February 21, 2014

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

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 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 2015. The following information is also included: preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2015, changes in payment methodology for CY 2015 for Part D benefits, and annual adjustments for CY 2015 to the Medicare Part D benefit parameters for the defined standard benefit. For 2015, CMS will announce the MA capitation rates on the first Monday in April 2014, 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 the changes in payment methodology for CY 2015 governing payment for Part C original Medicare benefits and rebates. Attachment III sets forth the changes in payment methodology for CY 2015 for Part D benefits. Attachment IV presents the annual adjustments for CY 2015 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 2015 Call Letter for Medicare Advantage (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: AdvanceNotice2015@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 7, 2014, release of the final Announcement of Calendar Year (CY) 2015 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 7, 2014.

/ s /
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Attachments

2015 ADVANCE NOTICE
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Attachment I. Preliminary Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2015

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 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 2015, 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.

CMS uses two trend factors to calculate county rates. CMS plans to rebase the county FFS rates for 2015 as part of the calculation of the rates for 2015. For 2015, the rate established under section 1853(k)(1) is the greater of: 1) the county's 2015 FFS rate or 2) the 2014 applicable amount increased by the CY 2015 national per capita MA growth percentage. For 2015, the specified amount will be based on a percentage of the 2015 FFS rate. The 2015 FFS rate is calculated, in part, using the FFS growth percentage.

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 2015 is -3.55 percent. This estimate reflects an underlying trend change for CY 2015 in per capita cost of -0.07 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 rates. Consistent with the 2014 payment announcement, the basis for the preliminary growth percentage reflects an assumption that Congress will act to prevent the projected cumulative 20.9 percent reduction in Medicare physician payment rates from occurring in 2015. 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" (SGR) formula.

Table I-1. National Per Capita MA Growth Percentage for 2015

	Prior Increases	Current Increases			
	2003 to 2014	2003 to 2014	2014 to 2015	2003 to 2015	NPCMAGP for 2015 With §1853(c)(6)(C) adjustment[1]
Aged+Disabled	49.06%	43.86%	-0.07%	43.77%	-3.55%

[1]Current increases for 2003-2015 divided by the prior increases for 2003 to 2014.

Section B. FFS Growth Percentage

The Affordable Care Act requires that the specified amount be calculated as a percentage of the county FFS amounts. Table I-2 below provides the current estimate of the increase 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 increase in the FFS USPCC is shown as the current projected FFS USPCC for 2015 divided by projected FFS USPCC for 2014.

Table I-2 also shows the increase 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 2015

	Aged + Disabled	Dialysis–only ESRD
Current projected 2015 FFS USPCC	$781.98	$7,218.98
Prior projected 2014 FFS USPCC	$795.11	$7,063.55
Percent increase	-1.65%	2.20%

Table I-3 compares last year's estimate of the total non-ESRD United States per capita cost (USPCC) with current estimates for 2003 to 2016, and Table I-4 compares last year's FFS non-ESRD USPCC estimates with this year's estimates for FFS. The USPCCs are the basis for the National Per Capita MA Growth Percentages. In addition, these tables show the current projections of the USPCCs through 2017. 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	$249.37	$249.37	$545.14	$545.14	1.000
2004	$313.80	$313.80	$273.97	$273.97	$587.77	$587.77	1.000
2005	$334.52	$334.52	$293.53	$293.53	$628.05	$628.05	1.000
2006	$344.97	$344.97	$314.44	$314.44	$659.41	$659.41	1.000
2007	$355.59	$355.59	$332.26	$332.26	$687.85	$687.85	1.000
2008	$371.88	$373.36	$352.69	$352.68	$724.57	$726.04	0.998
2009	$385.42	$385.74	$369.76	$369.93	$755.18	$755.67	0.999
2010	$384.96	$385.58	$378.40	$378.57	$763.36	$764.15	0.999
2011	$387.88	$390.04	$387.60	$388.44	$775.48	$778.48	0.996
2012	$375.37	$382.67	$394.60	$398.54	$769.97	$781.21	0.986
2013	$380.17	$386.10	$397.10	$409.27	$777.27	$795.37	0.977
2014	$372.80	$382.36	$411.46	$430.24	$784.26	$812.60	0.965
2015	$368.93	$383.54	$414.82	$442.62	$783.75	$826.16	0.949
2016	$374.54	$396.10	$426.53	$457.28	$801.07	$853.38	0.939
2017	$385.65		$445.05		$830.70		

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	372.39	373.21	376.95	377.18	749.34	750.39	0.999
2011	371.16	373.94	386.19	387.71	757.35	761.65	0.994
2012	353.92	363.60	394.19	398.83	748.11	762.43	0.981
2013	364.60	371.79	393.64	409.18	758.24	780.97	0.971
2014	368.00	375.59	400.68	419.52	768.68	795.11	0.967
2015	371.01	380.58	410.97	436.60	781.98	817.18	0.957
2016	376.38	393.40	422.20	451.66	798.58	845.06	0.945
2017	386.96		439.59		826.55		

These estimates are preliminary and could change when the final rates are announced on April 7, 2014 in the Announcement of Calendar Year (CY) 2015 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 7, 2014 Announcement.

Attachment II. Changes in the Part C Payment Methodology for CY 2015

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 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"). (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 fee-for-service (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 2015.

The Program for All Inclusive Care for the Elderly (PACE) 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 2015, for 2015 the applicable amount is the greater of: 1) the county's 2015 FFS rate or 2) the 2014 applicable amount increased by the CY 2015 National Per Capita Medicare Advantage Growth Percentage.

A2. Specified Amount

The specified amount is based upon the following formula.

(2015 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 specified at section 1853(k)(4);

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

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

Section 1853(n)(2)(C) of the Act requires CMS to determine applicable percentages for a year based on county FFS rate rankings for the most recent year that was a rebasing year. To determine the CY 2015 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2014 FFS costs, because 2014 is the most recent FFS rate rebasing year prior to 2015. 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 2015 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 (QBPs) to MA organizations that meet quality standards measured under a five-star quality rating system. In this document we refer to this quality bonus as the *quality bonus payment (QBP) percentage* instead of using the statutory term *applicable percentage quality increase*. The QBP percentage

is a percentage point increase to the applicable percentage for each county in a qualifying plan's service area, before multiplying the percentage by the FFS rate for the year to determine the specified amount.

In the Announcement of CY 2012 MA rates and payment policies, CMS announced a nationwide three-year demonstration in effect for 2012 through 2014 to test an alternative method for determining QBP percentages. The demonstration tested whether providing scaled bonuses to MA organizations for their contracts assigned three or more stars would lead to more rapid and larger year-to-year quality improvements in quality scores. During this demonstration, for contracts at or above three stars, QBP percentages were computed along a scale, where the higher a contract's Star Rating, the greater the QBP percentage.

The QBP Demonstration ends December 31, 2014. Thus, for CY 2015 payments, plans with less than 4 stars will no longer receive QBP percentage increases to the county rates, and plans with 4 or more stars will receive QBP percentage increases to the county rates, as set forth in sections 1853(n) and 1853(o) of the Act. CMS is not proposing to extend this demonstration. Finally, see section A.8 on rebate percentages under current law.

Table II-2 shows the QBP percentage for each Star Rating for 2015 payments.

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

Star Rating	2015 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 2015, 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

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.[1] These new MAs are treated as qualifying plans 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, 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. 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

Section 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 determine whether a low enrollment contract (i.e., all plans under that contract) is a qualifying contract and if so, what QBP percentage applies. 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.

For 2013 and 2014, the QBP demonstration rules for low enrollment contracts were in effect. Under the demonstration, low enrollment plans received a QBP add-on of 3 percentage points, because in general plans could receive bonuses if they had a Star Rating of at least 3 stars under the demonstration. For 2015 payments, we propose to treat low enrollment plans as qualifying plans, except that the QBP percentage will be 3.5 percentage points. We believe that for 2015 new MA plans and low enrollment MA plans should receive the same treatment for the purpose of the quality bonus payments.

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

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 average FFS county spending for 2015 that is less than the national average FFS spending for 2015. 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.

The 2015 FFS rates 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 2015 Announcement.

CMS will publish a complete list of qualifying counties in the final 2015 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 2014 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.

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, which began in 2012 and will end in 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)(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

	Two Year County Blend		Four Year County Blend		Six Year County Blend	
Year	**Pre-ACA**	**ACA**	**Pre-ACA**	**Pre-ACA**	**ACA**	**Pre-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 and Quality Bonus

Under section 1854(b)(1)(C) of the Act, except for MSA plans, the level of rebate is tied to the level of the plan's Star Rating. Rebates are calculated, for each plan bid, 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 that new rebate percentages apply based on a plan's Star Rating, as shown in Table II-4.

Table II-4. MA Plan Beneficiary Rebate Percentages

Star Rating	2015
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 beneficiary rebate percentage. The statute is silent on the rebate percentage to assign to low enrollment plans in years after 2012. We view this as a gap in the statute, particularly in light of the direction in section 1853(o)(3)(A)(ii) to treat low enrollment plans as qualifying plans for purposes of the quality bonus payment percentage. 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 beneficiary rebate percentage for 2015.

Section B. Calculation of Fee for Service Rates

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

In the 2014 Announcement, we announced that we would phase-in changes to the AGA methodology. Under this approach, CMS re-priced the inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2007 – 2011 to reflect the most current wage indices, and re-tabulated physician claims with the most current Geographic Practice Cost Index. The AGA used in payment for 2014 was a 50/50 blend of this re-priced AGA and the non-repriced AGA. For more details on the AGAs, please see Section II.F of the 2014 Advance Notice, available on the CMS website at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

For 2015, we are proposing a number of updates and refinements to the AGA calculation. First, we are proposing to update the claims data used to calculate the AGAs. We are proposing to fully phase-in the wage index and Geographic Practice Cost Index re-pricing that we began in 2014. In addition, we are proposing additional re-pricing refinements to reflect other changes in the FFS payment rules. These updates and refinements are discussed below.

B1. AGA Methodology for 2015

In the first step, for 2015, CMS will add the 2012 cost and enrollment data, and drop the 2007 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 2008-2012.

In the second step, CMS will make several adjustments for the following items to the 2012 costs (CMS has already made these adjustments to the 2009, 2010, and 2011 claims data):

- Exclusion of hospice costs
- Exclusion of FFS claims paid on behalf of cost plan enrollees

For Puerto Rico, CMS will only include claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment for all five years (2008 to 2012).

In the third step, we will re-price the historical inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2008 – 2012 to reflect the most current (i.e., FY 2014) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2014) Geographic Practice Cost Index.

Proposed Refinements for 2015. In addition to using the repriced data, CMS is considering making adjustments to account for the following two changes to Medicare FFS payment: Uncompensated Care Payments and competitive bidding for durable medical equipment as discussed below. We anticipate that these changes will be budget neutral overall.

B2. Uncompensated Care Payments

Section 3133 of the Affordable Care Act reduces hospital Medicare Disproportional Share Hospital (DSH) Payments by 75 percent beginning on October 1, 2013. As a partial replacement for the 75 percent reduction in DSH payments, eligible hospitals may receive uncompensated care payments (UCP).

Beginning in fiscal year 2014, CMS will calculate an aggregate uncompensated care amount based on 75 percent of estimated Medicare DSH payments for the fiscal year, adjusted by the percentage reduction in the national rate of insured. Eligible hospitals may each receive a share of this aggregate pool, based on their share of uncompensated care provided by all DSH hospitals.

For 2015, the relative county cost factors for the MA rates will be calculated using FFS claims for the period 2008-2012. Without adjustment, these historical claims would not reflect the changes in DSH and uncompensated care payments described above that would apply in 2015. For 2015, we are proposing to re-price the claims to account for the new uncompensated care payment.

Under this re-pricing approach, we would adjust the 2008 to 2012 claims for each DSH hospital to reflect the reduction in DSH payments and the allocation of the UCP for FY 2014. The adjustment would reflect hospital-specific UCP levels as follows:

- Calculate aggregate DSH payments in the base fiscal year (FY).
- Calculate an adjustment ratio equal to the aggregate base-year DSH payments * 75 percent * 94.3 percent / FY 2014 UCP payments from the final FY 2014 IPPS rule. Please note the 94.3 percent represents the FY 2014 statutory UCP "factor 2."
- Determine the per-claim UCP for the base year for each facility as the FY 2014 UCP * adjustment ratio / number of claims.
- Replace 75 percent of DSH payment for each claim in a given facility with the per-capita UCP amount calculated above.

While the UCP payments supporting this method may differ from the final amount that the hospital will ultimately be paid for CY2015, this approach is the best available approximation of what Medicare will pay in CY 2015. We believe that making the proposed adjustments will improve the accuracy of the relative county cost factors and, therefore, of the FFS county rates used as the basis for MA capitated payments.

B3. Competitive Bidding for Durable Medical Equipment (DME)

Section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a competitive bidding process for Part B DME, enteral nutrition, and off-the shelf orthotics as a permanent part of the Medicare program. This provision of law has been amended by subsequent legislation, including the Medicare Improvements for Patients and Providers Act of 2008 and the ACA.

Under the program, DME suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. The new, lower payment amounts resulting from the competition replace the Medicare DME fee schedule amounts for the bid items in these areas. The program sets more appropriate payment amounts for DME items that result in savings to the Medicare program.

CMS began the new payment system on January 1, 2011 in nine markets nationwide[2]. This round referred to as the DME "Round 1 Rebid" included nine DME product categories. The Round 1 Rebid contracts ended on December 31, 2013. In 2013, the program expanded to "Round 2" which includes an additional 91 metropolitan areas and adds a national mail order program for diabetic testing supplies. Round 2 and national mail-order contracts and prices

[2]These nine areas are: Charlotte, NC, Cincinnati, OH, Cleveland, OH, Dallas, TX, Kansas City, MO, Miami, FL, Orlando, FL, Pittsburgh, PA, and Riverside, CA.

became effective on July 1, 2013. "Round 1 Recompete" contracts and prices went into effect on January 1, 2014.

For 2015, we propose to re-price DME claims to account for the changes in prices associated with the competitive bid program. Specifically, we propose to re-price DME claims from 2008 to 2012 to reflect the most current DME prices in each of the Round 1 and Round 2 bidding areas. We will use the Round 1 Recompete and Round 2 prices.

It is important to note that the national effect on Medicare spending due to DME competitive bidding is taken into account in the trend factors that are used to update the county rates, i.e., the growth percentages. That is, the trend factors reflect the lower aggregate per capita Medicare spending nationally due to DME competitive bidding. Therefore, re-pricing DME claims for the purpose of calculating the county relative factors will increase or decrease individual county rates, but is likely to be budget neutral overall.

B4. Final Steps in AGA Calculation

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; and
- 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).

In the final step, the average of the five year geographic indices, based on the adjusted claims data, would be divided by the county's average five-year risk score from the 2015 risk model in order to develop the AGA for that county. This step is unchanged from previous years.

Section C. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1853(k) of the Act to require CMS to phase out indirect medical education (IME) amounts from MA capitation rates. Pursuant to section 1894(d) 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 2015, we will first calculate the 2015 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 2015 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. By statute, the maximum reduction for any specific county in 2015 is 3.6 percent of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2015 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section D. ESRD State Rates

In developing the 2015 ESRD Medicare Advantage rates, we obtain the FFS dialysis reimbursement and enrollment data by each state for the years 2008 – 2012. For each year, we compute the per capita cost by state. The geographic indices for each state 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 determined. As discussed above, the AGA is the 5-year weighted average of the geographic indices, which is standardized by dividing by the 5-year average risk scores. We calculated the 2012 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2012 data above, and using trend factors, develop the prospective 2015 FFS ESRD dialysis USPCC. The 2015 ESRD dialysis rates by state are determined by multiplying the 2015 FFS ESRD dialysis USPCC by the state AGA. The 2015 ESRD dialysis rate is adjusted by removing the direct graduate medical expenses (GME) and gradually removing the indirect medical expenses (IME).

Section E. Clinical Trials

In 2015, 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 2016

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 2016 in the final Announcement of Calendar Year (CY) 2015 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, 2014 enrollment data to identify the location of network areas for plan year 2016.

Section G. CMS-HCC Risk Adjustment Model for CY 2015

For the 2014 payment year, we implemented an updated, clinically revised CMS-HCC risk adjustment model and are blending the risk scores calculated using this model with the risk scores calculated using the CMS-HCC model used for 2013 payments, weighting the risk scores from the 2013 CMS-HCC model by 25 percent and the risk scores from the 2014 CMS-HCC model by 75 percent.

For the 2015 payment year, we propose to continue the same blending approach used to calculate risk scores for the 2014 payment year. For more details on the clinically revised CMS-HCC model, and this blending approach, please see Section II.G of the 2014 Advance Notice and Section III.D of the 2014 Rate Announcement.

We will continue to use the same risk adjustment model for PACE payments that we have used from 2012 through 2014. This model is described in the 2012 Rate Announcement in Tables 9 through 11.

Section H. Medicare Advantage Enrollee Risk Assessments

In the 2014 Advance Notice, we discussed Medicare Advantage (MA) enrollee risk assessments and their use as a tool to identify diagnoses that can be submitted to CMS for the purpose of risk adjusted payment. We expressed concern that these risk assessments could be used as a vehicle for collecting risk adjustment diagnoses without follow-up care or treatment being provided to the beneficiary. We announced that CMS would implement a new data collection requirement, beginning with 2013 dates of service, in which MA organizations would be required to flag diagnoses from MA enrollee risk assessments in their risk adjustment data submissions to CMS.

In addition, we stated that we were considering excluding, for risk adjustment purposes, the diagnoses collected from MA enrollee risk assessments that are not confirmed by a subsequent clinical encounter.

In the final Rate Announcement for 2014, we deferred the collection of flags for enrollee risk assessments until 2014 dates of service. In addition, we stated that we would propose and finalize a policy on the extent to which diagnoses from 2014 enrollee risk assessments would be used to calculate risk scores for payment year 2015 in the 2015 Advance Notice and Rate Announcement.

After the release of the 2014 Rate Announcement, we met with vendors and MA organizations to learn more about industry practices for enrollee risk assessments. We learned that generally MA enrollee risk assessments are performed in beneficiaries' homes and are typically conducted by healthcare professionals who are contracted by the vendor and are not part of the plan's contracted provider network, i.e., are not the beneficiaries' primary care providers. The assessments usually involve collecting diagnostic information, reviewing medications, assessing functional status, and identifying opportunities for case management. Results from an enrollee risk assessment and lab tests performed in the home are usually forwarded to the MA plan and/or the beneficiary's primary care physician, with suggestions for follow-up visits where appropriate. In general, treatment is not a component of these risk assessments, although lab tests pertinent to HEDIS measures may be performed (e.g., tests for chronic kidney disease, HgbA1c and LDL for diabetics). A few organizations, however, did express an interest in expanding treatment in the home in the future.

CMS supports the use of enrollee risk assessments for wellness, care coordination, and disease prevention. We also support such assessments as a tool for identifying beneficiaries in need of treatment. If medication management is improved and hospitalizations are avoided, beneficiaries receive better quality of care and MA organizations face reduced costs of care. However, there appears to be little evidence that beneficiaries' primary care providers actually use the information collected in these assessments or that the care subsequently provided to beneficiaries is substantially changed or improved as a result of the assessments. Therefore, we continue to be concerned that in-home enrollee risk assessments primarily serve as a vehicle for collecting diagnoses for payment rather than serve as an effective vehicle to improve follow-up care and treatment for beneficiaries.

The purpose of risk adjustment is to measure health status that is related to plan liability. In the case of these assessments, and the identification of risk adjustment diagnoses during the assessment, it is not clear that there is plan liability associated with the provision of treatment for the conditions identified during the assessment. As a result, we are concerned that the apparent significant increase in the prevalence of these assessments by MA organizations contributes to increased risk scores and differences in coding patterns between MA and FFS. If providers are

using the results of enrollee risk assessments performed at home to guide treatment, then we expect that diagnoses identified during home assessments will also be documented in medical records from the follow-up treatment visit(s) in a clinical setting. Thus, we propose for 2015 to exclude for payment purposes diagnoses identified during a home visit that are not confirmed by a subsequent clinical encounter.

This proposal does not conflict with or change the requirements at § 422.101(f) regarding the SNP Model of Care, which include the SNP Health Risk Assessment that promotes coordinated care for special needs individuals. As we noted above, CMS supports risk assessments as an important tool for enhancing care coordination for Medicare beneficiaries. We also note that this proposal does not affect in any way a beneficiary's eligibility to receive or a plan's ability to offer appropriate medical care in the home setting; this proposal relates exclusively to the treatment of risk adjustment data arising from in-home risk assessments.

We ask for comments on this proposal. Last year, we received a number of comments on our 2014 Advance Notice proposal regarding the use of diagnoses from home enrollee risk assessments for purposes of risk-adjusting payment. Many commenters from the industry expressed concern that CMS did not recognize the significant value of such assessments in the home. With appropriate follow-up treatment, we believe that home visits may improve care and would like comments on what treatment, if any, is provided during the home assessments and what evidence is available that home assessments are associated with follow-up treatment. Further, to the extent that the commenters believe that home assessments improve care, and are not just efforts to increase the diagnoses collected, we request that the commenters submit suggestions for specific and measurable ways that CMS could operationalize to use certain diagnoses from home visits for risk adjustment purposes in 2015. For example, we could establish a requirement that beneficiaries have a medical visit in a primary care setting within 60 days of the home visit in order for the diagnoses from the home visit to be used for risk adjustment. Any proposed approach to use certain diagnoses from home visits for risk adjustment purposes would need to address our concerns about coding efforts that do not have associated plan liability for medical care and would need to allow us to determine whether and how MA organizations are using home visits to improve care.

Section I. Adjustment for MA Coding Pattern Differences

We have updated the MA coding adjustment factor for 2015 to 5.16 percent.

Section J. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other

years, predictions for prior years have been lower and predictions for succeeding years have historically 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 is 1.0 in subsequent years.

The normalization factor is derived by first using the appropriate model to predict risk scores over a number of years. Next, we trend the risk scores to determine the annual percent change in the risk score. This annual trend rate is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor.

Below are the preliminary normalization factors for each model (values may not be exact due to rounding). The final normalization factors will be published in the final 2015 Announcement, to be released April 7, 2014.

J1. Normalization for the CMS-HCC Model

To calculate the preliminary normalization factor for each of the CMS-HCC risk adjustment models, CMS used the risk adjustment models to be used in 2015 payment to calculate two years of risk scores for the FFS population. For the 2015 normalization factors, CMS used 2012 and 2013 risk scores to calculate an annual trend. CMS used two instead of five years to calculate the annual trend in order to better capture more recent demographic changes in the Medicare population, e.g., the increased proportion of younger beneficiaries ("baby boomers") in the program. CMS then compounded this annual trend to adjust for FFS risk score growth: (1) over the three years from the 2012 model denominator year to the 2015 payment year for the model implemented in 2014; and (2) over the four years from the 2011 model denominator year to the 2015 payment year for the model implemented in 2013.

The Part C normalization factors are used to normalize 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.

CMS estimates the annual trends using a linear function applied to the following years' risk scores. See Table II.5.

Table II.5 Annual Trends for CMS-HCC Models

Clinically-revised model implemented in 2014 (denominator year of 2012)	Model implemented in 2013 (denominator year of 2011)
2012: 1.000 2013: 0.999	2012: 1.011 2013: 1.010

The linear annual trends over these two years (2012 and 2013) are -0.0011 and -0.0005, respectively. These annual trends are applied for the years between the appropriate denominator year and the payment year (2015) by taking it to the third or fourth power. The normalization factors are obtained as follows:

- Model implemented in 2014: $(1-0.0011)^3 = 0.997$
- Model implemented in 2013: $(1-0.0005)^4 = 0.998$

J2. Normalization Factor for the PACE Model

The preliminary 2015 normalization factor for the CMS-HCC risk adjustment model used for the PACE program is 1.004.

To calculate the normalization factor for the PACE risk adjustment model, CMS used the risk adjustment model to be used in 2015 payment to calculate two years of risk scores for the FFS population. For the 2015 normalization factor, CMS used 2012 and 2013 risk scores to calculate an annual trend. CMS used two instead of five years to calculate the annual trend in order to better capture more recent demographic changes in the Medicare population, e.g., the increased proportion of younger beneficiaries ("baby boomers") in the program. CMS then compounded this annual trend to adjust for FFS risk score growth over the six years from the model denominator year of 2009 to the payment year of 2015.

The normalization factor applied to the CMS-HCC model used for PACE is used to normalize 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.

CMS estimates an annual trend using a linear function applied to the following years' risk scores:

- 2012: 1.038
- 2013: 1.039

The linear annual trend over these two years (2012 and 2013) is 0.001. This annual trend is applied for the years between the denominator year (2009) and the payment year (2015) by taking it to the sixth power. The normalization factor is obtained as follows: $(1.001)^6 = 1.004$.

J3. Normalization Factor for the ESRD Dialysis Model

The preliminary 2015 normalization factor for the ESRD dialysis model is 0.990.

To calculate the normalization factor for the CMS-HCC ESRD dialysis model, CMS uses the ESRD risk adjustment model to be used in 2015 payment to calculate two years of dialysis risk scores for the FFS population. For the 2015 normalization factor, CMS used 2012 and 2013 risk

scores to calculate an annual trend. CMS used two instead of five years to calculate the annual trend in order to better capture more recent demographic changes in the Medicare population, e.g., the increased proportion of younger beneficiaries ("baby boomers") in the program. CMS then compounded this annual trend to adjust for FFS risk score growth over the six years from the model denominator year of 2009 to the payment year of 2015.

CMS estimates an annual trend using a linear function applied to the following years' risk scores:

- 2012: 1.025
- 2013: 1.023

The linear annual trend over these two years (2012 and 2013) is -0.002. This annual trend is applied for the years between the denominator year (2009) and the payment year (2015) by taking it to the sixth power. The normalization factor is obtained as follows: $(1\text{-}0.002)^6 = 0.990$.

J4. Normalization Factor for Functioning Graft Model

The preliminary 2015 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.004.

To calculate the normalization factor for the CMS-HCC ESRD post-graft risk adjustment model, CMS used the ESRD post-graft model to be used in 2015 payment to calculate two years of post-graft risk scores for the FFS population. For the 2015 normalization factor, CMS used 2012 and 2013 risk scores to calculate an annual trend. CMS used two instead of five years to calculate the annual trend in order to better capture more recent demographic changes in the Medicare population, e.g., the increased proportion of younger beneficiaries ("baby boomers") in the program. CMS then compounded this annual trend to adjust for FFS risk score growth over the six years from the model denominator year of 2009 to the payment year of 2015.

CMS estimates an annual trend using a linear function applied to the following years' risk scores:

- 2012: 1.038
- 2013: 1.039

The linear annual trend over these two years (2012 and 2013) is 0.001. This annual trend is applied for the years between the denominator year (2009) and the payment year (2015) by taking it to the sixth power. The normalization factor is obtained as follows: $(1.001)^6 = 1.004$.

J5. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The preliminary 2015 normalization factor for the RxHCC model is 1.014.

To calculate the normalization factor for the RxHCC risk adjustment model, CMS used the risk adjustment model to be used in 2015 payment and calculated two years of risk scores for the population of Medicare beneficiaries enrolled in Part D plans. For the 2015 normalization factor, CMS used 2011 and 2012 risk scores to calculate an annual trend. CMS used two instead of five years to calculate the annual trend in order to better capture more recent demographic changes in the Medicare population, e.g., the increased proportion of younger beneficiaries ("baby boomers") in the program. CMS then compounded this annual trend to adjust for Part D risk score growth over the three years from the denominator year of 2012 to the payment year of 2015.

The Part D normalization factor is used to normalize all Part D risk scores. The trend is calculated on the population of Medicare beneficiaries enrolled in PDP and MA-PD plans.

CMS estimates an annual trend using a linear function applied to the following years' risk scores:

- 2011: 0.995
- 2012: 1.000

The linear annual trend over these two years (2011and 2012) is 0.005. This annual trend is applied for the years between the denominator year (2012) and the payment year (2015) by taking it to the third power. The normalization factor is obtained as follows: $(1.005)^3 = 1.014$.

Section K. Frailty Adjustment for PACE organizations and FIDE SNPs

The statute 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 2015; the same frailty factors used in 2014 for PACE organizations will be used. These can be found in the 2012 Announcement in Attachment VI, Table 13. Furthermore, frailty for FIDE SNPs will be calculated similarly to the 2014 approach for which we used two sets of FIDE SNP frailty factors based on both models used for payment.

Thus, for CY 2015, we would calculate frailty scores using the frailty factors associated with the clinically revised model CMS-HCC model and using the frailty factors associated with the 2013 CMS-HCC model. The FIDE SNP frailty factors associated with the clinically revised CMS-HCC model are explained in greater detail below. The FIDE SNP frailty factors associated with the 2013 CMS-HCC model were first posted in the 2013 Advance Notice and are printed below.

CMS will separately calculate frailty scores for FIDE SNPs using each set of factors and blend the two frailty scores in the same manner as the 2015 risk scores. These blended frailty scores will be used both to determine a FIDE SNP's eligibility for frailty payments and, if eligibility is met, for payment.

For CY 2015, MA organizations that are planning to sponsor a FIDE SNP and wish to be considered for receiving frailty payments have already signed up for sampling for the Health Outcome Survey (HOS) at the level of the plan benefit package (PBP), per the memorandum sent by CMS on October 1, 2013. For 2015, these organizations have the option of administering either the HOS or Health Outcomes Survey Modified (HOS-M) for purposes of assessing the frailty of their FIDE SNP(s). MA Organizations need to contract with a vendor to field the HOS or HOS-M at the PBP level if CMS is to be able to calculate a frailty score for any FIDE SNP. Targeted sampling is needed when the FIDE SNP exists (1) at a sub-contract level; (2) at the contract level, but has less than 500 enrollees; or (3) at the contract-level, but wants HOS-M fielded in addition to HOS.

Frailty scores would be calculated as in previous years, with the changes discussed here for those FIDE SNPs that chose to administer the HOS-M for purposes of determining frailty payments. For FIDE SNPs that choose to administer the HOS-M, the frailty scores used in determining payment will be based on each PBP's HOS-M results, provided that at least 30 enrollees responded to the HOS-M survey. For PBPs that are the sole PBP in the contract and do not have a sufficient HOS-M response rate (due to insufficient enrollment or an insufficient response rate), frailty payment would be based on the PBP's HOS-based score. Furthermore, for single-PBP contracts that have a sufficient response rate for both the HOS-M and HOS surveys, CMS would calculate frailty based on the results from each survey, and the contract will receive the highest of the two frailty score calculations.

PBPs that are one of multiple PBPs in a contract that choose HOS-M and do not have a sufficient response rate would not receive consideration for frailty payment. CMS has attempted to inform MA organizations with PBPs that potentially could fall into this situation, to advise them to choose HOS for frailty purposes.

The frailty score derived from either HOS or HOS-M results would be compared with PACE frailty in the same manner as was done for 2014 to determine whether a FIDE SNP has a similar average level of frailty as PACE.

Table II-5 below presents the FIDE SNP frailty factors for CY 2015. These factors are the same as those used to calculate frailty scores for payment year 2014, and are the factors that are associated with the clinically-revised CMS-HCC model and the 2013 CMS-HCC model. For 2015, FIDE SNP frailty scores will be calculated using each set of factors below and blended in the same manner as the 2015 risk scores.

Table II-5. FIDE SNP Frailty Factors for CY 2015

ADL	Clinically Revised CMS-HCC Model Implemented in 2014		2013 CMS-HCC Model	
	Non-Medicaid	Medicaid	Non-Medicaid	Medicaid
0	−0.074	−0.156	−0.062	−0.198
1-2	0.143	0.000	0.151	0.000
3-4	0.278	0.195	0.276	0.154
5-6	0.278	0.446	0.276	0.387

Section L. MSP Factor

There is no change in the Medicare as Secondary Payer (MSP) factors for 2015. We will continue to use the MSP adjuster of 0.173 for working aged and working disabled beneficiaries. CMS will continue to apply the MSP adjustment to individual-level payments. We also will continue to use the ESRD MSP factor of 0.215.

Section M. 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 43 CFR 423.2400 through 423.2480. These requirements include the application of credibility adjustments at § 422.2440 and § 423.2440, which are intended to take into account the special circumstances of contracts with lower enrollment. An MA organization and Part D sponsor may add a credibility adjustment to a contract's MLR if the contract's experience is partially credible, as defined by CMS. Fully-credible contracts are not eligible for a credibility adjustment. Finally, for year when a contract has non-credible experience, the sanctions specified in the statute for having an MLR that does not meet the minimum requirement of 85 percent would not apply.

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. The regulations, at § 422.2440(d) and § 423.2440, 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.

For CY 2015, 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	Fully-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	Fully-credible

Section N. International Classification of Diseases-10 (ICD-10) Code Set and Diagnosis Data Sources for 2015 Risk Scores

The transition from ICD-9 to ICD-10 code sets is scheduled to take place by October 1, 2014. As in previous payment years, the data collection year for risk scores used for 2015 payment will use diagnoses from the prior calendar year (CY2014). Thus, both ICD-9 codes (from dates of service January 1, 2014 – September 30, 2014) and ICD-10 codes (from dates of service October 1, 2014 – December 31, 2014) will be used in calculating 2015 risk scores.

We will use diagnoses from the Encounter Data System (EDS) submissions for the calculation of 2015 risk scores (2014 dates of service). As 2015 will be the first year of using diagnoses from encounter data for calculating risk scores, we will also continue to use 2014 diagnoses submitted

to the Risk Adjustment Processing System (RAPS) to calculate 2015 risk scores. Data from RAPS will be treated as an additional source of diagnoses, along with diagnoses from FFS claims and EDS.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2015

Section A. Update of the RxHCC Model

For 2015, 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 2015 model will encompass the following changes:

1) Model revisions to map to the 2015 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); and
4) Inclusion of MA-PD data in the model calibration.

A1. Model revisions to map to the 2015 benefit structure

CMS recalibrated the RxHCC risk adjustment model to update the model to reflect the 2015 benefit structure. This update involves making adjustments to the Prescription Drug Event (PDE) data from the prediction year to approximate the 2015 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 gap. For 2015, plan liability for non-LIS beneficiaries in the gap will be 35 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 2015, we updated the underlying data, using diagnosis data from 2011 fee-for-service (FFS) claims and MA-PD RAPS files, along with 2012 expenditure data from PDE records.

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

The revised RxHCC risk adjustment model is the result of clinical input regarding the composition of each RxHCC and its contribution to total plan liability for prescription drug

costs. As a result of the clinical revisions, the 2015 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 includes conditions for major congenital heart disorders that were split from an existing RxHCC into a new RxHCC to improve the prediction of total drug expenditures. The new RxHCCs are:

- Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer
- Ventricular Septal Defect and Major Congenital Heart Disorders

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 conditions within the 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 2015 payment year diagnosis code to 2015 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 RxHCC 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 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 these 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.

Now that MA-PDs are submitting complete diagnostic data for the RxHCC model, we can recalibrate the RxHCC model using both FFS and MA-PD diagnoses. Therefore, in 2015, the updated version of the RxHCC model would include data for beneficiaries enrolled in MA-PD plans. To recalibrate the model for payment year 2015, diagnoses for 100 percent FFS and MA-PD beneficiaries enrolled in a Part D plan were used; 2011 diagnoses were used to predict 2012 expenditures. To be included in the model estimation sample, beneficiaries must be (1) enrolled in a PDP or MA-PD for at least one month in the base year (2011); (2) FFS or MA-PD for all 12 months of the base year (2011); and (3) enrolled in a PDP or an MA-PD for at least one month in the payment year. To recalibrate the model, data for the entire eligible population of FFS and MA, as described above, were used.

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 unique 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 at the industry level.

Recalibration of the RxHCC model can result in changes in risk scores for individual beneficiaries and for plan average risk scores, depending on each individual beneficiary's combination of diagnoses. In Attachment V of this Notice, we provide draft factors for each RxHCC for each segment of the model.

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 to condition categories are made based on each category's ability to predict costs 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 developed 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 2012 to create the relative factors for the model. The denominator, which is used to create relative factors for all segments of the model, is $998.95.

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.

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. Similarly, changes in the marginal cost attributable to one RxHCC relative to another RxHCC can change the relative factors associated with each RxHCC. In addition, changes in the relative factors will result from changes in the assignment of ICD-9 codes to RxHCCs, as well as the addition or deletion of RxHCCs to the model.

Section B. International Classification of Diseases-10 (ICD-10) Code Set and Diagnosis Data Sources for 2015 Risk Scores

The transition from ICD-9 to ICD-10 code sets is scheduled to take place by October 1, 2014. As in previous payment years, the data collection year for risk scores used for 2015 payment will use diagnoses from the prior calendar year (CY2014). Thus, both ICD-9 codes (from dates of service January 1, 2014 – September 30, 2014) and ICD-10 codes (from dates of service October 1, 2014 – December 31, 2014) will be used in calculating 2015 risk scores.

We will use diagnoses from the Encounter Data System (EDS) submissions for the calculation of 2015 risk scores (2014 dates of service). As 2015 will be the first year of using diagnoses from encounter data for calculating risk scores, we will also continue to use 2014 diagnoses submitted to the Risk Adjustment Processing System (RAPS) to calculate 2015 risk scores. Data from RAPS will be treated as additional sources of diagnoses, along with diagnoses from FFS claims and EDS.

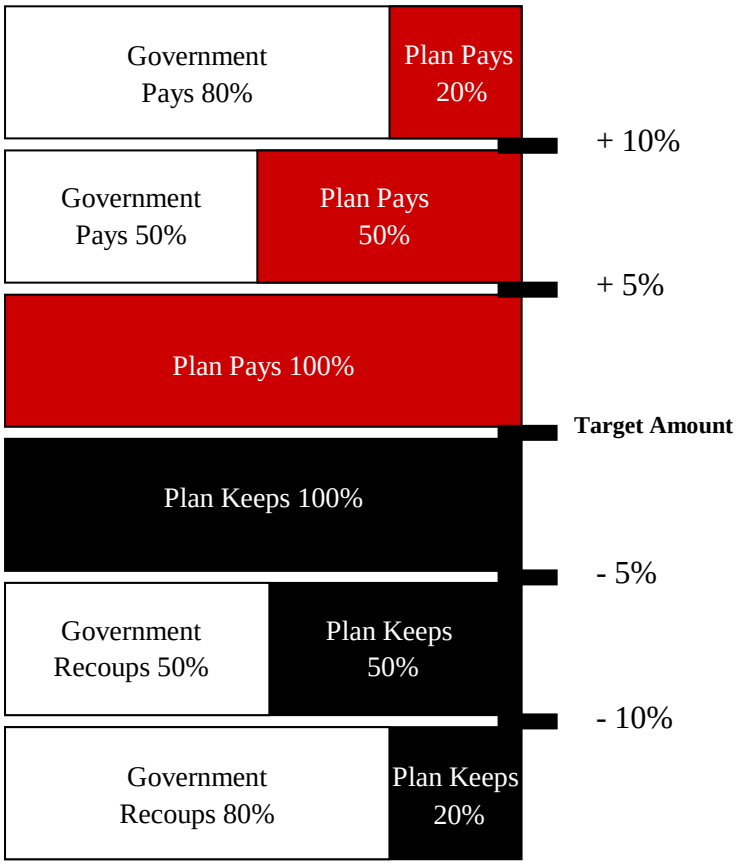
Section C. Payment Reconciliation

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 provided by CMS for 2007 – 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 in 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 2015. 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 2014. The risk percentages for the first and second thresholds remain at 5 percent and 10 percent of the target amount respectively for 2015. 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 2015.

Figure 1. Part D Risk Corridors for 2015



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

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

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

If a plan's AARCC is between the target amount and the first threshold lower limit (95 percent of the target amount), the plan keeps 100 percent of the difference between the target amount and the plan's AARCC. If a plan's AARCC is between the first threshold lower limit and the second threshold lower limit (90 percent of the target amount), the government recoups 50 percent of the difference between the first threshold lower limit and the plan's AARCC. The plan would keep

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

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2015

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.

D.1 Updates to Part D benefit parameters

The benefit parameters listed above will be increased by 4.02 percent for 2015 as summarized by Table III-1 below. This increase reflects the 2014 annual percentage trend of 4.07 percent as well as a multiplicative update of -0.05 percent 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 4.02 percent from their 2014 values.

D.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 0.87 percent for 2015 as summarized in Table III-1 below.

This increase reflects the 2014 annual percentage trend in CPI of 1.48 percent, as well as a multiplicative update of -0.60 percent for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase in the CPI.

D.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:

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

- Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries. This is an *estimate* of the average amount of total drug spending for an applicable (i.e., non-LIS) beneficiary to 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 percent beneficiary cost sharing in the deductible phase, 25 percent in the initial coverage phase, and in the coverage gap, 65 percent cost sharing for non-applicable (generic) drugs and 95 percent 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.

This is the last year we will publish these values because as of January 1, 2014, Enhanced Alternative Plan Mapping Rule 4 is no longer part of PDE reporting. Under this rule, if the YTD Gross Covered Drug cost was greater than the estimated total covered Part D spending at the Out-of-Pocket threshold, but True Out-of-Pocket (TrOOP) cost was less than or equal to the Out-of-Pocket (OOP) threshold, the Part D plan would map 15 percent of the ingredient cost, sales tax, and any fees falling within this rule (dispensing fee or vaccine administration fee) to the covered plan paid amount (CPP).

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 2014	Prior year revisions	Annual percentage increase for 2014
Applied to all parameters but (1)	4.07%	-0.05%	4.02%
CPI (all items, U.S. city average): Applied to (1)	1.48%	-0.60%	0.87%

Part D Benefit Parameters	2014	2015
Standard Benefit		
Deductible	$310	$320
Initial Coverage Limit	$2,850	$2,960
Out-of-Pocket Threshold	$4,550	$4,700
Total Covered Part D Spend at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,455.00	$6,680.00
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,690.77	$7,061.76
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.55	$2.65
Other	$6.35	$6.60
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries (category code 3)	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (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 (2)	$1.20	$1.20
Other (2)	$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	$2.55	$2.65
Other	$6.35	$6.60
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 ≤ $8,580 (individuals) or ≤ $13,620 (couples) (6) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.55	$2.60
Other	$6.35	$6.60

Part D Benefit Parameters	2014	2015
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,300 (individual) or $26,580 (couples) (6)		
(category code 4)		
Deductible	$63.00	$66.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.55	$2.65
Other	$6.35	$6.60
Retiree Drug Subsidy Amounts		
Cost Threshold	$310	$320
Cost Limit	$6,350	$6,600

(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 a couple) if the individual (couple) was not receiving home and community-based services qualify for zero cost-sharing as of January 1, 2012, 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 2014 values of $63.47, $1.18, and $3.55, respectively.

(6) The actual amount of resources allowable will be updated for contract year 2015.

Section E. 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 percent cost sharing for applicable drugs, prior to the application of any manufacturer discounts, and 25 percent 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 2015, the coinsurance under basic prescription drug coverage for certain beneficiaries is further reduced from 2014 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 65 percent. Also in 2015, 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 percent of the negotiated price, as a result of the application of 95 percent coinsurance and a 50 percent 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 65 percent coinsurance for non-applicable drugs and 45 percent 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 2015.

Section F. 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 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, applicable beneficiaries will pay 45 percent and plans will pay 55 percent in 2015.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2015

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 2015, 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, 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 $310 in 2014 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,850 in 2014 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,550 in 2014 and rounded to the nearest multiple of $50. The "annual percentage increase" applied to the out-of-pocket threshold includes the additional negative 0.25% adjustment required by the ACA.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.55 per generic or preferred drug that is a multi-source drug, and $6.35 for all other drugs in 2014, 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 $2.55 per generic or preferred drug that is a multi-source drug, and $6.35 for all other drugs in 2014, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $63[3] in 2014 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.55 per generic or preferred drug that is a multi-source drug, and $6.35 for all other drugs in 2014, 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 2014[4], 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 2015 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

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[3] 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 2014 value of $63.47

[4] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2014 values of $1.18 per generic or preferred drug that is a multi-source drug, and $3.55 for all other drugs.

$$\frac{August2013 - July2014}{August2012 - July2013} = \frac{\$2{,}920.29}{\$2{,}806.05} = 1.0407$$

In the formula, the average per capita cost for August 2012 – July 2013 ($2,806.05) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2013 – July 2014 ($2,920.29) is calculated based on actual Part D PDE data incurred from August – December, 2013 and projected through July, 2014.

The 2015 benefit parameters reflect the 2014 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 cost 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	4.25%	4.17%
2010	3.09%	3.02%
2011	2.45%	2.44%
2012	2.46%	2.44%
2013	1.83%	2.01%
2014	-2.76%	-2.82%

Accordingly, the 2015 benefit parameters reflect a multiplicative update of -0.05 percent for prior year revisions. In summary, the 2014 parameters outlined in Section A are updated by 4.02 percent for 2015 as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2014	4.07%
Prior year revisions	-0.05%
Annual percentage increase for 2015	4.02%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree with 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 2015, the

September 2014 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 2014 CPI based on the projected amount included in the President's FY2015 Budget.

The September 2013 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2015 is calculated as follows:

$$\frac{\text{Projected September 2014 CPI}}{\text{Actual September 2014 CPI}} \; or \; \frac{237.624}{234.149} = 1.0148$$

(Source: President's FY2015 Budget and Bureau of Labor Statistics, Department of Labor)

The 2015 benefit parameters reflect the 2014 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2013 annual percentage increase. The 2014 parameter update reflected an annual percentage trend in CPI of 1.80 percent. Based on the actual reported CPI for September 2013, the September 2013 CPI increase is now estimated to be 1.18 percent. Thus, the 2015 update reflects a multiplicative -0.60 percent correction for prior year revisions. In summary, the cost sharing items outlined in Section B are updated by 0.87 percent for 2015 as summarized by Table IV-3.

Table IV-3. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2014	1.48%
Prior year revisions	-0.60%
Annual percentage increase for 2014	0.87%

Note: Percentages are multiplicative, not additive. Values are carried to additional decimal places and may not agree with 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 $325 and $6,600, respectively,

for plans that end in 2013, and, as $310 and $6,350, respectively, for plans that end in 2014. For 2015, the cost threshold is $320 and the cost limit is $6,600.

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

For 2015, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $7,061.76. 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 beneficiary cost sharing in the deductible phase, 25 percent in the initial coverage phase and in the coverage gap, 65 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 0.18 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 0.09 percent to 94.91 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:

$$\text{ILC} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \text{ or } \$2{,}960 + \frac{\$3{,}720}{90.693\%} = \$7{,}061.76$$

One hundred percent of the 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* $4,700 - $980 = $3,720

- Weighted gap coinsurance factor is calculated as follows:

  (Brand GDCB % for non-LIS × 94.91% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 65% cost sharing for non-applicable drugs)

  or

  (85.9% × 94.91%) + (14.1% × 65%) = 90.693%

- 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 2013 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

  94.91% = [(99.82% × 95%) + (0.18% × 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 2013 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		-	0.241	-	0.403	1.849
35-44 Years		-	0.434	-	0.614	1.820
45-54 Years		-	0.518	-	0.704	1.589
55-59 Years		-	0.505	-	0.688	1.523
60-64 Years		-	0.472	-	0.636	1.432
65-69 Years		0.278	-	0.407	-	1.512
70-74 Years		0.274	-	0.420	-	1.426
75-79 Years		0.267	-	0.408	-	1.351
80-84 Years		0.267	-	0.394	-	1.289
85-89 Years		0.261	-	0.367	-	1.213
90-94 Years		0.246	-	0.314	-	1.102
95 Years or Over		0.188	-	0.222	-	0.916
Male						
0-34 Years		-	0.207	-	0.434	1.719
35-44 Years		-	0.348	-	0.560	1.665
45-54 Years		-	0.436	-	0.625	1.577
55-59 Years		-	0.448	-	0.603	1.431
60-64 Years		-	0.410	-	0.556	1.355
65-69 Years		0.288	-	0.336	-	1.406
70-74 Years		0.278	-	0.353	-	1.358
75-79 Years		0.233	-	0.340	-	1.300
80-84 Years		0.192	-	0.329	-	1.258
85-89 Years		0.155	-	0.298	-	1.201
90-94 Years		0.132	-	0.259	-	1.122
95 Years or Over		0.122	-	0.248	-	0.989
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.071	-	0.155	-	0.042
Originally Disabled_Male		-	-	0.114	-	0.042
Variable	**Description Label**					
RXHCC1	HIV/AIDS	2.397	3.021	2.962	3.449	1.564
RXHCC5	Opportunistic Infections	0.168	0.106	0.101	0.132	0.062
RXHCC15	Chronic Myeloid Leukemia	4.621	5.220	5.364	6.731	3.219

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
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	2.420	2.678	2.010	2.470	0.965
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	0.640	0.611	0.757	0.805	0.218
RXHCC18	Lung, Kidney, and Other Cancers	0.180	0.195	0.217	0.285	0.057
RXHCC19	Breast and Other Cancers and Tumors	0.076	0.037	0.076	0.077	0.041
RXHCC30	Diabetes with Complications	0.343	0.357	0.412	0.481	0.347
RXHCC31	Diabetes without Complication	0.238	0.211	0.296	0.312	0.243
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	1.649	6.140	1.542	6.984	0.197
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.101	0.137	0.048	0.156	0.055
RXHCC42	Thyroid Disorders	0.065	0.125	0.068	0.136	0.044
RXHCC43	Morbid Obesity	0.061	0.015	0.042	0.042	0.116
RXHCC45	Disorders of Lipoid Metabolism	0.093	0.090	0.139	0.187	0.079
RXHCC55	Chronic Viral Hepatitis	0.156	0.395	0.317	0.366	0.107
RXHCC65	Chronic Pancreatitis	0.166	0.148	0.078	0.096	0.083
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.076	0.143	0.062	0.096	0.020
RXHCC67	Inflammatory Bowel Disease	0.388	0.305	0.292	0.510	0.127
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.100	0.079	0.142	0.160	0.070
RXHCC80	Aseptic Necrosis of Bone	0.089	0.108	0.060	0.193	0.109
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.523	0.552	0.789	1.324	0.350
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.199	0.261	0.277	0.513	0.123
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.160	0.251	0.184	0.294	0.117
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.038	0.122	0.114	0.179	-

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
RXHCC95	Sickle Cell Anemia	0.073	0.217	0.110	0.761	0.219
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.460	0.651	0.474	0.603	0.433
RXHCC97	Immune Disorders	0.251	0.280	0.269	0.318	0.165
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.038	0.077	0.032	0.089	0.055
RXHCC111	Alzheimer's Disease	0.461	0.323	0.214	0.121	-
RXHCC112	Dementia, Except Alzheimer's Disease	0.208	0.083	0.057	-	-
RXHCC130	Schizophrenia	0.360	0.447	0.536	0.834	0.280
RXHCC131	Bipolar Disorders	0.310	0.363	0.345	0.565	0.252
RXHCC132	Major Depression	0.180	0.298	0.228	0.401	0.219
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.180	0.194	0.162	0.391	0.137
RXHCC134	Depression	0.143	0.167	0.133	0.240	0.137
RXHCC135	Anxiety Disorders	0.054	0.075	0.082	0.177	0.127
RXHCC145	Autism	0.180	0.194	0.416	0.474	0.137
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	0.106	0.194	0.416	0.326	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	0.106	0.116	0.278	0.200	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.127	0.048	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.275	0.341	0.251	0.517	0.100
RXHCC157	Spinal Cord Disorders	0.103	0.169	0.103	0.077	0.043
RXHCC159	Inflammatory and Toxic Neuropathy	0.171	0.400	0.180	0.318	0.095
RXHCC160	Multiple Sclerosis	1.197	1.908	1.284	2.855	0.568
RXHCC161	Parkinson's and Huntington's Diseases	0.491	0.669	0.301	0.393	0.184
RXHCC163	Intractable Epilepsy	0.273	0.427	0.205	0.712	0.027
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.118	0.096	0.042	0.136	-
RXHCC165	Convulsions	0.062	0.057	0.025	0.084	-
RXHCC166	Migraine Headaches	0.123	0.220	0.127	0.155	0.113

		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
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.106	0.224	0.135	0.202	0.153
RXHCC185	Primary Pulmonary Hypertension	0.511	1.280	0.523	1.211	0.238
RXHCC186	Congestive Heart Failure	0.181	0.137	0.251	0.130	0.129
RXHCC187	Hypertension	0.161	0.090	0.230	0.116	0.073
RXHCC188	Coronary Artery Disease	0.198	0.103	0.193	0.061	0.025
RXHCC191	Ventricular Septal Defect and Major Congenital Heart Disorders	0.057	0.471	0.036	0.171	0.119
RXHCC193	Atrial Arrhythmias	0.127	0.068	0.032	-	0.031
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.094	0.015	0.072	-	-
RXHCC207	Spastic Hemiplegia	0.173	0.243	0.054	0.173	0.030
RXHCC215	Venous Thromboembolism	0.046	0.082	-	0.100	0.018
RXHCC216	Peripheral Vascular Disease	0.031	0.034	0.078	0.044	-
RXHCC225	Cystic Fibrosis	0.297	1.917	0.337	2.609	0.276
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.297	0.158	0.337	0.266	0.176
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.152	0.158	0.106	0.243	0.019
RXHCC241	Diabetic Retinopathy	0.209	0.171	0.144	0.093	0.093
RXHCC243	Glaucoma	0.171	0.136	0.228	0.154	0.140
RXHCC260	Kidney Transplant Status	0.304	0.131	0.354	0.314	0.217
RXHCC261	Dialysis Status	0.178	0.249	0.306	0.643	0.268
RXHCC262	Chronic Kidney Disease Stage 5	0.105	0.088	0.118	0.112	0.068
RXHCC263	Chronic Kidney Disease Stage 4	0.105	0.088	0.105	0.112	0.068
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.104	0.119	0.037	0.072	0.031
RXHCC314	Pemphigus	0.237	0.516	0.217	0.320	0.011
RXHCC316	Psoriasis, Except with Arthropathy	0.144	0.196	0.266	0.444	0.181
RXHCC355	Narcolepsy and Cataplexy	0.570	0.752	0.572	1.041	0.309
RXHCC395	Lung Transplant Status	1.154	0.611	0.854	0.847	0.493
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.681	0.309	0.536	0.364	0.217
RXHCC397	Pancreas Transplant Status	0.247	0.131	0.354	0.314	0.217
Non-Aged Disease Interactions						

		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
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	1.350
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.272
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.254
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.188
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.140
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.098
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.026
NonAged_RXHCC145	NonAged * Autism	-	-	-	-	0.140
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	0.999
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.042

Note: The 2012 denominator of $998.95 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% 2012 PDE, 2011 Carrier NCH, 2011 Inpatient SAF, 2011 Outpatient SAF, 2012 HPMS, 2012 CME, 2011-2012 Denominator, Part D Intermediate File, and 2011 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	0.699	0.699	-	-
35-44 Years	0.982	0.983	-	-
45-54 Years	1.125	1.493	-	-
55-59 Years	1.125	1.669	-	-
60-64 Years	1.125	1.670	-	-
65 Years	0.581	1.701	1.085	1.701
66 Years	0.634	1.701	1.058	1.701
67 Years	0.648	1.701	1.058	1.701
68 Years	0.678	1.701	1.058	1.701
69 Years	0.683	1.701	1.058	1.701
70-74 Years	0.682	1.701	0.872	1.701
75-79 Years	0.679	1.701	0.679	1.701
80-84 Years	0.604	1.701	0.604	1.701
85-89 Years	0.499	1.701	0.499	1.701
90-94 Years	0.266	1.701	0.266	1.701
95 Years or Over	0.266	1.701	0.266	1.701
Male				
0-34 Years	0.384	0.516	-	-
35-44 Years	0.741	0.873	-	-
45-54 Years	0.947	1.400	-	-
55-59 Years	0.982	1.503	-	-
60-64 Years	0.982	1.645	-	-
65 Years	0.607	1.741	0.940	1.741
66 Years	0.675	1.741	0.850	1.741
67 Years	0.682	1.741	0.850	1.741
68 Years	0.722	1.741	0.850	1.741
69 Years	0.737	1.741	0.850	1.741
70-74 Years	0.735	1.741	0.780	1.741
75-79 Years	0.729	1.741	0.729	1.741
80-84 Years	0.630	1.741	0.630	1.741
85-89 Years	0.470	1.741	0.470	1.741
90-94 Years	0.329	1.741	0.329	1.741
95 Years or Over	0.329	1.741	0.329	1.741

Notes: The 2012 denominator of $998.95 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% 2012 PDE, 2011 NCH, 2012 HPMS, 2012 CME, 2011-2012 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	0.946	1.723	-	-
35-44 Years	1.390	1.885	-	-
45-54 Years	1.415	1.977	-	-
55-59 Years	1.304	2.005	-	-
60-64 Years	1.233	1.960	-	-
65 Years	0.929	2.022	1.139	2.022
66 Years	0.640	2.022	0.836	2.022
67 Years	0.640	2.022	0.836	2.022
68 Years	0.640	2.022	0.836	2.022
69 Years	0.640	2.022	0.836	2.022
70-74 Years	0.675	2.022	0.821	2.022
75-79 Years	0.696	2.022	0.821	2.022
80-84 Years	0.763	2.022	0.763	2.022
85-89 Years	0.694	2.022	0.694	2.022
90-94 Years	0.554	2.022	0.554	2.022
95 Years or Over	0.554	2.022	0.554	2.022
Male				
0-34 Years	0.822	1.947	-	-
35-44 Years	1.195	1.947	-	-
45-54 Years	1.217	1.947	-	-
55-59 Years	1.084	1.763	-	-
60-64 Years	1.007	1.739	-	-
65 Years	0.771	1.753	0.898	1.753
66 Years	0.481	1.753	0.571	1.753
67 Years	0.481	1.753	0.571	1.753
68 Years	0.481	1.753	0.571	1.753
69 Years	0.481	1.753	0.571	1.753
70-74 Years	0.532	1.753	0.532	1.753
75-79 Years	0.532	1.753	0.532	1.753
80-84 Years	0.532	1.753	0.532	1.753
85-89 Years	0.532	1.753	0.532	1.753
90-94 Years	0.488	1.753	0.488	1.753
95 Years or Over	0.488	1.753	0.488	1.753

Notes: The 2012 denominator of $998.95 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% 2012 PDE, 2011 NCH, 2012 HPMS, 2012 CME, 2011-2012 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	2.297	2.672
35-44 Years	2.297	2.672
45-54 Years	2.387	2.672
55-59 Years	2.368	2.672
60-64 Years	2.206	2.672
65 Years	2.206	2.672
66 Years	1.968	2.672
67 Years	1.968	2.672
68 Years	1.968	2.672
69 Years	1.968	2.672
70-74 Years	1.833	2.672
75-79 Years	1.739	2.672
80-84 Years	1.555	2.672
85-89 Years	1.319	2.672
90-94 Years	1.319	2.672
95 Years or Over	1.319	2.672
Male		
0-34 Years	2.031	2.635
35-44 Years	2.626	2.635
45-54 Years	2.349	2.635
55-59 Years	2.088	2.635
60-64 Years	2.047	2.635
65 Years	2.008	2.635
66 Years	1.835	2.635
67 Years	1.835	2.635
68 Years	1.835	2.635
69 Years	1.835	2.635
70-74 Years	1.790	2.635
75-79 Years	1.704	2.635
80-84 Years	1.602	2.635
85-89 Years	1.469	2.635
90-94 Years	1.469	2.635
95 Years or Over	1.469	2.635

Notes: The 2012 denominator of $998.95 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% 2012 PDE, 2011 NCH, 2012 HPMS, 2012 CME, 2011-2012 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	
15	Chronic Myeloid Leukemia	16, 17, 18, 19, 96, 98
16	Multiple Myeloma and Other Neoplastic Disorders	17, 18, 19, 96, 98
17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	18, 19
18	Lung, Kidney, and Other Cancers	19
30	Diabetes with Complications	31
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	
25	Chronic Viral Hepatitis	55	Chronic Viral Hepatitis	Liver
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	

Current RxHCC Risk Adjustment Model RxHCCs		Proposed RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
50	Aplastic Anemia and Other Significant Blood Disorders	98	Aplastic Anemia and Other Significant Blood Disorders	
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	
		191	Ventricular Septal Defect and Major Congenital Heart Disorders	
93	Atrial Arrhythmias	193	Atrial Arrhythmias	
97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	Cerebrovascular Disease

Current RxHCC Risk Adjustment Model RxHCCs		Proposed RxHCC Risk Adjustment Model RxHCCs		
RxHCC	**Description**	**RxHCC**	**Description**	**Category Short Name**
98	Spastic Hemiplegia	207	Spastic Hemiplegia	
100	Venous Thromboembolism	215	Venous Thromboembolism	Vascular
101	Peripheral Vascular Disease	216	Peripheral Vascular Disease	
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	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. 2015 Call Letter

2015 Announcement
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Attachment VI: 2015 Call Letter

How to Use This Call Letter

The 2015 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 2015 bids.

CMS has designed the policies contained in this Call Letter to improve the overall management of the Medicare Advantage and Prescription Drug programs with four major outcomes in mind. These outcomes are to ensure continued program 1) vibrancy and stability, 2) value for beneficiaries and tax-payers, 3) quality improvement, and 4) compliance improvement. This year, to achieve these overlapping outcomes, CMS' Call Letter activities follow four major themes: improving bid review, decreasing costs, promoting creative benefit designs, and improving beneficiary protections.

We expect this information will strengthen the Part C and D programs and will be helpful as Part C and D organizations prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

Since this year's final Call Letter will be released close to the expected final publication of the final rule (CMS-4159-F), the content is limited to clarification of current policy and operational guidance. However, requirements contained in the final rule may be included in this year's final Call Letter, even if they have not been included in this draft Call Letter. We encourage interested parties to submit comments on the pending notice of proposed rulemaking by the close of the comment date (March 7, 2014) in accordance with the instructions in the proposed rule (79 FR 1918).

If you have questions concerning this Call Letter, please contact: Nishamarie Sherry at Nishamarie.Sherry@cms.hhs.gov (Part C issues) and Stephanie Hammonds at Stephanie.Hammonds@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 MA, MA-PD, PDP, Medicare-Medicaid Plan (MMP), and cost-based plans. The calendar provides important operational dates for all organizations such as the date CMS bids are due, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings.

2015*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**
January 10, 2014	Release of the 2015 MAO/MA-PD/PDP/Service Area Expansion Applications.	✓	✓	✓
January 9 & 16, 2014	Industry training on 2015 Applications.	✓	✓	✓
February 21, 2014	2015 Applications are due to CMS.	✓	✓	✓
February 21, 2014	Renewing D-SNPs required to complete attestations in HPMS	✓		
February 21, 2014	SNPs, whose MOC approval expires at the end of CY 2014, are required to resubmit their MOCs for NCQA review.	✓		
Late February 2014	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓		
March 1, 2014	CMS releases guidance concerning updates to Parent Organization designations in HPMS.	✓	✓	✓
March 4, 2014	Deadline for D-SNPs meeting a high level of integration, as determined by CMS, to notify CMS of intent to offer additional supplemental benefits as a result of meeting the qualifying criteria.	✓		
March 15, 2014	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2014).	✓	✓	
Mid-Late March, 2014	Release of CY 2015 Formulary Training Video and 2015 Formulary Reference File (FRF)	✓	✓	
March 22, 2014	Release of the Fiscal Soundness Module in HPMS.	✓	✓	
March/April, 2014	CMS contacts Medicare Advantage Organizations (MAO) and Prescription Drug Plan (PDP) Sponsors with low enrollment plans.	✓	✓	✓
Early April 2014	CY 2015 Out-of-pocket cost (OOPC) estimates for each plan and an OOPC model will be made available to MAOs and Part D sponsors to download from the CMS website that will assist plans in meeting meaningful difference and MA total beneficiary cost requirements prior to bid submission.	✓	✓	
Early April, 2014	Information about renewal options for contract year 2015 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
April 2014	Conference call with industry to discuss the 2015 Call Letter.	✓	✓	✓

2015*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**
April 2014	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	
April 3, 2014	Industry training on CY 2015 Formulary Submission	✓	✓	
April 5, 2014	Release of the 2015 Plan Benefit Package (PBP) online training module	✓	✓	✓
April 7, 2014	2015 Final Call Letter released. Announce CY 2015 MA Capitation Rates and MA and Part D Payment Policies. *(Applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 11, 2014	Release of the 2015 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓
Mid April, 2014	Release of HPMS Memo: Contract Year 2015 Medicare Advantage Bid Review and Operations Guidance.	✓		
Mid/Late April, 2014	Submission of tiering request and justifications to the Regional Office for review and consideration.	✓		
Late April, 2014	Total Beneficiary Cost (TBC) data for CY 2015 Bid Preparation Release	✓		
May, 2014	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2014 will be available for all organizations.	✓	✓	✓
Early May, 2014	D-SNPs that applied to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications	✓		
May 2, 2014	CMS strongly encourages MA, MA-PD and PDP plans to notify us of its 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, by May 2, 2014. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓
May 6, 2014	Medicare Advantage and Part D Spring Conference	✓	✓	
May 9, 2014	Release of the 2015 Bid Upload Functionality in HPMS	✓	✓	✓
May 9, 2014	Release of 2015 Actuarial Certification Model	✓	✓	✓
May 9, 2014	Release of Health Plan System (HPMS) Formulary Submission Module	✓	✓	
May 19, 2014	Release of the 2015 Medication Therapy Management (MTM) Program Submission Module in HPMS.		✓	
May 31, 2014	Release of the 2012 DIR Submission Module in HPMS	✓	✓	
May 31, 2014	Plans / Part D Sponsors may begin to upload agent/broker compensation information in HPMS	✓	✓	✓
May 31, 2014	Release of the 2015 Marketing Module in HPMS. Note: Plans / Part D Sponsors may begin to submit 2015 marketing materials.	✓	✓	✓

2015*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**
Late May/Early June, 2014	Release of the 2015 Medicare Marketing Guidelines in HPMS (Chapter 3 of the Medicare Managed Care Manual/Chapter 2 of the Prescription Drug Benefit Manual)	✓	✓	✓
Late May/June, 2014	CMS sends qualification determinations to applicants based on review of the 2015 applications for new contracts or service area expansions.	✓	✓	
Late May/June to Early September, 2014	CMS completes review and approval of 2015 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	✓
June 2, 2014	Deadline for submission of CY 2015 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 2015 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2015 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 CY 2015 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Deadline for submission of a CY 2015 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 2015.	✓	✓	✓
June 3, 2014- June 6, 2014	Widow for submitting crosswalk exception requests through HPMS.	✓	✓	✓
June 6, 2014	Deadline for submission of CY 2015 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 6, 2014	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)*(12 p.m. EDT)	✓	✓	
Late June, 2014	Release of the CY 2015 Summary of Benefits (SB) hard copy change request module in HPMS.	✓	✓	✓
Late June, 2014	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.	✓	✓	✓

2015*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**
June 30, 2014	Final date to submit CY 2014 marketing materials to ensure timely CMS review and approval. NOTE: 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, 2014	2015 Plan Finder pricing test submissions begin	✓	✓	✓
July 1, 2014	Deadline for D- SNPs to have uploaded their required State Medicaid Agency Contract and Contract Matrix to HPMS	✓	✓	✓
July 1, 2014	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, 2014	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓		
Mid-Late July, 2014	CY 2015 Limited Formulary Update Window	✓	✓	
Late July, 2014	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓
Late July / Early August, 2014	CMS releases the 2015 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, 2014	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓
August 1, 2014	Plans are expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓
August 1, 2014	CMS informs currently contracted organizations of its decision to not renew a contract for 2015.	✓	✓	✓
August 22-26, 2014	First CY 2015 preview of the 2015 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	
August 28 – August 30, 2014	First CY 2015 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
August 31, 2014	2015 MTM Program Annual Review completed.		✓	
Late August 2014	Contracting Materials submitted to CMS.	✓	✓	✓
End of August/Early September 2014	Plan preview periods of Star Ratings in HPMS.	✓	✓	✓
Early-September 2014	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓
Mid- September 2014	All 2015 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓		✓

2015*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**
September 10 - September13, 2014	Second CY 2015 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
September 16 – 30, 2014	CMS mails the 2015 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓
Late September, 2014	D-SNPs that requested review for Fully Integrated Dual Eligible (FIDE) Special Needs Plan (SNP) determination notified as to whether they meet required qualifications.	✓		
September 24, 2014	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, 2014	CY 2015 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by September 30. Plans have the option to include Pharmacy/Provider directories in this mailing. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies with the ANOC/EOC to ensure current member receipt by September 30. Note: With the exception of the ANOC/EOC, LIS Rider, directories, and abridged or comprehensive formularies, no additional materials may be sent prior October 1.	✓	✓	✓
Early October, 2014	Release of the online CY 2016 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, 2014	Organizations may begin marketing their CY 2015 plan benefits. Note: Once an organization begins marketing CY 2015 plans, the organization must cease marketing CY 2014 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2014 materials upon request, conduct one-on-one sales appointments and process enrollment applications.	✓	✓	✓
October 1, 2014	Tentative date for 2015 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓

2015*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**
October 2, 2014	The final personalized beneficiary non-renewal notification letter must be received by PDPs, MA plan, MA-PD plans, 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, 2014.	✓	✓	✓
October 10, 2014	Star Ratings go live on medicare.gov on or around October 10, 2014.	✓	✓	✓
October 15, 2014	Part D sponsors must post PA and ST criteria on their websites for the 2015 contract year.		✓	
October 15, 2014	2015 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 9, 2014	Notices of Intent to Apply (NOIA) for CY 2016 due for MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	
Early November, 2014	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval	✓	✓	✓
Late November, 2014	Display measures data are posted in HPMS for plan preview.	✓	✓	✓
Late November, 2014	2015 Readiness Assessment due to CMS	✓	✓	✓
November – December, 2014	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, 2014	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.			✓
December 1, 2014	Cost-based plans must publish notice of non-renewal.			✓
December 7, 2014	End of the Annual Election Period.	✓	✓	
Mid- December, 2014	Display measures data on CMS.GOV updated.	✓	✓	✓
2015				
January 1, 2015	Plan Benefit Period Begins	✓	✓	✓
January 1 – February 14, 2015	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓		
Early January 2015	Release of CY 2016 MAO/MA-PD/PDP/SAE/EGWP applications.	✓	✓	
Mid-January, 2015	Industry training on CY 2016 applications.	✓	✓	✓
Late February 2015	Applications due for CY 2016.	✓	✓	✓

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 Part C and Part D plans are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY 2015, the bid submission deadline is June 2, 2014 at 11:59 PM Pacific Daylight Time.

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

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

MA, MA-PD, Section 1876 cost plan, and PDP entities ("entities") are responsible for ensuring complete and accurate bids are submitted by the June deadline. Like last year, CMS is making clear all components required for an organization's bid must be submitted by the deadline to constitute a complete submission. If any one of the required components is not submitted by the deadline, the bid submission will be considered incomplete and will not be 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) 2014 Bid Upload Functionality in HPMS," dated May 10, 2013).

The Health Plan Management System (HPMS) Bid Upload functionality, made available each May, allows all organizations to submit each required component of their bids well in advance of the deadline and reporting tools track those components which were successfully submitted and which are still outstanding. Given the resources available to organizations to monitor and verify the status of bid submissions, CMS expects all components of a bid will be submitted successfully and accurately by the submission deadline.

All entities are expected to contact CMS about any technical upload or validation errors well in advance of the bid submission deadline. CMS may give consideration to late submissions in rare situations if the late submission is the result of a technical issue beyond the organization's control. All entities 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 preventing the bid from proceeding to desk review.

Inaccurate Submissions

CMS approves a bid under 42 CFR §423.272(b) only if the plan and the sponsor offering the plan comply with all applicable Part D requirements, including those related to the provision of

qualified prescription drug coverage and actuarial determinations. Bids containing information that is clearly inaccurate under Part D requirements and established thresholds unnecessarily divert time and resources to getting the bids corrected and, among other things, call into question a plan sponsor's intent and ability to fully comply with Part D requirements.

Examples of bids containing information that is clearly inaccurate under Part D requirements and established thresholds are:

- An MA-PD submits a bid for an enhanced plan without submitting a bid for a basic plan, which is not in compliance with § 423.104(f)(2) (see also section 20.4.3 of Chapter 5 of the Prescription Drug Benefit Manual),
- A PDP submits a 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 is making clear that organizations and sponsors submitting clearly inaccurate bids under Part D requirements and established thresholds will receive a compliance notice in the form of a letter and/or a corrective action plan. Organizations and sponsors are also on notice that they might not be provided an opportunity to revise their bids to correct inaccuracies, and therefore, their bids will be denied. Organizations and sponsors should engage in sufficient due diligence to ensure their bid submissions are accurate before submission.

Formulary Submissions

The CY 2015 HPMS formulary submission window will open this year, from 12:00 am PDT on May 9, 2014 to 11:59 pm PDT on June 2, 2014. In addition, CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 2, 2014 in order for the formulary to be considered for review. The formulary is part of a Part D plan's complete bid and therefore a failure to submit and link a formulary to each plan by the June 2nd deadline will result in denial of that bid submission.

We continue to expect that the formulary structure submitted for Defined Standard plans will be consistent with the plan benefit package (PBP) submission that does not include tiers. Consistent with previous years, CMS will make an exception for those Defined Standard plans that are linked to tiered formulary that is also being used by at least one other plan with a tiered benefit type (i.e., Actuarial Equivalent, Basic Alternative, or Enhanced Alternative). However, beginning in 2015 formularies that are only associated with Defined Standard plans must be limited to one formulary tier as submitted in their bids. In addition, all marketing materials for Defined Standard plans must reflect a single tier regardless of whether that Defined Standard plan is associated with a single or multi-tier formulary.

CMS will release the first CY 2015 Formulary Reference File (FRF) tool in March 2014. The March FRF release will be used in the production of the OOPC model tool, scheduled to be released in April 2014, in order to assist plan sponsors in satisfying meaningful difference and MA total beneficiary cost (TBC) requirements prior to bid submission. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

CMS is planning to provide a May 2014 release of the 2015 FRF just prior to the new formulary submission deadline. Given the limited timeframe between the May release of the 2015 FRF and the new formulary submission deadline, CMS will be unable to accommodate an updated version of the 2015 OOPC model to incorporate the May FRF changes, as noted above. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2015 FRF will not be included in the 2015 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 2015 FRF, since additional limitations will be imposed on the summer formulary update window.

Plan Corrections

CMS expects that requests for MA, MA-PD, Section 1876 cost plans, and PDP corrections for CY 2015 will be minimal. As required by 42 CFR §§422.254, 423.265(c)(3) and 423.505(k)(4), submission of the final actuarial certification and the bid attestation 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 plan until the plan correction window in September. The plan correction window will be open from early September to September 24, 2014. Only changes to the PBP that are supported by the Bid Pricing Tool (BPT) will be allowed during the plan corrections period. No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide to organizations and sponsors any guidance and tools necessary to ensure a complete and accurate bid submission. These tools will include a Medicare Plan Finder (MPF) summary table report that will be released in HPMS during 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. Therefore, organizations and sponsors are encouraged to use this time prior to the bid submission deadline to ensure the bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance notice and will be suppressed in Medicare Plan Finder (MPF) until the first update in November. An organization or sponsor that has demonstrated a consistent pattern of bid submission errors over multiple contract years and/or that previously received a compliance notice for CY 2014 may receive a more severe type of compliance action if it requests a plan correction for CY 2015.

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years – Effective Date of Termination Authority

CMS reminds MA organizations and PDP sponsors that our regulatory authority (42 CFR §§422. 510(a)(14) and 423.509(a)(13)) to terminate the contracts of organizations that fail for three consecutive years to achieve at least three stars on their Part C or D performance may be used at the end of 2014, based on three years of data, beginning with 2012. When we published the termination authority, we announced that we would afford contracting organizations a three-year transition period to bring their star rating performance up to a level that would justify their continued participation in the Part C and D programs. That transition period ends with the star ratings released in the fall of 2014. At that time, CMS plans to terminate, effective December 31, 2014, those contracts that have failed to achieve a three-star rating for Part C or D in any of the 2013, 2014, or 2015 sets of ratings. CMS advises contracting organizations to examine their star rating performance history and assess their level of exposure to the risk of having CMS terminate their Medicare contract based on star ratings before the start of the 2015 contract year. It may be in the best interests of organizations and sponsors with "at risk" contracts to consider electing to non-renew those contracts. Alternatively, organizations and sponsors could explore whether it is allowable to consolidate membership currently enrolled in plans offered under low-performing contracts into other plans that will be offered during 2015 in the same service area under a different contract rated at three stars or better.

Proposed Enhancements to the 2015 Star Ratings and Beyond

One of CMS' most important strategic goals is to improve quality of care and general health status for Medicare beneficiaries. For the 2015 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 due to the link to payment, and providing advance notice of future changes.

In this document, we describe the enhancements being considered for the 2015 Star Ratings and beyond. Unless noted below, we do not anticipate changing the methodology from the 2014 Star

Ratings. The 2014 methodology can be found at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html under the 2014 Star Ratings link. 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 2015 with the most current data available.

In November 2013, CMS sent out a Request for Comments to Part C and D sponsors, stakeholders, and advocates via HPMS that described CMS' proposed changes for the 2015 Star Ratings and beyond for Medicare Advantage (MA) and Prescription Drug Plans. The purpose of that comment period was to provide plans and advocates with additional notice so CMS could identify any needed changes in advance of the Call Letter. We received approximately 115 comment letters. We have incorporated this feedback in developing the enhancements proposed in this draft Call Letter. (Summaries of the comments will be available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html). We welcome additional feedback that was not already submitted to CMS.

Some commenters to our Request for Comments requested a more formal rulemaking process for proposed Star Ratings changes, instead of relying on our authority under §1853(b), the relationship the quality Star Ratings have to payment rates, and the regulations at §§422.152(b) and 422.516(a) to use this Advance Notice / Call Letter process for these changes. We believe that our approach is better for administration of the Part C and D programs. We have initiated twice yearly comment periods on the Star Ratings in response to the need for transparency and advance notice. In the annual Request for Comments and the Call Letter we lay out the Star Ratings methodology for two or more years ahead. For example, the Request for Comments recently released in November 2013 announces potential changes for 2015, 2016, and beyond. When there are changes in clinical guidelines that impact the Star Ratings measures, we try to make these updates more quickly to align with the clinical standards. If we were to use a more formal rulemaking process for Star Ratings changes, we would not be able to quickly adjust the Star Ratings to reflect changes in the clinical guidelines. We have included more detail in the draft Call Letter about moving measures to the display page when significant changes in measure specifications happen during the measurement year without advance notice. We additionally publish detailed technical specifications and provide contract specific technical guidance in understanding how a contract scored on a measure.

CMS' initial work last year to identify and understand some best practices of high-performing plans found that their models of care and continuous quality improvement were not focused on year to year changes, but rather they identified areas for long-term improvements in clinical outcomes, access to care and beneficiary satisfaction. High-performing plans did not wait until CMS' announcement of industry initiatives, rather their approaches to these areas were often ahead of CMS' technical changes. We therefore believe CMS' current processes of proposing and planning modifications to the Star Ratings are best continued as they are.

A number of commenters were concerned about whether beneficiaries can respond to surveys and whether this is the appropriate method for gathering information for Star Ratings. Surveys are a valid way to gather information; the types of questions include in the CAHPS and HOS surveys are ones where the beneficiary is the best or only source for the information.

As part of our Request for Comments, we received several comments about Special Needs Plans (SNPs). Medicare Advantage organizations are permitted to design SNPs that target individuals dually eligible for Medicare and Medicaid, beneficiaries that have certain chronic conditions, or those receiving care in institutions. These options let plans target these populations, develop and implement approaches that enhance access to and coordination of care and improve quality of care. Over the past several years, organizations have argued that CMS should make special allowances in the Star Ratings program for these plans and others that enroll hard-to-reach populations. These possible allowances have included bonus points for SNP-specific measures, requests for case-mix adjustment for member characteristics, comparisons only to similar SNP subtypes, stratification in displays, and a Star Ratings system distinctly and uniquely for SNPs.

CMS maintains that all organizations can develop and implement approaches that enhance access to and coordination of care and improve the quality of care, which would then be reflected in higher Star Ratings. We believe that our existing payment and Star Ratings methodologies adequately address differences between these populations and other MA enrollees. For example, an analysis of SNP performance in the 2011 Plan Ratings found that increasing levels of SNP enrollment in contracts did not lead to lower ratings on either Part C or Part D. In fact, as we have stated previously, the number of contracts with less than a 3-star rating (below average performance) drops when SNP enrollment increases from 50 percent or more to 100 percent (77 FR. 22114, Apr. 12, 2012), which is comparable to contracts with fewer than 50 percent SNP enrollment. Thus, SNP enrollment in a contract does not adversely affect a contract's Star Rating. We believe that our current methodology supports a single standard of care for all Medicare beneficiaries and analysis of Star Ratings results suggests Medicare Advantage organizations can focus on SNP population needs without compromising broader population health goals.

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

A. New 2015 Measure:

CMS stated in the 2014 Call Letter that the following measure would be added to the 2015 Star Ratings. Since this would be a first year measure, the weight assigned to it will be "1".

Special Needs Plan (SNP) Care Management (Part C SNPs). This measure captures the completion of initial and annual standardized health risk assessments among SNPs. This measure is defined as the percent of eligible SNP enrollees who received a health risk assessment

(HRA) during the measurement year. The denominator for this measure is the sum of the number of new SNP enrollees for the organization and the number of SNP enrollees eligible for an annual reassessment for the organization. The numerator for this measure is the sum of the number of initial assessments performed on new SNP enrollees during the measurement period and the number of annual reassessments performed on SNP enrollees eligible for a reassessment. An organization must have a minimum of 30 SNP enrollees eligible to have a SNP assessment for the rate to be calculated. Organizations that did not score at least 95% on data validation for their reporting of the SNP care management reporting section and organizations not compliant with data validation standards will be shown with the following phrase instead of a rating: "CMS identified issues with this plan's data." (See http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.html for more information about data specifications.) For the 2015 Star Ratings, we will report data from 2013. The 2012 data will be reported on the 2015 display page. CMS feels the measure is ready to be incorporated into Star Ratings. However, CMS does acknowledge the continued need to clarify and train plans, especially regarding members who switch plans.

B. Changes to Measures for 2015

As a result of feedback from the Request for Comments, CMS is providing additional information about when a Star Ratings measure will be moved to the display page with a specification change. If the specification change has been announced in advance of the measurement period, there is no need to move the Star Ratings measure to the display page. If the specification change is announced during the measurement period ***and*** impacts the denominator or population covered by the measure, the measure will be moved to the display page for at least one year. If the change does not impact the denominator of the measure, CMS will continue to include it in the Star Ratings. For example, if during the measurement period, additional codes are added that would increase the number of numerator hits for the measure, CMS will continue to include the measure in determining the Star Ratings.

New guidelines on treatment of blood cholesterol and hypertension may impact the following HEDIS measures and indicators:

- Cholesterol management for Patients with Cardiovascular Conditions (CMS),
- Comprehensive Diabetes Care (CDC) – LDL-C Screening and LDL-C Control indicators,
- Controlling High Blood Pressure (CBP), and
- Comprehensive Diabetes Care (CDC) – Blood Pressure Control indicators.

All proposed changes to these measures for HEDIS 2015 will be available for public comment starting on February 19, 2014. CMS encourages stakeholders to review the HEDIS 2015 public comment material and submit comments, as appropriate, to NCQA. The public comment document will be available at http://www.ncqa.org. The final HEDIS 2015 measure set will be released by NCQA in July 2014.

Treatment of Blood Cholesterol

In November 2013, the American College of Cardiology / American Heart Association Task Force on Practice Guidelines released updated guidance for the treatment of blood cholesterol. The new recommendations differ greatly from the previous National Heart, Lung, and Blood Institute (NHLBI) guidance by removing treatments for LDL-C for the primary or secondary prevention of atherosclerotic cardiovascular disease (ASCVD) and instead, recommending high or moderate intensity statin therapy based on patient risk factors.

As part of NCQA's HEDIS 2015 public comment process, NCQA is seeking comments about the retirement of the Cholesterol Management for Patients with Cardiovascular Conditions (CMC) measure and the LDL-C Screening and LDL-C Control indicators from the Comprehensive Diabetes Care (CDC) measure.

Treatment of Hypertension

In December 2013, the panel members appointed to the eighth Joint National Committee (JNC 8) released updated guidance for the treatment of hypertension. The new 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. The latest guideline also recommends that all diabetic patients age 18 and older should be treated to a goal of <140/90 mm Hg and calls into question the use of other targets.

NCQA is seeking comments on whether it should stratify the ages and treatment goals for the Controlling High Blood Pressure (CBP) measure to match the new guidance. If NCQA goes ahead with this change, this would just change the numerator and not the population in the Blood Pressure Control measure. Therefore, CMS would keep the measure in the 2016 Star Ratings.

CMS is modifying the methodology for the following measures:

1. *Breast Cancer Screening (Part C).* The specification for the Breast Cancer Screening measure is being modified to reflect changes in HEDIS 2014. In HEDIS 2013 the measure was defined as the percentage of women 40 to 69 years of age who had a mammogram for breast cancer every two years. The specification for 2014 revises the age range from 40 to 69 years old to 50 to 74 years old and increases 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), 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. This change in specifications aligns the measure with the clinical guidelines that were first available in 2009. Since the measure specification changed during the measurement year and includes additional members for the denominator of the measure, we propose to move this measure to the display page for one year (2015). We plan to include this measure again in the 2016 Star Ratings.

2. *Annual Flu Vaccine (Part C).* NCQA is changing the flu shot question used in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey so respondents will be asked whether they received a flu shot since July of each year (instead of September) because the timeframe when people get flu shots has been getting earlier each year. This does not change the denominator for this measure, but members who get their flu shots earlier will be included. We will eliminate the pre-determined 4-star threshold for this measure for the 2015 Star Ratings due to the measure specification change.

3. *High Risk Medication (Part D).* As stated in the 2014 Call Letter, the updated Pharmacy Quality Alliance (PQA) HRM list, based on the American Geriatric Society (AGS) recommendations to the Beer's List, will be applied to calculate the HRM measure for the 2015 Star Ratings using 2013 Prescription Drug Event (PDE) data. CMS had first alerted plans about this change in the 2013 Call Letter, and has provided monthly HRM patient safety reports using the updated list since 2012. Also, at the beginning of 2012, the AGS published the updated 2012 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults in the *Journal of the American Geriatrics Society*. Therefore, sponsors were aware of the updated Beer's Criteria to consider updates to their procedures ahead of the 2013 contract year. CMS will not modify or remove medications from the PQA-endorsed HRM list. All Part D covered drugs, including barbiturates for which Part D coverage began in 2013, in the PQA HRM list will be included in the calculation for the 2015 Star Ratings (using 2013 PDE data).

4. *Medication Adherence for Diabetes Medications (Part D).* As stated in the 2014 Call Letter, CMS is adopting PQA's changes to this measure's specifications for the 2015 Star Ratings (using 2013 PDE data), specifically the addition of two additional drug classes to the numerator and denominator (meglitinides and incretin mimetic agents). These changes will result in a more complete measure of beneficiaries' adherence to diabetes therapy. Previously, beneficiaries changing to these medications could have been marked as non-adherent. This change will account for that utilization. We note that the PQA updated their specifications for 2014 to include sodium glucose co-transporter 2 (SGLT2) inhibitors. We propose to add this new drug class to the measure calculation for the 2016 Star Ratings using 2014 PDE.

5. *Beneficiary Access and Performance Problems (Part C and D).* Based on the comments received, CMS is going to move the Beneficiary Access and Performance Problems to the display page since there were significant methodological changes during the measurement period. We will incorporate the changes in the audit scoring methodology announced in the March 17, 2013 "Final Program Audit Scoring Methodology" memo (see http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS-Memo-Final-Program-Audit-Scoring-Methodology.pdf for more information). This change introduced a scoring system that generates an audit score for every organization/sponsor audited based on the number and severity of conditions detected in an organization/sponsor's operations. In this new scoring system, a lower score represents better performance on the audit. As indicated in the HPMS memo, CMS will no longer use the number of samples passed or failed in determining audit scores for the Star Ratings.

   Starting with the data for the 2015 Star Ratings, an audit score will be calculated by utilizing the audit results for each of the following program areas: Part D Formulary and Benefit Administration; Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organizational Determinations, Appeals, and Grievances (ODAG); and Part C and Part D Compliance Program Effectiveness. These four core program areas are used because they are consistently audited each year and have limited changes to the audit protocols from year to year.

   The final Star Rating audit score for an organization/sponsor will be calculated using the total number of audit points (determined based on both the number of unique conditions identified and the severity of those conditions) in these four areas, divided by the total number of audit elements tested (again in the four core program areas). Cut points to determine the point reductions for the audit finding will be determined by an analysis of cumulative data, beginning with the 2012 audit data.

   Depending on the final audit score, organizations/sponsors could be reduced by up to 50 points from the starting Star Rating score of 100 as a result of poor audit results. Appropriate cut points will be determined by an analysis of cumulative data, beginning with sponsors audited in 2012. The cut points will be established annually based on an analysis of cumulative industry performance. There will be no changes to the calculation and point deductions for sanctions, CMPs, and compliance letter (CAM Score) portions of the audit measure.

6. *Medication Adherence Measures (Part D).* Based on stakeholder feedback, beginning with the 2015 Star Ratings using 2013 PDE, we will adjust the three Medication Adherence measures to account for beneficiaries with hospice enrollment or Skilled Nursing Facility (SNF) stays, during which the Part D sponsor would not be responsible for providing prescription fills for relevant medications. These adjustments are an

extension of a similar adjustment currently applied to adherence measures to adjust for beneficiary stays in inpatient (IP) facilities. We tested these adjustments using 2013 data (with dates of service between January 1, 2013 and July 31, 2013, submitted by August 31, 2013), and we found a small proportion of beneficiaries included in the adherence measure that are enrolled in hospice. Adjustments to the measure for hospice enrollment have a negligible impact on overall adherence rates, increasing the rate on average by approximately 0.16 - 0.19 percentage points. After the SNF adjustment, overall adherence rates increase by approximately 0.37 - 0.45 percentage points. Although the impact of these two specification changes is small, they improve the validity of the measures.

We do not feel that the recent clarifications to address Part D payment for drugs for beneficiaries enrolled in hospice or how the guidance is finalized would conflict with this proposal to account for hospice stays. On the contrary, adjusting for hospice stays, as we already do for inpatient stays, should more accurately reflect drugs covered under the hospice benefit or waived through the beneficiary's hospice election. This adjustment should benefit the sponsor regardless of which party pays for the drugs.

While hospice information from the Medicare Enrollment Database (EDB) and inpatient claims from the Common Working File (CWF) are available for both PDPs and MA-PDs, SNF claims are only available for Medicare Fee-for-Service (FFS) beneficiaries who are also enrolled in PDPs. Therefore, the SNF adjustment will only impact PDP sponsors; when such data are available for MA-PD organizations, this adjustment will be expanded to include those organizations as well. We are unable to set-up processes for specific SNPs to provide their records of such data. We disagree that the application of SNF stays for PDPs is inequitable, as CMS' cut-points are determined for PDPs and MA-PDs separately.

CMS' patient safety reports provide information about adjustments for inpatient stays. If these changes are finalized for the 2015 Star Ratings, we will look to modify the 2013 reports to reflect these additional adjustments.

Adjustments to the proportion of days covered (PDC) calculation will be made using the following steps:

1. Identify start and end dates of relevant types of stays for beneficiaries included in adherence measures.

    a. Use IP claims from the CWF to identify IP stays.
    b. Use SNF claims with positive payment amounts from the CWF to identify SNF stays.[5]

[5] Although we do not generally observe SNF claims for Part C beneficiaries, due to enrollment changes and data anomalies we may observe a negligible number of claims for Part C beneficiaries.

c. Use hospice records from the EDB to identify hospice stays.

2. Remove days of relevant stays occurring during the measurement period from the numerator and denominator of the proportion-of-days covered calculation.

3. Shift days' supply from Part D prescription fills that overlap with the stay to uncovered days after the end of the relevant stay, if applicable. This assumes the beneficiary receives the relevant medication from a different source during the stay and "stockpiles" the Part D prescription fills for later use.

We are also considering modifications to the weight of the adherence measures. Please see below for a detailed description of this proposed change.

We received a number of comments regarding supplemental pharmacy data. CMS uses PDE data to calculate some of the Part D Star Ratings, including the Adherence measures. Every time a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record called the PDE data to CMS. The PDE data are not the same as individual drug claim transactions, but are summary extracts using CMS-defined standard fields. The PDE record contains prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. We do not accept other supplemental pharmacy data to calculate these measures.

Please refer to the May 11, 2012 'Prohibition on Submitting PDEs for non-Part D prescriptions' HPMS memo. The reporting of any PDE data that has not been submitted directly by network pharmacies or beneficiaries is prohibited, consistent with our existing guidance. We encourage Part D sponsors to develop incentives for network pharmacies to submit claims under the plan unless beneficiaries have explicitly requested otherwise. Also, please refer to the April 23, 2013 'May 2013 Updates to the Drug Data Processing System' HPMS memo. In 2013, CMS began to allow PDE records where the sum of the cost fields equals zero on all PDEs regardless of date of service (DOS). The memo discusses situations where this may be appropriate.

In addition, the PQA updated their specifications for calculating PDC for 2014 specifically making the following revisions to Step 2 of the numerator statement:

- Overlap adjustment should be based on generic ingredient rather than GCN when the product has a single medication. (This aligns with CMS' current calculation which uses generic name (ingredient name)).

- Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a

combination product to another combination product where at least one of the drugs is common.

We are considering making this change for the 2016 Star Ratings using 2014 PDE to factor combination products into the PDC calculation, and we are exploring enhancements with the PQA to their Adherence medication NDC lists to include ingredient name flags to be able to perform this adjustment programmatically.

7. *Obsolete NDCs.* Beginning with the 2015 Star Ratings and display measures (using 2013 PDE data), we will implement the PQA's 2013 specification change to account for obsolete NDCs. NDCs with obsolete dates will be included in the measure calculation if their obsolete dates are within the period of measurement (measurement year) as reported by PQA.

   For the 2016 Star Ratings and display measures (using 2014 PDE data), we propose to implement PQA's 2014 obsolete date methodology. Specifically, the PQA's 2014 obsolete date methodology includes the following steps:

   1. Query the MediSpan and First DataBank databases to develop an NDC list.

   2. 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.

   3. 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.

C. Retirement of Measures

We will remove the Glaucoma Testing (Part C) measure from the 2015 Star Ratings due to the U.S. Preventive Services Task Force's recent conclusion that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary open-angle glaucoma in adults.

D. Contracts with Low Enrollment

To help beneficiaries make more informed choices and to be as fully transparent as possible about the performance of all plans, CMS is moving toward including low enrollment contracts in the Star Ratings. 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. 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.

CMS proposes to delay for one year including these 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 be included in the 2016 Star Ratings, on the Medicare Plan Finder, and used for QBPs. 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.

The 2014 and 2015 display pages will include simulated Star Ratings for contracts with 500 to 999 enrollees, following a preview period. Using the most recent data for the 2014 Star Ratings, simulated overall ratings for 31 contracts with less than 1000 enrollees show 13% would have received 2.5 stars, 26% would have received 3 stars, 39% would have received 3.5 stars, 10% would have received 4 stars, and 13% would not have enough measures to be rated. Contracts with less than 1000 enrollees will not be included in the cut point calculations for the 2014 and 2015 Star Ratings, but contracts with 500 to 999 enrollees will be included in the cut point calculations for 2016 and going forward. 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.

E. Data Integrity

Protecting data integrity is a high priority for CMS, especially for measures using non-validated data. CMS' current 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 policy ensures that CMS is measuring true performance. Contracts are able to review and discuss CMS' findings prior to the final release of Star Ratings. While CMS maintains that it is the responsibility of the contract to follow CMS' requirements, we understand plans' request for CMS to establish the scope of errors made.

We note that HEDIS data, plan-reported data, and survey data already undergo data validation processes. However, data used to monitor areas such as contracts' processing of coverage determinations/exceptions or organization determinations are not consistently audited. CMS has frequently found evidence that sponsors fail to follow requirements to forward Part C denials and to auto-forward untimely Part D initial coverage determination or redetermination requests to the

IRE. Consequently, these contracts' data do not represent the contracts' actual processes. CMS cannot objectively measure those contracts, nor do we feel it appropriate to simply exclude them from these important beneficiary access measures. Without the ability to identify and reduce these contracts' ratings, there is risk that CMS will reward contracts with falsely high ratings in these measures, while penalizing those contracts that do follow the requirements. Ultimately, the measures would no longer yield fair evaluations of sponsors' performances.

CMS has restrictive timelines for production of the Star Ratings for each Fall AEP, review of QBP appeals, and final calculation of ratings for QBPs the following year. So, we are interested in suggestions that can balance CMS' high standards for compliance, our requirement to have accurate measure data that are unbiased from sponsors' errors or misprocessing, and the application of transparent and objective criteria for star reductions. One option could be for contracts to elect to have independent audits initiated to provide accurate evidence that would dispute CMS' reductions of their ratings. Audits would be conducted at the contract's expense, in an effort to quantify and qualify the degree of error existing in the entire dataset. Audits would be conducted following standards developed by CMS. Another option may be for CMS to apply incremental reductions to measures based on the number of errors found. Reductions could range from CMS subtracting a star from a contract's measure rating to CMS reducing the rating down to one star. Depending on the viability of proposals, CMS may implement these changes for 2015 or 2016 Star Ratings.

F. Changes for Measures Posted on the CMS Display Page

Display measures on www.cms.gov are not part of the Star Ratings. These may be measures that have been transitioned from the Star Ratings, or they could be new measures tested before inclusion into the Star Ratings. Similar to the 2014 display page, organizations/sponsors have the opportunity to preview their data on the display measures prior to release on CMS' website. 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. It is expected that all 2014 display measures will continue to be shown on www.cms.gov unless otherwise noted in this Call Letter.

Based on feedback from the Request for Comments, the following measures will remain on the display page for 2015.

1. *Pharmacotherapy Management of COPD Exacerbation (PCE) (Part C).* This measure is defined as the percentage of COPD exacerbations for members 40 years of age and older who had an acute inpatient discharge or emergency department encounter on or between January 1– November 30 of the measurement year and who were dispensed appropriate medications. This measure includes two rates: 1) Dispensed a systemic corticosteroid within 14 days of the event; and, 2) Dispensed a bronchodilator within 30 days of the event. (See HEDIS 2014 Technical Specifications, Volume 2 for more information about

data specifications.) Both rates from the HEDIS 2013 data are shown on the 2014 display page and will continue to be shown for 2015 on the display page. NCQA will be working with its advisory panels to investigate whether use of intravenous steroids and nebulizers can be added to the numerator of this measure. They anticipate any changes will be reflected in the October update to the HEDIS 2015 volume.

2. *Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (Part C).* This measure encourages people who have a new treatment episode to initiate and engage in treatment. However, CMS acknowledges the concerns the commenters raised in the Request for Comments, especially regarding the measure not including self-help groups such as AA and NA. Therefore, CMS plans to keep both the measure of Initiation of Alcohol and Other Drug Dependence Treatment and the measure of Engagement of Alcohol and Other Drug Dependence Treatment on the display page. (See HEDIS 2014 Technical Specifications, Volume 2 for more information about data specifications.) This measure will focus on individuals age 18 and older. The 2013 HEDIS data for this measure are shown on the 2014 display page.

3. *Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).* This measure is based on the Pharmacy Quality Alliance (PQA) endorsed measure, Completion Rate for Comprehensive Medication Review (CMR), which measures the percentage of beneficiaries who met eligibility criteria for the Medication Therapy Management (MTM) program and who received a CMR. We propose to defer adding this measure until the 2016 or 2017 Star Ratings, and maintaining this as a display measure for 2015 using 2013 data. This proposal is based on a number of factors including: feedback received during the Star Ratings Request for Comments regarding differences in rates of MTM eligibility, changes to the MTM requirements beginning 2013 including the requirement to provide CMR to LTC beneficiaries, and proposed revisions to Part D MTM requirements, with a proposed effective date of January 1, 2015 (CMS-4159-P, Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs). In addition, while variations among sponsors' MTM program eligibility criteria exist, it is unclear to CMS the best manner in which to equitably and appropriately adjust the CMR rates. Once this measure is added as a Star Rating, CMS plans to weight the CMR measure as a process measure (1x). We believe that this measure represents an initial step in measuring MTM performance, and we will consider other outcomes-based MTM measures when developed and endorsed through a consensus process.

   The denominator of this measure 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. Based on questions received during the Request for Comments, we reiterate that only those beneficiaries that meet the contracts' specified targeting criteria pursuant to §423.153(d) of the regulations are

included in this measure. Patients enrolled in MTM based on other expanded or plan-specific targeting criteria are not included. Furthermore, the CMR measure includes those beneficiaries who were enrolled in the MTM program for at least 60 days during the reporting period. Beneficiaries who opt out of the MTM program after 60 days are still included in the measure. The numerator is the number of beneficiaries included in the denominator who received a CMR during the reporting period. Only a CMR that complies with the requirements set forth in the regulations which includes providing an individualized, written summary of the CMR in CMS' standardized format shall be reported and counted as a CMR[6]. CMS will include LTC beneficiaries in the measure calculation, since Part D sponsors have been required since 2013 to offer CMRs at least annually to all beneficiaries enrolled in the MTM program regardless of setting.

CMS proposes to exclude hospice patients from this measure. Sponsors are not permitted to exclude hospice patients from their MTM program, and section 423.153(d) requires that CMRs be offered to all targeted beneficiaries enrolled in the MTM program. However, considering 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, we propose excluding these beneficiaries that have elected to receive hospice care from the measure calculation. Using data from the Enrollment Database (EDB), CMS would exclude an enrollee reported to have entered hospice at any point during the measurement year, regardless of whether the contract reported he/she as receiving a CMR.

An organization/sponsor must have 31 or more 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 to have an MTM CMR rate calculated. Organization/sponsors that did not score at least 95% on data validation for their reporting of the MTM program section or did not meet CMS' additional audit criteria will be shown with, "CMS identified issues with this plan's data." 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.

We are considering introducing the following measures to the 2015 display page. Some of these measures may be considered for inclusion in the 2016 Star Ratings:

1. *CAHPS measures about contact from a doctor's office, health plan, pharmacy, or prescription drug plan (Part C).* Parts C and D sponsors are accountable for the care provided by physicians, hospitals, and other providers to their enrollees. These measures have been included in the CAHPS survey since 2013. In response to requests for more

[2] Refer to Annual Medication Therapy Management (MTM) Program Submission guidance memo. Accessed at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html

SNP-specific data, CMS is soliciting suggestions for questions that could be added to the CAHPS survey that address SNP Care Teams.

2. *CAHPS – Health Information Technology – EHR measures (Part C).* There are many local, regional, and national initiatives to accelerate the adoption of electronic health records that we anticipate will result in changes in terms of how care is delivered. Given this significant change in the healthcare delivery system, it is important to assess the use of electronic health records from the perspective of patients. CMS added a small set of questions to the 2014 CAHPS survey to obtain information on the use of electronic health records from the patient perspective. For example, measures include questions that ask about whether a computer or handheld device was used during office visits; whether the patient found the provider's use of a computer or handheld device helpful; and whether the patient found it harder or easier to talk to provider when the provider used a computer or handheld device. This display measure is for informational purposes only. CMS recognizes that this is an evolving area so initially these measures would be collected and fed back to plans as part of their annual CAHPS Plan Reports for quality improvement.

3. *Transition monitoring (Part D).* We propose developing two display measures using results of the Transition Monitoring Program Analysis (TMPA). The TPMA investigates whether Part D sponsors, in accordance with 42 CFR §423.120 (b)(3), are adequately administering formulary transition requirements, providing enrollees with a one-time temporary supply of requested non-formulary drugs to allow time for the enrollees to switch to alternative therapies. We propose two separate contract-level display measures: 1) failure rates for drugs within the classes of clinical concern, and 2) failure rates for all other drugs.

4. *Combined MPF Price Accuracy (Part D).* In Fall 2013, CMS introduced a new display measure, "Plan Submitted Higher Prices for Display on MPF", which evaluates when an organization/sponsor's posted price for a Part D drug is higher than the actual price charged at the POS. It is, essentially, the counterpart of the MPF Price Accuracy Star Rating measure, which measures the opposite scenario – that is, when an organization/sponsor's posted price for a Part D drug is lower than the actual price charged at the POS. CMS is interested in industry feedback about the new display measure, and the feasibility of combining the two accuracy indices into one measure in the future. CMS would develop specifications for the combined measure for a display measure, and monitor the results of this combined measure to determine if and when it will be made a Star Ratings measure. CMS will also monitor the results and evaluate the combination of this Accuracy Measure with the current Accuracy Measure used for Star Ratings.

5. *Disenrollment Reasons (Part C and D).* CMS implemented the PDP and MA Plan Disenrollment Reasons survey in 2013. A random sample of voluntary disenrollees at each contract is surveyed as close as possible to the actual disenrollment. In the previous

pilot testing of this survey, beneficiaries frequently cited the following reasons for disenrollment: financial reasons, prescription drug benefits and coverage, patient experience with regard to prescription drugs, patient experience with regard to health plan, and coverage of doctors and hospitals. This is similar to the disenrollment reasons information that CMS formerly made public for health plans prior to 2006 when the reasons for disenrollment were linked to the disenrollment rates information. CMS will be providing individual reports back to contracts with results for their enrollees with comparisons to state, regional, and national estimates in August 2014. The primary purpose of the reports is to assist MA and PDP contracts with quality improvement efforts, and to that end, we will provide both composite measures of the primary reasons for disenrollment and drill-down item information. Composite measures of the primary reasons for disenrollment will be introduced to the 2015 display page. We are considering in the future to potentially include a drill-down on the MPF website that would include information about the primary reasons why beneficiaries left their plan. Prior to making a final decision about including this on MPF in the future, CMS will conduct testing with potential users of the site to ensure that they understand the information. Any further changes will be announced in a future Request for Comments.

We are considering the following changes to measure specifications on the 2015 display page:

6. *Drug-Drug Interactions Measure (Part D).* This measure uses the PQA Drug-Drug Interactions (DDI) measure specifications. It is defined as the percent of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or subsequent to the initial prescription. The PQA reviewed and updated the list of drug-drug interactions. We propose to implement the updated PQA DDI measure list for the 2015 display measure (using 2013 PDE data), as proposed in the 2014 Call Letter. The changes made to the DDI list include:

   I. Delete the DDIs - carbamazepine and propoxyphene; tamoxifen and bupropion, duloxetine, fluoxetine, and paroxetine; warfarin and cimetidine; warfarin and fibrates (fenofibrate, fenofibric acid, gemfibrozil).

   II. Add the DDIs - carbamazepine and clarithromycin, erythromycin and telithromycin.

   We note that PQA's 2014 specifications will delete the age criteria for this measure. Historically, we have not applied an age criteria for this measure, and will continue not to.

7. *Diabetes Medication Dosing (Part D).* CMS proposes to align with the PQA's measure specifications for this display measure by adding a minimum age criteria of 18 years of age. We expect this change to have minimal impact, and recommend this change for the 2015 Display Measure (using 2013 PDE).

8. Enrollment Timeliness (Part C and D). CMS previously excluded SNPs from this measure. For the 2015 display measure, we propose to include SNPs but use for their numerator the number of plan-generated enrollment transactions submitted to CMS within 21 calendar days of the application date.

G. Proposed Weighting Changes

As part of the Request for Comments, we solicited feedback on alternative weighting of measures, specifically: 1) modifying the current weight (3x) of the improvement measure(s) in order to further recognize organizations/sponsors' efforts in improving quality and 2) modifying the weight (3x) of the three Part D Medication Adherence measures. Both of these have underlying policy issues. For example, increasing the improvement measure's weighting as an outcomes measure (from 3x to 4x or 5x the weight of a process measure) could better reward lower-performing contracts' strides to raise their performance.

CMS received mixed reactions to changing the weighting of the improvement measure. Some wanted the weight reduced to 1, some liked the current weight of 3, and others supported increasing the weight from anywhere from 5x to 13x a process measure. Given the importance of improvement, CMS is proposing to increase the weight to 5x a process measure for the 2015 Star Ratings. This change would further align the Part C and D Star Ratings with value-based purchasing in Medicare fee-for-service.

CMS received both support to maintain the current weight of the three Part D Adherence measures, as well as requests to decrease their weight. We understand the current PQA-developed measures are claims-based, and therefore cannot measure true clinical outcomes of non-adherence. We disagree with the suggestion to combine these three measures into one composite measure which would contradict industry consensus and beneficiary testing. We welcome additional feedback during the Call Letter process, but would specifically solicit feedback on the option of CMS reducing the weight of these measures for the 2015 Star Ratings to a weight of 1.5, as access measures, versus maintaining their weight of 3 as outcomes measures. We will continue to consider future alternative measures of clinically significant non-adherence, which would be weighted as outcomes measures (3x).

H. Forecasting to 2016 and Beyond

1. 2016 Changes in the Calculation of the Overall Rating and the Part C and D Summary Ratings

a. Background

CMS wants to improve the accuracy of the assignment of overall and Part C and D summary ratings used for public reporting to Medicare beneficiaries and as the basis for Quality Bonus Payments (QBPs) for MA organizations. 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 "misclassifying" a contract's performance (e.g., scoring a "true" 4-star contract as a 3-star contract, or vice versa). Misclassification occurs in any measurement system because all performance measurement is a mixture of *signal* (true performance) and *noise* (random measurement error due to rounding, variation due to who is sampled, and similar factors). Over the years several features have been implemented in the quality rating system to simplify the information for consumers, as well as to make the ratings process and methodology more transparent for organization/sponsors. For example, we group the measure scores into star categories and round the data to make it easier for consumers to understand what a particular score means. We have also implemented pre-determined 4-star thresholds for some measures since the 2011 Star Ratings to increase transparency for organizations/sponsors and set a priori expectations for high performance. However, all of these features create more "noise" or measurement error in the system.

b. Current Scoring Method

The 2014 overall Star Rating is a composite measure constructed from 36 measures for Part C and from 15 measures for Part D. The measures are numeric scores such as counts and percentages of screening and testing, handling of chronic care, patient experience, customer service, and patient safety measures. Currently, each measure is assigned a rating from 1-5 stars. The principle for assigning a Star Rating for a measure is based on evaluating the maximum score possible and testing initial percentile star thresholds with the actual score. 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:

1. 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.

2. 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 2014 Star Ratings, 25 Part C and 5 Part D measures have pre-determined 4-star thresholds (68% of Part C measures, and 33% of Part D measures) not set by the clustering algorithm. For the 2015 Star Ratings, no new 4-star thresholds will be introduced. The previously set 4-star threshold for the Annual Flu Vaccine (Part C) measure will be eliminated for 2015 due to specification changes.

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. This 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 our measures is an indication that we can be more confident that an organization/sponsor's underlying operations and clinical services reflect the high quality of care they provide. In contrast, an organization/sponsor that demonstrates more erratic behavior in measures may not offer the same consistent quality, due to non-aligned operations or clinical services. An organization/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 an i-Factor, renamed as the "Reward 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 i-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 for contracts that have low variation and high mean performance in their individual measure scores. The 2014 Part C & D Star Rating Technical Notes provide more information about the calculations.

c. Concerns with Current Scoring Method

Using the whole-star individual measures, as well as pre-determined 4-star thresholds, results in a loss of information when aggregating up to the overall and summary ratings. Whole stars contain less information than the corresponding measure data because there is information loss associated with converting a numeric scale to a 1- to 5-star rating. That is, the range of values between whole numbers is not differentiated (e.g., a "high 3" looks the same as a "low 3"). While we understand sponsors' perceptions that pre-determined 4-star thresholds provide stability in 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% would receive 3 stars while a

contract that scores 81% would receive 4 stars when there may be no meaningful difference between a score of 79 and a score of 81). This is counter to the industry feedback given to CMS that these thresholds assist organization/sponsors in targeting their improvement efforts. 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. 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. In responding to the Request for Comments, some plans were concerned that it is difficult to improve without published targets for achieved 4 or more stars on a measure. However, data analyses of past Star Ratings found plans on average have more significant levels of improvements in Part C and D measures without pre-determined thresholds, as compared to measures where CMS has pre-set thresholds. We found that on average only 32% of contracts improved significantly across the 23 Part C measures with 4-star thresholds, compared to 52% of contracts that improved significantly across the eight Part C measures without 4-star thresholds. For Part D, on average, only 21% of contracts showed significant improvement across the five measures with 4-star thresholds, while 56% of contracts showed significant improvement across the five Part D measures without 4-star thresholds.

d. Proposed Changes to Thresholds for 2016

Based on extensive analyses of several options, we propose moving from the current scoring methodology to a new methodology for the 2016 Star Ratings by removing the pre-determined measure thresholds. However, we would continue to use the "Reward Factor" for contracts with consistently high performance and continue our evaluations if changes are needed. Contract-specific information on the impact of removing pre-determined 4-star thresholds will be posted in HPMS following the release of this Draft Call Letter.

2. Expected Changes to Measure Specifications or Calculations

For HEDIS 2015, NCQA is considering or has already made revisions to several measures included in the Part C Star Ratings. CMS also is also monitoring any additional measures developed by NCQA for incorporation into the Star Ratings. For example, NCQA is currently testing a measure of potentially avoidable hospitalizations based on the AHRQ Prevention Quality Indicators (PQI). The proposed measure has two composites that assess the rate of hospitalization for acute and chronic ambulatory care-sensitive conditions. Depending on the outcome of testing and the development of appropriate risk-adjustment models, these would be potential measures for inclusion in the future. Additionally, NCQA is currently developing potential new health plan quality measures that address the continuum of depression care from screening to outcomes. Specifically,

they are exploring quality measures of depression screening with a standardized tool, developing a follow-up plan, monitoring of depressive symptoms with a standardized tool, and remission of depressive symptoms. Where possible they are planning to align these measures with existing quality measures included in Meaningful Use, such as measures developed by CMS for clinician quality evaluation and measures developed by Minnesota Community Measurement. We appreciate the comments we received and are sharing them with NCQA.

a. Osteoporosis Management in Women who had a Fracture (Part C).

This measure assesses the percentage of women who had a fracture and received either screening or treatment for osteoporosis. One of the treatments for osteoporosis listed in the measure is a prescription for estrogen. However, estrogen is included in the American Geriatrics Society's recently published list of potentially harmful medications in the elderly (i.e., Beers criteria). NCQA is reviewing the most recent evidence for osteoporosis treatment with experts in the field to determine if treatment with estrogen should be removed from this measure. Other revisions under consideration include adding an upper age limit to the measure and adding an exclusion for dementia.

b. Monitoring Physical Activity (Part C).

This measure, collected through HOS, assesses the percentage of beneficiaries who discussed their level of physical activity with their health care provider and were advised to start, increase, or maintain their level of physical activity. NCQA is currently exploring the possibility of revising the underlying survey questions used in this measure. These revisions would facilitate the possible addition of an outcome indicator that assesses whether patients increased their level of physical activity.

c. Plan All-Cause Readmissions (Part C).

This is a measure of the percentage of hospital discharges resulting 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 risk-adjusted model. NCQA is considering two potential changes to this measure: 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. NCQA and its Measurement Advisory Panels believe these changes will improve the validity of the measure.

d. Improving Bladder Control (Part C).

This measure, collected through HOS, assesses the percentage of beneficiaries with a urine leakage problem who discussed their problem with their provider and received treatment

for the problem. NCQA made three changes to this measure. First, NCQA changed the denominator of both indicators to include all adults with urinary incontinence, as opposed to limiting the denominator to those who consider urinary incontinence to be 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 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.

e. Plan Makes Timely Decisions about Appeals (Part C).

CMS is revising the procedures relative to appeal dismissals beginning in January 2014. Beginning in 2014 organizations will be responsible for dismissing invalid appeal requests, rather than forwarding requests to the Independent Review Entity (IRE) for the dismissal decision. Therefore, the IRE will not be capturing data around the timeliness of dismissal cases, and consequently, dismissals will be excluded from this measure for the 2016 Star Ratings. CMS will not be moving this measure to the display page since this change was announced in advance.

f. Appeals Upheld (Part D).

In the Request for Comments, we proposed to modify this measure from using the current 6-month snapshot to use the same 12-month measurement period as the Part D Appeals Auto-forward measure. This change will allow consistency between the two appeals measures as well as expand the measurement period. Despite some comments submitted, CMS continues to believe that expansion to a full 12 months of data used in the measure will provide a more comprehensive and objective evaluation of a plan's performance than the current six month period. We understand, however, the requests to provide advance notice of this change. As a result of feedback received, CMS is deferring this change to the 2016 Star Ratings. We will re-evaluate and adjust as necessary the minimum number of cases. The pre-determined 4-star threshold for this measure will be eliminated for the 2016 Star Ratings due to this specification change. For the 2015 Appeals upheld measure, CMS will continue to use the first 6 months of 2014 IRE data.

g. Adherence (DM and Hypertension) and Diabetes Treatment (Part D):

PQA updated their specifications for 2014 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.

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. CMS will propose to make this change for the 2016 Star Ratings using 2014 PDE.

EDB data is available for all Part D beneficiaries, whereas ICD-9 codes are only available to MA-PDs. The EDB is also current data (after considering data lag), whereas RxHCCs do not reflect current diagnoses. CMS' testing of these indicators found a very high level rate of overlap between the ESRD indicators in the EDB and ICD-9 codes when calculating the final rates for these measures for purposes of the Star Ratings. While there is some lag in data updates, we found the overlap between the two data sources was greater than 95%.

h. Complaints about the Health/Drug Plan (CTM) (Part C and D):

For 2016 Star Ratings, CMS will modify the CTM measurement period from 6 months of the current contract year to 12 months of the prior contract year. We believe this expansion of the data used for this measure will provide a more comprehensive evaluation of the plan. Currently complaints filed in the 2nd half of a year are not accounted for in a contract's performance rating when only the 6-month period is used. CMS will continue to use complaint data from January-June 2014 for the 2015 Star Ratings.

i. MPF Accuracy (Part D):

This measure incorporates data from Part D sponsors' and MA-PD organizations' Medicare Plan Finder (MPF) files, specifically information about the types of claims dispensed by each pharmacy in an organization/sponsor's network. Currently, we exclude PDE claims from retail pharmacies that are also reported by sponsors as being long term care, mail order, or home infusion pharmacies. We will evaluate removing this restriction in the future, and use PDE data to appropriately identify retail claims for evaluation in this measure. We will also remove the restriction limiting evaluation to claims for 30-day supplies, and will evaluate claims for 30, 60, and 90-day supplies. During the Request for Comments, CMS received concerns about this proposed change because MPF only accepts one brand and one generic dispensing fee per pharmacy, regardless of the days' supply dispensed. CMS seeks further clarification about the magnitude of differences in dispensing fees for 30, 60 and 90 days. This change will also necessitate a change in the

pricing data submission requirements to account for all of the dispensing fees for the three different days of supply that are able to be displayed on the MPF.

j. CAHPS measures (Part C and D):

When we drop the pre-determined 4-star thresholds, we also propose slightly modifying the CAHPS methodology to permit low-reliability contracts to receive 5 stars or 1 star. Some low-reliability contracts with 5 base stars, while imprecisely measured, nonetheless have good evidence of performance that is well above the 4-star threshold. We propose as a modification of the CAHPS methodology a rule that would permit low-reliability contracts with 5 base stars that also exceed the 4-star threshold by 1 standard error to retain 5 stars for their final measure star. Likewise, some low-reliability contracts with 1 base star, while imprecisely measured, nonetheless have good evidence of performance that is well below the cutoff for 2 stars. We similarly propose that low-reliability contracts with 1 base star that also fall below the 2-star cutoff by 1 standard error retain 1 star for their final measure star.

I. Measurement Concepts

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. We appreciate the comments received and will consider them as we continue to look at these measurement concepts. We welcome additional feedback and suggestions for new measures.

1. Alternatives to individual measures' current level of evaluation. For example instead of measures being rated for each contract, should some be evaluated at the plan (PBP) level, or at the parent organization level? Are there other associations of contracts within business entities that could also be a measurement level?

2. Additional measures of care coordination focusing on how well providers and organizations coordinate services.

3. Measures of care transitions from one healthcare setting to another, for example, care transitions following hospital discharge.

4. Measures of patient-reported outcomes/intermediate outcomes collected through enrollee surveys, including additional ways to measure changes in health and mental health status.

5. Measures that are condition-specific (e.g., mental health such as depression screening, HIV/AIDs, COPD, cancer). This may include one or more measures for a particular condition.

6. Combined member dissatisfaction measure – CMS received support for exploring methodologies for combining complaints and grievance data. We will introduce any composite measure to the CMS display page for stakeholder feedback.

7. SNP-specific measures that would focus on any unique aspects of care provided by SNPs.

8. Alternative methods for measuring improvement that ensure that the efforts of lower-performing contracts to improve are recognized in the Star Rating system.

9. Feasibility of replicating current HEDIS measures by using FFS administrative data – CMS is interested in evaluating stand-alone PDPs' performances in areas that traditionally are based on medical record reviews.

Summary of Benefits

Based on industry feedback and CMS research, CMS is revising the Summary of Benefits (SB) template document beginning with CY 2015. Under §§ 422.111 and 423.128, as explained in the Medicare Marketing Guidelines, the SB is a standardized document that must be distributed with each enrollment form, and provides consumers an overview of plan benefits in a consistent and uniform manner so that individuals can compare plans offered by different MAOs.

Over the past few years, CMS has sought feedback from both beneficiaries and the industry about the utility of the SB. In 2011, CMS issued a Federal Register Notice for Comment regarding challenges faced by Medicare-Medicaid enrollees, including difficulties with cost-sharing information in the SB. In 2012, CMS consumer tested the SB through one-on-one participant interviews to determine whether beneficiaries could identify the purpose of the SB and identify opportunities for increasing beneficiary comprehension. In 2013, CMS sought industry feedback on draft templates significantly revised to address beneficiaries' difficulty using the SB to understand plan benefits or compare plan benefits against Original Medicare (OM). CMS reviewed all comments received as part of these feedback periods and has revised the template, which will be released in April 2014 with the PBP and SB software.

We anticipate that the revisions will focus largely on two areas: (1) limiting the description of benefits to those covered under the plan, addressing the scope, and removing the comparison of benefits against coverage under Original Medicare; and (2) describing plan benefits and cost-sharing using beneficiary-friendly language.

Section II – Part C

Overview of CY 2015 Benefits and Bid Review

Portions of this guidance apply to section 1876 cost plans, MA plans, including employer group plans, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs) and Institutional Special Needs Plans (I-SNPs). Employer group plans, D-SNPs, and section 1876 cost plans are excluded from our evaluation to identify mostly duplicative plans under §422.256(b)(4), also referred to as the "meaningful difference" evaluation. Similarly, employer group plans and section 1876 cost plans are not evaluated for low enrollment. Please note: CMS reserves the right to review employer group plans for low enrollment and/or meaningful difference in future years.

The Financial Alignment Demonstration for Medicare-Medicaid Plans is not subject to the requirements summarized in the table below. The Financial Alignment Demonstration for Medicare-Medicaid Plan guidance will be provided separately.

CMS has made 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 2, 2014 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 following chart displays key MA benefit 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 2015 and have provided explanations of these changes in each applicable section below. Consistent with last year, 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.

A. Plans with Low Enrollment

CMS will send each applicable MAO a list of plans that have been in existence for three or more years as of March 2014 (three annual election periods) and have fewer than 500 enrollees for non-SNP plans or fewer than 100 enrollees for SNP plans. The list will not include plans with low enrollment that CMS determines are located in service areas that do not have a sufficient number of competing options of the same plan type.

Under 42 CFR §422.506(b)(1)(iv), MAOs must confirm, through return email, that each of the low enrollment plans identified by CMS will be eliminated, consolidated with another of the organization's plans for CY 2015, or provide a justification for renewal. If CMS does not find there is a unique or compelling reason for maintaining a plan with low enrollment, we will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting business cases and what information is required in those submissions will be included with the list of low enrollment plans sent to the MAO. Note that these requirements do not apply to Section 1876 cost plans and employer plans.

CMS recognizes there may be certain factors, such as the specific populations served and geographic location, that lead to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because of their focus on a subset of enrollees with certain medical conditions. CMS will consider all such information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs are to follow the CY 2015 renewal/non-renewal guidance in the final Call Letter to determine whether a low enrollment plan may be consolidated with another plan(s).

MAOs should monitor the proposed MA regulation (§ 422.504(a)(19)), that would place a two year limitation on submitting a new bid in an area where an MA plan has been required to

terminate due to low enrollment[7]. The proposed requirement stipulates that the MA organization agrees not to submit a new bid of the same plan type that has been non-renewed under § 422.506(b)(1)(iv) in the same service area as the non-renewed plan for two years after such a non-renewal.

B. Meaningful Difference (Substantially Duplicative Plan Offerings)

Pursuant to §422.254(a)(4), MAOs offering more than one plan in a given service area must ensure the plans are substantially different; 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 2015, 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. All documentation and instructions associated with running the OOPC model are posted on the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.

As indicated in the CY 2014 Final Call Letter, CMS will combine HMO and HMO-POS as one plan type for evaluating meaningful difference, unless the HMO-POS plan covers all Parts A and B services outside the network, in which case the HMO-POS plan will continue to be considered meaningfully different from an HMO plan. For CY 2016, CMS may also require HMO-POS plans to not place geographic or provider limitations on the out-of-network benefits in order to be considered meaningfully different.

CMS will evaluate meaningful differences among CY 2015 non-employer and non-cost contractor plans offered by the same MAO, in the same county, as follows:

1. The MAO's non-SNP 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). D-SNPs are excluded from the meaningful difference evaluation.

[7] See the proposed rule published January 10, 2014, 79 FR 1919, "Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (CMS-4159-P).

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. We consider a difference of at least $20.00 PMPM between the OOPC for each plan offered by the same MAO in the same county to be meaningful for purposes of applying the meaningfully different standard. Plan premium is not included in the meaningful difference evaluation.

Please note using different providers or serving different populations are not considered meaningfully different characteristics between two plans of the same type.

CMS expects MAOs to submit CY 2015 plan bids that meet the meaningful difference requirements, but will not prescribe how the MAOs should redesign benefit packages to achieve the differences. Furthermore, MAOs 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 requirements. MAOs must follow the CY 2015 renewal/non-renewal guidance in the final Call Letter to determine if their plans may be consolidated with other plans.

C. 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 requirement. A plan's TBC is the sum of 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 ensure beneficiaries 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).

Consistent with past years, CMS will continue to incorporate adjustments in the TBC calculation for payment rate and quality bonus changes, in addition to an adjustment for a change in the national factor for the MA coding pattern difference and other technical adjustments for changes in the PBP software. CMS proposes to establish the TBC threshold at $32.00 PMPM for CY 2015, compared to $34.00 PMPM for CY 2014. Thus, a plan experiencing a net increase in adjustments must have an effective TBC change amount below the $32.00 PMPM requirement. Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the $32.00 PMPM requirement. We remind MAOs that the Office of the Actuary extends flexibility on margin requirements so MAOs can meet the TBC

requirement. CMS will provide detailed operational guidance via an HPMS memo and will post TBC adjustment factors in HPMS, both in mid-April.

CMS reserves the right to further examine and request additional changes to a plan bid even if a plan's TBC is within the required amount, if we find it is in the best interest of the MA program. We believe this approach not only protects beneficiaries from significant increases in cost sharing or decreases in benefits, but also ensures beneficiaries have access to viable and sustainable MA plan offerings. For organizations consolidating multiple CY 2014 plans into a single CY 2015 plan, CMS will use the enrollment-weighted average of the CY 2014 plan values to calculate the TBC. Otherwise, these plans will be treated as any other plan for the purpose of enforcing the TBC requirement. Please note for CY 2016, CMS is considering (a) requiring each individual plan to be "crosswalked" into another plan to meet the TBC threshold on its own merit and (b) discontinuing use of the enrollment-weighted average for multiple plans "crosswalked" into one plan to determine TBC. We invite MAOs to provide comments to CMS regarding this potential change in policy for CY 2016.

D. Maximum Out-of-Pocket (MOOP) Limits

Table 2 below displays the CY 2015 mandatory and voluntary MOOP amount 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), (5) and (6), 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 2014 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

E. 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 2015: Inpatient Facility, Skilled Nursing Facility (SNF), Home Health, 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 2015.

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 (Part A only) *(BPT Col. n)*	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	1.393	$35.24	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.069	$10.57	$0.26	Fail
Home Health[1]	$0.01	$0.30	$0.00	0.150	$0.05	$0.00	Pass
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] Home health has no cost sharing under Original Medicare, so the comparison amount (#5) is calculated by multiplying the Medicare allowed amount (#2) by the Part B Adjustment Factor (#4).

F. Part C Cost-Sharing Standards

CMS is continuing, in evaluating whether bids and benefits meet regulatory standards, its 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 violative of the applicable standards. CY 2015 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.

The following list provides an overview of changes for CY 2015:

- Inpatient and home health requirements have been updated to reflect estimated changes in Original Medicare costs for 2015.
- The Skilled Nursing Facility (SNF) cost sharing limit for the first 20 days has been reduced from $50 to $40 per day for voluntary MOOP plans and from $25 to $0 per day for mandatory MOOP plans to provide greater protection for beneficiaries. The allowable cost sharing requirement for SNF days 21 to 100 has been updated to reflect estimated changes in Original Medicare costs for 2015. Since cost sharing for the overall

SNF benefit (i.e., both benefit periods) must be no higher than the actuarially equivalent cost sharing in Original Medicare, the cost sharing requirement change for the first benefit period should not impact the overall plan costs associated with the SNF benefit.

- Occupational Therapy, Physical Therapy and Speech-language Pathology have been added as a requirement for CY 2015.

Table 4. CY 2015 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	$4,123
Inpatient - 10 days	1a	$2,392	$1,913
Inpatient - 6 days	1a	$2,171	$1,737
Mental Health Inpatient - 60 days	1b	$2,544	$2,035
Mental Health Inpatient - 15 days	1b	$1,911	$1,528
Skilled Nursing Facility – First 20 Days[1]	2a	$40/day	$0/day
Skilled Nursing Facility – Days 21 through 100[2]	2a	$156.50/day	$156.50/day
Emergency Care/Post Stabilization Care	4a	$65	$65
Urgently Needed Services	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[3]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

[1] MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 CFR §§417.454(e) and 422.100(j)).
[2] 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] 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 a 20% coinsurance or $75 copayment to that particular benefit. Pursuant to section 1852(a)(1)(B) of the Act, MAOs are required to meet the Per Member Per Month Actuarial Equivalence requirement for the overall SNF benefit, which encompasses days 1-100. The cost sharing requirement for SNF is separated into two periods to reflect Original Medicare: days 1 to 20 and days 21 to 100. Although Original Medicare has no cost sharing during the first 20 days, MA plans with a Voluntary MOOP in CY 2015 may charge some cost sharing during the first 20 days as defined annually by CMS. If a plan exercises the option to have cost sharing during the first 20 days, it will have to offset those charges by setting the cost sharing amounts for days 21-100 at less than $156.50 per day in order to satisfy the Per Member Per Month Actuarial Equivalence requirement.

Please note MAOs with benefit designs using a coinsurance or copayment amount for which CMS does not have an established amount (e.g., coinsurance for inpatient or copayment for durable medical equipment) must submit with their initial bid a document that clearly demonstrates how the coinsurance or copayment amount satisfies CMS service category requirements. This document 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 2015, Appendix B-Supporting Documentation.

G. Part C Optional Supplemental Benefits

As part of our evaluation whether the bid and benefits are not discriminatory against enrollees with specific health needs, CMS will continue to review non-employer bid submissions to ensure enrollees electing optional supplemental benefits are receiving reasonable value. 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 meet the following thresholds: (a) margin is no greater than 15% and (b) retention, defined as margin plus administrative expenses, 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.

Part C Policy Updates

A. Increasing Transparency for Beneficiary Part C Cost Sharing for Inpatient Stays

We have become aware that some MA plans' representation of cost sharing for inpatient services is not as transparent as it should be, particularly in MA plans that do not use original Medicare benefit periods as the basis for charging cost sharing. As an example, an MA plan may charge inpatient cost sharing for each inpatient admission that includes the inpatient deductible and per diem cost-sharing beginning with admission to an inpatient acute hospital. In the event that the enrollee is subsequently transferred to an inpatient rehabilitation hospital, the plan may then charge a second round of cost-sharing (e.g., a second inpatient deductible and other cost-sharing) upon admission to the rehabilitation hospital. Thus, the enrollee is charged two inpatient deductibles and per diem cost-sharing, even though the second stay (at the rehabilitation hospital) is a transfer that is required by the enrollee's medical condition.

In contrast, under Original Medicare, beneficiaries pay only one inpatient deductible (Part A) during a benefit period, even if the beneficiary is transferred from one inpatient hospital type to another (e.g., from an inpatient acute hospital to an inpatient rehabilitation hospital) or has multiple stays, for any reason, during the benefit period. That is, the cost sharing is charged based on the original Medicare-defined benefit period.

Thus, we believe that there is a need to increase beneficiary awareness of such alternative benefit structures because there is the potential for higher-than-expected out-of-pocket spending associated with inpatient hospitalization in those plans. We also wish to address confusion expressed by some enrolled beneficiaries and other stakeholders. We are considering whether or not there are regulatory changes needed, such as placing limits on MA plan inpatient cost sharing structures, in order to provide stronger beneficiary protections from excessively high inpatient cost sharing. However, any regulatory changes must be promulgated through notice and comment rulemaking and therefore would be effective no earlier than the 2016 contract year.

Therefore, in the interim, in order to increase beneficiary awareness of the differences in cost sharing structures across plans, we are proposing to revise the templates for Evidence of Coverage (EOC), Annual Notice of Change (ANOC) and Medicare Plan Finder (MPF) to more clearly show each plan's inpatient cost sharing structure. We have developed additional instructions and language for the EOC and ANOC for MA plans to clearly identify all cost sharing (deductible, copayments/coinsurance) for inpatient stays and the period for which such cost sharing would be charged, if applicable. Similarly, we intend to modify the MPF to ensure pertinent information is displayed for potential enrollees.

B. Transferability of MOOP Contributions When an Enrollee Changes Plans During the Contract Year

According to current guidance, when an MAO enrollee switches to another plan of the same type offered by the MA organization under the same contract, his/her accumulated annual contribution toward the annual MOOP limit in the previous plan to date is counted towards his/her MOOP limit in the new MA plan. We believe it is reasonable to further extend the transferability of the enrollee's contribution toward his/her annual MOOP to any MA plan type offered by the same MAO. Thus, if an enrollee makes a mid-year change from an HMO to a PPO offered by the same MAO, his/her current contribution toward the MOOP limit should follow the enrollee and be counted towards the MOOP limit in the new MA plan. This allows those enrollees who are eligible to make mid-year plan changes to freely select among the diverse MA plan options offered by an MAO. We note this guidance is also applicable to employer group waiver plans (EGWPs).

C. Memory Fitness Activities

MAOs have previously proposed to offer memory fitness activities (e.g., brain/memory exercises*)* as a stand-alone optional supplemental benefit. In consideration of emerging research, CMS will accept memory fitness activities when offered as a component within a broader health education supplemental benefit (as described in Chapter 4 of the Medicare Managed Care Manual, section). This health education benefit must be offered to all enrollees but marketing may be targeted to specific enrollees to assist them in building the skills necessary to enhance preventive and self-care capabilities due to cognitive impairment. Please note any proposed stand-alone, memory fitness benefit will continue to be disallowed as not being a health benefit.

D. Part C PBP Notes Update for CY 2015

CMS has generally allowed MAOs to include additional information about the benefit being offered in the notes sections in the PBP. The information in the notes sections should not contain any cost sharing for the benefit/service not reflected in the PBP data entry field for the benefit/service or conditions for coverage because such information is not captured in Summary of Benefits sentences. In addition, any information in a notes field must be consistent with the benefit/service as it is reflected in the PBP data entry fields. This is to ensure all cost sharing information is transparent to beneficiaries as they make plan comparisons.

Thus, an appropriate note contains only information applicable to the service category in which the note section is located and provides relevant information reviewers need for bid evaluation; it does not repeat the cost sharing information entered in the data entry field. Over the years, we have taken several steps to help plans present benefits in the PBP without the need for extensive

notes. We will include additional, minor clarifications regarding a number of supplemental benefits in a future HPMS memo to address our approval standards for mandatory supplemental benefits and the permissible scope of optional supplemental benefits.

We have also made multiple changes to the PBP for CY 2015 that address supplemental benefits described in Chapter 4 (Section 30.3). In developing supporting notes in the PBP, MAOs must use text fields to describe benefit attributes that cannot be discerned from either Chapter 4 guidance or the corresponding data entry fields. We realize, in the past, notes have often been used to support marketing material; therefore, we will continue to coordinate our efforts with our marketing review staff to limit plans' use of notes to providing additional information. MAOs are encouraged to review the forthcoming HPMS memo, which we expect to release in mid-April, for more information regarding CMS' expectations with respect to appropriate PBP notes.

E. Part C ER/Urgent Care Deductible

We are clarifying that enrollees utilizing the Emergency Care or Urgently Needed Care benefits are not subject to a service category or plan level deductible amount; however enrollee cost sharing associated with Emergency Care and Urgently Needed Care visits always apply toward a plan level deductible.

Consistent with this guidance, CMS has made changes in the CY 2015 Plan Benefit Package (PBP) including the removal of deductible questions in Section B for Emergency Care and Urgently Needed Care and adjusting "pick lists" for plan level and differential deductibles in Section D.

F. Requirements for Home Health Services

As provided in 42 CFR §424.22, the Medicare program provides for home health services only if a health care professional, as stipulated in the regulation, certifies the home health service appropriately meets the needs of the beneficiary. We wish to clarify the requirements of this regulation also apply to Medicare Advantage plans in their provision of home health services as a basic benefit under §422.100.

G. Tiered Cost Sharing of Medical Benefits

In our discussion of tiering in section 50.1 of Chapter 4 of the Medicare Managed Care Manual, we state tiering may not be based on the provider group that an enrollee selects in order to comply with the uniformity requirement of § 422.100(d). We wish to clarify that different cost sharing amounts may be associated with different physicians or groups of physicians, including primary care physicians, consistent with the regulatory uniformity requirement so long as all plan enrollees are charged the same cost sharing amount for any specific physician and all physicians are available to all enrollees in the plan.

We believe that allowing plans to establish different cost sharing tiers for physicians is consistent with the regulation when MAOs have established quality standards for physicians and wish to create incentives for enrollees to seek care from physicians that meet or exceed such standards. We will update the guidance on tiering and the uniformity requirements to reflect the clarification above. We note that Chapter 4 of the Manual provides additional guidance on when and how tiering structure(s) satisfy the regulatory requirements and are permissible. As a part of our enforcement of the uniformity requirement, MAOs must submit their tiering proposals for CMS review as described in our HPMS memo titled, "MA Bid Review and Operations Guidance," dated April 17, 2013. We welcome comments on our tiering guidance, including suggestions for additional flexibilities that may be consistent with the applicable law but would allow MAOs to create incentives for enrollees to seek care from high-performing physicians and other types of providers.

H. Part C Services Via Remote Access Technologies

Technologies that enable health care providers to deliver care to patients in locations remote from providers (hereafter referred to as "remote access technologies") are increasingly being used to complement face-to-face patient-provider encounters. We believe that the use of remote access technologies as a care delivery option for MA enrollees may improve access to and timeliness of needed care, increase communication between providers and patients, and enhance care coordination.

Some MAOs have asked CMS to consider allowing the inclusion of remote access technology-furnished services as part of MA plan basic benefits. However, the basic benefits are Medicare Parts A and B services and, except for the Medicare narrowly-defined telehealth benefit, services furnished via remote access technologies are not covered by Medicare. Although we encourage MA plans to develop and implement innovative services and benefit design, at this time we are limited by the statutory definitions of services that may be covered by Medicare. Instead, CMS intends to continue to allow MAOs to use such technologies in contract year (CY) 2015 as mandatory supplemental benefits. We currently define the following as remote access technologies as supplemental benefits: Telemonitoring, and Web- and Phone-based Technologies, Nurse Hotline,' and other similar services. For CY 2015, we would also allow MA organizations to furnish medical services to enrolled beneficiaries via real-time interactive audio and video technologies as a mandatory supplemental benefit.

Services that are furnished via such means should not replace face-to-face provider/patient interactions but rather supplement and complement traditional office visits, as appropriate. In addition, MAOs would be able to use remote access technologies as an option for enrolled beneficiaries who are willing and able to participate in this mode of service delivery. MA plans' networks must continue to meet our access standards; any remote access technologies would be in addition to, not a replacement of, an adequate provider network. Furthermore, MAOs must

ensure that providers who furnish services through such technologies are practicing within their scope of license or certification as defined by their licensing or certifying state. We seek comments on this approach to implementing our authority over mandatory supplemental benefits and the access requirements.

We are interested in continuing to develop our policy on remote access technologies through the identification of current programs or unique approaches that have demonstrated effectiveness. Therefore, we are also soliciting proposals or descriptions of current care delivery programs that may help CMS establish standards for such approaches.

I. 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 to certain brands or manufacturers. Limiting DME based on brand or manufacturer is permitted for categories of DME in which the items are essentially interchangeable. CMS has determined the items within certain categories of DME are specifically tailored to individual needs and, consequently, coverage of those items may not be limited. Section 42 CFR §422.100(l)(2)(vii) codifies the requirement MA plans provide full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories annually determined by CMS to require full coverage.

In our Final Call Letter for CY 2014, published on April 1, 2013, we identified several categories of DME (listed below) that may not be limited based on brand/manufacturer. The same is true for CY 2015.

Speech-Generating Devices: People who require speech-generating devices frequently have other disabilities; the speech-generating device is 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 devise; 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.

J. Innovations in Health Plan Design

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models that will lower costs and improve quality for Medicare, Medicaid, and CHIP beneficiaries. CMS is seeking to partner with private payers to test innovations in health plan design for CMS beneficiaries, including but not limited to value-based arrangements, beneficiary engagement and incentives, and/or care coordination. CMS will be issuing a formal Request for Information in the coming months. We look forward to your input.

Part C 1876 Cost Plan Contract Application

We want to remind organizations that CMS will not accept any new cost plan applications. CMS 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 2015, 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 contractor'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 at least two competing MA local or two MA regional coordinated care plans that meet specified enrollment thresholds are available.

Cost Contract Plan Competition

In accordance with the Bipartisan Budget Act of 2013 (Pub. L. No. 113-67), beginning Contract Year (CY) 2015, 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 2016.

We will non-renew any portion of a cost plan's service area if there are at least two competing MA local or two MA regional coordinated care plans with a minimum of 5,000 enrollees (urban areas) or 1,500 enrollees (non-urban areas) for the entire year prior to the non-renewal. We will use 2014 enrollment data to determine the cost plans subject to non-renewal and contact affected plans at the end of 2014 to permit cost contractors wishing to convert to Medicare Advantage plans for CY 2016 time to make the necessary arrangements, including filing a notice of intent to apply with CMS.

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-based plan non-renewal or service area reduction. However, for purposes of a cost plan's mid-year service area expansion, the MA plans must only meet minimum enrollment requirements as of the date of the proposed expansion. (*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 may offer a mid-year service area expansion consistent with 42 CFR §417.402 and as noted above. Cost plans that offer Part D as Cost-PD plans are also subject to the same restriction on mid-year service area expansions as MA-PD plans in that they cannot expand into an area served by an MA-PD or PDP plan.

Minimum Enrollment Guidance

An organization must meet minimum enrollment requirements in order to hold a Medicare Advantage contract with CMS (see 42 CFR §422.514). The minimum enrollment requirement is an indicator that the organization applying for a Medicare Advantage contract is able to handle risk and capitated payments. CMS expects that an organization is able to effectively manage a health care delivery system including the enrollment and disenrollment of members and the timely payment of claims, provide quality assurances, and have systems to handle grievances and appeals.

CMS recognizes that new applicants may believe they are capable of administering and managing an MA contract although they do not meet the minimum enrollment requirements. Our regulations at 42 CFR §422.514(b) provide for a transition period allowing CMS to waive the minimum enrollment requirements during an organization's first three years of operation.

For each waiver request, the applicant must provide, as an upload in HPMS, a statement that demonstrates to CMS's satisfaction that it 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.

Part C Provider Contract Termination Guidance

CMS Guidance Related to MAO Network Changes

MAOs have considerable discretion to select the providers with whom to contract in order to build high-performing, cost effective provider networks and are able to make changes to these networks at any time during the contract year, as long as they continue to furnish all Medicare covered services in a non-discriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees. (These requirements are discussed in more detail in Chapter 4 of the Medicare Managed Care Manual.) Recent significant mid-year changes to MAOs' provider networks have prompted CMS to reexamine its current guidance on these requirements and to consider augmenting such guidance in response to such changes. We describe these proposed changes below and welcome comments on these changes.

CMS considers significant changes to provider networks as those that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of the MAO's enrollees. While CMS believes MAOs may be in the best position to determine whether or not a planned provider termination(s) is significant enough to meet this threshold, we are soliciting comments on whether a uniform standard or threshold that constitutes a "significant" change may be identified and applied globally. Specifically, we are interested in learning whether a quantifiable definition of such network changes would be preferable and, if so, what elements should be included in that definition, (e.g., percent of total enrollees affected, number/percent/type of physicians being terminated, hospitals included in termination, etc.).

Notifying CMS of Significant Terminations

We propose to institute a new procedural rule to facilitate CMS oversight of MAO compliance with access requirements when a significant change to a provider network is contemplated. We would require MAOs to notify their respective CMS Regional Office Account Managers (AM) no less than 90 days prior to the effective date of the planned termination(s). Such notification would allow MAOs to coordinate with their AM to ensure that affected providers and enrollees receive timely notification of such changes and allow CMS to ensure that the MAO will continue to meet required network standards if the planned network changes are implemented. Furthermore, engaging CMS early in the process would enable MAOs and CMS to work together to prevent, and address, potential enrollee/provider concerns.

CMS solicits comments on the manner and form by which the MAO would demonstrate that it will continue to meet applicable access requirements if the planned network changes are implemented. For example, CMS could require that such changes be supported through GeoNetwork reports, Quest reports, HSD tables, or other data sources that evidence the adequacy of the remaining provider network. We expect that MAOs would have validated that their

networks meet Medicare access standards prior to submitting network data to CMS. In addition to such evidence, we also propose that MAOs develop and submit to CMS, upon request, a written plan that provides a detailed description of the steps the MAO will take to ensure that affected enrollees are able to locate new providers that meet their individual needs. This plan would describe how continuity of care would be maintained for affected enrollees. The plan would be, in effect, a narrative description of how the network access and continuity of care requirements of §422.112 will continue to be met by the MAO as it transitions to providing care via a more limited provider network. We would also expect that MAOs be able to provide, upon request, information about the number and dispensation of continuity of care requests that they receive so that CMS may confirm that the MAO is in compliance with all applicable requirements.

It should be noted that, under our existing guidance, when CMS determines that an impending network change would not meet existing Medicare access standards, the MAO may be required to augment its network by contracting with additional providers or, if necessary in order to meet immediate access needs, to allow members to access care from non-contract providers and limit members cost sharing to in-network amounts. Furthermore, it may be necessary for MAOs to allow care to continue to be furnished on an interim, transitional basis, by providers who have been terminated from the network in order to adequately address continuity of care needs for affected enrollees. Finally, we wish to remind MAOs that, when they submit their plan benefit packages (PBPs) each year for CMS' review and approval, they attest that the benefits included in those packages "…will be offered in accordance with all applicable Medicare program authorizing statutes and regulations and program guidance that CMS has issued to date…" Thus, MAOs' PBPs for the upcoming contract year must meet, and continue to meet, Medicare network adequacy standards, as outlined in applicable regulations and guidance.

Notification to Enrollees Affected by Provider Contract Terminations

We believe that, as a "best practice," MAOs that are making significant network changes should provide enrollees more than the required 30 days' advance notice. Our experience has shown that a longer notification period is important, not only to address enrollee concerns, furnish enrollees with needed assistance in selecting new providers and manage the continuity of care for those undergoing medical treatment, but also for maintaining enrollee satisfaction. Furthermore, we believe that a longer notification period would afford enrollees additional time to transition to the new provider(s). We are considering whether to use the notice and comment rulemaking process to require more than 30 days' advance notice to enrollees, and welcome comments on the appropriate advance notice for enrollees affected by provider contract terminations.

We also believe that as a best practice, MAOs should include the following information in notices to enrollees in addition to the mandatory identification of the provider(s) being terminated from the network:

- Names and phone numbers of in-network providers that enrollees may access for continued care;
- Information regarding how enrollees can request continuation of ongoing medical treatment or therapies with their current providers; and
- Customer service number(s) where answers to questions about the network changes will be available.

MAOs should develop detailed scripts, call center talking points and frequently asked questions so they can effectively respond to phone inquiries from enrollee and other stakeholders.

In addition to the proposed procedural rule described above, we are considering whether to use the rulemaking process to broaden our authority to limit MAOs' ability to terminate provider contracts without cause at any time during the year. We are sympathetic to some concerns by stakeholders that MAO provider contract terminations that become effective during or shortly after the end of the AEP place beneficiaries in the position of making plan selections for the upcoming contract year based on inaccurate plan network information. When the enrollee learns that his or her provider is no longer in the network, s/he no longer has the ability to change plans, and is only permitted to disenroll back to Original Medicare. CMS has been asked by some stakeholders to prohibit MAOs from terminating provider contracts during the AEP or to require that notice of such terminations be provided prior to the start of the AEP so that enrollees have additional time to review their plans' network and consider other available plan options. We solicit comments on whether we should require, through rulemaking, that enrollees be notified prior to the start of the AEP of any provider contract terminations that have already been initiated by the organization and will be effective on or after January 1 of the following year. We also solicit comments on whether any changes accomplished through such rulemaking should be effective for the AEP for 2015, which begins on October 15, 2014.

While this proposed change would address some of the concerns raised by stakeholders, changes could still be made in an organization's provider network at other times during the contract year. In fact, during any given contract year, there will be changes to an organization's provider network due to a myriad of circumstances, some of which are outside the control of the MAO, and, as such, unknown to the organization in advance of the AEP. It appears that the only way that we could provide some type of guarantee of stability in the network would be to prohibit network changes after a certain point in the calendar year. We are concerned, of course, about the resulting impact on MAO's ability to establish cost-effective, high-performing networks under such limitations, and the resulting consequences for all MA enrollees. We welcome comments on these proposed changes and any other alternative approaches that would address the concerns outlined above.

We also are strengthening our current requirements regarding plans' responsibilities to notify enrollees of network changes in their Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) materials, which are provided to all enrollees each Fall. These modifications

will require MA plans to explicitly notify enrollees of their rights should a plan make changes to their provider network during the year. The required language is included below:

> It is important that you know that we may make changes to the hospitals, doctors and specialists (providers) that are part of your plan during the year. There are a number of reasons why your provider might leave your plan but if your doctor or specialist does leave your plan you have certain rights and protections summarized below:
>
> - Even though our network of providers may change during the year, Medicare requires that we furnish you with uninterrupted access to qualified doctors and specialists.
> - When possible we will provide you with at least 30 days' notice that your provider is leaving our plan so that you have time to select a new provider.
> - We will assist you in selecting a new qualified provider to continue managing your health care needs.
> - If you are undergoing medical treatment, you have the right to request, and we will work with you to ensure, that the medically necessary treatment you are receiving is not interrupted.
> - If you believe we have not furnished you with a qualified provider to replace your previous provider or that your care is not being appropriately managed you have the right to file an appeal of our decision.
> - If you find out your doctor or specialist is leaving your plan please contact us so we can assist you in finding a new provider and managing your care.

In addition, CMS will verify that plans included language regarding such changes in their ANOC and EOC if they make changes to their provider network during or shortly after the AEP.

Contracted Provider Notification and Right of Appeal

Consistent with our belief that longer notification periods would be beneficial for enrollees, we believe that affording providers more than 60 days' notice of a contract termination is appropriate, and in many cases, preferable. A longer period would give providers sufficient time to exercise their appeal rights and for the appeals process to conclude, perhaps before affected enrollees are notified of the change. Using current timeframes, there are instances in which the notice of a termination reaches the affected enrollees while the provider is appealing the termination. If the termination is later overturned and the provider is reinstated, the enrollee may be unaware of that reinstatement and may, at that point, have already chosen a new provider.

We believe the approach and expectations described above promote a more structured, efficient process that will minimize confusion and disruption for MAO operations, enrollee care, providers and CMS. We welcome comments on this proposed new guidance and our contemplated rulemaking.

Part C ANOC/EOC Review Timeframe

CMS would like to notify MAOs and Plan sponsors that they must complete retrospective reviews of ANOC/EOCs and submit errata sheets correcting identified errors by November 1st. This date will provide sufficient time to ensure members still have enough opportunity to review their choices during the Annual Enrollment Period (AEP) after receiving the corrected materials.

Part C Third-Party Marketing of Non-Health-Related Benefits

CMS has become aware of numerous instances in which health clinics are advertising non-health-related services to Medicare beneficiaries. Some of the services are being advertised by clinics that are contracted providers of MAOs. Such services cannot be paid for with Medicare dollars. Non-health related items may not be part of an MAO's bid.

In addition, MAOs may not advertise non-health related items or services as plan benefits, and are responsible for ensuring that their downstream entities also adhere to this prohibition. Advertisements for non-health related items or services by an MAO, or one of its contracted clinics, to MAO enrollees could be construed as, among other things, inappropriate steerage to particular clinics and, ultimately, into a specific MAO that contracts with that clinic. CMS regulations at 42 CFR §422.2268 specifically prohibit engaging in activities which could mislead or confuse Medicare beneficiaries and marketing non-health care related products to prospective MA enrollees. For more information please see our HPMS Memo, entitled, "Third Party Oversight of Non-Health Related Items" dated December 18, 2013.

Ongoing, Off-cycle Submission of Summaries of MOC Changes

CMS has emphasized the importance of the Model of Care (MOC) as a fundamental component of the SNP quality improvement framework. CMS continues to encourage SNPs to develop and submit comprehensive and thoughtful MOCs for initial NCQA approval. However, we also recognize that, in order to continue providing high quality improvement, the SNP may need to revise its approved MOC to address the particular needs of its beneficiaries. CMS intends to implement a process for SNPs that revise their MOC during an approval cycle to submit a summary of those changes to CMS.

The summary will focus on pertinent revisions to the approved MOC. CMS is contemplating the creation of a new component in the HPMS MA Quality Module where SNPs can submit, as applicable, these summaries at any time during an approved MOC cycle. We envision that NCQA will review the summaries to determine that the revisions are consistent with acceptable high-quality standards as indicated in the original MOC and the associated score/approval period. There will be no rescoring of the MOC based on the revisions; therefore, the existing approval period (i.e. 1-year or multi-year) would not change as a result of NCQA's review of the summary.

This process will ensure that CMS and NCQA are apprised of real time and up-to-date information regarding a SNP's MOC and strengthens CMS's ability to fulfill its obligation to adequately monitor the MOC and ensure that it continues to meet established standards.

Part C Change of Ownership Transactions Requiring Service Area Expansions

CMS requires that MAOs that are planning to undergo a change of ownership transaction notify CMS at least 60 days prior to the date of the planned change of ownership. In instances where such a transaction would require a CMS approved novation of the MAO's contracts, CMS will find under §422.552 that the novation is in the best interest of the Medicare program if the entity acquiring the novated contracts is an existing MA organization that has offered a MA plan that, at a minimum, has the same service area as the contracts that are being novated. Normally, organizations seeking a service area expansion (SAE) are required to submit a service area expansion application during CMS's yearly MA application cycle. Although, in special circumstances, CMS has allowed MAOs to file an "off-cycle" SAE application (i.e., at other times during the year, instead of during our annual application cycle) in order to align their organization's service area with the service area of a contract that they wish to acquire through a novation, we continue to encourage MAOs that require an SAE in order to match the service area of contracts they are receiving to request such an expansion during our annual SAE application cycle. CMS is reminding organizations that it is not inclined to approve off-cycle SAE requests unless special circumstances warrant such approval.

We want to remind organizations that CMS will not accept any new cost plan applications. CMS will continue to accept applications to modify cost plan contracts in order to expand service areas in accordance with 42 CFR §417.402.

Section III – Part D

Additional Guidance for All Enhanced Alternative (EA) Plans

Consistent with our bid submission requirements provided at 42 CFR §423.265, a Part D sponsor's bid submission must reflect differences in benefit packages or plan costs that we determine to represent substantial differences relative to a sponsor's other bid submissions. We also strive to ensure plan bids are non-discriminatory and without barriers to coverage that would compromise patient care and clinical outcomes.

Under the Affordable Care Act, beginning in 2011 all formulary drugs are subject to some level of reduced cost-sharing regardless of the Part D plan benefit type. Each year until the coverage gap is closed in 2020, there will be incremental reductions for applicable beneficiaries of 7 percentage points in the cost-sharing for non-applicable (i.e., generic) drugs under the defined standard coverage gap drug benefit. There are similar reductions of 2.5 percentage points every

1-2 years for applicable (i.e., brand) drugs. Therefore under the defined standard gap coverage benefit in 2015, cost-sharing for applicable beneficiaries for generic drugs will be lowered to 65% coinsurance and for brand drugs to 45% coinsurance (after applying the plan liability of 5% and the manufacturer discount of 50% for brand drugs).

For CY 2015 we expect that all EA plans will offer additional reduced cost-sharing on all formulary generic drugs. In addition, if an EA plan elects to provide additional reduced cost-sharing on brand drugs we would expect that it also offer this benefit for all formulary brand drugs. However, we are interested in any comments as to whether we should have different expectations for brand drugs. These parameters for additional cost-sharing reductions over the defined standard benefit apply to both enhanced alternative PDPs and MA-PDs. Given the extent of cost-sharing reduction in the gap that is now required of all Part D plans under the defined standard coverage gap benefit, we believe this policy is necessary to ensure meaningful benefits are offered by EA plans. This policy will also improve our ability to prevent discrimination resulting from bids that are designed to select for healthier beneficiaries by limiting cost-sharing reductions to the earlier phases of the benefit. In addition, extending cost-sharing reductions over the entire benefit will reduce barriers to obtaining medications, thus promoting continued adherence once a beneficiary enters the coverage gap and improved clinical outcomes.

This is a relatively minor change from our policy in past years for "high value" EA PDPs to offer reduced cost-sharing in the coverage gap to ensure meaningful differences. Although all EA plans have not been expected to provide this benefit in previous years, at least half of all MA-PD and PDP enhanced alternative (EA) plans have elected to offer additional cost-sharing reductions in the coverage gap at beneficiary cost-sharing levels that are well below that mandated under the defined standard gap coverage benefit. This policy will serve to further smooth out differences in coverage across the benefit phases for all EA plans and would not represent a significant increase in coverage for those EA plans that have already adopted a policy of additional cost-sharing reductions in the gap.

For CY 2015 the copay thresholds in the coverage gap will remain the same as the thresholds set for pre-ICL cost-sharing (see Table 1 for details). Consistent with previous years, we will also establish a generic coinsurance cost-sharing maximum of 45% and brand coinsurance cost-sharing maximum of 15% (for purposes of PBP data entry, the brand coinsurance maximum that may be entered would be 65% which reflects a plan liability of 35%, but excludes the 50% manufacturer discount).

These values were determined using the same methodology as in past years to ensure that additional cost-sharing reductions offered by EA plans will provide a benefit that is significantly better than the defined standard gap coverage cost-sharing. We have annually lowered the maximum coinsurance cost-sharing threshold for generic drugs to coincide with the incremental reductions in the defined standard gap cost-sharing for generic drugs. In addition, for the last

two years the established maximum beneficiary coinsurance cost-sharing value for generic drugs in the coverage gap was at least 20 percentage points less than the defined standard cost-sharing amount. Therefore, consistent with previous years for CY 2015 we will decrease the maximum gap coinsurance cost-sharing amount that may be entered in the PBP for generic drugs to 45%. Similarly, in accordance with the incremental change in the 2015 defined standard gap cost-sharing for brand drugs, the maximum gap coinsurance cost-sharing amount that may be entered in the PBP for brands drugs will decrease nominally to 65%.

Therefore, beginning in 2015 we expect all PDPs and MA-PDs to impose beneficiary cost sharing of no greater than 45% coinsurance in the coverage gap on all formulary generic drugs. In addition, we expect an EA plan offering additional cost-sharing reductions for brand drugs in the coverage gap, to provide this benefit for all brand drugs at no greater than 15% coinsurance (inclusive of the 50% manufacturer discount).

The new policy expectation that EA plans provide additional gap cost-sharing reductions for all formulary generics impacts plans whose formulary tiers include a mix of brand and generic drugs in the following way. When all drugs on a specific tier are offered with reduced cost-sharing in the coverage gap and that tier includes at least one generic drug, the coinsurance maximum for generic drugs will be applied to that tier. Therefore, the brand coverage gap coinsurance maximum would only apply when all drugs on the tier are brands. We will rely on the FDA marketing category to determine whether these thresholds have been met for formulary generic and brand drugs. For CY 2015 sponsors may wish to consider the new policy for reduced cost-sharing in the coverage gap when designing their formularies, especially if they intend to include mixed tiers.

The expectation for EA plans to uniformly offer additional reduced cost-sharing in the coverage gap for all formulary generic drugs at a maximum cost-sharing of 45% and when offered, for all brand drugs at a maximum cost-sharing of 15%, is considered an extension of our current policy. Expanding cost-sharing reductions beyond the early coverage phases will ensure substantial and meaningful EA plan benefit offerings that are easily recognizable to beneficiaries when comparing plans, reduce barriers to coverage, and protect against discrimination towards less healthy beneficiaries that reach the coverage gap. In addition, a cost-sharing maximum of 45% for generic drugs would standardize the level of cost-sharing paid by beneficiaries for both brand (under the defined standard benefit) and generic drugs.

Furthermore, because cost-sharing reductions are required under the ACA for applicable beneficiaries for all drugs, and additional reductions would be expected for all formulary generics (and possibly on all formulary brand drugs if the plan elects to offer a gap cost-sharing benefit for brand drugs), the use of labels to describe the proportion of formulary drugs with coverage in the gap is no longer particularly relevant. Therefore, beginning in 2015 these gap coverage labels will no longer be used in marketing materials or on Plan Finder.

Lastly, we note that in the past PDPs have been allowed to request CMS approval to change from a basic plan in the current contract year to an EA plan in the next contract year. However, we believe that because EA plans will provide additional cost-sharing reductions on all formulary generic drugs in the coverage gap, this conversion would no longer be available given the limited conditions under which we previously approved these conversions. Already in prior years, PDPs interested in this option have had difficulty demonstrating that they can meet the cost-sharing OOPC meaningful difference test or that the benefit type change would result in an EA plan with the same or lower Part D premium and the same or better benefits than the existing basic plan. Under the new policy for additional cost-sharing reductions in the gap by all EA plans, it will be increasingly more difficult or impossible to meet these conditions for converting a basic PDP to an enhanced PDP. Therefore, beginning with the CY 2015 submissions, we will no longer accept proposals to approve a change from a basic PDP to an enhanced PDP.

Access to Preferred Cost Sharing

The number of Part D and MA-PD plans offering preferred cost sharing for prescription drugs has increased significantly in the past few years, from just 163 in 2011 to 853 in 2014. In 2014, over 70% of standalone Part D plans offer preferred cost sharing. Under these arrangements, to access the preferred (lower) cost sharing, beneficiaries must obtain their prescriptions from a selected subset of pharmacies in the plan's network. As the number of plans offering preferred cost sharing has increased, various parties have drawn our attention toward concerns with these arrangements, particularly regarding beneficiaries' access to the advertised lower cost sharing in these plans. Some plans provide very limited access to preferred cost sharing; for instance, we became aware of one plan that offered preferred cost sharing at only seven pharmacies in a PDP region. We have also heard concerns about access to preferred cost sharing from beneficiaries, particularly in rural areas, and a number of pharmacy trade groups have complained that retail pharmacies have not been given the opportunity to accept the terms necessary to offer preferred cost sharing. We are concerned that offers of preferred cost sharing may be influencing beneficiaries to enroll in plans in which they do not have meaningful and/or convenient access to preferred cost sharing. This may have the effect of misleading or otherwise making material misrepresentations to beneficiaries in violation of our marketing requirements at 42 CFR §423.2264(d).

To address some of these concerns, our proposed rule published in the Federal Register on January 10, 2014 includes provisions that, if finalized, would require sponsors to include the necessary terms and conditions to offer preferred cost sharing, as well as for standard cost sharing, in their any willing pharmacy contracts. We have also proposed requiring that in return for their preferred cost sharing pharmacies not only offer lower cost sharing to beneficiaries, but also offer consistently lower negotiated prices to plans and the Part D program. We believe that these changes, if adopted, will promote the goal of ensuring that beneficiaries have meaningful access to preferred cost sharing.

In order to further analyze this issue, we have awarded a contract to study beneficiary access to preferred cost sharing. This study will analyze beneficiaries' geographic access (i.e., time and distance) to pharmacies offering preferred cost sharing in plans' networks. Based on the results of this study and the outcome of the 2015 proposed rule, we wil1 evaluate whether we should set standards for network adequacy for pharmacies offering preferred cost sharing, similar to current standards for retail network adequacy. Therefore, we are currently soliciting comments on beneficiary access to preferred cost sharing. We are particularly interested in comments regarding potential network adequacy standards and current access to preferred cost sharing, including comments on the effect network adequacy standards would have on costs to beneficiaries and the Part D program.

Although we are not adopting any network adequacy standards at this time, sponsors should be aware that we are continuing to monitor beneficiary access to preferred cost sharing in plans that purport to offer it. For the 2014 and 2015 plan years, we will continue to review the retail networks of plans offering preferred cost sharing and will take appropriate action regarding any plan whose network of pharmacies offering preferred cost sharing appears to offer too little meaningful access to the preferred cost sharing. For instance, a stand-alone PDP that offers preferred cost sharing at only seven pharmacies in a PDP region may be asked to increase the number of pharmacies offering preferred cost sharing or to restructure its benefit design during the bid negotiation process. The intent of these negotiations will be to ensure that beneficiaries are not misled into enrolling in a plan only to discover that they do not have meaningful access to the advertised lower cost sharing.

Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status

Consistent with 42 CFR §423.153(b), Part D sponsors must establish utilization management controls, such as prior authorizations (PA), in order to reduce costs when medically appropriate and to prevent over- and under-utilization of prescribed medications. We currently allow plans to implement Point-of-Sale (POS) PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication (as defined in section 1860D-2(e)(4) of the Act) or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1860D-2(e)(2) of the Act (e.g., symptomatic cold treatment). While POS PA edits must be reviewed and approved by CMS, we have previously left the determination of which drugs should be subjected to these POS edits to the individual plans.

Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual (available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf) discusses medically-accepted indications. Sponsors are reminded that they are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted

indications. Although they are not required to, Part D sponsors may rely on utilization management policies, including PAs, to make such determinations.

With almost 8 years of experience with the Part D program, CMS and Part D sponsors have (or should have) a good understanding of which drugs have the highest likelihood of non-Part D covered uses. Therefore, we believe that all Part D sponsors should consistently utilize PAs for such drugs, including drugs that are not likely to be covered under Part D in the sponsor's experience or as directed by CMS. While most plans appear to effectively utilize these edits to prevent Part D coverage of non-Part D drugs, other plans have failed to implement edits for such drugs or to take other measures such as retrospective review to ensure Part D coverage before submission of related PDEs. Consequently, we have seen instances where the lack of a POS PA edit or other check has resulted in inappropriate Part D coverage of non-Part D drugs.

For example, the labeled indications and compendia citations for Transmucosal Immediate Release Fentanyl (TIRF) drugs only support their use for the management of breakthrough pain in patients with cancer, who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent pain. Additionally, the risks associated with TIRF medications are so severe that the FDA required a Risk Evaluation and Mitigation Strategy (REMS) program designed to ensure informed risk-benefit decisions before initiating treatment with these drugs and during treatment to ensure appropriate use of TIRF medicines. The purpose of the TIRF REMS access program is to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications, including death, due to medication errors with the use of TIRF medicines. As a result, we were surprised to find in an internal analysis that although most Part D plans have implemented POS PA edits for TIRF medicines, not all have done so.

Similarly, Cialis (tadalafil) has an FDA-approved indication at 5mg per day (2.5 mg per day for patients with renal insufficiency) for benign prostatic hypertrophy (BPH), which would constitute an approved Part D use. However, these same daily doses are also approved to treat erectile dysfunction (ED), which is not an approved Part D use, pursuant to section 1860D-2(e)(2)(A) of the Act. Again, we find most, but not all, Part D plans have instituted PA to ensure appropriate Part D use.

As a result, we are establishing in this draft Call Letter criteria for which CMS would expect plan sponsors to implement POS edits for PA on qualifying drugs and/or drug classes that pose the greatest risk for non-Part D covered uses according to the following criteria:

- High likelihood that coverage is available under Parts A or B (versus D) for the drug as prescribed and dispensed or administered,
- High likelihood that the drug is excluded from Part D coverage (e.g., a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act), or

- High likelihood of use for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act.

We intend to conduct outlier checks during our annual formulary review process and will share information with sponsors, so that sponsors may determine if they wish to submit a PA for approval or continue ensuring Part D coverage through other means, such as retrospective review.

There has also been confusion from plan sponsors about how such edits are appropriately used during transition periods. Section 30.4.8 of Chapter 6 of the Prescription Drug Benefit Manual (available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf) discusses edits for transition fills.

The requirements to verify payment for Part D uses, maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and establish quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use apply regardless of the transitional status of an enrollee's medication(s). In other words, such POS PA edits are appropriate, even during transition.

In particular, some sponsors have interpreted the section 30.4.8 language, "Drug utilization management edits that are appropriate during a beneficiary's transition period include … edits to prevent coverage of non-Part D drugs (i.e., excluded drugs)" to mean that excluded drugs[8] is the only condition for which they should implement POS PA during transition pursuant to this criterion. This is incorrect. Drug utilization management edits to prevent coverage of non-Part D drugs include those which prevent coverage of a formulary drug that is being dispensed for an indication that is not medically accepted. Because our clarified guidance of this criterion is focused on those drugs that pose the greatest risk for non-Part D-covered indications, CMS would not expect to see excessive use of POS PA edits during transition for drugs as a result of this clarified guidance.

With respect to EGWPs and this section of the Call Letter, we recognize that EGWPs may not want to implement prior authorization edits to determine whether a drug is a Part D covered drug, if they cover non-Part D covered drugs under supplemental non-Medicare benefits. However, in this situation, we remind sponsors that they are responsible for determining whether a drug is a Part D covered drug before submitting a PDE to CMS. In addition, we note that brand drugs that are not Part D covered drugs are not eligible for the 50% manufacturer discount, and EGWPs must have a mechanism to ensure the discount is not applied once the determination has been made that a brand drug is not a covered Part D drug.

[8] A drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act.

Enhancements and Clarifications on Improving Utilization Review Controls

The proposed revisions described in this section will strengthen our overutilization policy, which took effect on January 1, 2013. This policy set forth our expectations that Part D sponsors use improved retrospective drug utilization review programming and case management to prevent dangerous overutilization of medications by Medicare Part D beneficiaries. On July 31, 2013, CMS implemented the Overutilization Monitoring System (OMS) to monitor sponsors' implementation of this policy. Analyses of OMS findings indicate that additional attention is necessary to address the overutilization of acetaminophen (APAP) and opioids among Medicare Part D beneficiaries.

Background

In the section entitled, "Improving Drug Utilization Review Controls in Part D" of the Final CY 2013 Call Letter issued on April 2, 2012 and in supplemental guidance issued on September 6, 2012, CMS described how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of opioids. In addition, sponsors were reminded to prevent the dispensing of acetaminophen (APAP) above the U.S. Food and Drug Administration (FDA) daily maximum dose of 4 grams to any beneficiary. In general, the guidance addressed the following expectations for sponsors to address overutilization of opioids effective January 1, 2013:

• Appropriate controls at point of sale (POS), including safety edits and quantity limits.
• Improved retrospective drug utilization review (DUR) to identify at-risk beneficiaries.
• Case management with the beneficiaries' prescribers.
• Data-sharing between Part D sponsors regarding beneficiary overutilization.

Under the guidance, sponsors may implement beneficiary-specific POS edits as appropriate after case management to control access to medications containing opioids. Sponsors are expected to send 30-day advance written notice of the planned POS edit to the beneficiary, the beneficiary's prescribers who request the results of case management, and to the CMS account manager and the central office mailbox PartDPolicy@cms.hhs.gov in a secure manner. We remind sponsors that for the purposes of sending the written notice to CMS, we consider an email that contains personally identifiable information (PII) secure only if it is encrypted and password protected.

That guidance also stated that CMS would develop monitoring protocols to ensure sponsors were implementing effective but appropriate controls to prevent opioid overutilization. Sponsors that fail to establish appropriate controls to prevent drug overutilization may be subject to a compliance action. Subsequently, on July 31, 2013, CMS implemented the Overutilization Monitoring System (OMS) to operationalize our monitoring protocols and ensure that sponsors have established reasonable and appropriate drug utilization management programs to prevent the overutilization of prescribed medications as described above (see HPMS memo, Medicare Part D Overutilization Monitoring System, released on July 5, 2013). Additional information

about the OMS and the CMS overutilization policy are available on the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

Acetaminophen (APAP)

The use of more than 4 grams of APAP daily is contraindicated by the FDA due to the potential for severe liver injury and death. We remind sponsors that they are expected to implement sufficient controls to prevent the cumulative dispensing to any beneficiary of more than 4 grams of APAP per day across all products containing APAP. Analysis of 2011 Part D prescription drug event (PDE) data indicated that nearly 650,000 beneficiaries may have exceeded the maximum APAP dose for at least 5 consecutive days, and 221,000 beneficiaries received more than 4 grams per day for at least 10 consecutive days. From January through December 2013, the OMS identified 56,414 potential APAP overutilizers (0.15% of Part D enrollees) who received more than 4 grams per day for at least 30 days within a six-month period.

Although the use of improved DUR edits in 2013 may have reduced overutilization of APAP, CMS believes that Part D sponsors should implement hard formulary safety edits at POS for all their enrollees to further reduce the number of APAP overutilizers. Sponsors' P&T committees should develop the specifications for the POS edits to prevent cumulative APAP overutilization based upon their own enrollee data, while minimizing false positives by accounting for known exceptions, such as reasonable early refills. Of course, a beneficiary may request a coverage determination to dispute the hard POS edit.

While we are concerned about the risk of APAP overdose in beneficiaries, we recognize that there are circumstances that justify dispensing a prescription that would otherwise appear to be inappropriate based solely on claims data. However, we remind sponsors that a pattern of overutilization related to repetitive early refills or other reasons may be an indication of actual overutilization, stockpiling, or diversion, which should prompt additional investigation by the sponsor and verification of the ongoing medical necessity with the prescribers. For example, a beneficiary who receives an original prescription plus five refills of a 30-day supply of medication and refills the prescription each time after 75% of the days' supply has expired from the date of dispensing will actually receive 180 days' supply within 111 days. In this example, if each fill is for 100 tablets, the cumulative excess supply is potentially 133 tablets.

While sponsors may determine how to define the allowance for early refills, sponsors should identify, address, and resolve potential overutilization issues, including developing criteria for evaluating if a beneficiary's pattern of early refills warrants additional review. In addition, in the event that hard formulary safety edits at POS for all enrollees fail to address all cases of potential APAP overutilization, we remind sponsors that they may apply case management principles and implement a beneficiary-specific POS edit to address overutilization of APAP, as they may for

any other medication. However, as with any formulary safety edit based on FDA dosage limits, it is not necessary to provide advance written notice to the beneficiary or to CMS.

CMS expects the use of hard POS edits will reduce the overutilization of APAP. OMS will continue to be used to monitor sponsors' efforts to prevent overutilization of APAP and opioids based on criteria described in the Overutilization Monitoring System User Guide, which is available to all plan sponsors through the Patient Safety Analysis Website.

Finally, we remind Part D sponsors of FDA's additional APAP safety initiatives (http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm165107.htm). The FDA asked manufacturers of approved prescription drug products containing more than 325 mg of APAP to request the withdrawal of approval of the product's application by January 14, 2014. According to their Federal Register Notice (http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0021-0001), FDA intends to utilize their authority to initiate withdrawal proceedings for the combination products that contain greater than 325 mg that remain on the market after January 14, 2014. The FDA also has recommended that health care professionals discontinue prescribing and dispensing combination drug products containing more than 325 mg of APAP. As a result of these safety initiatives, CMS will be removing all combination prescription drug products that contain more than 325 mg of APAP from the CY 2015 Formulary Reference File.

Opioids

In the supplemental guidance issued in September 2012 (HPMS memo, September 7, 2012, Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html), CMS described a drug utilization review methodology based on morphine equivalent dose (MED) to identify beneficiaries who are at high risk for an adverse drug event due to their use of opioids and for whom focused case management may be appropriate. Analysis of 2011 Part D PDE with this methodology identified 22,222 Part D beneficiaries (0.07% of Part D enrollees) at high risk for an opioid-related adverse drug event. CMS also indicated that each sponsor's targeting criteria should be set by its P&T committee to identify patterns of apparent duplicative therapy over sustained periods of time from multiple prescribers and at high daily doses using MED methodology. Based on CMS' opioid overutilization methodology (which identifies beneficiaries whose daily MED is greater than 120 mg for at least 90 consecutive days, and who used more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims), in January 2014, the OMS identified 27,275 beneficiaries (0.07% of Part D enrollees) who exceeded the opioid threshold between January 1, 2013 and December 31, 2013. While direct comparison of these data do not show a positive trend, the 2013 methodology would be expected to identify a larger number of potential opioid overutilizers than the 2011 methodology, primarily due to the significantly expanded list of opioids and the count of beneficiaries' prescribers and pharmacies for their opioid fills through

the entire year in the 2013 methodology. Neither the 2013 nor the 2011 reported data were adjusted to account for changes in methodology.

CMS is concerned by responses received from some sponsors in OMS that a beneficiary's opioid use does not meet the sponsor's internal criteria for review, when that beneficiary's opioid utilization is clearly in excess of the methodology CMS described. For the October 2013 OMS reports, 60% of the potential opioid overutilization responses were BSC - No further review planned; Beneficiary did not meet the sponsor's internal criteria. It appears that some sponsors' criteria or processes to identify and address potential opioid overutilization may be insufficient. Therefore, in light of the potential safety issues for such beneficiaries, we clarify that the CMS methodology should be the minimum threshold used by sponsors. Accordingly, beginning no later than January 1, 2015, each sponsor's targeting threshold for retrospective identification of opioid overutilization and subsequent case management should be no less restrictive than 120 mg MED daily dose over at least 90 consecutive days as used by CMS. Sponsors may use lower MED and/or consecutive day thresholds to be more inclusive, and may vary other criteria including the number of prescribers and pharmacies.

Recent studies referenced in educational materials from the Centers for Disease Control and Prevention indicate that morphine equivalent doses as low as 100mg per day are associated with a significant increased risk for opioid overdose and death (see http://www.cdc.gov/primarycare/materials/opoidabuse/ and http://www.cdc.gov/primarycare/materials/opoidabuse/docs/managingpain-508.pdf). In light of this information from CDC, CMS will consider adopting 100mg MED in our threshold as early as contract year 2016.

Revisions to Outlier Methodology and Policy

In January 2014, the OMS was enhanced to collect potential opioid overutilization issues that were identified through Part D sponsors' own internal criteria but not previously identified by CMS. Effective January 1, 2015, sponsors should submit these internally-identified potential overutilization issues to the OMS quarterly along with the status of each beneficiary case. CMS will continue to report beneficiaries with potential overutilization issues identified through analyses of PDE and beneficiaries referred by the CMS Center for Program Integrity (CPI) due to possible utilization issues to sponsors on a quarterly basis. Sponsors are reminded that they should respond to CMS within 30 days on the status of each beneficiary case.

Improved Drug Utilization Controls for Other Drug Classes

Sponsors are reminded that if they choose to implement improved drug utilization controls and case management for medications that do not contain opioids, the sponsor should apply the same level of diligence and internal documentation with respect to those medications that we expect for medications containing opioids. At this time, our guidance applies only to opioids, and thus it should not be characterized as applying to overutilization of other medications.

Medication Therapy Management

In this section, we describe changes to Medication Therapy Management (MTM) programs to increase the number of beneficiaries eligible for MTM services, improve the standardized format for summaries of comprehensive medication reviews (CMRs), and ensure compliance with regulations and guidance. These changes are also aimed at increasing standardization among MTM programs, improving the integrity of data for the Part D Star Rating for MTM, and using MTM services to reduce the overutilization of opioids.

MTM Program Requirements

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. Pursuant to § 423.153(d)(2)(B), 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 2014 MTM program annual cost threshold was $3,017.

In addition, we have recently published a notice of proposed rulemaking in the Federal Register [Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (CMS-4159-P)] that includes several proposed revisions to Part D MTM requirements, with a proposed effective date of January 1, 2015. Revisions include proposed changes to the MTM eligibility criteria to target more beneficiaries (including lowering the MTM program annual cost threshold) and requirements for sponsors to have an outreach strategy designed to effectively engage at-risk beneficiaries enrolled in the plan. Sponsors should review the proposed rule and submit comments according to the instructions in the Federal Register; comments on the proposed rule should not be submitted in response to this draft Call Letter.

In addition, Part D sponsors are required to provide an individualized, written summary in CMS' standardized format to beneficiaries after a CMR as part of the MTM program. Pursuant to the Paperwork Reduction Act (PRA), we have proposed minor changes for 2015 to the text of the standardized format based upon feedback from beneficiaries and stakeholders about their experience with the standardized format since implementation (https://federalregister.gov/a/2014-00916). Sponsors have the opportunity to submit comments through that process, and final changes will be effective January 1, 2015.

MTM Monitoring

Last year, CMS sponsored an MTM monitoring effort to assess Part D sponsors' ability to implement their CMS-approved MTM programs in accordance with §423.153(d) and related CMS guidance. Beneficiary-level and parent organization (PO)-level data for contract years

(CY) 2011 and 2013 were reviewed for a total of 25 sponsors across four domains: Enrollment and Targeting, CMR, Targeted Medication Reviews (TMR), and Additional MTM Services. It should be noted that the CY 2013 data reviewed precedes any data validation efforts as part of the Part D Reporting Requirements.

The main findings from this study can be summarized as follows:

- MTM Enrollment and Targeting: In CY 2011 and CY 2013, the majority of sponsors we monitored were able to provide a valid MTM opt-out reason and MTM opt-out documentation that supported beneficiaries' MTM opt-out reasons and dates.
- CMR Offers: In CY 2011 all eligible beneficiaries in the sample were offered a CMR; in CY 2013, 91 percent of all eligible beneficiaries sampled were offered a CMR. However, in CY 2013, 26 percent of all CMR offers were untimely.
- CMR Written Summaries: Three out of 21 sponsors in CY 2011 and six out of 25 sponsors in CY 2013 did not provide a written summary to all beneficiaries who received a CMR consultation. Moreover, of the 19 sponsors in CY 2013 that did provide CMR written summaries, seven did not use the approved standardized format or did not provide timely CMR written summaries. Less than half of the sampled CY 2013 sponsors were in full compliance with the CMR written summary regulations and guidance.
- TMRs: Nine out of 21 sponsors did not perform quarterly TMRs in CY 2011 with at least one of their MTM enrollees. The most common reason provided by plan sponsors for not performing quarterly TMRs was a change in the TMR computer system or IT code that prevented the plans from conducting or recording TMR performance.

We remind sponsors that they must auto-enroll the targeted beneficiaries when they meet the eligibility criteria, and upon enrollment in the MTM program, begin performing TMRs at least quarterly with follow-up interventions as necessary, begin providing prescriber interventions, and offer the annual CMR in a timely manner per the guidance. Sponsors should not wait for the beneficiary to accept the offer for the CMR before performing TMRs or providing interventions to the beneficiary's prescriber. A CMR must comply with the requirements established by §423.153(d) and cannot be counted as a CMR unless a summary in CMS' standardized format is delivered to the beneficiary following the consultation. The standardized format for the CMR summary is a requirement, and not an option, and should be delivered to the beneficiary within 14 calendar days of the CMR. As a result of the findings of the MTM Monitoring project described above, sponsors identified as non-compliant with MTM program requirements may be subject to compliance actions. In addition, CMS is exploring the development of new audit performance elements for MTM programs, which may be piloted in 2014 and fully implemented in 2015. Findings from the audits may also impact sponsors' Part D Star Ratings for MTM.

Sponsors must operate their MTM programs in compliance with §423.153(d) and related CMS guidance. 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 2015 will be released after finalization of the 2015 Call Letter and Final Rule.

Standards

We continue to encourage industry to develop and use standards for Health Information Technology (HIT) for MTM service documentation. We also encourage the industry to reach consensus on more robust definitions for MTM, CMRs, and drug therapy recommendations and resolutions for service delivery and performance measurement. Otherwise, CMS will work with the industry to convene Technical Expert Panels to develop additional standards and definitions which will be proposed in future rulemaking for adoption by all Part D sponsors.

MTM Administrative Costs in Bids

CMS considers MTM program services provided to targeted beneficiaries as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit. An MTM program is based on the contract year. The plan's bid should take into account MTM costs for the applicable contract year, as MTM programs can change from year to year.

However, the CMS eligibility targeting requirements are established as the minimum threshold. Therefore, we believe that as part of their broader efforts with respect to drug utilization management and quality assurance, sponsors may also elect to offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under section 423.153(d). Sponsors may incorporate these additional costs of providing MTM services to an expanded population in the administrative costs in their bids.

Management of Opioids

Overutilization of opioids is a significant concern, especially in the treatment of patients with noncancer chronic pain, as discussed in the Enhancements and Clarifications on Improving Utilization Review Controls section of this draft Call Letter. Noncancer chronic pain is currently not one of the core chronic diseases per the guidance for targeting beneficiaries for the MTM program (HPMS memo, April 5, 2013, CY 2014 Medication Therapy Management Program Guidance and Submission Instructions, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html). Therefore we encourage (but do not require) sponsors to also offer MTM services to beneficiaries who meet the sponsors' internal criteria for retrospective identification of opioid overutilization, but do not otherwise qualify for MTM. These beneficiaries may benefit from MTM services including the CMR, targeted medication reviews, and interventions with their prescribers. Offering MTM to this population could complement the current drug utilization management requirements to reduce overutilization of opioids, assist in coordination of care, and improve pain management.

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. Since no changes have occurred in how we establish these parameters for CY 2015, or in the applicable regulations, the benefit parameters for CY 2015 are set forth in Table 1 below. We note that beginning in 2015, we will no longer use the terms "preferred" and "non-preferred" to describe network pharmacies, but rather will describe such pharmacies as offering standard or preferred cost-sharing.

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 their retail network.

The methodology for developing the CY 2015 out-of-pocket costs (OOPC) model is consistent with last year's methodology except for inclusion of free first fill benefits in the OOPC calculations. Customary updates for utilization data as well as PBP and formulary data used for CY 2015 bid submissions are also included in the 2015 model. Using this model, the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $20. The minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $25. For CY 2015, there will also be additional cost-sharing reductions in the coverage gap that will apply to all EA plans, not just high value EA PDPs as in previous years. This is discussed in more detail in a separate section.

We note that tier labeling and hierarchy requirements remain unchanged and are included in the Plan Benefit Package (PBP) tool, and that the review of specific tier cost sharing is in addition to the review for actuarial equivalence to the defined standard benefit across all tiers. As in all previous years, sponsors may continue to include a mix of both plan defined brand and generic drugs on each tier; however, for purposes of determining whether coverage gap cost-sharing

thresholds specified in Table 1 have been met we will rely on the FDA marketing status to identify formulary drugs as brand or generic.

Our regulation at 42 CFR §423.578(a)(7) allows Part D sponsors to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. This tier is referred to as the "specialty tier". Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit or to an equivalent total amount for sponsors with decreased or no deductible under alternative prescription drug coverage designs. (Example: a $310 deductible and 25% cost-sharing of an initial coverage limit of $2850 is essentially the equivalent of $945 in out-of-pocket expenses, whereas no deductible and 33% cost-sharing of the same initial coverage limit is essentially the equivalent of $940.50 in out-of-pocket expenses.)

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. These are referred to as specialty tier-eligible drugs. 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.

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 when the final Call Letter is released.

Table 1: Benefit Parameters

	CY 2015 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$20
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$25
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S[2,3]
Preferred Generic/Generic Tier	$10
Non-Preferred Generic Tier	$33
Preferred Brand/Brand Tier	$45
Non-Preferred Brand Tier	$95
Injectable Tier	$95
Select Care/Diabetic Tiers[4]	$10
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S[2,3]
Preferred Generic/Generic Tier	25%

	CY 2015 Threshold Values
Non-Preferred 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 (all tier designs)	S[3]
Generic Drugs (regardless of tier)	45%
Brand Drugs on fully covered tiers that include generics	45%
Tiers that only include Brand Drugs	65%
Minimum Specialty Tier Eligibility	
1 month supply at in-network retail pharmacy	$600

[1]These thresholds are based on the 95th percentile of the October CY 2014 Bid Data run through the CY 2014 OOPC MPF model which incorporates CY 2014 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 minimum Enhanced Alternative Plan vs. Enhanced Alternative Plan threshold.

[2] These thresholds are based on the 95th percentile of the CY 2014 Bid Data. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary and for meaningful benefit offering tiers that have low or $0 cost-sharing (i.e., special needs plans targeting one or more specific conditions). We continue to expect cost sharing for the Vaccine tier to be $0.

[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.

Employer Group Waiver Plan (EGWP) Policy Reminders

Beginning January 1, 2014, CMS implemented a change to the definition of the Part D supplemental benefits in 42 CFR §423.100 that specifically excludes all supplemental benefits offered through EGWPs. Therefore, as of January 1, 2014 the Part D component of EGWP prescription drug plans has been limited to the defined standard benefit. Any additional benefits have been treated as Other Health Insurance (OHI). We also remind Part D sponsors that since the beginning of the Part D program EGWPs have <u>not</u> been permitted to increase the deductible or catastrophic limit of their Part D benefits. [See section 20.9 of Chapter 12 of the *Medicare Prescription Drug Benefit Manual*, states that "to assure that the actuarial equivalence of the standard Part D benefit design is maintained, CMS requires all PDP sponsors offering EGWPs to

ensure that the total employer/union sponsored plan (including adjusting for any supplemental coverage) provides at least the standard Part D coverage, including a deductible no higher than that of defined standard Part D, and catastrophic coverage after the true-out-of-pocket limit is met."] Therefore, for 2015 EGWP sponsors may not offer any benefit plans (the combination of the defined standard Part D benefit and any additional retiree OHI) to Part D beneficiaries that have a deductible higher than $320 or an out-of-pocket threshold for catastrophic coverage higher than $4,700.

We would also like to remind sponsors about the expectations regarding formulary changes to base-level EGWP formularies. While CMS waives the requirement to submit a unique formulary for each individual employer/union sponsored group health plan, sponsors are required to submit at least one base-level formulary to represent these plans. The base-level formulary should represent the most restrictive formulary in terms of the drug content and utilization management criteria that will be used by the associated EGWPs.

EGWPs may only make enhancements to their approved formularies that increase the value for any beneficiary who uses the drug(s). This means that the only enhancements allowed without our approval are adding Part D eligible drugs to the formulary, moving Part D formulary drugs to lower cost-sharing tiers, and removing utilization management edits. For CY 2015 we thus remind sponsors that the base-level formulary submitted for EGWPs must meet the minimum drug coverage requirements applicable to all Part D plans and must be marketed and administered using the tier design approved by CMS. These base-level formularies must also follow the same rules for formulary enhancements applicable to all Part D plans. Furthermore, the enhancements offered may not be based on an average or actuarially equivalent increase in value for some EGWP members or as compared to commercial offerings. In other words, the EGWP formulary enhancements must incontrovertibly enrich the Part D benefit for any beneficiary who uses the drugs affected by the formulary change. Such enhancements are limited to increases in the overall number of formulary drugs, reductions in cost-sharing as a result of tier changes, and elimination of utilization management edits. Any other formulary change would be considered a negative change and therefore subject to the negative change request and approval process applicable to all Part D plans. In addition, we clarify that the tier structure, including the total number of tiers, of any approved formulary is not an attribute that may be modified. Therefore, sponsors are required to submit a sufficient number of base-level formularies to accommodate differences in tiering structures as well as content and utilization management criteria, offered by the EGWPs.

Finally, we point sponsors' attention to the Section, "Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status**"** for specific information about this policy clarification and EGWPs. To summarize here: An employer that offers a plan that includes drugs that are not covered under Part D as described in that section are not able to submit PDEs to CMS for such drugs. In addition, brand drugs that are not covered under Part D are not eligible for the 50% manufacturer discount.

Antipsychotic Drug Use Data

A recent study published in Psychiatric Services analyzing 2009 claims data from private insurance claims found that 58 percent of individuals prescribed psychotropic medication in 2009 had no psychiatric diagnosis during the year (*Psychiatric Services 2013*; doi:11.1176/appi.ps.201200557). Additionally, on September 20, 2013, the American Psychiatric Association released a "list of specific uses of antipsychotic medications that are common, but potentially unnecessary and sometimes harmful", including a recommendation not to prescribe these drugs "as a first-line intervention to treat behavioral and psychological symptoms of dementia" (http://www.psychiatry.org/choosingwisely).

CMS is particularly concerned with unnecessary use of antipsychotic drugs in nursing homes and, as a result, continues to pursue strategies to increase awareness of antipsychotic use in long term care (LTC). We began in 2013 to calculate a general atypical antipsychotic utilization rate for the 2013 Part D Display Measures using 2011 data. Contract-level rates were also calculated using 2012 data and included in the 2014 Part D Display Measures now available on the CMS Web site at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

The measure is the percent of Medicare Part D beneficiaries 65 years and older who are continuously enrolled in a nursing home and who received atypical antipsychotic (AA) medication fills during the period measured. The numerator for the measure is the number of Part D beneficiaries in the denominator who received at least a 90-day supply of AA medication(s) during the nursing home stay in the measurement period. The denominator includes beneficiaries who:

- Beginning in January, had institutional status for payment purposes as identified via the Monthly Long Term Institutional (LTI) flag for all months of the measurement period or until death;
- Were alive for at least 90 days at the beginning of the measurement period;
- Were enrolled in Part D for all months of the measurement period; and
- Whose first reason for Medicare enrollment was aging-in.

Table 1: 2011 and 2012 Rates of Atypical Antipsychotic Drugs by Organization Type

Organization Type	**Atypical Antipsychotic Drug Rate**	
	2011	**2012**
MA-PD	21.3	21.1
PDP	24.3	24.2
Low Income Newly Eligible Transition (LINET) Contractor	24.5	22.6
Total	23.8	23.8

Although we expected to see a general decline in the rate as a result of MTM services and other increased efforts to curtail AA drug use in LTC, as Table 1 shows, the average rate remained relatively constant. As a result, CMS is working with LTC and mental health stakeholders to

further raise awareness of the lack of improvement in the rate. Because our goal is not only to educate, but also to initiate a dialogue with stakeholders, we solicit comments on what interventions plans and providers can implement to lower AA utilization.

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 2015 COB user fee will be collected at a monthly rate of $0.136 for the first 9 months of the coverage year (for an annual rate of $0.102 per enrollee per month) for a total user fee of $1.22 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2015 bids.

In contract year 2015, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The new Benefit Coordination and Recover Center (BCRC) operation and maintenance; the BCRC combines most of the operations of the Coordination of Benefits Contract (COBC) and the Medicare Secondary Payer Recovery Contract (MSPRC);
- 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;
- Enhancements to the collection of other health insurance data to improve the efficiency of enrollees' benefits paid in the proper order; and
- Review of Workers' Compensation settlement set-aside funds, which ensure that medical services are paid for by the appropriate party.

Extended Days' Supply Indicator

Drugs that are offered at an extended day supply must be provided with a symbol and the days' supply amount in the Part D plan sponsor's marketing formulary documents. It is our expectation that a symbol will be added for drugs that are available at an extended day supply when all of the drugs on the formulary are not offered at an extended day supply. For CY 2016, CMS is exploring the possibility of requiring an additional supplemental file to identify the drugs which are offered at an extended day supply.

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 2014, 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 ensure that all Part D plans offered in the marketplace are attractive to beneficiaries and do not add to their confusion in selecting a plan best suited to their prescription drug coverage needs.

Renewal of LI NET Demonstration

The Medicare Part D Demonstration for Retroactive and Point of Sale Coverage for Certain Low-Income Beneficiaries (Medicare's LI NET Demonstration) is a demonstration designed to eliminate gaps in coverage for low income beneficiaries by providing temporary Part D drug coverage. The current demonstration ends December 31, 2014. In order to ensure availability of the benefits provided by Medicare's LI NET Demonstration, CMS is working toward renewing the demonstration for a period of five years (January 1, 2015 through December 31, 2019).

Appendix 1 – Contract Year 2015 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 3, 2014) pursuant to 42 CFR §423.507(a)(2)(i). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal 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 2015 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 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 combine 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 one or more entire PBPs must designate which of the renewal PBP IDs will be retained following the consolidation; the organization's designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary's election by moving him or her into the designated renewal plan ID. 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.

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 identification 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 2, 2014. CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan. 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 combine 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 consolidated 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. Plan sponsors should use the CMS model for this special notice.

Appendix 2 – Contract Year 2015 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 2015 that is not linked to a 2014 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 2014 PBP in CY 2015. The same PBP ID number must be retained in order for all current enrollees to remain in the same PBP in CY 2015.	HPMS Plan Crosswalk Definition: A 2015 plan that links to a 2014 plan and retains all of its plan service area from 2014. The 2015 plan must retain the same plan ID as the 2014 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 PBP sponsor does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2015. 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 2014 into a single renewal PBP for CY 2015. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2015 after consolidation.	HPMS Plan Crosswalk Definition: Two or more 2014 plans that consolidate into one 2015 plan. The 2015 plan ID must be the same as one of the consolidating 2014 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 2015.	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 2014 prescription drug PBP in CY 2015 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 2015.	HPMS Plan Crosswalk Definition: A 2015 800-series plan that links to a 2014 800-series plan and retains all of its plan service area from 2014, but also adds one or more new regions. The 2015 plan must retain the same plan ID as the 2014 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 2015. 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 2014 PBP.	HPMS Plan Crosswalk Definition: A 2014 plan that is no longer offered in 2015. 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 combines 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 2015 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 consolidation of one 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 2015. New enrollees must complete enrollment request.	Current enrollees are sent a special notice along with a standard ANOC.