concurrent use of CNS depressants, inappropriate concurrent use of HIV drugs). In addition to comments on which drugs or classes of drugs would be appropriate or inappropriate to target and why, we would be interested in thoughts on targeting methodology(ies), such as maximum dose, duplicative therapy or other principles of drug use review, to identify potential cases of overutilization or misuse of any drugs or classes of drugs identified. We note that current CMS guidance is that sponsors may adapt Part D overutilization policy to non-opioid medications, including HIV drugs, as long as they use the same level of diligence and documentation that CMS expects with respect to opioids, including written notice to the beneficiary when implementing POS claim edits.

Research, Guidelines, and Training Materials

CMS encourages Part D sponsors and members of their P&T committees to keep abreast of current research, guidelines, and training materials related to the appropriate use of opioids, such as the following information:

- *Common Elements in Guidelines for Prescribing Opioids for Chronic Pain*, published by the Centers for Disease Control and Prevention (CDC) at CDC.gov (http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html)

- *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain,* Publication No. 14-E005-EF, September 2014, published by the Agency for Healthcare Research and Quality (AHRQ) at AHRQ.gov (http://www.ahrq.gov/research/findings/evidence-based-reports/opoidstp.html)
- *Opioids for chronic noncancer pain*, A position paper of the American Academy of Neurology, published in the September 30, 2014 issue of the journal *Neurology*, and available at AAN.com (https://www.aan.com/uploadedFiles/Website_Library_Assets/Documents/6.Public_Policy/1.Stay_Informed/2.Position_Statements/3.PDFs_of_all_Position_Statements/Position%20and%20Policy%20Documents.pdf)
- *NIDAMED: Medical & Health Professionals* provides tools, resources, continuing education and training for medical and health professions through the website of the National Institute on Drug Abuse (http://www.drugabuse.gov/nidamed-medical-health-professionals)

Medication Therapy Management (MTM)

Annual MTM Eligibility Cost Threshold

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per §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 §423.104(d)(5)(iv). The 2015 MTM program annual cost threshold is $3,138. The 2016 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2016 Call Letter.

A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The guidance memo for CY 2016 will be released approximately one month before the 2016 MTM program submission deadline. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Access to Preferred Cost-Sharing Pharmacies

In the CY 2015 Call Letter, CMS announced that we had received complaints from interested parties that some Part D plan sponsors were not providing their enrollees with reasonable access to network pharmacies that offered preferred cost sharing. CMS noted that we were concerned that beneficiaries might be misled into selecting plans based on advertised low preferred cost sharing only to find later that no preferred cost sharing pharmacies (PCSPs) were located within a reasonable distance from their residence. We stated that we had engaged a contractor to study the issue and, based on the results of the study, would consider whether to adopt network adequacy standards for PCSPs.

Currently, CMS evaluates Part D sponsor retail networks against TRICARE standards[14] as established for the Part D program by Congress; no distinction is made between standard cost sharing and preferred cost sharing pharmacies. In the spring of 2014, CMS initiated a new study, using Medicare Plan Finder (MPF) data to calculate plan-level beneficiary access to PCSPs. The MPF data was selected as the source of the plans' PCSP networks because it is the updated snap-shot of the plans' pharmacy networks, is the basis for beneficiaries' plan selections, and is provided to CMS directly from the plans. If plans submit erroneous pharmacy network data to CMS, then those errors are reflected in the findings for that plan.

In October 2014, CMS received findings from the analysis of beneficiaries' access to PCSPs offered under Part D. The analysis indicates that some beneficiaries residing in all types of geographic areas, but particularly in urban areas, face limited or, in some instances, no access to PCSPs. For instance, the study showed that, of the 641 plans with PCSP networks that do not meet the urban access standard (constituting 54% of all plans), 103 provide access to a PCSP within 2 miles of a beneficiary's urban residence to less than 30% of beneficiaries (33 of those plans provide such access to less than 10% of beneficiaries). The remaining 538 plans in this category provided PCSP access within 2 miles of their residence to between 31% and 89% of urban beneficiaries in their service area.

Overall, 46% of plans provide a level of access to PCSPs in urban areas equivalent to the convenient access standard in 42 C.F.R. §423.120(a)(1) for all (i.e., preferred and non-preferred) retail pharmacies; 87% have PCSP networks that meet the suburban retail convenient access standard; and 95% have PCSP networks that meet the rural retail convenient access standard. Though the great majority of Part D plans provide access to PCSPs at rates consistent with the regulatory convenient access standards in suburban and rural areas, there are some outliers in those areas as well.

Based on this analysis, we are concerned that beneficiaries residing in areas of low access to PCSPs may be unable to obtain the lower cost sharing as advertised in plan materials. We believe this may make marketing material misleading or otherwise misrepresent available cost sharing to beneficiaries in violation of our marketing requirements at 42 C.F.R. §423.2264(d). While we are not proposing to establish access standards for PCSPs at this time, we do plan to take a two-pronged approach to ensuring that beneficiaries are clearly informed of their options

[14] The minimum standard for pharmacy [preferred or non-preferred] network access, based on the TRICARE standard, is as follows – urban areas: at least 90 percent of beneficiaries reside within 2 miles of a network retail pharmacy; suburban areas: at least 90 percent of beneficiaries reside within 5 miles of a network retail pharmacy; rural areas: at least 70 of beneficiaries reside within 15 miles of a network retail pharmacy.

with respect to plans offering preferred cost sharing and increasing access to preferred cost sharing in areas where access is now low.

First, CMS will publish information on PCSP access levels for each plan offering a preferred cost sharing benefit structure. This approach will offer more transparency to beneficiaries about their drug plan options.

Second, during bid review and negotiation, CMS will work with plans whose PCSP networks are outliers (i.e., the bottom 10th percentile compared to all Part D plans in given geographic type) to either increase access to PCSPs in those areas or prevent plans from marketing themselves as offering preferred cost sharing in areas where the benefit is not meaningfully available. For urban areas, using 2014 Plan Finder data, outliers based on the 10th percentile would consist of plans offering access to a PCSP within 2 miles of fewer than 40% of beneficiaries' residences. For suburban areas, this would be plans offering access to a PCSP within 5 miles of fewer than 87% of beneficiaries' residences. For rural areas, where the bottom 10th percentile is currently at 77%, plans that offer access to PCSP at a rate lower than the current convenient access standard would be considered outliers. Where necessary, CMS will use our authority to negotiate bids (under §1860D-11(d) of the Social Security Act and our authority at 42 C.F.R. §423.2264(d)) to prohibit marketing that misleads beneficiaries concerning a benefit to which they will not have meaningful access. CMS will continue to monitor access levels to PCSPs subsequent to the bidding process, and we may consider broadening our outlier review to include additional plans in the future.

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 CFR §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.

Threshold Calculations and Inflation Factor

The benefit parameters for CY 2016 are set forth in Table 1 below. Consistent with previous years, these thresholds are based on the 95th percentile of the CY 2015 Bid Data. For CY 2016, we will be implementing an inflation factor of 5.5% to the copayment cost sharing thresholds, consistent with the inflation value that is used in the out-of-pocket cost (OOPC) model for 2015, to account for the rising cost in drug prices. The inflation factor will not apply to the generic tiers given that the cost sharing thresholds for these tiers are already changing for CY 2016 based on the 95th percentile, as well as in consideration of the other changes that we intend to implement for the generic tiers as noted below.

Tier Labeling and Composition

A growing number of stakeholders are expressing concerns over the increasing cost sharing being applied to generic drugs, pointing to the significant copay differentials that exist between the cost sharing thresholds for preferred and non-preferred generic tiers, as well as the perception that certain generic drugs are "non-preferred" based on current tier labeling and hierarchy. Therefore, the tier labeling for generic tiers will change in CY 2016. This change merges the generic and non-preferred generic tiers into one standard "Generic" Tier, with the option of having a "Preferred Generic" tier with lower cost sharing for a subset of generic drugs.

While sponsors are not prohibited from having a mix of both brand and generic drugs on each tier, we remind sponsors that it is our expectation that a Drug Tier Label should be representative of the drugs that largely make up that tier. We are seeing a growing trend of generic drug products being shifted to non-preferred brand tiers resulting in significant increases in cost sharing and beneficiary out of pocket costs. Moving forward, we will be evaluating this trend as part of the bid review process and will communicate any outliers.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 1 have been met, we will continue to rely on the FDA marketing status to identify formulary drugs as applicable or non-applicable. The maximum coinsurance of 65% applies to tiers that contain only applicable drugs. If non-applicable (i.e., generic) drugs or a combination of both generic and applicable drugs are on a tier, then the maximum coinsurance of 38% 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 to determine whether the coinsurance values are discriminatory. (Please note that for the Select Care/Diabetic Drug Tiers, although the maximum allowable coinsurance value is less than 25%, we will conduct the same cost-sharing analysis for these tiers.) 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.

Despite ACIP recommendations and Healthy People 2020 targets, adult immunization rates, while increasing, still remain quite low. We are restating our expectation that cost sharing be set at $0 for dedicated Vaccine tiers, as well as for Select Care/Select Diabetes Drug tiers that contain vaccine products. We encourage Part D sponsors to consider offering a $0 or low cost sharing for vaccines, if not doing so already, to promote this important benefit.

The methodology for developing the CY 2016 out-of-pocket costs (OOPC) model is consistent with last year's methodology except for the following enhanced modifications: 1) how plan deductible and category level deductibles interact in the OOPC calculations; and 2) how average drug prices in Part D formulary tiers are calculated. For more information, please reference the following [please reference the HPMS memorandum dated January 7, 2015 entitled Medicare Plan Finder (MPF) Plan Version (V1) of Out-of-Pocket Cost (OOPC) Model for CY 2015 and Updated Total Beneficiary Costs (TBC) Data Released on HPMS.]. Customary updates for utilization data, as well as PBP and formulary data used for CY 2016 bid submissions, are also included in the 2016 model. Using this model, the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $18. The minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $30. These meaningful difference requirements apply to all stand-alone PDPs, including those belonging to sponsors under a consolidation plan. We will 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.

We also note that for CY 2017, we may change our approach with respect to cost-sharing and premiums by instituting a Total Beneficiary Cost (TBC) measure for PDPs, similar to what has been in place for Managed Care Organizations. We believe this will meet CMS' goals of establishing a more transparent and predictable process so that beneficiaries can select a plan that best meets their health care needs, while also being protected from high or unexpected cost sharing that could discourage enrollment by certain beneficiaries. More specifically, we are considering using an out-of-pocket cost (OOPC) or market basket approach to set thresholds for increases in cost-sharing and premiums whereby we would deny Part D plan bids with significant increases, pursuant to our authority in Section 3209 of the Affordable Care Act.

Table 1: Benefit Parameters

	CY 2016 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$18
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$30

	CY 2016 Threshold Values
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S[2,3]
Preferred Generic Tier	<$15
Generic Tier	$15
Preferred Brand/Brand Tier	$47
Non-Preferred Brand Tier	$100
Injectable Tier	$100
Select Care/Diabetic Tiers[4]	$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 Brand Tier	50%
Injectable tier	33%
Select Care/Diabetic Tiers[4]	15%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs) [5]	S[3]
Preferred Generic Tier	38%
Generic Tier	38%
Preferred Brand/Brand Tier	65%
Non-Preferred Brand Tier	65%
Injectable Tier	65%
Select Care/Diabetic Tiers[4]	65%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$600

[1]The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 95th percentile of the October CY 2015 Bid Data run through the CY 2015 OOPC MPF model which incorporates CY 2015 Formulary Data, 2009/10 MCBS Data, and FDA data for brand/generic determinations related to coverage gap cost-sharing estimates. 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 2015 Bid Data. The maximum copay threshold for the Generic Tier was established by taking the average of the copay thresholds, based on the 95th percentile, that would have been set forth for the Generic and Non-Preferred Generic Tiers had the Tier Labeling Hierarchy used for CY 2015 been maintained. 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]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.

[5] 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 38% 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 & Deductible

This year the minimum specialty tier eligibility threshold remains $600 (refer to Table 1). To make the Specialty Tier methodology transparent, we will post it at the following site upon the release of the Final CY 2016 Call Letter: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html.

By placing these drugs on a specialty tier, plan sponsors are restricted to charging cost sharing no greater than that permitted under the defined standard benefit. In return Part D sponsors are shielded from tier exceptions for the most expensive drugs, and need not increase their bids and all Part D premiums to maintain actuarial equivalence for an estimate of increased plan liabilities arising from approved tier exceptions.

Also, Part D sponsors are permitted under 42 CFR § 423.578(a)(7) to exempt a specialty tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. In order to make sure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that comply with the following in accordance with Section 30.2.4 of the Prescription Drug Benefit Manual:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit (or an actuarially equivalent for sponsors with decreased or no deductible under alternative prescription drug coverage designs).
- Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar-per-month threshold and are intended for inclusion in the specialty tier.
- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must make sure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

Thus, in accordance with the first bullet above and annual Call Letter guidance, Part D sponsors offering prescription drug benefit plans with a Specialty Tier are limited to the defined standard cost-sharing of 25%, if the plan requires a deductible, and to 33% cost-sharing if no deductible is required, or some percentage in-between dependent on a decreased deductible. (Example: a $320 deductible and 25% cost-sharing of an initial coverage limit of $2960 is essentially the equivalent of $980 in out-of-pocket expenses, whereas no deductible and 33% cost-sharing of the same initial coverage limit is essentially the equivalent of $976.50 in out-of-pocket expenses.)

It has come to our attention that some Part D sponsors are offering alternative prescription drug benefit plans that include Specialty Tiers when the plans also feature decreased or no deductible, but only for certain tiers, and in some cases only for the Specialty Tier. This is contrary to what we intended. Moreover, we believe it is misleading to beneficiaries who may choose these plans without realizing that the reduced or no deductible feature only applies to certain tiers and not all tiers. Therefore, we are clarifying our guidance in Section 30.2.4 that the cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit, or to the benefit parameters established in the annual Call Letter, when there is decreased or no deductible for all tiers under alternative prescription drug coverage designs.

Maximum Allowable Cost (MAC) Pricing

Effective January 1, 2016, drug pricing based on maximum allowable cost (MAC) is subject to the regulations governing the disclosure and updating of prescription drug pricing standards at 42 CFR §§423.501; 423.505(b)(21); and 423.505(i)(3)(vii). When updating MAC prices, the regulations will also require Part D sponsors to disclose the drug prices to the applicable pharmacies in advance of their use for reimbursement, if the source for any prescription drug pricing standard is not publicly available. We explained in the preamble to the final rule (4159-F) that these changes mean that Part D sponsors will have to convey to network pharmacies the actual MAC prices to be updated in advance (70 Fed. Reg. 29883, May 24, 2014). We also stated in the preamble that final rule does not specify any particular time period for advance notice of MAC prices to network pharmacies.

In the final rule, we declined to require a certain format layout and delivery method for disclosure of maximum allowable cost prices. However, we stated in the preamble that an option could be a secure internet site that allowed network pharmacies to look up their drug prices. We further stated that the site or other delivery method to convey MAC prices would have to enable the pharmacies to connect a claim to the correct drug price at the appropriate point in time in order to validate the price (70 Fed. Reg. 29884, May 24, 2014).

We are concerned that some Part D sponsors may be planning to send applicable network pharmacies constant updates of MAC prices, whether electronically, or by facsimile, or by some other method, and with no particular organization, other than perhaps in time order of update. We caution Part D sponsors that updates of MAC prices must be disclosed to network pharmacies in a manner that is usable by pharmacies because, as noted above, the manner of updating MAC prices must enable pharmacies to validate prices.

Mail Order and Changes to Applying for Exceptions to the Auto-Ship Policy

The auto-ship policy (Auto-Ship Refill Programs in Part D) announced in the 2014 Call Letter has two exceptions available to sponsors (announced in memoranda dated 10/28/2013 and 12/12/2013), which have been widely applied since 01/01/2014. The exceptions address automatic shipments of mail order prescriptions without obtaining prior beneficiary consent, provided that refunds are available to beneficiaries who receive unneeded or unwanted medications, and the other conditions described below are met.

Starting in 2016, Part D sponsors interested in offering automatic deliveries of <u>new</u> prescriptions (as described in the 12/12/2013 memo) will no longer need to request an exception to the auto-ship policy by emailing CMS. Instead, the exception will be available to all Part D plans, without the need to specifically submit a request. Plans are permitted to start or continue automatic shipments, provided they meet the conditions listed in the authorizing memoranda and also listed below. Similarly, starting in 2016, Employer Group Waiver Plan (EGWP) sponsors interested in offering automatic deliveries of refill prescriptions (as described in the 10/28/2013 memo) will no longer need to separately request an exception to the Auto-Ship policy by emailing CMS.

Current Policy:

The current process for requesting one or both exceptions is that the sponsor should send an e-mail request to CMS providing the sponsor name, contract number(s) affected, and an acknowledgement that the automatic delivery arrangement meets all of the conditions detailed for the exception. As a reminder, the exception to automatically send refill medications without obtaining prior beneficiary consent (provided that refunds are available and all other exception terms are met) is only available to EGWP sponsors.

As stated in previous guidance, medications coordinated and shipped or delivered by Programs of All-Inclusive Care for the Elderly, do not need to obtain beneficiary consent prior to coordinating new or refill prescriptions for their enrollees.

2016 Policy:

For Contract Year 2016, any Part D sponsors that automatically send prescriptions not directly initiated by the beneficiary may do so without submitting a specific request to CMS, but are still expected to meet all of the conditions listed in the applicable memoranda.

Review of Exception Requirements:

The conditions listed for the 10/28/2013 and 12/12/2013 exceptions are included below. As noted in a clarifying memo issued 03/21/2014, if a beneficiary has experience using mail-order or other automatic delivery programs under the plan, sponsors and their network pharmacies do not need to establish an additional opt-in procedure for obtaining consent to participate in automatic delivery programs. Given this clarification, annual consent for beneficiaries with recent history of mail order use is not necessary. However, if a beneficiary has had no previous mail-order, home delivery, or other automatic shipment experience under the plan, a prescription for that beneficiary should not be automatically shipped under an exception. In these cases, a sponsor should have its mail order pharmacy contact the beneficiary (or authorized representative) to obtain consent prior to shipping, as described in the Auto-Ship policy.

Further, for plans applying either exception, beneficiaries should be able to easily opt-out of automatic deliveries at any time. The sponsor should respond in a timely fashion to all opt-out requests, and any automatic shipments sent without prior consent after a beneficiary has opted-out should be eligible for a full refund. Additionally, once a plan receives notification that a member is deceased, automatic shipments should be cancelled and any medications that are automatically shipped to deceased beneficiaries should be refunded and deleted from the PDE data. A beneficiary who chooses to opt-out of automatic deliveries should still be permitted to use mail order services if they choose. If opted-out out of automatic deliveries, the pharmacy would obtain consent prior to shipping any new or refill medication orders not directly initiated by the beneficiary (or authorized representative), as detailed in the original policy in the 2014 Call Letter.

12/12/2013 Exception for New Prescription Delivery (Available to all Part D plan sponsors)

1. Enrollee participation in the automatic delivery program is voluntary and opt-in only. (Per 03/21/2014 guidance, plans may cite recent mail order use.)

2. After the initial fill of a new prescription, any shipments of authorized refills not initiated by the beneficiary should conform with the policy described in the 2014 Call Letter, with the pharmacy obtaining beneficiary or authorized representative consent prior to each delivery.

3. Printed and online beneficiary materials should have easy to locate and easy to understand information on how to dis-enroll from automatic delivery programs. Plans will respond within 30 days to any dis-enrollment requests.

4. The plan will provide a refund to the beneficiary for the full amount of the cost-sharing and will delete the prescription drug event (PDE) for any new prescription sent to a beneficiary in an automatic delivery program that the beneficiary reports as unneeded or otherwise unwanted. Beneficiary materials related to refunds must be easy to locate and easy to understand. Plans providing no-fee return of unneeded or unwanted drugs do not need to provide a full refund or delete the PDE when the prescription has been fully or partially used or consumed.

5. The plan will confirm at least annually with the beneficiary if he/she wants to continue in the automatic delivery program. (Per 03/21/2014 guidance, plans may cite recent mail order use.)

6. The plan will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected Medicare hospice coverage.

7. The plan agrees to monitor all grievances and complaints related to mail order and to determine if concerns with unwanted initial fills have decreased to a minimal level. If not, plans will identify processes to correct the delivery program accordingly. The format and schedule for defining and determining such decreases will be announced by CMS at a later time.

10/28/2013 Exception for Refill Prescription Delivery (Available to EGWP sponsors only)

1. Enrollee participation in the automatic delivery program is voluntary and opt-in only.

2. The automatic delivery program only applies to prescription refills and does not apply to new prescriptions that are e-prescribed, faxed, mailed, or phoned-in directly to the pharmacy, even if the new prescription is a continuation of existing therapy.

3. The EGWP has easy to locate and easy to understand beneficiary materials on how to dis-enroll from automatic delivery programs, and the EGWP responds promptly to all dis-enrollment requests.

4. The EGWP will provide a refund to the beneficiary and delete the PDE for any auto-shipped refill that the beneficiary reports as unneeded or otherwise unwanted. Beneficiary materials related to refunds must be easy to locate and easy to understand. Plans providing no-fee return of unneeded or unwanted drugs do not need to provide a full refund or delete the PDE when the prescription has been fully or partially used or consumed.

5. The EGWP will confirm whether the beneficiary wants to continue in the automatic delivery program at least annually and upon receipt of a new prescription from a provider, even if the new prescription is a continuation of existing therapy

6. The EGWP will promptly discontinue automatic delivery after notification that a beneficiary entered a skilled nursing facility, or elected Medicare hospice coverage.

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 2016 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 2016 bids.

In contract year 2016, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The Benefit Coordination and Recover Center (BCRC) operation and maintenance;
- Drug data processing system management, which is used to collect prescription drug event (PDE) data for Part D payment purposes and to produce invoices for the coverage gap discount program;
- Medicare Advantage and Prescription Drug (MARx) system management of COB data; and
- Review of Workers' Compensation settlement set-aside funds, which verify that medical services are paid for by the appropriate party.

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: http://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 2015, we will notify plans with less than 1,000 enrollees of available 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 verify 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.

Appendix 1 – Contract Year 2016 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals

Prescription Drug Plan (PDP) regions are defined by CMS and consist of one or more entire states (refer to Appendix 3, Chapter 5, of the Prescription Drug Benefit Manual for a map of the 34 PDP regions). Each PDP sponsor's Plan Benefit Packages (PBPs) must be offered in at least one entire region and a PDP sponsor's PBP cannot be offered in only part of a region. Please note that PDP bidding rules require PDP sponsors to submit separate bids for each region to be covered. HPMS only accepts a PDP sponsor's PBPs to cover one region at a time for individual market plans (e.g., a PDP sponsor offering a "national" PDP must submit 34 separate PBP bids in order to cover all PDP regions).

A PDP sponsor may expand the service area of its offerings by submitting additional bids in the PDP regions the sponsor expects to enter in the following contract year, provided the sponsor submits a PDP Service Area Expansion (SAE) application and CMS approves that application and then approves the sponsor's submitted bids for the new region or regions. For more information about the application process, refer to: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html.

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June (June 1, 2015). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products because the individual plan is being non-renewed. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal of the plan by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with regulatory requirements, CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance, Chapter 3 of the Prescription Drug Benefit Manual and annual summer CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2016 is summarized below and defined in Appendix 2. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

1. New Plan Added

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor offering the PBP must submit enrollment transactions to MARx. No beneficiary notice is required in this case beyond receipt of the Evidence of Coverage (EOC), and other documents as required by current CMS guidance, following enrollment.

2. Renewal Plan

A PDP sponsor may continue to offer a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number and benefit design (basic or enhanced alternative) as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions to MARx for current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

3. Consolidated Renewal Plan

PDP sponsors are permitted to merge two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk. A PDP sponsor may not split a current PBP among more than one PBP for the following contract year. A PDP sponsor consolidating two or more entire PBPs must make certain that the consolidated renewal PBP ID is the same as one of the original consolidating PBP IDs. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. When consolidating two existing PBPs into a single renewal PBP, it is permissible for the single renewal PBP to result in a change from:

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

Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees.

Current enrollees of a consolidated renewal plan must receive a standard ANOC.

CMS will no longer approve bids that include a PBP that would change a basic plan to an EA plan because of the potential for beneficiary confusion and disruption, as noted above, absent a compelling reason in CMS' determination, such as a sponsor that is under a under a consolidation plan.

4. Renewal Plan with a Service Area Expansion ("800 Series" EGWPs only)

A PDP sponsor offering an 800 series EGWP PBP in the current contract year may expand its EGWP service area to include additional PDP regions for the following contract year through the Part D application process. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP ID number for the following contract year.

Current enrollees will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5. Terminated Plan (Non-Renewal)

A PDP sponsor may elect to terminate a current PBP for the following contract year and must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) by June 1, 2015. CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan, which includes the sponsor's basic plan if that is the only plan available. In this situation, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period, as well as information about alternative options.

6. Consolidated Plans under a Parent Organization

For purposes of ensuring compliance with transition requirements following an acquisition or merger under our significant differences policy, or to make plan transitions following a novation, CMS may elect to allow the merger of two or more entire PBPs offered under different contracts (the contracts may be offered by the same legal entity or represent different legal entities). PDP sponsors must complete this renewal option by submitting a crosswalk exception request through HPMS. CMS will provide detailed technical instructions for completing a crosswalk exception request through HPMS in forthcoming guidance. Requests will be reviewed and, if approved, the action will be completed on behalf of the requesting PDP. Current enrollees of a plan or plans being merged across contracts in this manner will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees.

Current enrollees of a consolidated renewal plan must receive a special notice along with a standard ANOC.

Appendix 2 – Contract Year 2016 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals - Table

	Activity	**Definitions**	**HPMS Plan Crosswalk**	**Systems Enrollment Activities**	**Enrollment Procedures**	**Beneficiary Notifications**
1	New Plan (PBP) Added	A PDP sponsor creates a new PBP.	HPMS Plan Crosswalk Definition: A new plan added for 2016 that is not linked to a 2015 plan. HPMS Plan Crosswalk Designation: New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
2	Renewal Plan	A PDP sponsor continues to offer a CY 2015 PBP in CY 2016. The same PBP ID number and benefit design (basic or enhanced alternative) must be retained in order for all current enrollees to remain in the same PBP in CY 2016.	HPMS Plan Crosswalk Definition: A 2016 plan that links to a 2015 plan and retains all of its plan service area from 2015. The 2016 plan must retain the same plan ID as the 2015 plan. HPMS Plan Crosswalk Designation: Renewal Plan	The renewal PBP ID must remain the same so that current enrollees will remain in the same PBP ID. The PDP sponsor does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2016. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan	A PDP sponsor combines two or more PBPs offered in CY 2015 into a single renewal PBP for CY 2016. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2016 after consolidation.	HPMS Plan Crosswalk Definition: Two or more 2015 plans that merge into one 2016 plan. The 2016 plan ID must be the same as one of the consolidating 2015 plan IDs. HPMS Plan Crosswalk Designation: Consolidated Renewal Plan	The PDP sponsor's designated renewal PBP ID must remain the same so that CMS can consolidate current enrollees into the designated renewal PBP ID. The PDP sponsor does not submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2016.	Current enrollees are sent a standard ANOC.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
4	Renewal Plan with an SAE (applicable only to employer/union group waiver plans)	A PDP sponsor continues to offer an 800 series CY 2015 prescription drug PBP in CY 2016 and expands its EGWP service area to include additional regions. The PDP sponsor must retain the same PBP ID number in order for all current enrollees to remain in the same PBP in CY 2016.	HPMS Plan Crosswalk Definition: A 2016 800-series plan that links to a 2015 800-series plan and retains all of its plan service area from 2015, but also adds one or more new regions. The 2016 plan must retain the same plan ID as the 2015 plan. HPMS Plan Crosswalk Designation: Renewal Plan with an SAE	The renewal PBP ID must remain the same so that current enrollees in the current service area will remain in the same PBP ID. The PDP sponsor does not submit enrollment transaction for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2016. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5	Terminated Plan (Non-Renewal)	A PDP sponsor terminated the offering of a 2015 PBP.	HPMS Plan Crosswalk Definition: A 2015 plan that is no longer offered in 2016. HPMS Plan Crosswalk Designation: Terminated Plan	CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan. The PDP sponsor does not submit disenrollment transactions. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization must submit enrollment transactions to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
6	Consolidated Plans across Contracts under the Same Parent Organization	A parent organization merges two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk.	Exceptions Crosswalk Request: Sponsors must submit an exceptions request to CMS, which will complete the crosswalk on behalf of the sponsor HPMS Plan Crosswalk Designation: The plan being crosswalked must be marked as a terminated plan in the HPMS crosswalk. The remaining 2016 plan must be active and contain the applicable service area from the terminated plan being crosswalked.	PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. CMS will effectuate this renewal option and HPMS will record the merger of two or more whole PBPs. The PDP sponsor does not submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment election for current enrollees to remain enrolled in the renewal PBP in 2016. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix 3

Measure – Beneficiary Access and Performance Problems (Revised Methodology)

Labels for Stars: Problems Medicare Found in Members' Access to Services and in the Plan's Performance (more stars are better because it means fewer serious problems)

Label for Data: Problems Medicare Found in Members' Access to Services and in the Plan's Performance (on a scale from 0 to 100, **higher numbers** are better because it means fewer serious problems)

Description: To check on whether members are having problems getting access to services and to be sure that plans are following all of Medicare's rules, Medicare conducts several different types of reviews. Medicare gives the plan a ***lower*** score (from 0 to 100) when it finds problems. The score combines ***how severe*** the problems were, ***how many*** there were, and ***how much*** they affect plan members directly. A higher score is better, as it means Medicare found fewer problems.

Metric: This measure is based on CMS' sanctions, civil monetary penalties (CMP) as well as Compliance Activity Module (CAM) data (this includes: notices of non-compliance, warning letters {with or without business plan}, and ad-hoc corrective action plans (CAP) and the CAP severity).

- Contracts' scores are based on a scale of 0 -100 points.
- The starting score for each contract works as follows:
  - Contracts with an effective date of 1/1/2014 or later are marked as "Plan too new to be measured".
  - All contracts with an effective date prior to 1/1/2014 begin with a score of 100.
- Contracts placed under sanction anytime during the data time frame are reduced to a score of 0. This is separate from the deduction applied at the overall score level for contracts with more recent sanctions.
- The following deductions are taken from contracts whose score is above:
- For each CMP, Contracts that received a CMP with beneficiary impact related to access: 40 points.
- Contracts that have a CAM score (CAM score calculation is discussed below) are reduced as follows:
    - 0– 2 CAM Score – 0 points
    - 3 – 9 CAM Score – 20 points
    - 10 – 19 CAM Score – 40 points
    - 20 – 29 CAM Score – 60 points

- $\geq$ 30 CAM Score – 80 points

Calculation of the CAM Score combines the notices of noncompliance, warning letters (with or without business plan) and ad-hoc CAPs and their severity. The formula used is as follows:

CAM Score = (NC × 1) + (woBP × 3) + (wBP × 4) + (NAHC × (6 × CAP Severity))

Where: NC = Number of Notices of Non Compliance
woBP = Number of Warning Letters without Business Plan
wBP = Number of Warning Letters with Business Plan
NAHC = Number of Ad-Hoc CAPs
CAP Severity = Sum of the severity of each individual ad-hoc CAP given to a contract during the measurement period. Each CAP is rated as one of the following:
3 – ad-hoc CAP with beneficiary access impact
2 – ad-hoc CAP with beneficiary non-access impact
1 – ad-hoc CAP no beneficiary impact

Data Source: CMS Administrative Data

Data Source Description: Findings of CMS compliance actions that occurred during the 12 month past performance review period between January 1, 2014 and December 31, 2014. For compliance actions, the date the action was issued is used when pulling the data from HPMS.

CMS Framework Area: Population/Community Health

NQF#: None

Data Time Frame: 01/01/2014 – 12/31/2014

General Trend: Higher is better

Statistical Method: Relative Distribution and Clustering

Improvement Measure: Not Included

Weighting Category: 1.5

Data Display: Rate with no decimal point

Reporting Requirements:

1876 Cost	Demo	Local, E-local, RPPO, CCP w/o SNP	Local, E-local, RPPO, CCP w/ SNP	MSA	E-PDP & PDP	E-PFFS, PFFS
Yes	Yes	Yes	Yes	Yes	No	Yes

4- Star threshold: Not predetermined

Appendix 4 - Improvement measures (Part C & D):

Part	Measure	Improvement Measure
C	Breast Cancer Screening	No
C	Colorectal Cancer Screening	Yes
C	Annual Flu Vaccine	Yes
C	Improving or Maintaining Physical Health	No
C	Improving or Maintaining Mental Health	No
C	Monitoring Physical Activity	Yes
C	Adult BMI Assessment	Yes
C	Special Needs Plan (SNP) Care Management	Yes
C	Care for Older Adults – Medication Review	Yes
C	Care for Older Adults – Functional Status Assessment	Yes
C	Care for Older Adults – Pain Assessment	Yes
C	Osteoporosis Management in Women who had a Fracture	Yes
C	Diabetes Care – Eye Exam	Yes
C	Diabetes Care – Kidney Disease Monitoring	Yes
C	Diabetes Care – Blood Sugar Controlled	Yes
C	Controlling Blood Pressure	Yes
C	Rheumatoid Arthritis Management	Yes
C	Reducing the Risk of Falling	Yes
C	Plan All-Cause Readmissions	Yes
C	Getting Needed Care	Yes
C	Getting Appointments and Care Quickly	Yes
C	Customer Service	Yes
C	Rating of Health Care Quality	Yes
C	Rating of Health Plan	Yes
C	Care Coordination	Yes
C	Complaints about the Health Plan	No
C	Members Choosing to Leave the Plan	Yes
C	Beneficiary Access and Performance Problems	No
C	Health Plan Quality Improvement	No
C	Plan Makes Timely Decisions about Appeals	No
C	Reviewing Appeals Decisions	Yes
C	Call Center – Foreign Language Interpreter and TTY Availability	No
D	Call Center – Foreign Language Interpreter and TTY Availability	No
D	Appeals Auto–Forward	Yes
D	Appeals Upheld	No
D	Complaints about the Drug Plan	No
D	Members Choosing to Leave the Plan	Yes
D	Beneficiary Access and Performance Problems	No
D	Drug Plan Quality Improvement	No
D	Rating of Drug Plan	Yes
D	Getting Needed Prescription Drugs	Yes
D	MPF Price Accuracy	No
D	High Risk Medication	Yes
D	Diabetes Treatment	Yes
D	Medication Adherence for Diabetes Medications	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Yes
D	Medication Adherence for Cholesterol (Statins)	Yes
D	Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews	No