February 19, 2016

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

**SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 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 2017. Also included with this notice are proposed changes in the payment methodology for CY 2017 for Part D benefits and annual adjustments for CY 2017 to the Medicare Part D benefit parameters for the defined standard benefit. For 2017, CMS will announce the MA capitation rates and final payment policies on Monday, April 4, 2016, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Attachment I shows the preliminary estimates of the national per capita MA growth percentage and the national Medicare fee-for-service growth percentage, which are key factors in determining the MA capitation rates. Attachment II sets forth changes in the Part C payment methodology for CY 2017. Attachment III sets forth the changes in payment methodology for CY 2017 for Part D benefits. Attachment IV presents the annual adjustments for CY 2017 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 2017 Call Letter for MA organizations; section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including both employer/union-only group health plans and direct contract plans. The CY 2017 Call Letter contains proposals relating to the quality rating system and information these plan sponsor organizations will find useful as they prepare their bids for the new contract year.

Finally, CMS would like to note that Title II, § 201 of the Consolidated Appropriations Act of 2016, provides a one-year moratorium for 2017 of the Annual Fee on Health Insurance Providers that was originally established in Sec. 9010 of the Affordable Care Act. In keeping with current policy regarding the treatment of this fee in MA and Part D bids, we expect that MA Organizations and Part D Plan Sponsors will reflect the impact of this moratorium in their 2017 bid submissions. Wherever possible, we would expect MA Organizations to reflect these lower costs through lower bids, higher rebates and more supplemental benefits for Medicare Advantage enrollees.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2017@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 4, 2016 release of the final Announcement of Calendar Year 2017 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 4, 2016.

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Attachments

**2017 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 2017

The Affordable Care Act, by amendments to section 1853 of the Social Security Act, establishes a new methodology for calculating each MA county rate as a percentage of Fee for Service (FFS) spending in each respective county. The Affordable Care Act provides for a transitional period during which each county rate is calculated as a blend of the pre-Affordable Care Act rate set under section 1853(k)(1) of the Social Security Act (the "applicable amount") and the new FFS-based Affordable Care Act rate set under section 1853(n)(2) of the Social Security Act (the "specified amount"). For 2017, all counties will be fully transitioned to the new rate methodology. Section 1853(n)(4) of the Social Security Act requires that the benchmark (which is increased by quality bonus payment percentages where applicable) be capped at the level of the 1853(k)(1) applicable amount.

For 2017, the MA county rates are now based on the specified amount (100 percent of the 2017 FFS rate, estimated as described herein). As required under section 1853(n)(4) of the Act, the benchmark is capped at the level of the 1853(k)(1) applicable amount. The 2017 FFS rate is calculated, in part, using the FFS growth percentage. CMS intends to rebase the county FFS rates for 2017 as part of the calculation of the rates for 2017.

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 2017 is 2.92 percent. This estimate reflects an underlying trend change for CY 2017 in per capita cost of 2.68 percent and, as required under section 1853(c)(6)(C) of the Act, adjustments to the estimates for prior years as indicated in the table below.

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

**Table I-1. Increase in the National Per Capita MA Growth Percentages for 2017**

| | Prior Increases | Current Increases | | | NPCMAGP for 2017 With §1853(c)(6)(C) adjustment[1] |
|---|---|---|---|---|---|
| | 2003 to 2016 | 2003 to 2016 | 2016 to 2017 | 2003 to 2017 | |
| Aged+Disabled | 50.20% | 50.56% | 2.68% | 54.58% | 2.92% |

[1]Current increases for 2003-2017 divided by the prior increases for 2003-2016

**Section B. FFS Growth Percentage**

Section 1853(n)(2) of the Act, as amended by the Affordable Care Act, requires that the specified amount for a county be calculated as a percentage of the county FFS costs. Table I-2 below provides the current estimate of the change in the Aged/Disabled FFS United States per capita cost (USPCC), which will be used for the county FFS rate. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2017 divided by the prior projected FFS USPCC for 2016.

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

**Table I-2 - Increase in the USPCC Growth Percentage for CY 2017**

| | Total USPCC – Non-ESRD | FFS USPCC – Non-ESRD | Dialysis-only ESRD |
|---|---|---|---|
| Current projected 2017 USPCC | $840.69 | $824.73 | $6,983.84 |
| Prior projected 2016 USPCC | $816.83 | $800.21 | $7,155.20 |
| Percent increase | 2.92% | 3.06% | −2.39% |

Table I-3 compares last year's estimate of the total non-ESRD USPCC with current estimates for 2003 to 2019, and Table I-4 compares last year's FFS non-ESRD USPCC estimates with current estimates. The total USPCCs are the basis for the National Per Capita MA Growth Percentages. In addition, these tables show the current projections of the USPCCs through 2019. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide. None of the data presented here pertain to the Medicare prescription drug benefit.

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

| | Part A | | Part B | | Part A & Part B | | |
|---|---|---|---|---|---|---|---|
| Calendar Year | Current Estimate | Last Year's Estimate | Current Estimate | Last Year's Estimate | Current Estimate | Last Year's Estimate | Ratio |
| 2003 | $296.18 | $296.18 | $247.66 | $247.64 | $543.84 | $543.82 | 1.000 |
| 2004 | $314.08 | $314.08 | $271.06 | $271.03 | $585.14 | $585.11 | 1.000 |
| 2005 | $334.83 | $334.83 | $292.86 | $292.83 | $627.69 | $627.66 | 1.000 |
| 2006 | $345.30 | $345.30 | $313.70 | $313.67 | $659.00 | $658.97 | 1.000 |
| 2007 | $355.44 | $355.47 | $330.68 | $330.65 | $686.12 | $686.12 | 1.000 |
| 2008 | $371.90 | $371.93 | $351.04 | $351.01 | $722.94 | $722.94 | 1.000 |
| 2009 | $383.93 | $383.89 | $367.95 | $367.92 | $751.88 | $751.81 | 1.000 |
| 2010 | $382.99 | $385.42 | $376.82 | $376.84 | $759.81 | $762.26 | 0.997 |
| 2011 | $389.78 | $389.75 | $386.30 | $386.33 | $776.08 | $776.08 | 1.000 |
| 2012 | $379.27 | $379.07 | $392.89 | $392.90 | $772.16 | $771.97 | 1.000 |
| 2013 | $381.31 | $381.24 | $399.71 | $400.31 | $781.02 | $781.55 | 0.999 |
| 2014 | $371.88 | $371.91 | $418.26 | $419.91 | $790.14 | $791.82 | 0.998 |
| 2015 | $372.27 | $369.18 | $430.39 | $430.51 | $802.66 | $799.69 | 1.004 |
| 2016 | $377.08 | $375.14 | $441.70 | $441.69 | $818.78 | $816.83 | 1.002 |
| 2017 | $384.26 | $386.12 | $456.43 | $460.23 | $840.69 | $846.35 | 0.993 |
| 2018 | $392.68 | $405.23 | $467.97 | $484.64 | $860.65 | $889.87 | 0.967 |
| 2019 | $402.45 | | $493.14 | | $895.59 | | |

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

| | Part A | | Part B | | Part A & Part B | | |
|---|---|---|---|---|---|---|---|
| Calendar Year | Current Estimate | Last Year's Estimate | Current Estimate | Last Year's Estimate | Current Estimate | Last Year's Estimate | Ratio |
| 2010 | $369.90 | $373.09 | $374.91 | $374.89 | $744.81 | $747.98 | 0.996 |
| 2011 | $373.81 | $373.73 | $384.47 | $384.47 | $758.28 | $758.20 | 1.000 |
| 2012 | $359.57 | $359.23 | $392.07 | $392.02 | $751.64 | $751.25 | 1.001 |
| 2013 | $365.58 | $365.16 | $395.98 | $396.51 | $761.56 | $761.67 | 1.000 |
| 2014 | $365.88 | $364.88 | $408.37 | $409.90 | $774.25 | $774.78 | 0.999 |
| 2015 | $368.49 | $362.92 | $423.11 | $422.05 | $791.60 | $784.97 | 1.008 |
| 2016 | $370.96 | $368.54 | $430.57 | $431.67 | $801.53 | $800.21 | 1.002 |
| 2017 | $377.29 | $380.46 | $447.44 | $451.24 | $824.73 | $831.70 | 0.992 |
| 2018 | $385.22 | $398.27 | $458.41 | 473.81 | $843.63 | $872.08 | 0.967 |
| 2019 | $394.43 | | $482.65 | | $877.08 | | |

These estimates are preliminary and could change when the final rates are announced on April 4, 2016 in the Announcement of CY 2017 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 4, 2016 Announcement.

## Attachment II. Changes in the Part C Payment Methodology for CY 2017

### Section A. MA Benchmark, Quality Bonus Payments and Rebate

As noted in Attachment I, the Affordable Care Act (ACA) amends section 1853 of the Act to establish a new methodology for calculating each MA county rate as a percentage of FFS spending in each county. The Affordable Care Act provides for a transitional period during which each county rate is calculated as a blend of the pre-Affordable Care Act rate set under section 1853(k)(1) of the Social Security Act (the "applicable amount") and the new FFS-based Affordable Care Act rate set under section 1853(n)(2) of the Social Security Act (the "specified amount"). (Please note that throughout this document, the terms "benchmark" and "county rate" are used interchangeably, and the term "service area benchmark" indicates the bidding target for a plan.)

Section 1853(c)(1)(D)(ii) of the Act requires CMS to rebase the county FFS rates, which form the basis of the specified amount, periodically but not less than once every three years. When the rates are rebased, CMS updates its estimate of each county's FFS costs using more current FFS claims information. CMS intends to rebase the county FFS rates for 2017.

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 2017, the applicable amount for 2017 is the greater of: (1) the county's 2017 FFS rate or (2) the 2016 applicable amount increased by the CY 2017 National Per Capita Medicare Advantage Growth Percentage. Note that, for 2017, the MA county rates are now fully transitioned to the specified amount. However, as discussed in Section A7, Section 1853(n)(4) of the Act requires that the benchmark for each county must be capped at the county's applicable amount.

#### *A2. Specified Amount*

The specified amount is based upon the following formula:

(2017 FFS rate minus IME phase-out amount) × (applicable percentage + applicable percentage quality increase)

Where:

IME phase-out amount is the indirect costs of medical education phase-out amount as specified at section 1853(k)(4);

Applicable percentage is a statutory percentage applied to the county's base payment amount, as described at 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 2017 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2016 average per capita FFS costs, because 2016 is the most recent FFS rate rebasing year prior to 2017. 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 2017 applicable percentages by county with the Advance Notice at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. Each county's applicable percentage is assigned based upon its quartile ranking, as follows:

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

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

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

### *A3. Quality Bonus Payment Percentage*

The Affordable Care Act provides for CMS to make quality bonus payments to MA organizations that meet quality standards measured under a five-star quality rating system.[1] In this document, we refer to this quality bonus as the *quality bonus payment (QBP) percentage* instead of using the statutory term *applicable percentage quality increase*. The QBP percentage is a percentage point increase to the applicable percentage for each county in a qualifying plan's service area, before multiplying the percentage by the FFS rate for the year to determine the specified amount.

Table II-2 shows the QBP percentage for each Star Rating for 2017 payments. For CY 2017 payments, plans with fewer than 4 stars will not receive a QBP percentage increase to the county rates, and plans with 4 or more stars will receive a QBP percentage increase to the county rates, as set forth in sections 1853(n) and 1853(o) of the Act. See Section A8 for rebate percentages for CY 2017.

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

| Star Rating | 2017 QBP Percentage* |
|---|---|
| Fewer than 3 stars | 0% |
| 3 stars | 0% |
| 3.5 stars | 0% |
| 4 stars | 5% |
| 4.5 stars | 5% |
| 5 stars | 5% |

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

An MA plan's Star Rating is the rating assigned to its contract. MA plans with a Star Rating of 4 or more stars will bid against their service area benchmarks that include the 5 percentage point QBP add-on to the applicable percentage for the benchmark in each county in the service area. For 2017, MA plans with a Star Rating of fewer than 4 stars will bid against service area benchmarks that do not include QBP add-ons to the county rates, with the exceptions of new MA plans and low enrollment plans. As discussed below, all benchmarks 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.

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

**New MA Plans**

The method for determining the QBP percentage for a new MA plan is different from the method described above. Per section 1853(o)(3)(A)(iii)(II) of the Act, for the purpose of determining a QBP percentage, the term "new MA plan" refers to an MA plan offered by a parent organization that has not had another MA contract in the preceding three-year-period. New MA plans are treated as qualifying plans that are eligible to receive a QBP percentage increase to the county rates, except that the QBP percentage will be 3.5 percentage points, per section 1853(o)(3)(A)(iii)(I)(cc) of the Act. That is, new MA plans will bid against a service area benchmark that reflects a 3.5 percentage point increase to the applicable percentage used to set the benchmark for each county in the plan's service area. As discussed below, all rates are capped at the section 1853(k)(1) amount – 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 preceding three-year-period, any new MA contract under that parent organization will receive an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts. Such plans may qualify for a QBP increase based on the enrollment-weighted average rating of the parent organization. CMS finalized this policy in the 2012 Announcement (page 2), found on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html, and will continue to apply it for 2017.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) contained provisions to permit reasonable cost reimbursement contracts to transition into MA plans by CY 2019, and allowed Medicare Advantage Organizations (MAOs) to deem the enrollment of their cost enrollees into successor affiliated MA plans that meet specific conditions. MACRA amended Section 1853(o)(4) of the Social Security Act such that, for the first three years as a converted MA plan receiving deemed enrollment, the converted plan shall not be treated as a new MA plan as defined in Section 1853(o)(3)(A)(iii)(II).

**Low Enrollment Plans**

Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at § 422.258(d)(7)(iv)(B),[2] provides that for 2013 and subsequent years, CMS shall develop a method for determining whether an MA plan with low enrollment is a qualifying plan for purposes of receiving an increase in payment under section 1853(o). We apply this determination at the contract level, and thus determine whether a contract (meaning all plans under that contract) is a qualifying contract. Pursuant to § 422.252, a low enrollment contract is one that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a

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

lack of a sufficient number of enrollees to reliably measure the performance of the health plan. For additional information regarding low enrollment contracts, please refer to the Call Letter.

Section 1853(o)(3)(A)(ii) of the Act does not address the amount of the increase for low enrollment contracts. As in 2016, for 2017 payments, we propose that low enrollment contracts be included as qualifying contracts that receive the QBP percentage of 3.5 percentage points, similar to the QBP percentage increase applied to new MA plans. We interpret section 1853(o)(3) of the Act as establishing two types of qualifying plans for purposes of applying the QBP, with the amount of the QBP determined by the basis for treatment of the plan as a qualifying plan (i.e., whether the amount is based on the score produced under the Star Rating system or based on the default increase specified in the case of new MA plans). Because the rationale for treating new MA plans as qualifying plans is the same as doing so in the case of low enrollment plans (i.e., there is no reliable data on which to assign a star value), we believe that new MA plans and low enrollment MA plans should receive the same treatment for the purpose of establishing the amount of quality bonus payments. Further, this is consistent with our treatment of low enrollment contracts for purposes of determining the rebate available to the plan.

### *A4. Qualifying County Bonus Payment*

Beginning with payment year 2012, section 1853(o)(2) of the Act extends a double QBP percentage to a qualifying plan located in a "qualifying county." Section 1853(o)(3)(B) of the Act defines a qualifying county as a county that meets the following three criteria:

> (1) has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000;
>
> (2) as of December 2009, had at least 25 percent of MA-eligible beneficiaries residing in the county enrolled in a MA plan; and
>
> (3) has per capita FFS county spending for 2017 that is less than the national monthly per capita cost for FFS for 2017.

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

CMS will publish a complete list of qualifying counties in the final 2017 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 2016 Rate Calculation Data file (columns Y and Z) on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The 2017 FFS rates, which are necessary for the third criterion, are not available at the time this Advance Notice is published. The FFS rates and the national average FFS spending amount will be published in the final 2017 Announcement.

### *A5. Affordable Care Act County Rates Transitional Phase-In*

The blend of the specified amount and applicable amount used to set the county benchmarks, as discussed above, was phased in on a transitional basis. This transition began in 2012 and will be complete in 2017. For 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 assignment 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 period for each county (2, 4, or 6 years) was published with the 2012 Advance Notice and can be found on the CMS website at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

### *A6. Blended Benchmark Calculations.*

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

**Table II-3. Blended Benchmark Calculations**

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

### *A7. Cap on Benchmarks.*

Section 1853(n)(4) of the Act requires that the benchmark for a county must be capped at the level of the county's applicable amount determined under section 1853(k)(1). This provision specifies that the QBP increase must be included in the 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. We note that the President's budget includes a provision that would remove this cap to incentivize quality improvement for all MAOs.

### *A8. Rebate*

Under section 1854(b)(1)(C) of the Act, except for MSA plans, the level of rebate is tied to the plan's Star Rating. Rebates are calculated, for each plan, as a percentage of the difference between the risk-adjusted service area benchmark and the risk-adjusted bid. Under § 422.266(b), plans may use rebates to fund supplemental benefits and/or to buy down beneficiary premiums for Part B and/or prescription drug coverage. Section 1854(b)(1)(C) stipulates rebate percentages that apply based on a plan's Star Rating, as shown in Table II-4.

**Table II-4. MA Rebate Percentages**

| Star Rating | 2017 |
|---|---|
| 4.5+ Stars | 70% |
| 3.5 to < 4.5 stars | 65% |
| < 3.5 stars | 50% |

Section 1854(b)(1)(C)(vi)(II) of the Act requires that, for purposes of determining the rebate percentage, a new MA contract under a new parent organization will be treated as having a Star Rating of 3.5 stars for 2012 and subsequent years. The statute is silent on the rebate percentage to assign to low enrollment plans in years after 2012. We view this as a gap in the statute, particularly in light of the direction in section 1853(o)(3)(A)(ii) to treat low enrollment plans as qualifying plans for purposes of the quality bonus payment percentage. As we did for 2016,

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

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

**Section B. Calculation of Fee for Service Cost**

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

In the 2016 Announcement, we announced updates and refinements to the AGA calculation methodology to reflect changes in FFS payment rules. Historical claims data were repriced to reflect the most current wage and cost indices. CMS re-priced hospital inpatient, hospital outpatient, skilled nursing facility, and home health claims to reflect the most current wage indices, and re-tabulated physician claims with the most current Geographic Practice Cost Index.

Also in 2016, we repriced historical claims to account for the changes made by the ACA to payments to disproportionate share hospitals. We also repriced durable medical equipment claims to account for the change in prices associated with the competitive bidding program.

For 2017, we are proposing to update the claims data used to calculate the AGAs, and to continue the repricing of historical data in the AGA calculation. Repricing historical claims, in conjunction with rebasing rates for 2017, ensures that the 2017 FFS county rates reflect the most current FFS fee schedules and payment rules. We are also proposing a change to the tabulation of county-level risk scores, which are used to standardize the AGAs for the risk profile of the population.

***B1. AGA Methodology for 2017***

In the first step, CMS is proposing to add the 2014 cost and enrollment data, and drop the 2009 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 2010 – 2014.

In the second step, CMS will exclude hospice expenditures and FFS claims paid on behalf of cost plan enrollees from the 2014 claims. Comparable adjustments were previously made to 2010 – 2013 claims data.

For Puerto Rico, CMS will continue to only include claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment for all five years (2010 – 2014). While most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in

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

Some stakeholders have suggested that there is insufficient FFS data in Puerto Rico to set accurate MA benchmarks in the Commonwealth and, therefore, CMS should instead use a proxy to set benchmarks for counties in the Commonwealth. These stakeholders have recommended that an appropriate proxy would be the state with the next lowest benchmarks.

CMS is not proposing to use a proxy to set Puerto Rico benchmarks for several reasons. First, after investigating this issue extensively over the past 12 months, we believe that the FFS data in Puerto Rico are sufficient for establishing accurate MA benchmarks. We have not been able to validate any of the criticisms of the current rates identified by these stakeholders. Moreover, we note that even if CMS concurred that the FFS data from Puerto Rico were insufficient for establishing accurate MA benchmarks, we cannot arbitrarily choose benchmarks from another jurisdiction as a proxy for Puerto Rico. The law requires that Medicare Advantage benchmarks be based on a county's average Medicare Fee-for-Service per-capita cost. There is no evidence that fee-for-service costs in Puerto Rico are higher than the costs observed in the FFS claims data, and thus no basis for overhauling Puerto's Rico's Medicare Advantage benchmarks. We believe the law requires us to use data that best approximate the actual FFS costs in Puerto Rico. We have seen no evidence to suggest that FFS costs in another jurisdiction are a reliable proxy for FFS in Puerto Rico. We believe that the benchmarks in Puerto Rico are reasonable as currently calculated.

One of the criticisms of the FFS data used to establish MA benchmarks in Puerto Rico is the fact that a larger proportion of FFS beneficiaries in Puerto Rico have zero claims than is found in other parts of the United States. Stakeholders have suggested this will unfairly bias the MA benchmarks. We appreciate this input and are exploring it further. We are concerned that in Puerto Rico there is a disproportionate percentage of beneficiaries who enroll in MA compared with the rest of the nation, which may be causing the FFS claims experience in Puerto Rico not to be representative of the FFS costs that MA beneficiaries in Puerto Rico would accrue if they were enrolled in FFS. For example, we are exploring the possibility of adjusting the FFS experience in Puerto Rico to reflect the propensity of zero claimants nationwide. We will review the data and comments and determine in the final Rate Announcement any actuarially supportable adjustment that may be necessary. We are seeking comment on this or alternative methodologies. We welcome public input on the magnitude of this effect and suggestions as to corrective actions that could be taken, if appropriate.

In the third step, CMS will re-price the historical inpatient, hospital outpatient, skilled nursing facility, and home health claims from 2010 – 2014 to reflect the most current (i.e., FY 2016) wage indices, and re-tabulate physician claims with the most current (i.e., CY 2016) Geographic

Practice Cost Index. For 2017, CMS will also continue to adjust historical FFS claims to account for section 3133 of the ACA, which replaced 75 percent of hospital Medicare Disproportionate Share Hospital (DSH) Payments with uncompensated care payments (UCP) beginning on October 1, 2013. Consistent with the methodology implemented for 2016, CMS would adjust claims for fiscal year (FY) 2010 through FY 2013 for each DSH hospital to reflect the reduction in DSH payments and the allocation of the UCP by incorporating the corresponding requirements of the final FY 2016 Inpatient Prospective Payment System (IPPS) rule. Similarly, we are proposing to adjust the UCP represented in the FY 2014 and 1st quarter FY 2015 claims to reflect the requirements of the final FY 2016 IPPS rule. For 2017, repricing will reflect the Consolidated Appropriations Act, 2016 (P.L. 114-113, section 601), which amended Section 1886(d)(9)(E) of the Social Security Act (42 U.S.C. 1395ww(d)(9)(E)) to increase the Medicare inpatient rates for hospitals in Puerto Rico.

Also for 2017, we will continue re-pricing Durable Medical Equipment (DME) claims from 2010 – 2014 to reflect the most current DME prices associated with the Competitive Bidding Program (CBP), and will continue using the Round 1 and Round 2 prices in making these adjustments. Section 1847(b)(5) of the Social Security Act requires that "single payment amounts" replace the current Medicare DMEPOS fee schedule amounts for selected DMEPOS items in specific competitive bidding areas (CBAs). Included in Round 2, 8 HCPC codes for diabetic supplies were expanded beyond CBAs to be part of a National Mail Order (NMO) program. In addition to previous re-pricing of historical FFS claims for CBP adjustments, we are proposing to also include in the single payment amounts for NMO DMEPOS items to re-price the historical payments for DME claims. Starting January 1, 2016, the ACA generally mandates adjustments to the fee schedule amounts in non CBAs based on CBP payment information. The adjusted fee schedule amounts were developed using the average of SPAs from CBPs to be applied in eight different regions and separated by rural and non-rural areas. For the first 6 months the payments will be phased in based on 50% of the unadjusted fee schedule amount and 50 percent of the adjusted fee schedule amount. Beginning on July 1, 2016, the fully adjusted fees will apply. We are proposing to use the fully adjusted fees to adjust the FFS claims to reflect the payments that will be in place for 2017.

We are proposing to make an additional adjustment to the 2012, 2013, and 2014 claims to account for shared savings payments and shared losses made to Medicare Shared Savings Program (MSSP) ACOs and Pioneer ACOs. The key aspects of these adjustments are:

- Allocate ACO shared savings or shared loss amounts geographically, as applicable based on each ACO's unique experience, according to the distribution of counties in which each ACO's assigned beneficiaries reside.
- Represent such allocated shared savings payments and shared losses on per-capita basis based on total FFS enrollment as of July 1 of the experience year.
- Exclude per-capita shared savings and losses attributed to beneficiaries in ESRD status as of July 1 of the experience year.

- Shared savings payments made to providers in the MSSP and Pioneer programs will be reflected as additional expenditures in the experience (i.e., when the payments were incurred rather than when they were paid) year. Shared losses will be included as negative expenditures in the experience year. The amounts will be represented in the county level Part A and Part B expenditures proportional to the Part A and Part B share of the FFS USPCC for the experience year.

We are also proposing to change the source of the county designation of beneficiaries used in the summarization of the risk scores, to be consistent with the county assignment used for the ratebook FFS claims and enrollment. For contract years 2016 and earlier, the county assignment for each fee-for-service (FFS) beneficiary was based on the zip code associated with the beneficiary's mailing address. Beginning with the 2017 ratebook, we are proposing to use the county provided by the Social Security Administration, which is the same county assignment as the ratebook FFS claims and enrollment.

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

As in prior years, CMS will (1) make additional adjustments to the FFS rates for the items detailed below, and (2) the average of the five year geographic indices, based on the adjusted claims data, will be divided by the county's average five-year risk score from the 2017 risk model in order to develop the AGA for that county.

**Additional Adjustments**

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

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)
- 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
- DOD: apply a cost ratio (an increase to claim costs) to counties with significant Tricare enrollment in the Uniformed Services Family Health Plan (USFHP) (section 1853(c)(1)(D)(iii) of the Act).

- VA: apply an adjustment to the county quality bonus payment (QBP) rates for experience of Medicare beneficiaries who are also eligible to receive care through the Veterans Health Administration (VHA).

### *B2. Adjustment to FFS per Capita Costs for DoD Costs*

For CY 2017, we are proposing to continue to adjust the FFS rates by the Department of Defense (DoD) ratios applied to the CY 2016 FFS rates. We are proposing an additional adjustment for beneficiaries who receive care through Veterans Affairs.

### *B3. Adjustment to FFS per Capita Costs for Veterans Affairs (VA) Costs*

To approximate an adjustment to the county fee for service (FFS) payment rates, we first analyzed the cost impact of removing Veterans Affairs (VA) dual-benefit eligibles from the Medicare claims and enrollments.[3] Specifically, we calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding VA dual-benefit eligibles (or all non-veteran beneficiaries) to all Medicare beneficiaries (or all beneficiaries) for each county. The analysis was based on FFS data for calendar years 2011 – 2013.

We then multiplied 2016 FFS rates by the ratios calculated and analyzed the resulting change in rates for each county. We looked at the rate changes between the 2016 FFS rates calculated for all beneficiaries and the rates calculated for the non-VA beneficiaries only. The rate changes do not reflect the impact of any payment rate minimums. OACT found that the impact for adjusting total FFS costs to non-VA FFS costs produces results that approximately 76% of the counties would receive an increase, and 24% of the counties would receive a decrease. The average of the impact on 2016 FFS rate is $6.23. (i.e., a rate increase of $6.23).

When we looked at the QBP payment rate, we found that the impact is somewhat smaller than the impact on the FFS rate. For 0 percentage point QBP rate, approximately 67% of the counties would receive an increase, 33% of the counties would receive a decrease, and the average impact is an increase of $4.70. For 3.5 percentage point QBP rate, approximately 60% of the counties would receive an increase, 40% of the counties would receive a decrease, and the average impact is an increase of $3.98. For 5 percentage point QBP rate, approximately 58% of the counties would receive an increase, 42% of the counties would receive a decrease, and the average impact is an increase of $3.73.

Based on the above analysis, we propose to make appropriate adjustments to the 2017 QBP rates for experience of VA dual-benefit eligible beneficiaries.

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[3] For this analysis, VA dual-benefit eligibles are defined as those Medicare beneficiaries who are also eligible to receive care through the Veterans Health Administration (VHA).

**Section C. IME Phase Out**

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1853(k)(4) of the Act to require CMS to phase out indirect medical education (IME) amounts from MA capitation rates. Pursuant to section 1894(d)(3) of the Act, PACE programs are excluded from the IME payment phase-out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under fee-for-service Medicare.

For purposes of making this adjustment for 2017, we will first calculate the 2017 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 2017 rates. The absolute effect of the IME phase-out on each county will be determined by the amount of IME included in the initial FFS rate. Under section 1853(k)(4)(B)(ii) of the Act, the maximum reduction for any specific county in 2017 is 4.8 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 2017 ratebook. We will also publish the rates with and without the IME reduction for the year.

**Section D. ESRD Rates**

In developing the 2017 ESRD Medicare Advantage benchmarks, we obtain the FFS dialysis reimbursement and enrollment data for each state for the years 2010 – 2014. For each year, we compute the per capita costs by state. The geographic indices for each year are calculated by dividing the state per capita cost by the total per capita cost of the nation. The average geographic adjustment (AGA) by state is then determined by calculating a 5-year weighted average of the geographic indices, which is standardized by dividing by the 5-year average risk scores. We calculated the 2014 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2014 data above, and using trend factors, develop the prospective 2017 FFS ESRD dialysis USPCC. The 2017 ESRD dialysis rates by state are determined by multiplying the 2017 FFS ESRD dialysis USPCC by the state AGA. The 2017 ESRD dialysis rate is adjusted by removing the direct graduate medical education (GME) expenses and gradually removing the indirect medical education (IME) expenses.

**Section E. Clinical Trials**

In 2017, CMS will continue to pay on a fee-for-service basis for qualified clinical trial items and services provided to MA enrollees in clinical trials that are covered under the Clinical Trials National Coverage Determination (Medicare NCD Manual, Pub. 100-3, Part 4, Section 310.1). Therefore, the payment and coverage standards applicable to NCDs under 42 CFR 422.109 apply. CMS has previously made the determination that all clinical trials covered under NCD 310.1 trigger the significant cost threshold such that coverage and payment are controlled by § 422.109(c).

As detailed in the 2016 Rate Announcement, MA enrollees are able to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. CMS does not require MA enrollees to relinquish their MA coverage if they wish to participate in a clinical trial.

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

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

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

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

The policy of requiring MAOs to pay the difference between original Medicare cost sharing and in-network cost sharing for clinical trial services is unchanged from 2011. For more information on these policies, please refer to the Medicare Managed Care Manual, Pub. 100-16, Chapter 4 (Benefits and Beneficiary Protections), section 10.7 (Clinical Trials).

**Section F. Location of Network Areas for PFFS Plans in Plan Year 2018**

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) 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 42 CFR 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 2018 in the final Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. We will also include the list on the CMS website at https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html. We will use January 1, 2016 enrollment data to identify the location of network areas for plan year 2018.

**Section G. MA Employer Group Waiver Plans**

We are proposing to waive the bidding requirements for all MA employer/union-only group waiver plans (EGWPs). CMS has authority under section 1857(i) of the Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. CMS believes that waiving the requirement to submit 2017 Part C bids will facilitate the offering of Part C plans for employers and unions seeking to establish high quality coverage for their Medicare eligible retirees by avoiding the cost and administrative burden of submitting complex bids.

In connection with this waiver, CMS is proposing an alternate payment policy for EGWPs. For MA EGWPs in 2017, CMS is proposing, as a condition of the waiver of the bidding requirements and the waivers otherwise provided to EGWPs, to establish payment amounts as described here. Beginning with the 2017 contract year, Part C entities offering employer/union-only group waiver plans would not be required to submit Part C bids.

Specifically, we are proposing to use individual market non-EGWP plan bids, including RPPOs, submitted for 2017 to establish Part C county level payment amounts for EGWPs. We are proposing to calculate the EGWP county payment rates as follows:

- First, a weighted average bid-to-benchmark ratio will be calculated at the quartile[4] level. The calculation would be: (weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts by actual enrollment)/(weighted average of the county standardized benchmarks by actual enrollment) = percentage by quartile. [5]

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

- In order to calculate a county rebate payment, each county level EGWP Part C base payment amount will then be compared to the corresponding published 5%, 3.5% and 0% bonus county benchmarks to determine the amount of savings. The savings amount will be multiplied by the corresponding star rebate percentage to determine the Part C EGWP county level rebate amount.

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

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

CMS would release county level total payment amounts by star rating (base county payment rate + county rebate) at the same time that the Regional MA benchmarks are released.

As a result of this proposal, each 3-star EGWP in a given county would receive the same payment amount that includes the same rebate amount, multiplied by their beneficiaries' risk scores. MA EGWPs would no longer be able to distinguish between the amount they are paid for basic benefits and the amount they are paid for rebates. In light of this, CMS would waive the requirement for MA EGWPs to allocate rebate dollars to any specific purpose. MA EGWPs would also no longer be permitted to buy down Part B premiums for their enrollees from the Part C payment. Under current rules, when an MAO uses rebates to buy-down a portion of the Part B premiums for their beneficiaries, CMS retains the rebate amount identified by the MAO and coordinates directly with the Social Security Administration to ensure that each beneficiary's Part B premiums is appropriately calculated and withheld from the beneficiary's Social Security check or billed to the beneficiary. However, under this proposal, since specific rebate amounts will not be identifiable, this process would no longer be available to MA EGWPs. Very few MA EGWPs currently use rebate dollars to buy down any portion of the Part B premium for their

[4] As described in more detail in Section A2 above, to determine the CY 2017 applicable percentages CMS ranks counties from highest to lowest based upon their 2016 average per capita FFS costs and places the rates into four quartiles. The 2017 quartile rakings will be used for this calculation.

[5] Territories will not be included in the weighted average bid-to-benchmark ratio, but will be assigned the weighted average of the quartile within which their counties fall.

enrollees, so this is not expected to have a significant impact on beneficiaries enrolled in these plans. EGWPs will also continue to be prohibited to separately refund Part B premiums for their enrollees.

With regard to how this policy will impact regional MA plans, the standardized benchmark for each MA region is currently a blend of two components: a statutory component consisting of the weighted average of the county capitation rates across the region; and a competitive component consisting of the weighted average of all of the standardized A/B bids for regional plans in the region. Part C Regional PPO EGWP bids are currently included in the calculation of both of the MA regional benchmark components. Should the proposed policy be implemented, Part C Regional PPO EGWP bids would not be included in the calculation of the MA regional benchmarks. The statutory components of the regional standardized A/B benchmarks will continue to be published each year as part of the Announcement of Medicare Advantage Payment Rates. CMS will also continue to publish the final MA regional standardized A/B benchmarks in early August, which will reflect the average bid component of the regional benchmark based on non-EGWP bid submissions.

For RPPO EGWPs, the weighted average bid-to-benchmark ratios will be calculated as described above. To establish the Part C base RPPO EGWP payment amount, we would also apply the same methodology as described above. In order to calculate the regional rebate amounts, however, these percentages would be applied for each county within a region to the published regional benchmarks to establish the savings amount and rebate amounts by star rating and quartile. So the payment formula for RPPO EGWPs would be: (base county payment rate + regional rebate) × beneficiary level risk score.

Further, there are concerns regarding the competitiveness of the bids submitted by MAOs for EGWPs which would be addressed and resolved by adoption of this payment policy. MA plans that exclusively serve employer/union groups do not compete in the open market, but are offered through negotiated arrangements between the MAO and employers and/or union groups.

In reviewing bids from recent years, we found that the projected average risk scores for employer group members are lower than for individual market plan MA enrollees. However, the average employer group bids are higher than those for individual market MA plans. For example, for the 2016 bids, the projected risk score is more than 9 percent lower for EGWPs than individual market plans, yet the projected plan A/B bid (i.e., the projected revenue required to provide services covered under traditional Medicare for enrolled beneficiaries) for EGWPs is actually 1 percent higher. As a result, the average rebate (which is a percentage of the difference between the plan's bid and their benchmark) is significantly higher for individual market MA plans than for EGWPs. All else being equal, one would expect the bid to be lower if the risk score is lower because a healthier population should have lower expected health care costs. Moreover, the administrative costs related to enrollment and marketing for EGWPs should be lower than those for individual market plans.

We believe there is an incentive for EGWPs to bid as close as possible to the benchmark in order to maximize revenue for the plan. EGWPs do not need to use the rebate dollars (and the supplemental benefits they support) in order to attract enrollees, as is the case in the individual market. As the Medicare Payment Advisory Commission (MedPAC) noted in its March 2009 Report to Congress (page 259), "the closer the bid is to the benchmark the better it is for the plans and employer, because a higher bid brings in more revenue from Medicare, potentially offsetting expenses that would have required a higher pay-in from employers.[6]"

Due to this bidding behavior, the bid-to-FFS ratio and payment-to-FFS ratio have been much lower for non-EGWPs than EGWPs for the past several years. These findings are consistent with MedPAC's conclusions. In particular, MedPAC found that the average bid, in 2014, of non-employer plans was 86 percent of their benchmarks, while EGWPs submitted bids that averaged 95 percent[7]. In 2015, MedPAC found that the average bid for EGWPs was 105 percent of the FFS rate, whereas the average bid for all MA plans was 94 percent of the FFS rate. Excluding EGWP plans from that calculation lowered the average non-EGWP bid to 92 percent of the FFS rate[8].

As of 2015, about 3 million beneficiaries, or approximately 19 percent of all MA enrollees, were enrolled in EGWPs. CMS first expressed concern regarding EGWP bids in the 2012 Advance Notice and asked for comments to explain and address the differences in EGWP bidding. The comments received did not seem to provide strong evidence for why EGWP plans have higher costs but lower risk scores. CMS' more recent review of bids has continued to find that EGWP bids are higher with no apparent rationale or explanation for the higher costs. CMS believes it is likely that CMS' current payments to EGWPs help subsidize the wrap-around coverage otherwise covered by employers. CMS also recognizes that, to the extent that CMS' payments are reduced, the result would be that employers pay higher premiums for current levels of supplemental coverage or that employers would choose to reduce the supplemental coverage provided to employees under these plans.

Notwithstanding the proposed changes to payment as described above, entities offering MA EGWPs must continue to meet all of the CMS requirements that are not otherwise specifically waived or modified, including, but not limited to, submitting information related to plan service areas and plan benefit packages. CMS would establish this new payment policy under our Section1857(i) waiver authority, by requiring plans to agree to the payment terms as a condition

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[6] MedPAC has recognized the EGWP bidding patterns and has publicly reported on this issue several times see, e.g. http://medpac.gov/documents/reports/march-2009-report-to-congress-medicare-payment-policy.pdf (p.259); http://www.medpac.gov/documents/reports/chapter-13-the-medicare-advantage-program-status-report-(march-2015-report).pdf?sfvrsn=0 (p. 325)

[7] http://medpac.gov/documents/reports/mar14_entirereport.pdf (p. 334)

[8] http://www.medpac.gov/documents/reports/chapter-13-the-medicare-advantage-program-status-report-(march-2015-report).pdf?sfvrsn=0

of the waivers provided to such plans (e.g., enrollment, service area, marketing, submission of bids, etc.).

The proposed changes align Part C payments for EGWPs with the approach we use for Part D payments to EGWPs.[9] Under this approach, payments to EGWPs will more closely align with payments made to MAOs under a competitive MA bidding structure.

**Section H. CMS-HCC Risk Adjustment Model for CY 2017**

In 2017, CMS proposes to implement an updated version of the CMS-HCC risk adjustment model. We propose to use this updated CMS-HCC model in Part C payment for aged/disabled beneficiaries enrolled in MA plans, including Medicare-Medicaid Plans (MMPs). The proposed model would encompass the following updates:

- Updates to the data years used to recalibrate the model;
- Revisions to the community model that replace the single community segment with six separate model segments (non-dual aged, non-dual disabled, full benefit dual aged, full benefit dual disabled, partial benefit dual aged, partial benefit dual disabled); each segment would have relative factors that are independently developed for that segment and would reflect the specific relative costs for an HCC for that subgroup;
- Updates to disease interactions; and
- Updates to the community and long term institutional (LTI) segments, such that the community risk score will depend on the dual status in the payment month and the LTI risk scores will include a Medicaid factor based on Medicaid status in the payment year.

CMS received numerous comments on the HPMS memo "Proposed Changes to the CMS-HCC Risk Adjustment Model for Payment Year 2017," released in October 2015. A compilation of the 87 comments received prior to the comment deadline is posted at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/RiskProposedChanges.html. Most of the commenters commended CMS and offered support for the work CMS is conducting to revise the CMS-HCC Model and appreciate CMS' transparency with results of the analyses, particularly the predictive ratios. Commenters highlighted that the revised model will eliminate payment inaccuracies and provide an equitable approach to improve the overall accuracy of the risk-adjustment model for complex vulnerable populations, including full benefit dual aged and full benefit dual disabled beneficiaries. They specifically supported the incorporation of dual status in the payment year and advocated for implementation of the model without a phase in period.

[9] In 2008, CMS eliminated bidding for Part D EGWPs and since then has based our direct subsidy payments to Part D EGWPs on the average of individual Part D plan bids.

Commenters that opposed our proposed approach to revising the model expressed concerns about payment changes for plans that did not enroll many full benefit dual eligible beneficiaries. These commenters made several suggestions, including that, in order to focus on correcting payment accuracy for dual eligible beneficiaries, CMS apply an adjustment factor only to the payment for dual eligible beneficiaries. They also suggested delaying implementation of the model or making the model change budget neutral for the MA program. Plan sponsors that enroll a large partial dual population also expressed concern.

Commenters also asked for clarification regarding a number of issues. A few commenters were interested in the addition of other disease interaction terms to the model. Commenters also asked about the ability of the model to predict for low risk disabled beneficiaries and offered suggestions to improve the prediction of their costs. Some commenters wanted more information on our methodology and rationale used to develop the proposed model. A number of commenters requested that CMS provide the impact of the proposed model on the MA program overall.[10] A number of commenters also asked for coefficients ahead of the PY2017 Advance Notice so that they could have more than 14 days to predict their risk scores under the new model and make meaningful comments.

We received numerous comments from PACE organizations in response to our proposal to implement a revised CMS-HCC risk adjustment model for both MAOs and PACE organizations: although commenters expressed interest in the new model structure, they also expressed concern about changing to a different set of HCCs. One comment we received requested that CMS recognize that some beneficiaries in Puerto Rico would be partial dual eligible if the Commonwealth established a program for QMBs and SLMBs, and account for that population for MA payment purposes.

In drafting this section of the Advance Notice (related to the revision of the CMS-HCC model), we incorporated additional information in order to address many of the comments we received.

We note that many of the comments we received related to how CMS would implement the new model in payment. Questions include how CMS would identify monthly dual eligible status in payment, how CMS would make updates to monthly payments as States reported new or changing dual status after prospective payments had been made, and how the MMR and other reports would be changed to reflect the risk scores used in payment. CMS is in the process of developing technical specifications for how we would implement the proposed model and plan to release information regarding the operational implementation after the CY 2017 Rate Announcement has been published.

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[10] In response to these comments, CMS posted risk score data for each contract on January 23rd on the Health Plan Management System (HPMS) web page, as well as risk model coefficients, which are posted at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/RiskProposedChanges.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.

## Background

The CMS-HCC risk adjustment model is used to calculate risk scores to adjust capitated payments made for aged and disabled beneficiaries enrolled in Medicare Advantage (MA) plans and certain demonstrations. The CMS-HCC model has historically been calibrated using two full risk segments with separate coefficients to reflect the unique cost patterns of beneficiaries in the community and beneficiaries residing in long term care institutional facilities. The community segment of the model predicts costs for beneficiaries who reside in the community or have been in an institution for fewer than 90 days. The institutional segment of the model predicts costs for beneficiaries who have been in an institution for 90 days or longer.

The CMS-HCC risk adjustment model is prospective: it uses health status in a base year to predict costs in the following year (payment year). In addition to diagnoses, base year factors in the current models include Medicaid status. There are different Medicaid factors by gender, aged/disabled Medicare entitlement status, and whether a beneficiary lives in the community or in an institution. These Medicaid factors complement the diagnoses in the model as prospective predictors of costs. The coefficients for the Medicaid factors reflect that, on average, dual eligible beneficiaries cost more than non-dual eligible beneficiaries with otherwise similar disease and demographic profiles. Medicaid status is defined as having at least one month of Medicaid eligibility during the base year.

## Research and Findings

In response to new Medicare products that focus on enrolling exclusively dual eligible beneficiaries, along with concerns raised about the accuracy of the current model for predicting costs for dual eligible beneficiaries, CMS' research and model development work focused on determining the accuracy of the CMS-HCC model for paying for dual eligible beneficiaries and identifying model changes to improve payment accuracy. Specifically, CMS studied how well the model predicts costs based on beneficiaries' dual eligible statuses in the payment year, which is when beneficiaries are enrolled in the health plan that is being paid for them. CMS has not undertaken a revision of the set of HCCs included in the model.

To measure model performance, CMS calculated predictive ratios for key subgroups of beneficiaries. A predictive ratio—the ratio of a group's predicted cost to its actual cost—measures the accuracy of the model in predicting the average cost of a group. A predictive ratio close to 1.0 indicates that the model is accurately predicting that group's average cost. A ratio greater than 1.0 indicates over-prediction, while a ratio less than 1.0 indicates under-prediction. The 2014 model predicts accurately overall, and for diseases and characteristics included in the model. We note that we calculated predictive ratios using the Fee-For-Service (FFS) population because we did not have expenditures for the MA-enrolled population.

CMS measured the predictive ratios (PR) for the beneficiaries based on community and institutional status by dual status, and also on dual status by aged/disabled status.

*Institutional Segment*. Since the long-term institutionalized population is predominantly dual eligible (83.5%) – and specifically, full benefit dual eligible (83.3%) – the institutional segment of the model predicts very well for dual eligible beneficiaries (the predictive ratio for all dual eligible beneficiaries is 0.998; the predictive ratio for full benefit dual eligible beneficiaries is 0.999).

*Community Segment*. Our findings show that the community segment of the 2014 model overpredicts for both non-dual eligible beneficiaries (PR=1.015) and for partial benefit dual eligible beneficiaries (PR=1.092), while it under-predicts for full benefit dual eligible beneficiaries (PR=0.914) (see Table II-5). Based on these findings, we focused our model development efforts on the community segment of the CMS-HCC model.

**Table II-5. Predictive Ratios for Community Population, 2014 Model**

| | |
|---|---|
| FFS population | 1.000 |
| Non-dual | 1.015 |
| Dual | 0.957 |
| Full benefit duals | 0.914 |
| Partial benefit duals | 1.092 |

Notes: Predictive ratios are the ratio of predicted cost to actual cost for the applicable subgroup. Dual status is defined in the payment year.
Source: RTI International analysis of 2010-2011 Medicare 100% data.

### Model Development

Given our findings, we focused on making at least two specific changes: (1) splitting the community dual eligibles into full benefit duals and partial benefit duals and (2) incorporating dual status from the payment year (rather than using prior year dual status to predict payment year costs).

In order to improve the ability of the model to predict costs for full benefit and partial benefit dual eligible beneficiaries in the community, CMS explored different approaches to revising the CMS-HCC risk adjustment model by developing several analytic models and assessing their impact on the ability of the model to predict costs for various dual eligible groups, including:

1. Creating separate concurrent factors for full and partial benefit duals within a single community segment of the model;
2. Developing multiplicative factors for full and partial benefit duals, relative to a base community model;
3. Creating three community segments for non-dual, full benefit, and partial benefit dual beneficiaries;

4. Creating six community segments for non-dual aged and non-dual disabled, full benefit dual aged and full benefit dual disabled, and partial benefit dual aged and partial benefit dual disabled beneficiaries; and
5. Exploring whether combining some subgroups (i.e., having fewer than six community segments in the model) could simplify the model without reducing the ability of the model to predict costs.

In developing each model for analysis, we defined dual status by month and identified non-duals, full benefit duals, and partial benefit duals as follows (see Table II-6):

- Full benefit dual eligibles are those who are eligible for full Medicaid benefits under title XIX of the Social Security Act. Full benefit dual eligibles include those who are eligible as Qualified Medicare Beneficiaries (QMBs) or Specified Low Income Medicare Beneficiaries (SLMBs) *in addition to* full Medicaid benefits (i.e., QMB Plus and SLMB Plus).

- Partial benefit dual eligibles include those who are eligible only as a Qualified Medicare Beneficiaries (QMBs), a Specified Low Income Medicare Beneficiaries (SLMBs), and under other categories of beneficiaries who are not eligible for full Medicaid benefits under title XIX.

For payment purposes, we will use Medicaid data from three sources: the MMA State files, the Point of Sale data, and the monthly Medicaid file that the Commonwealth of Puerto Rico submits to CMS. We will identify full benefit dual status for a month using dual status codes 02, 04, and 08, and presence on the Puerto Rico file to indicate full dual status. We will identify partial benefit dual status for a month using dual codes 01, 03, 05, and 06.

We note that Puerto Rico has requested that, for payment purposes, CMS treat some of their non-duals as partial benefit duals, since the Commonwealth has not established a Medicaid program for QMBs and SLMBs (categories that are classified as "partial benefit duals"). Puerto Rico has proposed that CMS establish a ratio of the average risk scores for partial duals vs non-duals, estimate a proportion of beneficiaries who would be treated as partial benefit duals within the Puerto Rico non-dual population enrolled in MA plans by using the proportion of partial duals to non-duals in MA plans in the non-Territory jurisdictions, and use these data to apply a partial dual factor to the entire non-dual population in Puerto Rico. CMS is requesting comment on this proposal, including whether or not we should proceed with a different methodology for determining dual status for beneficiaries enrolled in Puerto Rico plans, whether this approach of applying an adjustment amount to non-dual risk scores in Puerto Rico is reasonable, and whether we should use data from all non-Territory jurisdictions or from specific States instead. Further, we seek comment on whether there are other approaches, such as identifying specific beneficiaries who should be considered partials duals in Puerto Rico and having the Commonwealth identify them on their monthly files, so that an adjustment would be made to

individual risk scores and flow through payment as it does for all beneficiaries. We seek comment on how to identify individuals who would be partial benefit duals if QMB and SLMB benefits were part of the Puerto Rico Medicaid program and on factors that could be used as proxies for partial dual status. Because of the payment implications of such risk score adjustments, we are trying to determine if an adjustment to risk scores of non-duals enrolled in Puerto Rico MA plans - either by using an adjustment that reflects the estimated proportions of partial dual and non-dual beneficiaries in Puerto Rico or by identifying specific individuals to consider as partial dual beneficiaries - would increase payment accuracy.

**Table II-6. Dual Status Codes for Beneficiaries Who are Entitled to Medicare**

| Dual Status Code | Category |
|---|---|
| 01 | QMB only |
| 02 | QMB and Medicaid coverage |
| 03 | SLMB only |
| 04 | SLMB and Medicaid coverage |
| 05 | Qualified Disabled and Working Individuals (QDWI) |
| 06 | Qualifying individuals (QI) |
| 08 | Other Dual Eligibles (Non QMB, SLMB, QWDI or QI) with Medicaid coverage |
| 09 | Other Dual Eligibles but without Medicaid coverage |

In analyzing the various model approaches, our research explored whether the coefficients differed significantly for different populations and whether the predictive ratios for each subgroup were improved relative to the current model. Our findings included the following:

- In one analytical revised version of the CMS-HCC model, we retained a single community segment but replaced the existing prospective Medicaid factors with new concurrent factors. These new concurrent Medicaid factors were additive in the same manner as the existing Medicaid factors and the HCCs, and we created one each for full benefit and partial benefit duals. CMS found that, while the regression coefficients were not significantly different from the current CMS-HCC model, the overall predictive ratios for most of the six subgroups were improved. However, for some deciles, the predictive ratios for the subgroups were further from 1.0 than those under the current model.

- In another analytical revised version of the CMS-HCC model, we created three community segments (non-dual, full dual, and partial dual). When we compared the coefficients among these three community segments, we found substantial differences in the regression

coefficients for both the age-sex factors and HCCs. The majority of regression coefficients for the full benefit duals were higher than those for the partial benefit duals. Similarly, the majority of the coefficients for the partial benefit duals were higher than those for the non-duals. With the three community segment model, predictive ratios at the HCC level and demographic level are 1.0 for each of the 3 dual status groups.

- We also assessed an analytical revised version of the CMS-HCC model that retained a single community segment, but replaced the existing Medicaid factors with multiplicative factors, i.e., factors that multiplied a base risk score by a uniform factor, depending on dual status. We note that, in determining whether or not multiplicative factors would improve the ability of the model to predict costs by dual status, we compared the coefficients of the analytical revised version model with three community segments, and found that the relationships between the coefficients were not consistent across factors. For example, not all of the coefficients were higher by the same amount. This suggests that a multiplicative term for either full and/or partial duals would be an imprecise approach to improving the predictive ability of the model, thus limiting its effectiveness in improving the model. In fact, the predictive ratios for the multiplicative approach show that this model variant does not improve predictive ratios across deciles.

- In considering the value added of a six community-segment model versus a three community-segment model, our analyses showed that the cost and disease patterns of the non-dual, full benefit dual, and partial benefit dual, and the aged versus disabled segments, were distinct, both within the dual types (e.g., full benefit dual aged versus full benefit dual disabled) and between the dual types (e.g., full benefit dual disabled versus partial benefit dual disabled). Furthermore, the differences in cost patterns varied significantly both overall and by HCC disease category. We note that the predictive ratio for each of the six groups would be 1.0 under either a 3- or 6-segment model. The key differences are that the model with six community segments produces predictive ratios that are substantially similar or closer to 1.0 at the decile level and the predictive ratios for each of the 6 subgroups are 1.0 at the HCC level only with the 6-segment model. See section below on "Initial Results of Proposed Model" for more information.

Because the cost and disease patterns for the six dual subgroups are distinct, we believe that in order to improve the ability of the model to predict costs by dual status, it is appropriate to establish six separate segments. For payment year 2017, we propose a CMS-HCC model with a separate community model segment for each of the six subgroups of dual eligibles described above.

**Disease interactions**

Since the proposed CMS-HCC community model contains separate segments by aged/disabled dual status, it effectively contains interactions for disease, dual status, and aged/disabled status

for every payment HCC. The majority of the predictive ability of the proposed model is captured additively across the demographic factors and the HCCs and, as a result, adding disease-disease (HCC x HCC) interactions only marginally increases the model's explanatory power. However, to better recognize the medical characteristics of each of the six community populations, we re-examined the disease-disease interactions for the revised model. After extensive analysis, we have determined that all of the community model segments will have six disease-disease interactions, with one additional disease-disease interaction term for the disabled model segments.

CMS examined high frequency disease-disease interactions for each of the six subgroups (non-dual aged, non-dual disabled, partial benefit dual aged, partial benefit dual disabled, full benefit dual aged, and full benefit dual disabled) separately. We examined individual HCC x individual HCC interactions, individual HCC x HCC group interactions, and HCC group x HCC group interactions. Disease-disease interactions were evaluated based on several criteria, including: sample size, magnitude of coefficient, statistical significance, statistical stability, and clinical plausibility. We identified disease-disease interactions that were clinically significant, empirically strong, and improved the predictive accuracy for the segment subgroups, and reviewed these disease interaction candidates with clinicians. For example, the simultaneous presence of Congestive Heart Failure (CHF) and Chronic Obstructive Pulmonary Disease (COPD) leads to higher expected costs than would be calculated by adding the separate increments for CHF and COPD alone. The disease-disease interactions for each of the six separate community models are the same, except for one disease-disease interaction (Substance Abuse and Psychiatric) that is only included in the three disabled community models.

Below is the list of disease interactions that will be used in the 6-segment community model:

<u>All Aged and Disabled Segments</u>

- Cancer HCC group × disorders of immunity individual HCC
- CHF individual HCC ×diabetes HCC group
- CHF individual HCC ×COPD HCC group
- CHF individual HCC ×renal HCC group
- CHF individual HCC ×specified heart arrhythmias individual HCC
- COPD HCC group ×cardio respiratory failure HCC group

<u>Disabled Segments Only</u>

- Psych HCC group × substance abuse HCC group

*<u>Institutional segment</u>.* Other than recalibrating the institutional segment of the CMS-HCC model, the only change we are proposing is to measure dual status concurrently (based on payment year status). Although the institutional segment of the model already predicts well for dual eligibles, we are making this change to be consistent with the community segments of the revised model.

We will retain a single institutional segment. We explored creating separate dual factors for full benefit duals and partial benefit duals, but our model showed that separate risk factors for full benefit dual status and partial benefit dual status did not meaningfully improve the overall predictive accuracy of the institutional model. As a result, we decided to continue including a single risk factor for any dual status (full benefit or partial benefit).

*New enrollee segment*. The new enrollee segment of the CMS-HCC model is used in Part C payment for beneficiaries who do not have adequate diagnoses history to calculate a risk score. We operationalize this approach by defining new enrollees as those beneficiaries without 12 months of Part B enrollment in the data collection year. The new enrollee segment of the CMS-HCC model comprises demographic factors: age, sex, Medicaid status, and originally disabled status. The new enrollee model for payment year 2017 is recalibrated on 2014 Medicare FFS claims data. Otherwise, the new enrollee model is unchanged from the new enrollee segment of the 2014 CMS-HCC model. Medicaid status in the new enrollee model is already concurrent in the payment year and our model research showed that separate risk factors for full benefit dual status and partial benefit dual status did not meaningfully improve the overall predictive accuracy of the new enrollee model. As a result, we decided to continue including a single factor for any dual status (full benefit or partial benefit).

**Initial Results of Proposed Model**

Predictive ratios for each of the six community subgroups, defined by dual eligible status and aged/disabled status, are 1.0 for the revised model, indicating that the six segment model predicts costs more accurately than the 2014 model (see Table II-7). The non-dual and partial benefit dual aged and disabled subgroups are no longer over-predicted, and the full benefit dual aged and disabled subgroups are no longer under-predicted. In addition, the predictive ratios at the HCC level and demographic level are 1.0 for each of the six community subgroups, which is an important improvement over the 2014 model. Furthermore, the revised model improves prediction for each of the six subgroups across deciles of predicted costs. The deciles were created by sorting the predicted expenditures in ascending order, then equally dividing each subpopulation amongst the ten groups. For the non-dual aged, full benefit dual aged, and partial benefit dual aged segments, the predictive ratios for the revised model are closer to 1.0 compared to those for the 2014 model across most deciles (see Table II-7).

We note that the CMS-HCC model has typically under-predicted expenditures for low risk beneficiaries. The majority of beneficiaries in the lowest predicted groups have no HCCs included in the model. The predicted costs for beneficiaries without model HCCs are determined by CMS-HCC model demographic factors only and the values for these demographic factors are the same for both beneficiaries without HCCs and those with model HCCs. For those beneficiaries with HCCs, the age-sex factors have modest importance in explaining costs. The actual effect in dollars of the under-prediction in lower deciles is quite small; it is a percentage of a relatively small expenditure level.

For beneficiaries in the highest decile of predicted costs for all six model segments, the revised model effectively eliminates the over-prediction for non-dual and partial benefit dual beneficiaries and the under-prediction for full benefit dual beneficiaries.

For the non-dual disabled and partial benefit dual disabled segments, the revised model predicts costs more accurately than the 2014 model does for deciles four through ten. For the full benefit dual disabled segment, the revised model's predictive ratios are generally closer to 1.0 for deciles five through ten than the 2014 model's predictive ratios. However, for the lower risk deciles in all three dual disabled segments, the under-prediction for costs observed under the 2014 model is not fully eliminated by the revised model. We note the majority of beneficiaries in these lowest deciles have few or no HCCs that are included in the model.

**Table II-7. Comparison of Predictive Ratios by Deciles of Predicted Expenditures, Community Beneficiaries – 2014 Model and Revised CMS-HCC Model**

| | Non-Dual Aged | | Full Benefit Dual Aged | | Partial Benefit Dual Aged | |
|---|---|---|---|---|---|---|
| Decile | 2014 model | Revised model | 2014 model | Revised model | 2014 model | Revised model |
| Overall | 1.012 | 1.000 | 0.892 | 1.000 | 1.123 | 1.000 |
| 1st | 0.904 | 0.935 | 0.814 | 0.961 | 1.043 | 0.933 |
| 2nd | 0.925 | 0.952 | 0.862 | 0.954 | 1.206 | 0.968 |
| 3rd | 0.950 | 0.970 | 0.952 | 0.987 | 1.234 | 0.966 |
| 4th | 0.968 | 0.977 | 0.906 | 0.993 | 1.174 | 0.977 |
| 5th | 1.006 | 1.007 | 0.920 | 1.005 | 1.152 | 0.994 |
| 6th | 1.001 | 1.003 | 0.908 | 0.999 | 1.146 | 0.997 |
| 7th | 1.021 | 1.015 | 0.908 | 1.014 | 1.138 | 1.022 |
| 8th | 1.026 | 1.014 | 0.901 | 1.014 | 1.133 | 1.022 |
| 9th | 1.040 | 1.019 | 0.892 | 1.013 | 1.103 | 1.022 |
| 10th | 1.036 | 1.000 | 0.868 | 0.995 | 1.074 | 0.997 |

| | Non-Dual Disabled | | Full Benefit Dual Disabled | | Partial Benefit Dual Disabled | |
|---|---|---|---|---|---|---|
| Decile | 2014 model | Revised model | 2014 model | Revised model | 2014 model | Revised model |
| Overall | 1.042 | 1.000 | 0.947 | 1.000 | 1.072 | 1.000 |
| 1st | 0.787 | 0.928 | 0.860 | 0.949 | 0.799 | 0.912 |
| 2nd | 0.886 | 0.910 | 0.888 | 0.880 | 0.865 | 0.884 |
| 3rd | 1.012 | 0.952 | 0.837 | 0.873 | 0.950 | 0.891 |
| 4th | 0.905 | 0.953 | 1.061 | 0.904 | 1.069 | 0.978 |
| 5th | 1.033 | 0.969 | 1.009 | 0.993 | 1.165 | 1.030 |
| 6th | 1.061 | 0.989 | 1.036 | 1.024 | 1.120 | 1.014 |
| 7th | 1.072 | 1.004 | 1.024 | 1.029 | 1.133 | 1.025 |
| 8th | 1.092 | 1.032 | 1.004 | 1.053 | 1.140 | 1.041 |
| 9th | 1.114 | 1.053 | 0.968 | 1.050 | 1.114 | 1.039 |
| 10th | 1.039 | 0.997 | 0.877 | 0.991 | 1.049 | 0.991 |

Source: RTI International analysis of 2011-2012 Medicare 100% data.

## Calibration

CMS calibrated the revised CMS-HCC model using 2013-2014 Medicare FFS data. Specifically, 2013 diagnoses were used to predict 2014 expenditures. We did not conduct a clinical revision of the hierarchical condition categories (HCCs) for the proposed model revision. Each of the six community model segments (non-dual aged, non-dual disabled, full benefit dual aged, full benefit dual disabled, partial benefit dual aged, and partial benefit dual disabled) will have the same HCCs that were in the 2014 model, while the coefficients will differ by segment to reflect the specific relative costs for a demographic factor or an HCC for each subgroup. The demographic factors (e.g., age, sex, originally disabled) will remain the same, with the exception of the Medicaid factors, which are no longer included in the model as an additional factor. The Medicaid factors are no longer necessary, since there are separate segments based on dual status.

As in all model calibrations, the denominator will be the average predicted cost across the FFS Medicare population and will be used to convert model coefficients in each segment into relative factors. For the proposed CMS-HCC model, the denominator year is 2015 and the denominator is $9,350.78. The denominator sets the average FFS risk score to 1.0 in the year of the denominator. We note that, in setting the average risk score at 1.0 in a year, all risk scores are relative to this average. In other words, if, in updating the model, some beneficiaries' risk scores increase to reflect a higher predicted relative risk, other beneficiaries' risk scores will decrease to reflect a lower predicted relative risk.

We note that several commenters asked that we implement the model so that it is budget neutral to the MA program. We are not proposing to make any changes to the model in order to retain the average MA risk score at the same level that it was under the current model. The change in the aggregate MA risk score is almost entirely due to the different distribution of duals than is in FFS. Given that we believe that this model improves the predictive ability of the model, it is appropriate to allow MA risk scores to change in response to the revised model.

The model sample comprises beneficiaries who have at least one month in FFS in the prediction year (2014) and all twelve months of FFS in the prior year (2013). Community versus Long Term Institutional (LTI) status is determined in the prediction year (2014) and on a monthly basis; the appropriate month is placed into the appropriate model segment. If a beneficiary has LTI status in a month, then that month's costs are placed in the LTI model segment. Dual status (non-dual, full benefit dual, and partial benefit dual) is assigned in the LTI segment if the beneficiary is dual any time in the prediction year.

Similarly, if a beneficiary has community status in a month, then that month's costs are placed in the appropriate segment among the six community segments. Dual status (non-dual, full benefit dual, and partial benefit dual) is assigned for these community segments in the prediction year and on a monthly basis.

CMS will continue to determine age for a year as of February 1, and this age will determine whether a beneficiary is considered either aged or disabled for purposes of selecting the

appropriate model segment(s) during that year. For each segment, model coefficients for hierarchical condition categories (HCCs) are estimated by regressing the total annualized expenditure for Medicare Parts A and B benefits for each beneficiary onto their demographic factors and hierarchical condition categories, as indicated by their diagnoses. Expenditures are based on annualized costs of months that a beneficiary is in for each relevant status: LTI or one of six community segments.

The distribution of beneficiaries in the model sample is shown in Table II-8: 13.4% of the model sample are full benefit duals and 5.3% are partial benefit duals. We observed that full benefit duals have higher costs than partial benefit duals, and partial benefit duals have higher costs than non-duals (also see Table II-8 for average costs by subgroup).

For payment, we would determine the appropriate risk score for each monthly payment based on a beneficiary's status in the payment month. If a beneficiary has LTI status in a payment month, we will apply an LTI risk score for payment. If a beneficiary has community status in a payment month, the appropriate community segment is used (the six community segments are mutually exclusive) for a month. This is similar to how we determine which risk score to use in payment today. Further, similar to how we currently determine LTI v community status in payment, we will use available information when we initially calculate prospective monthly payments and then, at a later date, retroactively reconcile monthly payments with actual monthly dual status. As we mention above, we are developing technical specifications for implementing the proposed model in payment and will provide operational detail at a later date.

*New enrollee model.* In the revised HCC model that we are proposing for 2017, we will again directly estimate each possible risk score, as we did for the 2014 CMS-HCC model. For example, we directly estimate the risk score for a specific new enrollee type, such as female 70-74, Medicaid, and originally disabled. We took this approach for the 2014 CMS-HCC model and are continuing with the practice.

*New Enrollee Risk Scores for Chronic SNPs.* Beginning in 2011, in accordance with changes that Section 3205 of the Affordable Care Act made to section 1853(a)(1)(C)(iii) of the Act, CMS implemented a new enrollee risk adjustment model designed specifically to pay new enrollees in chronic care special needs plans (C-SNPs). This model is based on the known underlying risk profile and health status of C-SNP enrollees generally, given that these beneficiaries must have certain conditions to be enrolled in these plans. New enrollee risk scores are used to pay for those beneficiaries who do not have 12 months of Part B in the data collection year. Because chronic SNP enrollees must as a condition of enrollment have specific conditions, the average new enrollee risk score is likely to understate these beneficiaries' risks.

The C-SNP new enrollee factors were developed by calculating an average risk score for continuing enrollees in C-SNPs using the standard new enrollee model. We then adjusted the current new enrollee risk scores to take into account the incremental risk of continuing enrollees

in chronic SNPs. As with the standard new enrollee model, the C-SNP new enrollee factors include factors that differ depending on age, sex, Medicaid, and originally disabled status. The C-SNP new enrollee factors comprise the standard new enrollee factors, plus an incremental amount.

For 2017, CMS will continue to utilize new enrollee risk scores calculated from the C-SNP segment of the revised CMS-HCC model in Part C payment for aged/disabled beneficiaries enrolled in C-SNPs.

**Table II-8. Costs and Percent of Model Sample of Different Full Risk Subgroups (2014)**

| | Mean actual costs | Proportion of model sample |
|---|---|---|
| Community full benefit dual – aged | $15,204 | 6.5% |
| Community full benefit dual – disabled | $10,684 | 6.9% |
| Community partial benefit dual – aged | $10,689 | 2.8% |
| Community partial benefit dual – disabled | $9,649 | 2.5% |
| Community non-dual – aged | $8,968 | 72.0% |
| Community non-dual –disabled | $8,152 | 6.8% |
| Institutional | $18,714 | 2.5% |

Source: RTI International analysis of 2013-2014 Medicare 100% data.

Table II-9 compares the current CMS-HCC model to the proposed CMS-HCC model.

**Table II-9. Comparison of the 2014 Model and Revised CMS-HCC Model**

| | **2014 Model** | **Revised Model** |
|---|---|---|
| Segments | Two Full Risk segments:<br>• Institutional<br>• Community | Seven Full Risk Segments<br>• Institutional<br>• Community: Full benefit dual aged<br>• Community: Full benefit dual disabled<br>• Community: Partial benefit dual aged<br>• Community: Partial benefit dual disabled<br>• Community: Non-dual aged<br>• Community: Non-dual disabled |
| Dual status for full risk beneficiaries identified in: | Base year | Payment year |

| | **2014 Model** | **Revised Model** |
|---|---|---|
| Hierarchical condition categories | 79 HCCs | Same HCCs as 2014 model |

| | **2014 Model** | **Revised Model** |
|---|---|---|
| Disease Interaction terms | Community model:<br>• Cancer*Immune Disorders<br>• Congestive Heart Failure*Chronic Obstructive Pulmonary Disease<br>• Congestive Heart Failure*Renal Disease<br>• Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure<br>• Diabetes*Congestive Heart Failure<br>• Sepsis*Cardiorespiratory Failure<br><br>Institutional model:<br>• Artificial Openings for Feeding or Elimination*Pressure Ulcer<br>• Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer<br>• Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias<br>• Schizophrenia*Congestive Heart Failure<br>• Schizophrenia*Chronic Obstructive Pulmonary Disease<br>• Schizophrenia*Seizure Disorders and Convulsions<br>• Sepsis*Artificial Openings for Feeding or Elimination<br>• Sepsis*Aspiration and Specified Bacterial Pneumonias<br>• Sepsis*Pressure Ulcer Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer<br>• Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias<br>• Schizophrenia*Congestive Heart Failure<br>• Schizophrenia*Chronic Obstructive Pulmonary Disease<br>• Schizophrenia*Seizure Disorders and Convulsions<br>• Sepsis*Artificial Openings for Feeding or Elimination<br>• Sepsis*Aspiration and Specified Bacterial Pneumonias<br>• Sepsis*Pressure Ulcer | Community models – all segments:<br>• Cancer*Immune Disorders<br>• Congestive Heart Failure*Chronic Obstructive Pulmonary Disease<br>• Congestive Heart Failure*Renal Disease<br>• Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure<br>• Diabetes*Congestive Heart Failure<br>• Congestive Heart Failure*Specified Heart Arrhythmias<br><br>Community models – disabled segments only:<br>• Psych*Substance Abuse<br><br>Institutional model:<br><No changes> |

***Summary:***

Our analyses indicate that the revised CMS-HCC model would improve predictive performance for aged and disabled full benefit dual, partial benefit dual, and non-dual beneficiaries in the community. The updated model results in more appropriate relative weights for the HCCs because the relative weights reflect the disease and expenditure patterns of each of the six community segments. For PY2017, we propose to apply this revised model to payment to MAOs.

In light of comments submitted by PACE organizations, we have decided not to implement the revised model HCC model with six community dual segments for PACE organizations for 2017, but we will continue to study the feasibility and value of such a model for PACE for future payment years. We propose to continue to use the same risk adjustment model for PACE payments we have used from 2012 through 2016.

In Attachment V of this Notice, we provide draft relative factors for each HCC in each segment of the aged-disabled model. Table 1 in Attachment V provides the draft factors of the community and institutional segments of the CMS-HCC model. Table 2 provides the new enrollee risk scores. Table 3 provides the C-SNP new enrollee risk scores. Table 4 provides the hierarchies for the HCCs.

**Section I. Medicare Advantage Coding Pattern Adjustment**

For 2017, CMS proposes to update the MA coding adjustment factor to the statutory minimum of 5.66 percent. In order to properly pay health plans that enroll sicker-than-average beneficiaries, CMS adjusts payments to MAOs for the relative risk of their enrolled population. CMS uses claims data from FFS to estimate the risk adjustment model and applies this model to diagnostic data submitted by MAOs. While this approach is a significant improvement over previous risk adjustment methodologies (which relied largely on demographic data), it can result in higher payments for the same levels of risk when MAOs submit diagnoses more comprehensively than is done in FFS. The higher level of reported diagnoses can arise for a variety of reasons including plans seeking to better understand the health status of their enrollees so they can provide better care to plans reporting more diagnoses for enrollees to generate higher revenue. While the motivation behind the higher level of reported diagnoses can vary, the effect on the risk adjustment model is the same. That is, higher levels of diagnostic documentation generally lead to higher payments than would be the case if MAOs coded like FFS providers.

CMS has engaged in two bodies of work to correct for this. First, risk adjustment data validation, also known as RADV reviews diagnoses for a sample of enrollees at selected plans to identify diagnoses that are unsupported by the medical record.

Second, at the direction of Congress, each year CMS implements an across-the-board adjustment to offset the effects of higher levels of coding intensity in MA. For 2017, this statutorily-required offset will be 5.66 percent.

As enrollment in Medicare Advantage grows, the imperative for CMS to adjust payments appropriately in response to greater coding intensity will grow. MA coding has the potential to threaten the solvency of the Hospital Insurance (HI) trust fund and lead to higher part B premiums for all Medicare enrollees, not just Medicare Advantage enrollees. For example, a 1% increase in MA risk scores due to differential coding for 2017 would increase government payments to plans by about $2 billion. For this reason, CMS will continue to monitor coding intensity closely and will utilize its authority to increase the coding intensity offset as appropriate.

**Section J. Normalization Factors**

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

The normalization factor is derived by first using the risk model to be used in the payment year to calculate risk scores over a number of historical years. We then fit a trend line to the risk scores. For the 2016 payment year, CMS applied a quadratic functional form to the historical risk scores; this functional form better reflected more recent changes in the population trends. For the 2017 payment year, we propose to again use a quadratic functional form and to apply that functional form to the updated set of historical risk scores. We will use 2012 through 2015 risk scores to calculate the normalization factor for the CMS-HCC model, PACE model, ESRD Dialysis model, and Functioning Graft model. The preliminary normalization factors and annual trends for each of these models are shown below in J1 through J3.

We will use 2011 through 2014 risk scores to calculate the normalization factor for the RxHCC model; these factors and annual trends are shown in J4. The final normalization factors will be published in the final 2017 Announcement, to be released April 4, 2016.

The formula used to calculate each normalization factor is as follows:

$$\text{Factor} = b0 + (b1 \times Y) + (b2 \times Y^2), \text{ where } Y = \text{the year}$$

We provide the historical risk scores used to calculate each normalization factor in the sections below. Using this formula, the normalization factor is calculated as the projected average risk score for PY 2017.

### *J1. Normalization for the CMS-HCC Model*

The preliminary 2017 normalization factor for the model implemented in 2017 is: 0.993.

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

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

2012: 0.9806
2013: 0.9787
2014: 0.9822
2015: 0.9832

### *J2. Normalization Factor for the PACE Model*

The preliminary 2017 normalization factor for the CMS-HCC risk adjustment model used for the PACE program is 1.067.

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

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

2012: 1.0424
2013: 1.0426
2014: 1.0480
2015: 1.0516

### *J3. Normalization Factor for the ESRD Dialysis Model*

The preliminary 2017 normalization factor for the ESRD dialysis model is 1.017.

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

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

2012: 0.9722
2013: 0.9739
2014: 0.9808
2015: 0.9891

### *J4. Normalization Factor for Functioning Graft Model*

The preliminary 2017 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.067.

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

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

2012: 1.0424
2013: 1.0426
2014: 1.0480
2015: 1.0516

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

The preliminary 2017 normalization factor for the RxHCC model is 0.996. The normalization factor for the RxHCC model is applied to all Part D risk scores for beneficiaries enrolled in a Part D plan. The trend is calculated on the population of both FFS and MA beneficiaries.

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

2011: 0.9956
2012: 1.0018
2013: 0.9946
2014: 0.9999

## Section K. Frailty Adjustment for PACE organizations and FIDE SNPs

Section 1894(d)(2) of the Act requires CMS to take into account the frailty of the PACE population when making payments to PACE organizations, and Section 1853(a)(1)(B)(iv) 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 and is updated whenever the CMS-HCC model is updated. Since CMS is proposing an updated CMS-HCC model for 2017 MAOs, we have also updated the frailty factors for 2017 to be used to

determine frailty scores for FIDE SNPs. The frailty factors for PACE organizations will not change for PY 2017.

MAOs that are planning to sponsor a FIDE SNP, and that wish to receive frailty payments in 2017, must contract with a certified vendor to field the 2016 Health Outcomes Survey (HOS), or the 2016 Modified Health Outcomes Survey (HOS-M) at the PBP level. CMS uses activities of daily living (ADLs) obtained from the HOS survey or HOS-M survey, to calculate frailty scores. A FIDE SNP's frailty score will be compared with PACE frailty in the same manner as for PY 2016 to determine whether that FIDE SNP has a similar average level of frailty as PACE.

Table II-10 below presents the preliminary recalibrated frailty factors for CY 2017.

**Table II-10. FIDE SNP Frailty Factors for CY 2017**

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

**Section L. Medical Loss Ratio Credibility Adjustment**

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

In Section II.F of the preamble to the final rule, we published two tables of credibility factors: Table 1a—MLR Credibility Adjustments for MA–PD Contracts and Table 1b—Proposed MLR Credibility Adjustments for Part D Stand-Alone Contracts.

For CY 2017, we are not proposing any changes to the credibility adjustments published in the final rule.

**Section M. Encounter Data as a Diagnosis Source for 2017**

For PY 2016 CMS initiated the transition to Encounter Data based risk scores by blending the risk scores, weighting the risk score from Risk Adjustment Processing System (RAPS) and FFS by 90% and the risk score from the Encounter Data System (EDS) and FFS by 10%. For PY 2017, we propose to continue calculating risk scores by blending two risk scores calculated as follows: one risk score calculated using diagnoses with 2016 dates of service from the Risk Adjustment Processing System (RAPS) and FFS, and another separate risk score using diagnoses

with dates of service from 2016 from the Encounter Data System (EDS) and FFS. We propose to blend the two risk scores, weighting the risk score from RAPS and FFS by 50% and the risk score from EDS and FFS by 50%. CMS has been working with plans since 2012 to assist in the submissions of encounter data, and we will continue to do so. Our proposal for 2017 is a reasonable progression toward ultimately relying exclusively on encounter data for plan-submitted diagnosis information, particularly given that it will be the fifth year of the encounter data initiative.

For PACE organizations, we propose to continue the same method of calculating risk scores as used for the 2016 payment year, which is to pool diagnoses from the following sources to calculate a single risk score (with no weighting): (1) EDS data valid for risk adjustment with 2016 dates of service; (2) RAPS data valid for risk adjustment with 2016 dates of service; and (3) diagnoses from FFS claims valid for risk adjustment.

## Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2017

### Section A. Update of the RxHCC Model

For 2017, 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 2017 model will encompass the following changes:

1) Update to reflect the 2017 benefit structure; and,
2) Updates to the data years used to calibrate the model.

#### *A1. Update to reflect the 2017 benefit structure*

CMS recalibrated the RxHCC risk adjustment model to reflect the 2017 benefit structure. This update involved making adjustments to the Prescription Drug Event (PDE) data from the prediction year to approximate the 2017 benefit structure. The adjustments to the PDE data are similar to those made in previous years' model calibrations in that we incorporated the payment year plan liability in the coverage gap. For 2017, plan liability for non-LIS beneficiaries in the coverage gap will be 49 percent for non-applicable (generic) drugs and 10 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 model being used for PY 2016 is calibrated on 2012 diagnoses and 2013 expenditure data from the PDE records. As part of this recalibration for 2017, we updated the underlying data, using diagnosis data from 2013 fee-for-service (FFS) claims and MA-PD RAPS files, along with 2014 expenditure data from PDE records.

#### *A3. Chronic Viral Hepatitis C RxHCC*

Several medications to treat chronic Hepatitis C entered the market in 2013 and 2014. These newly approved medications have high cure rates and are substantially more costly than previously approved therapies. Due to the effectiveness of these new agents and the prevalence of chronic Hepatitis C, the cost of these medications is having a significant impact in Medicare Part D.

The PY 2016 RxHCC model was calibrated using diagnosis data from 2012 and expenditure data from 2013. Therefore, the estimated coefficient for the RxHCC for chronic Hepatitis C did not initially account for expenditures associated with treating patients with Hepatitis C with the new

medications. To capture the substantial cost of these medications that were expected in the payment year, CMS applied an actuarial adjustment to the coefficient of the new chronic Hepatitis C RxHCC. In the 2016 Advance Notice, CMS stated we would continue to monitor the patterns of diagnosis and expenditures of chronic Hepatitis C medications. In addition, we noted that the influx of these new medications in 2014 could result in an overestimated coefficient when we calibrated the PY 2017 RxHCC model using 2013-2014 data. As a result, we anticipated the need to apply a downward adjustment to the chronic Hepatitis C coefficient for the 2017 payment year.

As part of recalibration of the RxHCC model on more recent data (2013-2014), we reviewed patterns of chronic Hepatitis C medication utilization for beneficiaries with one of the chronic Hepatitis C diagnoses that map to the payment model. Based on the diagnosis data from 2013 and PDEs from 2006 through 2015, a small percentage of beneficiaries with the chronic Hepatitis C diagnosis received treatment for chronic Hepatitis C and a majority of treatment occurred in either 2014 or 2015. The projected coefficient for chronic Hepatitis C RxHCC reflects the costs of drug therapy in 2014 for beneficiaries with chronic Hepatitis C diagnosis in the payment model of 2013. The relative factor for PY 2017 is lower than the PY 2016 relative factor for several reasons, including: 1) the PY 2016 factor included an actuarial adjustment to the coefficient based on an estimation of what plan liability would have been (assuming 100% of beneficiaries were treated), had the recently approved chronic Hepatitis C medications existed in 2013, and 2) the PY 2017 factor reflects the actual percentage of beneficiaries treated for chronic Hepatitis C in 2014. The diagnosis and utilization data suggests continued uncertainty regarding the pattern of chronic Hepatitis C among Medicare beneficiaries and current expenditures continue to reflect the influx of these medications onto the market. As a result, CMS is proposing not to apply a downward adjustment to the coefficient for PY 2017.

Similar to other CMS-HCC risk adjustment models, the RxHCC model is prospective; in other words, we use historical data to predict future costs. Our objective using a prospective model is to identify chronic, predictable conditions, not acute events. Thus, the Part D risk adjustment model is not designed to predict the costs based on diseases that are primarily diagnosed, treated and cured in the same year. CMS recognizes that chronic Hepatitis C treatment over the next few years presents a unique situation. Given the clinical ramifications, as well as the continued uncertainty regarding the future pattern of diagnosis and utilization, CMS will continue to closely observe the pattern of the diagnosis and treatment of chronic Hepatitis C.

### *A4. Recalibration*

To recalibrate the model for payment year 2017, diagnoses from FFS and MA-PD beneficiaries enrolled in a Part D plan were used; 2013 diagnoses were used to predict 2014 expenditures. To be included in the model estimation sample, beneficiaries must be: (1) FFS or Medicare Advantage (MA-PD or MA-only) for all 12 months of the base year (2013); and (2) enrolled in a PDP or an MA-PD for at least one month in the payment year (2014).

Coefficients for condition categories were estimated by regressing the plan liability, adjusted as discussed above, for the Part D basic benefit for each beneficiary onto their demographic factors and condition categories, as indicated by their diagnoses. Resulting dollar coefficients represent the marginal (additional) cost of the condition or demographic factor (for example, age/sex group, low income subsidy status, disability status). Changes in the coefficients for each condition category are the result of the extent to which each category predicts plan liability for Medicare Part D benefits.

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 by using data from Medicare beneficiaries enrolled in both MA-PDs and PDPs. We do this in order to set the average RxHCC risk score to 1.0 for the enrolled Part D population. We used a denominator of average per capita cost for 2014 to create the relative factors for the model. The denominator, which is used to create relative factors for all segments of the model, is $1,014.31.

In a final step, hierarchies were imposed on the condition categories, ensuring that more advanced and costly forms of a condition are reflected in a higher coefficient.

When recalibrating a model based on more recent data, differences between the current model and the revised model will occur for several reasons. Changes in the marginal cost attributable to an RxHCC and relative to changes in the average cost can alter the relative factor associated with that RxHCC. Recalibration of the RxHCC model can result in changes in risk scores for individual beneficiaries and for plan average risk scores, depending on each individual beneficiary's combination of diagnoses.

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

**Section B. Encounter Data as a Diagnosis Source for 2017**

For PY 2016 CMS initiated the transition to Encounter Data based risk scores by blending the risk scores, weighting the risk score from Risk Adjustment Processing System (RAPS) and FFS by 90% and the risk score from the Encounter Data System (EDS) and FFS by 10%. For PY 2017, we propose to continue calculating risk scores by blending two risk scores calculated as follows: one risk score calculated using diagnoses with dates of service of 2016 from the Risk Adjustment Processing System (RAPS) and FFS and another separate risk score using diagnoses with 2016 dates of service from the Encounter Data System (EDS) and FFS. We will blend the two risk scores, weighting the risk score from RAPS and FFS by 50% and the risk score from

EDS and FFS by 50%. CMS has been working with plans since 2012 to assist in the submissions of encounter data, and we will continue to do so. We believe that our proposal for 2017 is a reasonable progression toward ultimately relying exclusively on encounter data for plan-submitted diagnosis information, particularly given that it will be the fifth year of the encounter data initiative.

For PACE organizations, we propose to continue the same method of calculating risk scores as used for the 2016 payment year, which is to pool diagnoses from the following sources to calculate a single risk score (with no weighting): (1) EDS data valid for risk adjustment with 2016 dates of service; (2) RAPS data valid for risk adjustment with 2016 dates of service; and (3) diagnoses from FFS claims valid for risk adjustment.

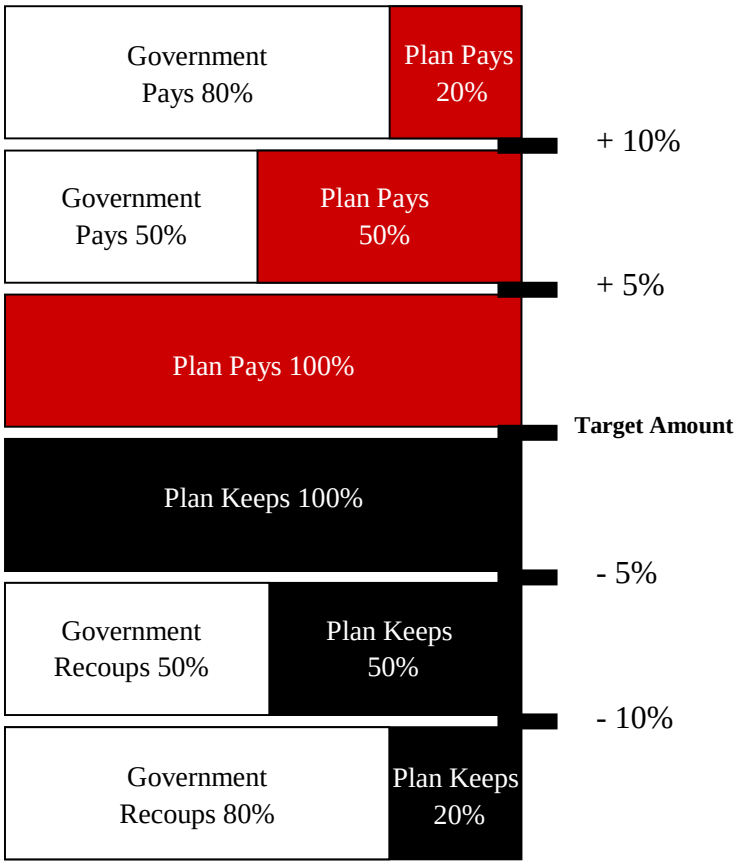
**Section C. Part D Risk Sharing**

The risk sharing payments provided by CMS limit Part D sponsors' exposure to unexpected drug expenses. Pursuant to section 1860D-15(e)(3)(C) of the Act and the regulations at 42 CFR 423.336 (a)(2)(ii), CMS may establish a risk corridor with higher threshold risk percentages for Part D risk sharing beginning in contract year 2012. Widening the risk corridor would increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS. While CMS may widen the risk corridors, the statute does not permit CMS to narrow the corridors relative to the 2011 thresholds.

CMS has evaluated the risk sharing amounts for 2007 – 2014 to assess whether they have decreased or stabilized. A steady decline or stabilization in the Part D risk sharing amounts would suggest that Part D sponsors have significantly improved their ability to predict Part D expenditures. However, CMS has found that risk sharing amounts continue to vary significantly in aggregate from year to year and among Part D sponsors in any given year. Therefore, we do not believe it is appropriate to adjust the parameters at this time, and we will apply no changes to the current threshold risk percentages for contract year 2017. We will continue to evaluate the risk sharing amounts each year to determine if wider corridors should be applied for Part D risk sharing.

Thus, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2016. The risk percentages for the first and second thresholds remain at 5 percent and 10 percent of the target amount, respectively, for 2017. The payment adjustments for the first and second corridors are 50 percent and 80 percent, respectively. Figure 1 below illustrates the risk corridors for 2017.

**Figure 1. Part D Risk Corridors for 2017**




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

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

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

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

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

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

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

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

## Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2017

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

- the deductible, initial coverage limit, and out-of-pocket threshold[11] 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

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

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

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

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

The benefit parameters indexed to the API will be increased by 11.75% for 2017, as summarized by Table III-1 below. This increase reflects the 2016 annual percentage trend of 6.99% as well as a multiplicative update of 4.45% 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 also indexed to the API. Thus, the cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 11.75% from their 2016 values.

### *D2. Annual Percentage Increase in Consumer Price Index*

Section 1860D-14(a)(4) of the Act requires CMS to use the annual percentage increase in the CPI for the 12 month period ending in September 2016 to update the maximum copayments up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal poverty line for 2017. These maximum copayments will be increased by 0.18% for 2017 as summarized in Table III-1 below.

This increase reflects the 2016 annual percentage trend in CPI of 1.67% as well as a multiplicative update of −1.46% for prior year revisions.

Additionally, section 1860D-2(b)(4) of the Act requires that the out-of-pocket threshold for contract years 2016 through 2019 be updated from the previous year by the lesser of (1) the API or (2) two percentage points plus the annual percentage increase in CPI. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The cumulative annual percentage increase in CPI for 2016 as of July 2016 is −0.15%. This figure reflects the 2016 annual percentage increase in CPI of 1.13% as well as a multiplicative update of −1.26% for prior year revisions. This value plus two percentage points is less than the 11.75% cumulative API described above. Thus, the out-of-pocket threshold will be increased by 1.85% for 2017.

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

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

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

- Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries. This is the amount of total drug spending for a non-applicable (i.e., LIS) beneficiary to reach the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement, this amount may be higher. This amount is calculated based on 100% cost sharing in the deductible and coverage gap phases and 25% in the initial coverage phase.

- Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries. This is an *estimate* of the average amount of total drug spending for an applicable (i.e., non-LIS) beneficiary to reach the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement, this amount may be higher. This amount is estimated based on 100% beneficiary cost sharing in the deductible phase, 25% in the initial coverage phase, and in the coverage gap, 51% cost sharing for non-applicable (generic) drugs and 90% for applicable (brand) drugs. Please see Attachment IV for additional information on the calculation of the estimated total covered Part D spending for applicable beneficiaries.

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

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

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

**Annual Percentage Increases**

| | Annual percentage trend for 2016 | Prior year revisions | Annual percentage increase for 2017 |
|---|---|---|---|
| API: Applied to all parameters but (1) and (2) | 6.99% | 4.45% | 11.75% |
| July CPI (all items, U.S. city average): Applied to (1) | 1.13% | −1.26% | −0.15% |
| September CPI (all items, U.S. city average): Applied to (2) | 1.67% | −1.46% | 0.18% |

**Part D Benefit Parameters**

| | 2016 | 2017 |
|---|---|---|
| **Standard Benefit** | | |
| Deductible | $360 | $400 |
| Initial Coverage Limit | $3,310 | $3,700 |
| Out-of-Pocket Threshold | $4,850 | $4,950 |
| Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3) | $7,062.50 | $7,425.00 |
| Estimated Total Covered Part D Spending for Applicable Beneficiaries (4) | $7,515.22 | $8,071.16 |
| Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit | | |
| Generic/Preferred Multi-Source Drug | $2.95 | $3.30 |
| Other | $7.40 | $8.25 |
| **Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (6)** | | |
| Deductible | $0.00 | $0.00 |
| Copayments for Institutionalized Beneficiaries (category code 3) | $0.00 | $0.00 |
| Copayments for Beneficiaries Receiving Home and Community-Based Services (5) (category code 3) | $0.00 | $0.00 |
| Maximum Copayments for Non-Institutionalized Beneficiaries | | |
| Up to or at 100% FPL (category code 2) | | |
| Up to Out-of-Pocket Threshold (1) | | |
| Generic/Preferred Multi-Source Drug (6) | $1.20 | $1.20 |
| Other (6) | $3.60 | $3.70 |
| Above Out-of-Pocket Threshold | $0.00 | $0.00 |
| Over 100% FPL (category code 1) | | |
| Up to Out-of-Pocket Threshold | | |
| Generic/Preferred Multi-Source Drug | $2.95 | $3.30 |
| Other | $7.40 | $8.25 |
| Above Out-of-Pocket Threshold | $0.00 | $0.00 |
| **Full Subsidy-Non-FBDE Individuals** | | |

| | 2016 | 2017 |
|---|---|---|
| Applied or eligible for QMB/SLMB/QI or SSI and income at or below 135% FPL and resources ≤ $8,780 (individuals) or ≤ $13,930 (couples) (7) (category code 1) | | |
| Deductible | $0.00 | $0.00 |
| Maximum Copayments up to Out-of-Pocket Threshold | | |
| Generic/Preferred Multi-Source Drug | $2.95 | $3.30 |
| Other | $7.40 | $8.25 |
| Maximum Copayments above Out-of-Pocket Threshold | $0.00 | $0.00 |
| **Partial Subsidy** | | |
| Applied and income below 150% FPL and resources below $13,640 (individual) or $27,250 (couples) (7) (category code 4) | | |
| Deductible (6) | $74.00 | $82.00 |
| Coinsurance up to Out-of-Pocket Threshold | 15% | 15% |
| Maximum Copayments above Out-of-Pocket Threshold | | |
| Generic/Preferred Multi-Source Drug | $2.95 | $3.30 |
| Other | $7.40 | $8.25 |
| **Retiree Drug Subsidy Amounts** | | |
| Cost Threshold | $360 | $400 |
| Cost Limit | $7,400 | $8,250 |

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

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

(3) For 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.

(4) 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.

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

(6) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2016 values of $73.79, $1.21, and $3.64, respectively.

(7) These resource limit figures will be updated for contract year 2017.

**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. This gradual reduction in cost sharing began in CY 2011 and continues through CY 2020, ultimately resulting in 75 percent cost sharing for applicable drugs, prior to the application of the 50 percent manufacturer discounts required by the ACA, and 25% cost sharing for other covered Part D drugs (non-applicable drugs). Applicable drugs are defined at section 1860D-14A(g)(2) of the Act and are generally covered Part D brand drugs that are either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic, licensed under section 351 of the Public Health Service Act (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 2017, the beneficiary coinsurance under basic prescription drug coverage is reduced to 51 percent for *non-applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit. After having applied the 50 percent manufacturer discount, the beneficiary coinsurance under basic prescription drug coverage is reduced to 40 percent for *applicable* covered Part D drugs purchased during the coverage gap phase of the Part D benefit in 2017.

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

As beneficiary liability for covered Part D drug costs in the coverage gap decreases, plan liability increases. Therefore, we further specify that the increased plan liability amounts do not count toward TrOOP. Part D sponsors must account for the reductions in cost sharing and increased plan liability when developing their Part D bids for payment year 2017.

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

As described in the previous section, 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. Consistent with our policy on liability for dispensing and vaccine administration fees, as described in the Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, applicable beneficiaries will pay a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance in the coverage gap. The Part D sponsor will pay the remainder of the dispensing fee (and vaccine administration fee, if any). In 2017, applicable

beneficiaries will pay 40 percent and plans will pay 60 percent of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap.

**Section G. Part D Calendar Year Employer Group Waiver Plans**

For the first two years Part D was in effect, Calendar Year Employer Group Waiver Plans (CY EGWPs) submitted bids for Part D coverage to CMS. In early 2007, CMS decided to waive the Part D bid submission requirement for EGWPs beginning with payment year (PY) 2008[12]. CMS modified several payment methodologies and operations to accommodate bids not being submitted as a result of the waiver. For EGWPs offering Part D[13], the payment methodology was changed as follows: (1) monthly Part D risk adjusted direct subsidy payments are based on the Part D national average bid[14]; (2) monthly low-income premium subsidy (LIPS) payments are based on the national Base Beneficiary Premium[15]; (3) reinsurance payments are paid retrospectively during reconciliation with no prospective amounts paid monthly[16]; (4) LICS payment amounts are paid retrospectively during reconciliation with no prospective amounts paid monthly[17]; and (5) risk sharing payments are not available[18].

The rationale articulated for the bid waiver was that waiving the requirement to submit Part D bids would increase the number of plans for employers and unions seeking to retain coverage for their Medicare eligible retirees by avoiding the cost and administrative burden of submitting bids. At that time, CMS also believed that reinsurance payments to EGWP sponsors would continue to be relatively small since most employers/unions would be providing enhanced drug coverage through supplemental arrangements, resulting in the majority of these beneficiaries not reaching catastrophic benefit phase. The determination to pay reinsurance retrospectively was due in part to the fact that EGWPs were no longer able to provide an estimate of their per capita reinsurance costs in the course of bidding, which is what CMS uses to provide non-EGWP Part D sponsors with monthly prospective reinsurance payments throughout a payment year.

With the recent trend in specialty drug costs, however, catastrophic drug costs for EGWP sponsors have increased significantly and will likely continue to do so in the future. In light of the concerns about catastrophic costs and their impact on EGWPs in the Part D program, we

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[12] 42 CFR 423.265(b) (Requirement to submit a bid) waived

[13] These are the rules that apply to CY EGWPs – non-CY EGWPs do not receive reinsurance payments at all.

[14] 42 CFR 423.329(a)(1) (Basis of the risk adjusted direct subsidy) waiver to modify rule

[15] 42 CFR 423.800(b) (Administration of low-income premium subsidy (LIPS) payments) waiver to modify rule

[16] 42 CFR 423.329(c) (Catastrophic reinsurance payment methodology) waiver to modify rule

[17] 42 CFR 423.329(d)(2)(i) (Prospective LIS cost-sharing payments) waiver to modify rule

[18] 42 CFR 423.336 (Risk corridor payments) waived

propose a modification of the current waiver. Under the modified waiver, beginning in 2017 we would pay prospective reinsurance to CY EGWPs based on a CMS calculated methodology.

CMS has authority under Sections 1857(i) and 1866D-22(b) of the Social Security Act to waive or modify requirements that hinder the design of, the offering of, or enrollment in Part D plans that combine the Part D benefit with supplemental drug coverage offered by an employer. EGWP plans are either administered by insurance companies ("800-series EGWPs") or by employers or unions (Direct Contract EGWPs). Current regulations detailing the manner by which plans are to be paid reinsurance, are "based on a method that CMS determines" and for prospective payments made during the coverage year, CMS is to "establish a payment method by which payments of amounts under this section are made on a monthly basis during the year based on either estimated or incurred allowable reinsurance costs" per 42 CFR 423.329(c).

For 2017, CMS is proposing to make prospective reinsurance payments to all CY EGWPs based on the average per member per month (PMPM) actual reinsurance amounts paid to CY EGWPs for 2014. The 2014 reconciliation data is the most current actual total reinsurance amount available for publication in the 2017 Advance Notice/Rate Announcement. CMS is proposing this methodology as it is based on the most currently available actual CY EGWP experience. The average PMPM reinsurance amount paid to CY EGWPs for 2014 reconciliation was $26.50. This proposal will apply to all CY EGWPs. CMS is not proposing to change the current policy of not paying reinsurance payments to non-calendar year EGWPs. CMS seeks comments on this proposal.

## Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2017

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, 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 2017, and (3) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

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

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

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.

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

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

**Deductible:** From $360 in 2016 and rounded to the nearest multiple of $5.

**Initial Coverage Limit:** From $3,310 in 2016 and rounded to the nearest multiple of $10.

**Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit:** From $2.95 per generic or preferred drug that is a multi-source drug, and $7.40 for all other drugs in 2016, and rounded to the nearest multiple of $0.05.

**Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low Income Full Subsidy Eligible Enrollees:** From $2.95 per generic or preferred drug that is a multi-source drug, and $7.40 for all other drugs in 2016, and rounded to the nearest multiple of $0.05.

**Deductible for Low Income (Partial) Subsidy Eligible Enrollees:** From $74[19] in 2016 and rounded to the nearest $1.

**Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees:** From $2.95 per generic or preferred drug that is a multi-source drug, and $7.40 for all other drugs in 2016, and rounded to the nearest multiple of $0.05.

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

Section 1860D-14(a)(4) of the Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal poverty line. These copayments are increased from $1.20 per generic or preferred drug that is a multi-source drug, and $3.60 for all other drugs in 2016[20], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

Additionally, section 1860D-2(b)(4) of the Act requires that the "annual percentage increase" applied to the out-of-pocket threshold in 2017 is CPI+2%, which is the lesser of API and CPI+2%. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The threshold is increased from $4,850 in 2016 and rounded to the nearest multiple of $50.

**Section C. Calculation Methodology**

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

For contract years 2007 and 2008, the APIs, as defined in section 1860D-2(b)(6) of the Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with contract year 2009, the APIs

[19] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2016 value of $73.79.

[20] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2016 values of $1.21per generic or preferred drug that is a multi-source drug, and $3.64 for all other drugs.

are based on Part D program data. For the 2017 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2015–July\ 2016}{August\ 2014–July\ 2015} = \frac{\$3{,}615.90}{\$3{,}379.72} = 1.0699$$

In the formula, the average per capita cost for August 2014 – July 2015 ($3,379.72) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2015 – July 2016 ($3,615.90) is calculated based on actual Part D PDE data incurred from August 2015 – December 2015 and projected through July 2016.

The 2017 benefit parameters reflect the 2016 annual percentage trend as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table IV-1.

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

| Year | Prior Estimates of Annual Percentage Increases | Revised Annual Percentage Increases |
|---|---|---|
| **2007** | **7.30%** | **7.30%** |
| **2008** | **5.92%** | **5.92%** |
| **2009** | **4.17%** | **4.69%** |
| **2010** | **3.07%** | **3.14%** |
| **2011** | **2.48%** | **2.36%** |
| **2012** | **2.45%** | **2.16%** |
| **2013** | **1.95%** | **2.53%** |
| **2014** | **−2.72%** | **−3.13%** |
| **2015** | **9.18%** | **10.03%** |
| **2016** | **6.37%** | **9.91%** |

Accordingly, the 2017 benefit parameters reflect a multiplicative update of 4.45 percent for prior year revisions. In summary, the 2016 parameters outlined in Section A are updated by 11.75 percent for 2017, as summarized by Table IV-2.

**Table IV-2. Annual Percentage Increase**

| | |
|---|---|
| Annual percentage trend for July 2016 | 6.99% |
| Prior year revisions | 4.45% |
| Annual percentage increase for 2017 | 11.75% |

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

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

To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in September 2016 includes an estimate of the September 2016 CPI based on projections from the President's FY2017 Budget.

The September 2015 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2017 is calculated as follows:

$$\frac{\text{Projected September 2016 CPI}}{\text{Actual September 2015 CPI}} \; or \; \frac{241.918}{237.945} = 1.0167$$

(Source: President's FY2017 Budget and Bureau of Labor Statistics, Department of Labor)

The 2017 benefit parameters reflect the 2016 annual percentage trend in the September CPI of 1.67 percent, as well as a revision to the prior estimate for the 2015 CPI increase over the 12 month period ending in September 2015. Based on the actual reported CPI for September 2015, the September 2015 CPI increase is now estimated to be −0.04 percent. Accordingly, the 2017 update reflects a −1.46 percent multiplicative correction for the revision to last year's estimate. In summary, the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal poverty line are updated by 0.18 percent for 2017, as summarized by Table IV-3.

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

| | |
|---|---|
| Annual percentage trend for September 2016 | 1.67% |
| Prior year revisions | −1.46% |
| Annual percentage increase for 2017 | 0.18% |

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

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

As is the case when calculating the annual CPI trend as of September 2016, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in July 2016 includes an estimate of the July 2016 CPI based on projections from the President's FY2017 Budget.

The July 2015 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2017 is calculated as follows:

$$\frac{\text{Projected July 2016 CPI}}{\text{Actual July 2015 CPI}} \; or \; \frac{241.344}{238.654} = 1.0113$$

(Source: President's FY2017 Budget and Bureau of Labor Statistics, Department of Labor)

The 2017 benefit parameters reflect the 2016 annual percentage trend in the July CPI of 1.13 percent as well as a revision to the prior estimate for the 2015 CPI increase. Based on the actual reported CPI for July 2015, the CPI increase over the 12 month period ending in July 2015 is estimated to be 0.17 percent. The prior year revision here reflects the difference between this actual 0.17 percent increase in CPI observed in July 2015 and the 2015 CPI increase estimate from the CY 2016 Rate Announcement, which erroneously used September instead of July CPI values. Accordingly, the 2017 update reflects a -1.26 percent multiplicative correction for the revision to last year's estimate.

In summary, the cumulative annual percentage increase in July CPI for 2017 is -0.15 percent, as summarized by Table IV-4. This value plus two percentage points is less than the 11.75 percent cumulative API for 2017 described above. Thus, the out-of-pocket threshold will be increased by 1.85 percent for 2017.

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

| | |
|---|---|
| Annual percentage trend for July 2016 | 1.13% |
| Prior year revisions | −1.26% |
| Annual percentage increase for 2017 | −0.15% |

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

**Section D. Retiree Drug Subsidy Amounts**

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are also updated using the API, as defined previously in this document. The updated cost threshold is rounded the nearest multiple of $5 and the updated cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $320 and $6,600,

respectively, for plans that end in 2015, and, as $360 and $7,400, respectively, for plans that end in 2016. For 2017, the cost threshold is $400 and the cost limit is $8,250.

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

For 2017, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $8,071.16. The figure is calculated given the following basic assumptions:

- 100 percent beneficiary cost sharing in the deductible phase.
- 25 percent beneficiary cost sharing in the initial coverage phase and in the coverage gap.
- 51 percent beneficiary cost sharing for non-applicable (generic) drugs purchased in the coverage gap phase of the benefit.
- 90 percent cost sharing for the ingredient cost and sales tax for applicable (brand) drugs purchased in the coverage gap phase of the benefit – 40 percent beneficiary coinsurance and 50 percent coverage gap discount program discount.
- 40 percent cost sharing for the dispensing and vaccine administration fees for applicable (brand) drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is also assumed that the dispensing and vaccine administration fees account for 0.11 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 60 percent reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.05 percent to 89.95 percent in cost sharing for applicable (brand) drugs in the coverage gap.

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

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad or \quad 3{,}700 + \frac{\$3{,}725.00}{85.218\%} = \$8{,}071.16$$

- ICL is the Initial Coverage Limit equal to $3,700

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

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

  OOP threshold − OOP costs up to the ICL *or* $4,950 − $1,225.00 = $3,725.00

- Weighted gap coinsurance factor is calculated as follows:

  (Brand GDCB % for non-LIS × 89.95% gap cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 51% gap cost sharing for non-applicable drugs)

*or*

(87.9% × 89.95%) + (12.1% × 51%) = 85.218%

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries (i.e., non-LIS) attributable to applicable (brand) drugs, as reported on the 2015 PDEs.

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

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

  *or*

  89.95% = [(99.89% × 90%) + (0.11% × 40%)]

Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries (i.e., non-LIS) attributable to non-applicable (generic) drugs as reported on the 2015 PDEs.

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

**Attachment V. CMS-HCC and RxHCC Risk Adjustment Factors**

## Table 1. 2017 CMS-HCC Model Relative Factors for Community and Institutional Beneficiaries

| Variable | Description Label | Community, NonDual, Aged | Community, NonDual, Disabled | Community, FBDual, Aged | Community, FBDual, Disabled | Community, PBDual, Aged | Community, PBDual, Disabled | Institutional |
|---|---|---|---|---|---|---|---|---|
| **Female** | | | | | | | | |
| 0-34 Years | | – | 0.240 | – | 0.312 | – | 0.338 | 1.013 |
| 35-44 Years | | – | 0.298 | – | 0.300 | – | 0.377 | 0.982 |
| 45-54 Years | | – | 0.317 | – | 0.332 | – | 0.367 | 0.989 |
| 55-59 Years | | – | 0.344 | – | 0.381 | – | 0.364 | 0.968 |
| 60-64 Years | | – | 0.403 | – | 0.441 | – | 0.388 | 1.010 |
| 65-69 Years | | 0.306 | – | 0.417 | – | 0.335 | – | 1.178 |
| 70-74 Years | | 0.368 | – | 0.501 | – | 0.399 | – | 1.072 |
| 75-79 Years | | 0.440 | – | 0.600 | – | 0.475 | – | 0.977 |
| 80-84 Years | | 0.528 | – | 0.726 | – | 0.542 | – | 0.845 |
| 85-89 Years | | 0.652 | – | 0.901 | – | 0.666 | – | 0.736 |
| 90-94 Years | | 0.783 | – | 1.019 | – | 0.803 | – | 0.614 |
| 95 Years or Over | | 0.802 | – | 1.075 | – | 0.897 | – | 0.448 |
| **Male** | | | | | | | | |
| 0-34 Years | | – | 0.152 | – | 0.221 | – | 0.324 | 1.030 |
| 35-44 Years | | – | 0.187 | – | 0.200 | – | 0.262 | 1.055 |
| 45-54 Years | | – | 0.217 | – | 0.276 | – | 0.294 | 0.990 |
| 55-59 Years | | – | 0.266 | – | 0.365 | – | 0.301 | 1.036 |
| 60-64 Years | | – | 0.298 | – | 0.477 | – | 0.337 | 1.021 |
| 65-69 Years | | 0.295 | – | 0.483 | – | 0.328 | – | 1.247 |
| 70-74 Years | | 0.373 | – | 0.571 | – | 0.402 | – | 1.299 |
| 75-79 Years | | 0.458 | – | 0.679 | – | 0.482 | – | 1.308 |
| 80-84 Years | | 0.551 | – | 0.802 | – | 0.536 | – | 1.168 |
| 85-89 Years | | 0.682 | – | 0.991 | – | 0.667 | – | 1.109 |
| 90-94 Years | | 0.842 | – | 1.165 | – | 0.808 | – | 0.947 |
| 95 Years or Over | | 0.959 | – | 1.245 | – | 1.020 | – | 0.767 |

| Variable | Description Label | Community, NonDual, Aged | Community, NonDual, Disabled | Community, FBDual, Aged | Community, FBDual, Disabled | Community, PBDual, Aged | Community, PBDual, Disabled | Institutional |
|---|---|---|---|---|---|---|---|---|
| **Medicaid and Originally Disabled Interactions** | | | | | | | | |
| Medicaid | | - | - | - | - | - | - | 0.061 |
| Originally Disabled, Female | | 0.240 | - | 0.169 | - | 0.124 | - | - |
| Originally Disabled, Male | | 0.150 | - | 0.189 | - | 0.103 | - | - |
| **Disease Coefficients** | **Description Label** | | | | | | | |
| HCC1 | HIV/AIDS | 0.306 | 0.283 | 0.574 | 0.491 | 0.541 | 0.228 | 1.716 |
| HCC2 | Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock | 0.447 | 0.522 | 0.585 | 0.797 | 0.402 | 0.410 | 0.340 |
| HCC6 | Opportunistic Infections | 0.428 | 0.691 | 0.538 | 0.903 | 0.473 | 0.751 | 0.570 |
| HCC8 | Metastatic Cancer and Acute Leukemia | 2.579 | 2.598 | 2.497 | 2.718 | 2.399 | 2.536 | 1.123 |
| HCC9 | Lung and Other Severe Cancers | 0.953 | 0.910 | 0.956 | 1.007 | 0.938 | 0.863 | 0.714 |
| HCC10 | Lymphoma and Other Cancers | 0.665 | 0.644 | 0.700 | 0.747 | 0.656 | 0.566 | 0.394 |
| HCC11 | Colorectal, Bladder, and Other Cancers | 0.296 | 0.346 | 0.326 | 0.355 | 0.320 | 0.392 | 0.288 |
| HCC12 | Breast, Prostate, and Other Cancers and Tumors | 0.143 | 0.199 | 0.156 | 0.187 | 0.150 | 0.179 | 0.195 |
| HCC17 | Diabetes with Acute Complications | 0.312 | 0.365 | 0.339 | 0.423 | 0.348 | 0.416 | 0.433 |
| HCC18 | Diabetes with Chronic Complications | 0.312 | 0.365 | 0.339 | 0.423 | 0.348 | 0.416 | 0.433 |
| HCC19 | Diabetes without Complication | 0.102 | 0.126 | 0.096 | 0.157 | 0.096 | 0.134 | 0.157 |
| HCC21 | Protein-Calorie Malnutrition | 0.536 | 0.740 | 0.739 | 0.830 | 0.552 | 0.697 | 0.256 |
| HCC22 | Morbid Obesity | 0.268 | 0.223 | 0.403 | 0.366 | 0.240 | 0.238 | 0.502 |
| HCC23 | Other Significant Endocrine and Metabolic Disorders | 0.224 | 0.436 | 0.224 | 0.347 | 0.190 | 0.345 | 0.331 |
| HCC27 | End-Stage Liver Disease | 0.945 | 1.090 | 1.220 | 1.325 | 0.873 | 0.946 | 0.945 |
| HCC28 | Cirrhosis of Liver | 0.383 | 0.387 | 0.336 | 0.483 | 0.452 | 0.319 | 0.383 |
| HCC29 | Chronic Hepatitis | 0.162 | 0.262 | 0.037 | 0.393 | 0.258 | 0.319 | 0.383 |
| HCC33 | Intestinal Obstruction/Perforation | 0.242 | 0.515 | 0.362 | 0.495 | 0.318 | 0.501 | 0.329 |
| HCC34 | Chronic Pancreatitis | 0.271 | 0.666 | 0.327 | 0.859 | 0.405 | 0.834 | 0.237 |
| HCC35 | Inflammatory Bowel Disease | 0.289 | 0.475 | 0.328 | 0.602 | 0.205 | 0.487 | 0.240 |

| Variable | Description Label | Community, NonDual, Aged | Community, NonDual, Disabled | Community, FBDual, Aged | Community, FBDual, Disabled | Community, PBDual, Aged | Community, PBDual, Disabled | Institutional |
|---|---|---|---|---|---|---|---|---|
| HCC39 | Bone/Joint/Muscle Infections/Necrosis | 0.418 | 0.466 | 0.542 | 0.701 | 0.411 | 0.483 | 0.339 |
| HCC40 | Rheumatoid Arthritis and Inflammatory Connective Tissue Disease | 0.416 | 0.370 | 0.364 | 0.339 | 0.383 | 0.285 | 0.323 |
| HCC46 | Severe Hematological Disorders | 1.363 | 3.131 | 1.197 | 4.181 | 1.204 | 3.466 | 0.668 |
| HCC47 | Disorders of Immunity | 0.614 | 0.833 | 0.520 | 0.579 | 0.441 | 0.677 | 0.519 |
| HCC48 | Coagulation Defects and Other Specified Hematological Disorders | 0.217 | 0.333 | 0.263 | 0.371 | 0.221 | 0.375 | 0.149 |
| HCC54 | Drug/Alcohol Psychosis | 0.377 | 0.559 | 0.694 | 0.902 | 0.381 | 0.602 | 0.100 |
| HCC55 | Drug/Alcohol Dependence | 0.377 | 0.280 | 0.513 | 0.360 | 0.370 | 0.281 | 0.100 |
| HCC57 | Schizophrenia | 0.597 | 0.388 | 0.601 | 0.424 | 0.537 | 0.360 | 0.266 |
| HCC58 | Major Depressive, Bipolar, and Paranoid Disorders | 0.388 | 0.205 | 0.437 | 0.175 | 0.405 | 0.161 | 0.266 |
| HCC70 | Quadriplegia | 1.291 | 1.034 | 1.079 | 1.038 | 1.252 | 1.304 | 0.488 |
| HCC71 | Paraplegia | 0.989 | 0.691 | 0.904 | 1.001 | 0.941 | 0.892 | 0.458 |
| HCC72 | Spinal Cord Disorders/Injuries | 0.518 | 0.448 | 0.543 | 0.400 | 0.546 | 0.377 | 0.225 |
| HCC73 | Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease | 0.953 | 1.062 | 1.209 | 1.197 | 0.560 | 0.800 | 0.220 |
| HCC74 | Cerebral Palsy | 0.275 | 0.130 | - | - | 0.155 | 0.051 | - |
| HCC75 | Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy | 0.449 | 0.518 | 0.428 | 0.457 | 0.358 | 0.325 | 0.362 |
| HCC76 | Muscular Dystrophy | 0.496 | 0.449 | 0.543 | 0.503 | 0.421 | 0.165 | 0.102 |
| HCC77 | Multiple Sclerosis | 0.434 | 0.531 | 0.675 | 0.780 | 0.400 | 0.451 | - |
| HCC78 | Parkinson's and Huntington's Diseases | 0.662 | 0.574 | 0.737 | 0.507 | 0.618 | 0.387 | 0.143 |
| HCC79 | Seizure Disorders and Convulsions | 0.303 | 0.223 | 0.351 | 0.192 | 0.342 | 0.241 | 0.086 |
| HCC80 | Coma, Brain Compression/Anoxic Damage | 0.574 | 0.296 | 0.929 | 0.318 | 0.499 | 0.152 | 0.041 |
| HCC82 | Respirator Dependence/Tracheostomy Status | 1.036 | 1.006 | 2.263 | 1.547 | 0.898 | 0.664 | 1.602 |
| HCC83 | Respiratory Arrest | 0.646 | 0.767 | 1.014 | 0.475 | 0.691 | 0.421 | 0.714 |

| Variable | Description Label | Community, NonDual, Aged | Community, NonDual, Disabled | Community, FBDual, Aged | Community, FBDual, Disabled | Community, PBDual, Aged | Community, PBDual, Disabled | Institutional |
|---|---|---|---|---|---|---|---|---|
| HCC84 | Cardio-Respiratory Failure and Shock | 0.296 | 0.568 | 0.462 | 0.475 | 0.296 | 0.421 | 0.292 |
| HCC85 | Congestive Heart Failure | 0.317 | 0.405 | 0.349 | 0.408 | 0.315 | 0.360 | 0.187 |
| HCC86 | Acute Myocardial Infarction | 0.229 | 0.300 | 0.465 | 0.607 | 0.275 | 0.431 | 0.489 |
| HCC87 | Unstable Angina and Other Acute Ischemic Heart Disease | 0.214 | 0.300 | 0.330 | 0.607 | 0.275 | 0.431 | 0.489 |
| HCC88 | Angina Pectoris | 0.138 | 0.119 | 0.067 | 0.201 | 0.172 | 0.216 | 0.489 |
| HCC96 | Specified Heart Arrhythmias | 0.264 | 0.279 | 0.362 | 0.370 | 0.278 | 0.254 | 0.220 |
| HCC99 | Cerebral Hemorrhage | 0.259 | 0.277 | 0.466 | 0.678 | 0.273 | 0.275 | 0.112 |
| HCC100 | Ischemic or Unspecified Stroke | 0.259 | 0.191 | 0.466 | 0.351 | 0.266 | 0.228 | 0.112 |
| HCC103 | Hemiplegia/Hemiparesis | 0.529 | 0.319 | 0.538 | 0.427 | 0.592 | 0.394 | 0.031 |
| HCC104 | Monoplegia, Other Paralytic Syndromes | 0.388 | 0.254 | 0.367 | 0.375 | 0.549 | 0.394 | 0.031 |
| HCC106 | Atherosclerosis of the Extremities with Ulceration or Gangrene | 1.435 | 1.479 | 1.713 | 1.710 | 1.427 | 1.573 | 0.868 |
| HCC107 | Vascular Disease with Complications | 0.393 | 0.477 | 0.530 | 0.742 | 0.436 | 0.539 | 0.315 |
| HCC108 | Vascular Disease | 0.293 | 0.327 | 0.318 | 0.314 | 0.310 | 0.320 | 0.092 |
| HCC110 | Cystic Fibrosis | 0.609 | 2.493 | 0.967 | 3.305 | 0.351 | 2.811 | 0.299 |
| HCC111 | Chronic Obstructive Pulmonary Disease | 0.322 | 0.257 | 0.414 | 0.348 | 0.351 | 0.287 | 0.299 |
| HCC112 | Fibrosis of Lung and Other Chronic Lung Disorders | 0.206 | 0.257 | 0.132 | 0.317 | 0.169 | 0.171 | 0.056 |
| HCC114 | Aspiration and Specified Bacterial Pneumonias | 0.589 | 0.521 | 0.694 | 0.482 | 0.654 | 0.366 | 0.066 |
| HCC115 | Pneumococcal Pneumonia, Empyema, Lung Abscess | 0.217 | 0.126 | 0.159 | 0.048 | 0.297 | 0.216 | 0.066 |
| HCC122 | Proliferative Diabetic Retinopathy and Vitreous Hemorrhage | 0.213 | 0.168 | 0.219 | 0.279 | 0.272 | 0.191 | 0.452 |
| HCC124 | Exudative Macular Degeneration | 0.490 | 0.378 | 0.273 | 0.088 | 0.330 | 0.112 | 0.224 |
| HCC134 | Dialysis Status | 0.415 | 0.491 | 0.660 | 0.626 | 0.428 | 0.503 | 0.454 |
| HCC135 | Acute Renal Failure | 0.415 | 0.491 | 0.660 | 0.626 | 0.428 | 0.503 | 0.454 |
| HCC136 | Chronic Kidney Disease, Stage 5 | 0.233 | 0.139 | 0.240 | 0.164 | 0.181 | 0.144 | 0.428 |
| HCC137 | Chronic Kidney Disease, Severe (Stage 4) | 0.233 | 0.139 | 0.240 | 0.078 | 0.181 | 0.034 | 0.198 |

| Variable | Description Label | Community, NonDual, Aged | Community, NonDual, Disabled | Community, FBDual, Aged | Community, FBDual, Disabled | Community, PBDual, Aged | Community, PBDual, Disabled | Institutional |
|---|---|---|---|---|---|---|---|---|
| HCC157 | Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone | 2.125 | 2.164 | 2.828 | 2.579 | 2.233 | 2.608 | 0.908 |
| HCC158 | Pressure Ulcer of Skin with Full Thickness Skin Loss | 1.183 | 1.369 | 1.548 | 1.531 | 1.055 | 1.215 | 0.290 |
| HCC161 | Chronic Ulcer of Skin, Except Pressure | 0.525 | 0.625 | 0.744 | 0.620 | 0.575 | 0.609 | 0.288 |
| HCC162 | Severe Skin Burn or Condition | 0.315 | 0.342 | 0.003 | 0.527 | 0.516 | 0.117 | 0.074 |
| HCC166 | Severe Head Injury | 0.574 | 0.296 | 0.929 | 0.318 | 1.046 | 0.152 | 0.041 |
| HCC167 | Major Head Injury | 0.188 | 0.044 | 0.269 | 0.168 | 0.131 | 0.048 | - |
| HCC169 | Vertebral Fractures without Spinal Cord Injury | 0.486 | 0.448 | 0.543 | 0.400 | 0.507 | 0.377 | 0.206 |
| HCC170 | Hip Fracture/Dislocation | 0.410 | 0.504 | 0.511 | 0.656 | 0.376 | 0.475 | - |
| HCC173 | Traumatic Amputations and Complications | 0.261 | 0.334 | 0.405 | 0.377 | 0.229 | 0.228 | 0.263 |
| HCC176 | Complications of Specified Implanted Device or Graft | 0.587 | 0.856 | 0.708 | 1.136 | 0.573 | 0.860 | 0.493 |
| HCC186 | Major Organ Transplant or Replacement Status | 0.982 | 0.607 | 0.802 | 1.056 | 0.781 | 0.644 | 0.945 |
| HCC188 | Artificial Openings for Feeding or Elimination | 0.561 | 0.771 | 0.762 | 0.855 | 0.569 | 0.852 | 0.491 |
| HCC189 | Amputation Status, Lower Limb/Amputation Complications | 0.578 | 0.447 | 0.773 | 1.046 | 0.724 | 0.684 | 0.400 |
| **Disease Interactions** | | | | | | | | |
| HCC47_gCancer | Immune Disorders*Cancer | 0.877 | 0.663 | 0.801 | 0.640 | 0.763 | 0.794 | - |
| HCC85_gDiabetesMellit | Congestive Heart Failure*Diabetes | 0.151 | 0.094 | 0.201 | 0.157 | 0.175 | 0.137 | 0.151 |
| HCC85_gCopdCF | Congestive Heart Failure*Chronic Obstructive Pulmonary Disease | 0.186 | 0.171 | 0.235 | 0.213 | 0.183 | 0.178 | 0.161 |
| HCC85_gRenal | Congestive Heart Failure*Renal | 0.266 | 0.484 | 0.267 | 0.699 | 0.294 | 0.598 | - |
| gRespDepandArre_gCopdCF | Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease | 0.330 | 0.251 | 0.554 | 0.515 | 0.452 | 0.441 | 0.416 |

| Variable | Description Label | Community, NonDual, Aged | Community, NonDual, Disabled | Community, FBDual, Aged | Community, FBDual, Disabled | Community, PBDual, Aged | Community, PBDual, Disabled | Institutional |
|---|---|---|---|---|---|---|---|---|
| HCC85_HCC96 | Congestive Heart Failure*Specified Heart Arrhythmias | 0.103 | 0.280 | 0.196 | 0.398 | 0.114 | 0.313 | - |
| gSubstanceAbuse_gPsychiatric | Substance Abuse*Psychiatric | - | 0.187 | - | 0.229 | - | 0.226 | - |
| SEPSIS_PRESSURE_ULCER | Sepsis*Pressure Ulcer | - | - | - | - | - | - | 0.248 |
| SEPSIS_ARTIF_OPENINGS | Sepsis*Artificial Openings for Feeding or Elimination | - | - | - | - | - | - | 0.558 |
| ART_OPENINGS_PRESSURE_ULCER | Artificial Openings for Feeding or Elimination*Pressure Ulcer | - | - | - | - | - | - | 0.325 |
| gCopdCF_ASP_SPEC_BACT_PNEUM | Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias | - | - | - | - | - | - | 0.249 |
| ASP_SPEC_BACT_PNEUM_PRES_ULC | Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer | - | - | - | - | - | - | 0.360 |
| SEPSIS_ASP_SPEC_BACT_PNEUM | Sepsis*Aspiration and Specified Bacterial Pneumonias | - | - | - | - | - | - | 0.316 |
| SCHIZOPHRENIA_gCopdCF | Schizophrenia*Chronic Obstructive Pulmonary Disease | - | - | - | - | - | - | 0.357 |
| SCHIZOPHRENIA_CHF | Schizophrenia*Congestive Heart Failure | - | - | - | - | - | - | 0.170 |
| SCHIZOPHRENIA_SEIZURES | Schizophrenia*Seizure Disorders and Convulsions | - | - | - | - | - | - | 0.475 |
| **Disabled/Disease Interactions** | | | | | | | | |
| DISABLED_HCC85 | Disabled, Congestive Heart Failure | - | - | - | - | - | - | 0.315 |
| DISABLED_PRESSURE_ULCER | Disabled, Pressure Ulcer | - | - | - | - | - | - | 0.597 |
| DISABLED_HCC161 | Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer | - | - | - | - | - | - | 0.362 |
| DISABLED_HCC39 | Disabled, Bone/Joint Muscle Infections/Necrosis | - | - | - | - | - | - | 0.557 |
| DISABLED_HCC77 | Disabled, Multiple Sclerosis | - | - | - | - | - | - | 0.418 |
| DISABLED_HCC6 | Disabled, Opportunistic Infections | - | - | - | - | - | - | 0.272 |

NOTES:

1. The denominator is $9,350.78
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Immune Disorders = HCC 47
   Cancer = HCCs 8-12
   Congestive Heart Failure = HCC 85
   Diabetes = HCCs 17-19
   Chronic Obstructive Pulmonary Disease = HCCs 110-112
   Renal = HCCs 134 – 137
   Cardiorespiratory Failure = HCCs 82-84
   Specified Heart Arrhythmias = HCC 96
   Substance Abuse = HCCs 54-55
   Psychiatric = HCCs 57-58
   Sepsis = HCC 2
   Pressure Ulcer = HCCs 157-158
   Artificial Openings for Feeding or Elimination = HCC 188
   Aspiration and Specified Bacterial Pneumonias = HCC 114
   Schizophrenia = HCC 57
   Seizure Disorders and Convulsions = HCC 79
   Chronic Ulcer of Skin, except Pressure = HCC 161
   Bone/Joint/Muscle Infections/Necrosis = HCC 39
   Multiple Sclerosis = HCC 77
   Opportunistic Infections = HCC 6

   SOURCE: RTI International analysis of 2013-2014 Medicare 100% data and RTI International analysis of 2013-2014 Medicare 100% institutional sample.

**Table 2. 2017 CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees**

| | Non-Medicaid & Non-Originally Disabled | Medicaid & Non-Originally Disabled | Non-Medicaid & Originally Disabled | Medicaid & Originally Disabled |
|---|---|---|---|---|
| **Female** | | | | |
| 0-34 Years | 0.652 | 0.968 | - | - |
| 35-44 Years | 0.920 | 1.199 | - | - |
| 45-54 Years | 1.017 | 1.313 | - | - |
| 55-59 Years | 0.986 | 1.318 | - | - |
| 60-64 Years | 1.102 | 1.412 | - | - |
| 65 Years | 0.513 | 1.040 | 1.110 | 1.539 |
| 66 Years | 0.507 | 0.929 | 1.147 | 1.591 |
| 67 Years | 0.535 | 0.929 | 1.147 | 1.591 |
| 68 Years | 0.571 | 0.929 | 1.147 | 1.591 |
| 69 Years | 0.594 | 0.929 | 1.147 | 1.591 |
| 70-74 Years | 0.662 | 0.958 | 1.147 | 1.591 |
| 75-79 Years | 0.876 | 1.072 | 1.147 | 1.591 |
| 80-84 Years | 1.047 | 1.371 | 1.147 | 1.591 |
| 85-89 Years | 1.300 | 1.432 | 1.147 | 1.591 |
| 90-94 Years | 1.300 | 1.648 | 1.147 | 1.591 |
| 95 Years or Over | 1.300 | 1.648 | 1.147 | 1.591 |
| **Male** | | | | |
| 0-34 Years | 0.448 | 0.753 | - | - |
| 35-44 Years | 0.653 | 1.075 | - | - |
| 45-54 Years | 0.819 | 1.333 | - | - |
| 55-59 Years | 0.873 | 1.397 | - | - |
| 60-64 Years | 0.906 | 1.554 | - | - |
| 65 Years | 0.505 | 1.179 | 0.776 | 1.584 |
| 66 Years | 0.523 | 1.186 | 0.940 | 1.584 |
| 67 Years | 0.565 | 1.186 | 0.987 | 2.163 |
| 68 Years | 0.630 | 1.186 | 1.055 | 2.163 |
| 69 Years | 0.659 | 1.288 | 1.374 | 2.163 |
| 70-74 Years | 0.762 | 1.288 | 1.374 | 2.163 |
| 75-79 Years | 1.022 | 1.337 | 1.374 | 2.163 |
| 80-84 Years | 1.247 | 1.575 | 1.374 | 2.163 |
| 85-89 Years | 1.484 | 1.817 | 1.374 | 2.163 |
| 90-94 Years | 1.484 | 1.817 | 1.374 | 2.163 |
| 95 Years or Over | 1.484 | 1.817 | 1.374 | 2.163 |

NOTES:

1. The denominator is $9,350.78
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2013-2014 100% Medicare data.

**Table 3. 2017 CMS-HCC Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)**

| | Non-Medicaid & Non-Originally Disabled | Medicaid & Non-Originally Disabled | Non-Medicaid & Originally Disabled | Medicaid & Originally Disabled |
|---|---|---|---|---|
| **Female** | | | | |
| 0-34 Years | 1.116 | 1.604 | - | - |
| 35-44 Years | 1.384 | 1.835 | - | - |
| 45-54 Years | 1.481 | 2.031 | - | - |
| 55-59 Years | 1.590 | 2.085 | - | - |
| 60-64 Years | 1.659 | 2.139 | - | - |
| 65 Years | 0.985 | 1.519 | 1.716 | 2.123 |
| 66 Years | 0.979 | 1.519 | 1.753 | 2.175 |
| 67 Years | 1.044 | 1.541 | 1.773 | 2.232 |
| 68 Years | 1.080 | 1.541 | 1.773 | 2.232 |
| 69 Years | 1.103 | 1.541 | 1.773 | 2.232 |
| 70-74 Years | 1.247 | 1.745 | 1.898 | 2.372 |
| 75-79 Years | 1.453 | 1.938 | 2.059 | 2.530 |
| 80-84 Years | 1.657 | 2.124 | 2.212 | 2.793 |
| 85-89 Years | 1.886 | 2.339 | 2.212 | 2.793 |
| 90-94 Years | 1.886 | 2.556 | 2.212 | 2.793 |
| 95 Years or Over | 1.886 | 2.556 | 2.212 | 2.793 |
| **Male** | | | | |
| 0-34 Years | 1.027 | 1.306 | - | - |
| 35-44 Years | 1.232 | 1.629 | - | - |
| 45-54 Years | 1.477 | 1.920 | - | - |
| 55-59 Years | 1.601 | 2.054 | - | - |
| 60-64 Years | 1.641 | 2.148 | - | - |
| 65 Years | 0.953 | 1.452 | 1.626 | 2.185 |
| 66 Years | 0.972 | 1.458 | 1.662 | 2.185 |
| 67 Years | 0.997 | 1.572 | 1.675 | 2.318 |
| 68 Years | 1.062 | 1.572 | 1.703 | 2.318 |
| 69 Years | 1.092 | 1.673 | 1.749 | 2.318 |
| 70-74 Years | 1.279 | 1.864 | 1.841 | 2.314 |
| 75-79 Years | 1.495 | 2.043 | 1.964 | 2.536 |
| 80-84 Years | 1.727 | 2.189 | 2.214 | 2.536 |
| 85-89 Years | 2.011 | 2.499 | 2.214 | 2.536 |
| 90-94 Years | 2.011 | 2.499 | 2.214 | 2.536 |
| 95 Years or Over | 2.011 | 2.499 | 2.214 | 2.536 |

## Notes:

1. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
2. The relative factors in this table were calculated by estimating the incremental amount to the standard new enrollee risk model needed to predict the risk scores of continuing enrollees in C-SNPs.

**Source**: RTI analysis of 2013-2014 Medicare C-SNP community continuing enrollees.

**Table 4. Disease Hierarchies for the 2017 CMS-HCC Model**

| Hierarchical Condition Category (HCC) | If the Disease Group is Listed in this column… | …Then drop the Disease Group(s) listed in this column |
|---|---|---|
| | **Hierarchical Condition Category (HCC) LABEL** | |
| 8 | Metastatic Cancer and Acute Leukemia | 9,10,11,12 |
| 9 | Lung and Other Severe Cancers | 10,11,12 |
| 10 | Lymphoma and Other Cancers | 11,12 |
| 11 | Colorectal, Bladder, and Other Cancers | 12 |
| 17 | Diabetes with Acute Complications | 18,19 |
| 18 | Diabetes with Chronic Complications | 19 |
| 27 | End-Stage Liver Disease | 28,29,80 |
| 28 | Cirrhosis of Liver | 29 |
| 46 | Severe Hematological Disorders | 48 |
| 54 | Drug/Alcohol Psychosis | 55 |
| 57 | Schizophrenia | 58 |
| 70 | Quadriplegia | 71,72,103,104,169 |
| 71 | Paraplegia | 72,104,169 |
| 72 | Spinal Cord Disorders/Injuries | 169 |
| 82 | Respirator Dependence/Tracheostomy Status | 83,84 |
| 83 | Respiratory Arrest | 84 |
| 86 | Acute Myocardial Infarction | 87,88 |
| 87 | Unstable Angina and Other Acute Ischemic Heart Disease | 88 |
| 99 | Cerebral Hemorrhage | 100 |
| 103 | Hemiplegia/Hemiparesis | 104 |
| 106 | Atherosclerosis of the Extremities with Ulceration or Gangrene | 107,108,161,189 |
| 107 | Vascular Disease with Complications | 108 |
| 110 | Cystic Fibrosis | 111,112 |
| 111 | Chronic Obstructive Pulmonary Disease | 112 |
| 114 | Aspiration and Specified Bacterial Pneumonias | 115 |
| 134 | Dialysis Status | 135,136,137 |
| 135 | Acute Renal Failure | 136,137 |
| 136 | Chronic Kidney Disease, Stage 5 | 137 |
| 157 | Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone | 158,161 |
| 158 | Pressure Ulcer of Skin with Full Thickness Skin Loss | 161 |
| 166 | Severe Head Injury | 80,167 |

**How Payments are Made with a Disease Hierarchy: EXAMPLE:** If a beneficiary triggers Disease Groups 135 (Acute Renal Failure) and 136 (Chronic Kidney Disease, Stage 5), then DG 136 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 135 rather than DG 136.

## Table 5. RxHCC Model Relative Factors for Continuing Enrollees

### Continuing Enrollees (CE) RxHCC Model Segments

| Variable | Disease Group | Community, Non-Low Income, Age≥65 | Community, Non-Low Income, Age<65 | Community, Low Income, Age≥65 | Community, Low Income, Age<65 | Institutional |
|---|---|---|---|---|---|---|
| **Female** | | | | | | |
| 0-34 Years | | - | 0.290 | - | 0.423 | 1.918 |
| 35-44 Years | | - | 0.477 | - | 0.637 | 1.886 |
| 45-54 Years | | - | 0.563 | - | 0.735 | 1.682 |
| 55-59 Years | | - | 0.543 | - | 0.710 | 1.556 |
| 60-64 Years | | - | 0.504 | - | 0.645 | 1.414 |
| 65-69 Years | | 0.264 | - | 0.407 | - | 1.491 |
| 70-74 Years | | 0.264 | - | 0.396 | - | 1.382 |
| 75-79 Years | | 0.251 | - | 0.385 | - | 1.285 |
| 80-84 Years | | 0.237 | - | 0.357 | - | 1.197 |
| 85-89 Years | | 0.221 | - | 0.328 | - | 1.113 |
| 90-94 Years | | 0.183 | - | 0.268 | - | 1.002 |
| 95 Years or Over | | 0.126 | - | 0.178 | - | 0.813 |
| **Male** | | | | | | |
| 0-34 Years | | - | 0.227 | - | 0.470 | 1.660 |
| 35-44 Years | | - | 0.382 | - | 0.606 | 1.791 |
| 45-54 Years | | - | 0.498 | - | 0.660 | 1.618 |
| 55-59 Years | | - | 0.519 | - | 0.649 | 1.450 |
| 60-64 Years | | - | 0.478 | - | 0.595 | 1.334 |
| 65-69 Years | | 0.274 | - | 0.351 | - | 1.332 |
| 70-74 Years | | 0.279 | - | 0.353 | - | 1.275 |
| 75-79 Years | | 0.246 | - | 0.347 | - | 1.218 |
| 80-84 Years | | 0.188 | - | 0.317 | - | 1.167 |
| 85-89 Years | | 0.149 | - | 0.289 | - | 1.098 |
| 90-94 Years | | 0.093 | - | 0.260 | - | 1.021 |
| 95 Years or Over | | 0.071 | - | 0.216 | - | 0.864 |
| **Originally Disabled Interactions with Sex** | | | | | | |
| Originally Disabled_Female | | 0.101 | - | 0.180 | - | 0.066 |
| Originally Disabled_Male | | – | - | 0.127 | - | 0.066 |
| **Disease Coefficients** | **Description Label** | | | | | |
| RXHCC1 | HIV/AIDS | 2.913 | 3.350 | 3.437 | 3.881 | 2.206 |
| RXHCC5 | Opportunistic Infections | 0.221 | 0.011 | 0.145 | 0.148 | 0.160 |
| RXHCC15 | Chronic Myeloid Leukemia | 6.271 | 6.682 | 7.000 | 8.912 | 4.011 |
| RXHCC16 | Multiple Myeloma and Other Neoplastic Disorders | 3.405 | 3.628 | 2.791 | 3.246 | 1.044 |

## Continuing Enrollees (CE) RxHCC Model Segments

| Variable | Disease Group | Community, Non-Low Income, Age≥65 | Community, Non-Low Income, Age<65 | Community, Low Income, Age≥65 | Community, Low Income, Age<65 | Institutional |
|---|---|---|---|---|---|---|
| RXHCC17 | Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer | 1.435 | 1.390 | 1.346 | 1.385 | 0.421 |
| RXHCC18 | Lung, Kidney, and Other Cancers | 0.255 | 0.281 | 0.280 | 0.287 | 0.050 |
| RXHCC19 | Breast and Other Cancers and Tumors | 0.087 | 0.029 | 0.078 | 0.085 | 0.050 |
| RXHCC30 | Diabetes with Complications | 0.396 | 0.437 | 0.461 | 0.608 | 0.431 |
| RXHCC31 | Diabetes without Complication | 0.263 | 0.259 | 0.300 | 0.354 | 0.299 |
| RXHCC40 | Specified Hereditary Metabolic/Immune Disorders | 2.785 | 11.019 | 2.945 | 9.727 | 0.138 |
| RXHCC41 | Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders | 0.111 | 0.179 | 0.052 | 0.183 | 0.064 |
| RXHCC42 | Thyroid Disorders | 0.095 | 0.160 | 0.092 | 0.155 | 0.065 |
| RXHCC43 | Morbid Obesity | 0.067 | - | 0.066 | 0.068 | 0.169 |
| RXHCC45 | Disorders of Lipoid Metabolism | 0.054 | 0.038 | 0.094 | 0.126 | 0.063 |
| RXHCC54 | Chronic Viral Hepatitis C | 1.921 | 2.461 | 1.713 | 1.989 | 0.508 |
| RXHCC55 | Chronic Viral Hepatitis, Except Hepatitis C | 0.322 | 0.396 | 0.860 | 0.586 | 0.251 |
| RXHCC65 | Chronic Pancreatitis | 0.239 | 0.238 | 0.148 | 0.163 | 0.143 |
| RXHCC66 | Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis | 0.094 | 0.238 | 0.084 | 0.163 | 0.106 |
| RXHCC67 | Inflammatory Bowel Disease | 0.470 | 0.403 | 0.388 | 0.718 | 0.205 |
| RXHCC68 | Esophageal Reflux and Other Disorders of Esophagus | 0.098 | 0.074 | 0.151 | 0.170 | 0.076 |
| RXHCC80 | Aseptic Necrosis of Bone | 0.162 | 0.201 | 0.149 | 0.135 | 0.108 |
| RXHCC82 | Psoriatic Arthropathy and Systemic Sclerosis | 0.720 | 0.792 | 1.116 | 1.802 | 0.538 |
| RXHCC83 | Rheumatoid Arthritis and Other Inflammatory Polyarthropathy | 0.318 | 0.383 | 0.406 | 0.710 | 0.172 |
| RXHCC84 | Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies | 0.202 | 0.331 | 0.233 | 0.341 | 0.107 |
| RXHCC87 | Osteoporosis, Vertebral and Pathological Fractures | 0.054 | 0.152 | 0.121 | 0.195 | - |
| RXHCC95 | Sickle Cell Anemia | 0.085 | 0.185 | 0.070 | 0.777 | 0.482 |
| RXHCC96 | Myelodysplastic Syndromes and Myelofibrosis | 0.738 | 0.883 | 0.653 | 0.682 | 0.518 |
| RXHCC97 | Immune Disorders | 0.428 | 0.448 | 0.484 | 0.403 | 0.377 |
| RXHCC98 | Aplastic Anemia and Other Significant Blood Disorders | 0.085 | 0.180 | 0.070 | 0.228 | 0.039 |
| RXHCC111 | Alzheimer`s Disease | 0.475 | 0.206 | 0.180 | 0.093 | - |

## Continuing Enrollees (CE) RxHCC Model Segments

| Variable | Disease Group | Community, Non-Low Income, Age≥65 | Community, Non-Low Income, Age<65 | Community, Low Income, Age≥65 | Community, Low Income, Age<65 | Institutional |
|---|---|---|---|---|---|---|
| RXHCC112 | Dementia, Except Alzheimer`s Disease | 0.198 | 0.094 | 0.040 | - | - |
| RXHCC130 | Schizophrenia | 0.291 | 0.336 | 0.457 | 0.756 | 0.203 |
| RXHCC131 | Bipolar Disorders | 0.291 | 0.319 | 0.317 | 0.509 | 0.203 |
| RXHCC132 | Major Depression | 0.154 | 0.269 | 0.185 | 0.364 | 0.189 |
| RXHCC133 | Specified Anxiety, Personality, and Behavior Disorders | 0.154 | 0.239 | 0.179 | 0.362 | 0.106 |
| RXHCC134 | Depression | 0.150 | 0.191 | 0.140 | 0.227 | 0.106 |
| RXHCC135 | Anxiety Disorders | 0.060 | 0.112 | 0.092 | 0.197 | 0.101 |
| RXHCC145 | Autism | 0.154 | 0.239 | 0.374 | 0.410 | 0.106 |
| RXHCC146 | Profound or Severe Intellectual Disability/Developmental Disorder | 0.026 | 0.114 | 0.374 | 0.309 | - |
| RXHCC147 | Moderate Intellectual Disability/Developmental Disorder | 0.026 | - | 0.224 | 0.172 | - |
| RXHCC148 | Mild or Unspecified Intellectual Disability/Developmental Disorder | - | - | 0.098 | 0.030 | - |
| RXHCC156 | Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease | 0.316 | 0.632 | 0.323 | 0.542 | 0.142 |
| RXHCC157 | Spinal Cord Disorders | 0.138 | 0.161 | 0.082 | 0.059 | 0.074 |
| RXHCC159 | Inflammatory and Toxic Neuropathy | 0.212 | 0.421 | 0.219 | 0.388 | 0.088 |
| RXHCC160 | Multiple Sclerosis | 1.904 | 3.250 | 1.807 | 3.809 | 0.856 |
| RXHCC161 | Parkinson`s and Huntington`s Diseases | 0.496 | 0.716 | 0.313 | 0.430 | 0.208 |
| RXHCC163 | Intractable Epilepsy | 0.293 | 0.494 | 0.260 | 0.899 | 0.078 |
| RXHCC164 | Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy | 0.112 | 0.046 | 0.034 | 0.139 | - |
| RXHCC165 | Convulsions | 0.062 | - | 0.034 | 0.087 | - |
| RXHCC166 | Migraine Headaches | 0.142 | 0.257 | 0.126 | 0.150 | 0.126 |
| RXHCC168 | Trigeminal and Postherpetic Neuralgia | 0.133 | 0.260 | 0.149 | 0.181 | 0.185 |
| RXHCC185 | Primary Pulmonary Hypertension | 0.621 | 1.784 | 0.570 | 1.468 | 0.229 |
| RXHCC186 | Congestive Heart Failure | 0.176 | 0.120 | 0.230 | 0.136 | 0.135 |
| RXHCC187 | Hypertension | 0.141 | 0.078 | 0.204 | 0.109 | 0.065 |
| RXHCC188 | Coronary Artery Disease | 0.130 | 0.035 | 0.142 | - | 0.012 |
| RXHCC193 | Atrial Arrhythmias | 0.230 | 0.097 | 0.098 | 0.014 | 0.068 |

## Continuing Enrollees (CE) RxHCC Model Segments

| Variable | Disease Group | Community, Non-Low Income, Age≥65 | Community, Non-Low Income, Age<65 | Community, Low Income, Age≥65 | Community, Low Income, Age<65 | Institutional |
|---|---|---|---|---|---|---|
| RXHCC206 | Cerebrovascular Disease, Except Hemorrhage or Aneurysm | 0.052 | – | 0.039 | – | – |
| RXHCC207 | Spastic Hemiplegia | 0.174 | 0.167 | 0.067 | 0.193 | – |
| RXHCC215 | Venous Thromboembolism | 0.111 | 0.151 | 0.069 | 0.115 | 0.039 |
| RXHCC216 | Peripheral Vascular Disease | – | – | 0.037 | – | – |
| RXHCC225 | Cystic Fibrosis | 0.365 | 3.541 | 0.352 | 3.683 | 0.775 |
| RXHCC226 | Chronic Obstructive Pulmonary Disease and Asthma | 0.311 | 0.144 | 0.352 | 0.249 | 0.200 |
| RXHCC227 | Pulmonary Fibrosis and Other Chronic Lung Disorders | 0.159 | 0.144 | 0.128 | 0.249 | 0.029 |
| RXHCC241 | Diabetic Retinopathy | 0.260 | 0.202 | 0.191 | 0.119 | 0.151 |
| RXHCC243 | Open-Angle Glaucoma | 0.266 | 0.199 | 0.306 | 0.260 | 0.222 |
| RXHCC260 | Kidney Transplant Status | 0.328 | 0.070 | 0.407 | 0.393 | 0.201 |
| RXHCC261 | Dialysis Status | 0.183 | 0.274 | 0.389 | 0.757 | 0.301 |
| RXHCC262 | Chronic Kidney Disease Stage 5 | 0.086 | 0.030 | 0.091 | 0.033 | 0.065 |
| RXHCC263 | Chronic Kidney Disease Stage 4 | 0.086 | 0.030 | 0.086 | 0.033 | 0.065 |
| RXHCC311 | Chronic Ulcer of Skin, Except Pressure | 0.143 | 0.131 | 0.071 | 0.090 | 0.048 |
| RXHCC314 | Pemphigus | 0.271 | 1.212 | 0.203 | 0.193 | 0.048 |
| RXHCC316 | Psoriasis, Except with Arthropathy | 0.188 | 0.219 | 0.345 | 0.630 | 0.228 |
| RXHCC355 | Narcolepsy and Cataplexy | 0.780 | 1.325 | 0.641 | 1.302 | 0.350 |
| RXHCC395 | Lung Transplant Status | 1.126 | 0.954 | 1.169 | 1.160 | 0.639 |
| RXHCC396 | Major Organ Transplant Status, Except Lung, Kidney, and Pancreas | 1.098 | 0.954 | 1.169 | 1.160 | 0.457 |
| RXHCC397 | Pancreas Transplant Status | 0.251 | 0.070 | 0.407 | 0.393 | 0.201 |
| **Non-Aged Disease Interactions** | | | | | | |
| NonAged_RXHCC1 | NonAged * HIV/AIDS | - | - | - | - | 1.009 |
| NonAged_RXHCC130 | NonAged * Schizophrenia | - | - | - | - | 0.268 |
| NonAged_RXHCC131 | NonAged * Bipolar Disorders | - | - | - | - | 0.268 |
| NonAged_RXHCC132 | NonAged * Major Depression | - | - | - | - | 0.206 |
| NonAged_RXHCC133 | NonAged * Specified Anxiety, Personality, and Behavior Disorders | - | - | - | - | 0.130 |
| NonAged_RXHCC134 | NonAged * Depression | - | - | - | - | 0.122 |
| NonAged_RXHCC135 | NonAged * Anxiety Disorders | - | - | - | - | 0.049 |
| NonAged_RXHCC145 | NonAged * Autism | - | - | - | - | 0.130 |
| NonAged_RXHCC160 | NonAged * Multiple Sclerosis | - | - | - | - | 1.227 |
| NonAged_RXHCC163 | NonAged * Intractable Epilepsy | - | - | - | - | 0.111 |

## Continuing Enrollees (CE) RxHCC Model Segments

| Variable | Disease Group | Community, Non-Low Income, Age≥65 | Community, Non-Low Income, Age<65 | Community, Low Income, Age≥65 | Community, Low Income, Age<65 | Institutional |
|---|---|---|---|---|---|---|
| NonAged_RXHCC164 | NonAged * Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy | - | - | - | - | - |
| NonAged_RXHCC165 | NonAged * Convulsions | - | - | - | - | - |

**Note:** The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.

**Source:** RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

## Table 6. RxHCC Model Relative Factors for New Enrollees, Non-Low Income

| Variable | Not Concurrently ESRD, Not Originally Disabled | Concurrently ESRD, Not Originally Disabled | Originally Disabled, Not Concurrently ESRD | Originally Disabled, Concurrently ESRD |
|---|---|---|---|---|
| **Female** | | | | |
| 0-34 Years | 0.653 | 0.653 | - | - |
| 35-44 Years | 1.074 | 1.100 | - | - |
| 45-54 Years | 1.290 | 1.536 | - | - |
| 55-59 Years | 1.228 | 1.732 | - | - |
| 60-64 Years | 1.227 | 1.898 | - | - |
| 65 Years | 0.562 | 1.756 | 1.163 | 1.756 |
| 66 Years | 0.616 | 1.756 | 1.111 | 1.756 |
| 67 Years | 0.623 | 1.756 | 1.111 | 1.756 |
| 68 Years | 0.645 | 1.756 | 1.111 | 1.756 |
| 69 Years | 0.669 | 1.756 | 1.111 | 1.756 |
| 70-74 Years | 0.688 | 1.756 | 1.100 | 1.756 |
| 75-79 Years | 0.687 | 1.756 | 0.687 | 1.756 |
| 80-84 Years | 0.643 | 1.756 | 0.643 | 1.756 |
| 85-89 Years | 0.537 | 1.756 | 0.537 | 1.756 |
| 90-94 Years | 0.317 | 1.756 | 0.317 | 1.756 |
| 95 Years or Over | 0.317 | 1.756 | 0.317 | 1.756 |
| **Male** | | | | |
| 0-34 Years | 0.427 | 0.714 | - | - |
| 35-44 Years | 0.803 | 0.885 | - | - |
| 45-54 Years | 1.091 | 1.493 | - | - |
| 55-59 Years | 1.152 | 1.493 | - | - |
| 60-64 Years | 1.110 | 1.836 | - | - |
| 65 Years | 0.595 | 1.773 | 0.961 | 1.773 |
| 66 Years | 0.657 | 1.773 | 0.925 | 1.773 |
| 67 Years | 0.668 | 1.773 | 0.925 | 1.773 |
| 68 Years | 0.686 | 1.773 | 0.925 | 1.773 |
| 69 Years | 0.714 | 1.773 | 0.925 | 1.773 |
| 70-74 Years | 0.745 | 1.773 | 0.762 | 1.773 |
| 75-79 Years | 0.737 | 1.773 | 0.737 | 1.773 |
| 80-84 Years | 0.657 | 1.773 | 0.657 | 1.773 |
| 85-89 Years | 0.545 | 1.773 | 0.545 | 1.773 |
| 90-94 Years | 0.332 | 1.773 | 0.332 | 1.773 |
| 95 Years or Over | 0.332 | 1.773 | 0.332 | 1.773 |

**Notes:**

1. The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

**Source**: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

## Table 7. RxHCC Model Relative Factors for New Enrollees, Low Income

| Variable | Not Concurrently ESRD, Not Originally Disabled | Concurrently ESRD, Not Originally Disabled | Originally Disabled, Not Concurrently ESRD | Originally Disabled, Concurrently ESRD |
|---|---|---|---|---|
| **Female** | | | | |
| 0-34 Years | 1.003 | 2.079 | - | - |
| 35-44 Years | 1.494 | 2.079 | - | - |
| 45-54 Years | 1.538 | 2.170 | - | - |
| 55-59 Years | 1.428 | 2.224 | - | - |
| 60-64 Years | 1.325 | 2.081 | - | - |
| 65 Years | 0.924 | 2.084 | 1.186 | 2.084 |
| 66 Years | 0.600 | 2.084 | 0.906 | 2.084 |
| 67 Years | 0.600 | 2.084 | 0.906 | 2.084 |
| 68 Years | 0.600 | 2.084 | 0.906 | 2.084 |
| 69 Years | 0.600 | 2.084 | 0.906 | 2.084 |
| 70-74 Years | 0.616 | 2.084 | 0.749 | 2.084 |
| 75-79 Years | 0.683 | 2.084 | 0.683 | 2.084 |
| 80-84 Years | 0.683 | 2.084 | 0.683 | 2.084 |
| 85-89 Years | 0.683 | 2.084 | 0.683 | 2.084 |
| 90-94 Years | 0.534 | 2.084 | 0.534 | 2.084 |
| 95 Years or Over | 0.534 | 2.084 | 0.534 | 2.084 |
| **Male** | | | | |
| 0-34 Years | 0.869 | 2.154 | - | - |
| 35-44 Years | 1.265 | 2.125 | - | - |
| 45-54 Years | 1.390 | 2.131 | - | - |
| 55-59 Years | 1.251 | 1.968 | - | - |
| 60-64 Years | 1.161 | 1.847 | - | - |
| 65 Years | 0.831 | 1.921 | 0.978 | 1.921 |
| 66 Years | 0.507 | 1.921 | 0.569 | 1.921 |
| 67 Years | 0.507 | 1.921 | 0.569 | 1.921 |
| 68 Years | 0.507 | 1.921 | 0.569 | 1.921 |
| 69 Years | 0.507 | 1.921 | 0.569 | 1.921 |
| 70-74 Years | 0.523 | 1.921 | 0.612 | 1.921 |
| 75-79 Years | 0.536 | 1.921 | 0.536 | 1.921 |
| 80-84 Years | 0.559 | 1.921 | 0.559 | 1.921 |
| 85-89 Years | 0.487 | 1.921 | 0.487 | 1.921 |
| 90-94 Years | 0.362 | 1.921 | 0.362 | 1.921 |
| 95 Years or Over | 0.362 | 1.921 | 0.362 | 1.921 |

**Notes:**

1. The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

**Source**: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

## Table 8. RxHCC Model Relative Factors for New Enrollees, Institutional

| Variable | Not Concurrently ESRD | Concurrently ESRD |
|---|---|---|
| **Female** | | |
| 0-34 Years | 2.353 | 2.767 |
| 35-44 Years | 2.353 | 2.767 |
| 45-54 Years | 2.405 | 2.767 |
| 55-59 Years | 2.400 | 2.767 |
| 60-64 Years | 2.137 | 2.767 |
| 65 Years | 2.280 | 2.767 |
| 66 Years | 1.970 | 2.767 |
| 67 Years | 1.970 | 2.767 |
| 68 Years | 1.970 | 2.767 |
| 69 Years | 1.970 | 2.767 |
| 70-74 Years | 1.820 | 2.767 |
| 75-79 Years | 1.545 | 2.767 |
| 80-84 Years | 1.514 | 2.767 |
| 85-89 Years | 1.321 | 2.767 |
| 90-94 Years | 1.082 | 2.767 |
| 95 Years or Over | 1.082 | 2.767 |
| **Male** | | |
| 0-34 Years | 2.290 | 2.614 |
| 35-44 Years | 2.692 | 2.614 |
| 45-54 Years | 2.340 | 2.614 |
| 55-59 Years | 2.124 | 2.614 |
| 60-64 Years | 2.011 | 2.614 |
| 65 Years | 2.002 | 2.614 |
| 66 Years | 1.889 | 2.614 |
| 67 Years | 1.889 | 2.614 |
| 68 Years | 1.889 | 2.614 |
| 69 Years | 1.889 | 2.614 |
| 70-74 Years | 1.791 | 2.614 |
| 75-79 Years | 1.676 | 2.614 |
| 80-84 Years | 1.467 | 2.614 |
| 85-89 Years | 1.343 | 2.614 |
| 90-94 Years | 1.343 | 2.614 |
| 95 Years or Over | 1.343 | 2.614 |

**Notes:**

1. The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

**Source**: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

## Table 9. List of Disease Hierarchies for RxHCC Model

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

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

**Source**: RTI International.

**Attachment VI. CY2017 Draft Call Letter**

**CY2017 Call Letter**
**Table of Contents**

**How to Use This Call Letter**

The 2017 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs), Part D sponsors, and Medicare-Medicaid Plans (MMPs) need to take into consideration in preparing their 2017 bids.

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

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

## Section I – Parts C and D

### *Annual Calendar*

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

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| January 12, 2016 | Release of Contract Year CY 2017 Initial and Service Area Applications for MA/MA-PD/PDP, SNP, EGWP, 1876 Cost Plan Expansions | ✓ | ✓ | ✓ | |
| January 12, 2016 | MOC Renewal Submission period begins for SNP and MMP MOCs with approvals ending at the end of CY 2016 | ✓ | | | ✓ |
| January 12 & 14, 2016 | Industry Training and Technical Assistance for CY 2017 Model of Care (MOC) Submissions | ✓ | | | ✓ |
| January 13 & 20, 2016 | Industry training on 2017 Applications | ✓ | ✓ | ✓ | |
| January 15, 2016 | Deadline for D-SNPs meeting a high level of integration, as determined by CMS, to submit a request to CMS to offer additional supplemental benefits | ✓ | | | |
| February 17, 2016 | CY 2017 Initial and Service Area Expansion Application for MA/MA-PD/PDP, SNP, EGWP, 1876 Cost Plan Expansion are due in HPMS by 8pm EST | ✓ | ✓ | ✓ | |
| February 17, 2016 | MOC Renewals Submissions for SNP and MMP MOCs with approvals ending at the end of CY 2016 are due in HPMS by 8pm EST. | ✓ | | | ✓ |
| Late February, 2016 | Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals | ✓ | | | |
| Early-Mid February, 2016 | D-SNPs that requested to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications | ✓ | | | |
| February, 2016 | CMS notifies MA, MA-PDs and PDPs regarding non-renewal of their contract(s) for CY 2017 due to consistently low star ratings | ✓ | ✓ | | |
| February 2016 | CMS releases guidance concerning updates to Parent Organization designations in HPMS | ✓ | ✓ | ✓ | ✓ |
| March 17, 2016 | Parent Organization Update requests from sponsors due to CMS (instructional memo released in February 2016) | ✓ | ✓ | ✓ | ✓ |
| Mid-Late March, 2016 | Release of CY 2017 Formulary Training Video and 2016 Formulary Reference File (FRF) | ✓ | ✓ | ✓ | ✓ |
| March 25, 2016 | Release of the Fiscal Soundness Module in HPMS | ✓ | ✓ | ✓ | ✓ |
| March/April, 2016 | CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2017 | ✓ | ✓ | ✓ | |

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| Early April, 2016 | CY 2017 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs, 1876 Cost Plans submitting MA conversion bids, and Part D sponsors for download from the CMS website. Information will assist plans in meeting meaningful difference and Total Beneficiary Cost (TBC) requirements prior to bid submission | ✓ | ✓ | ✓ | |
| Early April, 2016 | Information about renewal options for contract year 2017 (including HPMS crosswalk charts) provided to plans | ✓ | ✓ | | |
| April 2016 | Conference call with industry to discuss the 2017 Call Letter | ✓ | ✓ | ✓ | ✓ |
| April 4, 2016 | Release of the 2017 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released, including the CY 2017 Call Letter | ✓ | ✓ | ✓ | ✓ |
| April 6, 2016 | Industry training on CY 2017 Formulary Submission | ✓ | ✓ | ✓ | ✓ |
| April 8, 2016 | Release of the 2017 Plan Benefit Package (PBP) online training module | ✓ | ✓ | ✓ | ✓ |
| April 8, 2016 | Release of the 2017 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS | ✓ | ✓ | ✓ | ✓ |
| April 11, 2016 | Deadline for MAOs to submit requests for full contract consolidations for CY 2017 | ✓ | | ✓ | |
| Mid-April, 2016 | Release of HPMS Memo: Contract Year 2017 Medicare Advantage Bid Review and Operations Guidance | ✓ | | | |
| April 18, 2016 | Release of the 2017 Medication Therapy Management (MTM) Program Submission in HPMS | | ✓ | | ✓ |
| April 22, 2016 | Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training | ✓ | ✓ | ✓ | ✓ |
| Mid-Late April, 2016 | MAOs submit plan requests for tiering of medical benefits and justifications to CMS for review and consideration | ✓ | | | |
| Late April, 2016 | Total Beneficiary Cost data for CY 2017 Bid Preparation Release | ✓ | | | |
| May, 2016 | Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, pharmacy directory, and MMP models for 2017 available for all organizations | ✓ | ✓ | ✓ | ✓ |
| May 1, 2016 | MA, MA-PD and PDP plans to notify CMS of intention to non- renew a county (ies) for individuals, but continue the county (ies) for “800 series” EGWP members, convert to offering employer-only contracts, or reduce its service area at the contract level. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June | ✓ | ✓ | ✓ | |
| May 2, 2016 | Deadline for submission of CY 2017 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (except those participating in the Enhanced MTM Model test) (11:59pm PDT) | | ✓ | | ✓ |

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| May 5, 2016 | 2016 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast | ✓ | ✓ | ✓ | ✓ |
| May 6, 2016 | Release of the 2017 Bid Upload Functionality in HPMS | ✓ | ✓ | ✓ | ✓ |
| May 6, 2016 | Release of 2017 Actuarial Certification Module in HPMS | ✓ | ✓ | ✓ | |
| May 16, 2016 | Release of 2017 Formulary Submission Module in HPMS | ✓ | ✓ | ✓ | ✓ |
| Mid-Late May, 2016 | Release of CY 2017 Formulary Reference File Update | ✓ | ✓ | ✓ | ✓ |
| May 27, 2016 | Plans/Part D sponsors begin to upload agent/broker compensation information in HPMS | ✓ | ✓ | ✓ | ✓ |
| May 27, 2016 | Release of the 2017 Marketing Module in HPMS. Plans/Part D sponsors begin to submit 2017 marketing materials | ✓ | ✓ | ✓ | ✓ |
| Late May/Early June, 2016 | Release of the 2017 Medicare Marketing Guidelines in HPMS | ✓ | ✓ | ✓ | ✓ |
| Late May, 2016 | CMS sends qualification determinations to applicants based on review of the 2017 applications for new contracts or service area expansions | ✓ | ✓ | | |
| June 2016 | Release of state-specific marketing guidance for MMPs. | | | | ✓ |
| June 1, 2016 | Release of the 2015 DIR Submission Module in HPMS | ✓ | ✓ | ✓ | ✓ |
| June 6, 2016 | Deadline for submission of CY 2017 bids (including Service Area Verification) for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2017 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT) Deadline for submission of CY 2017 Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT) Deadline for submission of a CY 2017 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 2017 | ✓ | ✓ | ✓ | ✓ *Non-bid related items only* |
| Early June to Early September, 2016 | CMS completes review and approval of 2017 bid data. Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications | ✓ | ✓ | ✓ | |
| June 7-10, 2016 | Window for submitting first round of crosswalk exception requests through HPMS | ✓ | ✓ | ✓ | |
| June 10, 2016 | Deadline for submission of CY 2017 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, Home Infusion file, and Non-Extended Day Supply file through HPMS (11:59 a.m. EDT) | ✓ | ✓ | ✓ | ✓ |

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| June 10, 2016 | Deadline for submission of Medicare Advantage Value Based Insurance Design (VBID) file *(Only applicable to Medicare Advantage Plans that have been preapproved for Part D VBID benefits)* (11:59 a.m. EDT) | ✓ | ✓ | | |
| June 10, 2016 | Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)* (11:59 a.m. EDT) | | | | ✓ |
| June 16, 2016 | 2016 MA and PDP Audit and Enforcement Conference and Webcast | ✓ | ✓ | ✓ | ✓ |
| Late June, 2016 | CMS sends an acknowledgement letter to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area | ✓ | ✓ | ✓ | ✓ |
| Early July, 2016 | 2017 Plan Finder pricing test submissions begin | ✓ | ✓ | ✓ | ✓ |
| July 1, 2016 | Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS | ✓ | | | |
| July 1, 2016 | 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, 2016 | Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review. | ✓ | | | |
| Mid July 2016 | Release of CY 2017 FRF Update in advance of the Limited Formulary Update Window | ✓ | ✓ | ✓ | ✓ |
| Mid-Late July, 2016 | CY 2017 Limited Formulary Update Window | ✓ | ✓ | ✓ | ✓ |
| Late July, 2016 | Submission deadline for agent/broker compensation information via HPMS | ✓ | ✓ | ✓ | ✓ |
| Mid-Late July 2016 | Second window for submitting HPMS crosswalk exceptions | ✓ | ✓ | ✓ | |
| Late July / Early August, 2016 | CMS releases the 2017 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, 2016 | Rebate reallocation period begins after release of the above bid amounts | ✓ | ✓ | ✓ | |
| No Later Than July 29, 2016 | CMS informs currently contracted organizations of its decision to not renew a contract for 2017 | ✓ | ✓ | ✓ | |
| August 1, 2016 | Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS | ✓ | ✓ | ✓ | |
| August 16, 2016 | Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts. | ✓ | ✓ | ✓ | ✓ |
| August 18-22, 2016 | CY 2017 preview of the 2017 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs) | ✓ | ✓ | | ✓ |

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| August 24-26, 2016 | First CY 2017 Medicare Plan Finder (MPF) Preview and Out- of-Pocket Cost (OOPC) Preview in HPMS | ✓ | ✓ | ✓ | ✓ *MPF only* |
| August 31, 2016 | 2017 MTM Program Annual Review completed | | ✓ | | ✓ |
| Late August 2016 | Contracting Materials submitted to CMS | ✓ | ✓ | ✓ | |
| End of August/Early September 2016 | Plan preview periods of Part C & D Star Ratings in HPMS | ✓ | ✓ | ✓ | |
| Early September 2016 | CMS begins accepting plan correction requests upon contract approval | ✓ | ✓ | ✓ | |
| Mid- September 2016 | All 2017 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS) | ✓ | ✓ | ✓ | |
| September 6-9, 2016 | Second CY 2017Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS | ✓ | ✓ | ✓ | ✓ *MPF only* |
| September 16 -30, 2016 | CMS mails the 2017 *Medicare & You* handbook to Medicare beneficiaries | ✓ | ✓ | ✓ | ✓ |
| Late September, 2016 | D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications | ✓ | | | |
| September 21, 2016 | Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS. | ✓ | ✓ | ✓ | |
| September 30, 2016 | The following documents are due to current enrollees by September 30, 2016:<br>• Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D).<br>• Standardized ANOC with the Summary of Benefits for D-SNPs and MMPs that choose to separate the ANOC from the EOC.<br>• Abridged or comprehensive formularies<br>• LIS rider<br>• Pharmacy/Provider directories<br>• The multi-language insert should be sent with the ANOC/EOC and the SB.<br>• The documents identified above are the only documents permitted to be sent prior to October 1, 2016 | ✓ | ✓ | ✓ | ✓ |

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| October 1, 2016 | Organizations may begin marketing their CY 2017 plan benefits.<br>Note: Once an organization begins marketing CY 2017 plans, the organization must cease marketing CY 2016 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2016 materials upon request, conduct one-on-one sales appointments, and process enrollment applications | ✓ | ✓ | ✓ | ✓ |
| October 1, 2016 | Tentative date for 2017 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs) | ✓ | ✓ | ✓ | ✓ |
| October 2, 2016 | The final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, and cost-based plan enrollees<br>PDPs, MA plans, MA-PD plans, and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2016 | ✓ | ✓ | ✓ | |
| October 13, 2016 | Part C & D Star Ratings go live on medicare.gov on or around October 13, 2016 | ✓ | ✓ | ✓ | |
| October 15, 2016 | Part D sponsors must post PA and ST criteria on their websites for the 2017 contract year | | ✓ | | ✓ |
| October 15, 2016 | 2017 Annual Election Period begins<br>All organizations/sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1) | ✓ | ✓ | ✓ | ✓ |
| Mid October, 2016 | Release of the online CY 2018 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs) | ✓ | ✓ | ✓ | ✓ |
| November 14, 2016 | Notices of Intent to Apply (NOIA) for CY 2018 due for MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs. | ✓ | ✓ | | ✓ |
| Early November, 2016 | First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval | ✓ | ✓ | ✓ | ✓ |
| Late November, 2016 | Part C & D display measures data are posted in HPMS for plan preview | ✓ | ✓ | ✓ | |
| November – December, 2016 | CMS issues "close out" information and instructions to MA plans, MA-PD plans, MMPs, PDPs, and cost-based plans that are non- renewing or reducing service areas | ✓ | ✓ | | ✓ |
| December 1, 2016 | Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC | | | ✓ | |
| December 1, 2016 | Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR. | | | ✓ | |
| December 7, 2016 | End of the Annual Election Period | ✓ | ✓ | | ✓ |

| **2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.** | | ***Part C** | ***Part D** | **Cost** | **MMP** |
|---|---|---|---|---|---|
| Mid December, 2016 | Part C & D display measures data on cms.gov updated | ✓ | ✓ | ✓ | |
| December 31, 2016 | Deadline for MMPs that separated the ANOC from the EOC to provide the EOC to enrollees | | | | ✓ |
| **2017** | | | | | |
| January 1, 2017 | Plan Benefit Period Begins | ✓ | ✓ | ✓ | ✓ |
| January 1 – February 14, 2017 | Annual 45-Day Medicare Advantage Disenrollment Period (MADP) | ✓ | | | |
| Early January 2017 | Release of CY 2018 MAO/MA-PD/MMP/PDP/SAE/EGWP applications | ✓ | ✓ | | ✓ |
| Mid-January, 2017 | Industry training on CY 2018 applications | ✓ | ✓ | ✓ | ✓ |
| Mid-February 2017 | Applications due for CY 2018 | ✓ | ✓ | ✓ | ✓ |

### *Incomplete and Inaccurate Bid Submissions*

#### Incomplete Submissions

Under Sections 1854(a)(1)(A) and 1860D-11(b) of the Social Security Act, initial bid submissions for all MA, MA-PD, PDPs and cost-based plans are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY 2017, the bid submission deadline is June 6, 2016 at 11:59 PM Pacific Daylight Time.

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

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

MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids are submitted by the June deadline. Consistent with past years, CMS reminds organizations that all required components of an organization's bid must be submitted by the deadline in order for the bid to be considered complete. If any of the required components are not submitted by the deadline, the bid submission will be considered incomplete and not accepted by CMS absent extraordinary circumstances. This policy is consistent with previous years (for

example, please refer to the memo "Release of Contract Year (CY) 2016 Bid Upload Functionality in HPMS," dated May 8, 2015).

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

All organizations are expected to contact CMS about any technical upload or validation errors well in advance of the bid submission deadline. CMS will not accept late submissions unless they are the result of a technical issue beyond the organization's control, in what is expected to be very rare and unique circumstances. All organizations should make sure that appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that might prevent the bid from proceeding to desk review.

**Inaccurate Submissions**

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

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

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

Organizations and sponsors that submit clearly inaccurate bids on June 6, 2016 and organizations that resubmit bids prior to approval to change or correct items, such as rebate reallocation and

fail to meet Part C and D requirements, and/or established thresholds, will receive a compliance notice in the form of a letter and/or a corrective action plan. In addition, organizations and sponsors that submit inaccurate bids may not be allowed to revise their bids to correct inaccuracies, and the bids may be denied. Organizations and sponsors should engage in sufficient due diligence to make certain their bids are accurate before submission.

***Plan Corrections***

As required by 42 CFR §§422.254, 423.265(c)(3) and 423.505(k)(4), submission of the final actuarial certification serves as documentation that the final bid submission has been verified and is complete and accurate at the time of submission. A request by an organization or sponsor for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's or sponsor's ability to submit correct bids and the validity of the final actuarial certification and bid attestation.

After bids are approved, CMS will not reopen the submission gates to correct errors identified by the organization or sponsor until the plan correction window in September. The plan correction window will be open from early September to late September 2016. The only changes to the PBP that will be allowed during the plan correction period are those that modify the PBP data to align with the BPT. No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide organizations and sponsors the guidance and tools necessary for a complete and accurate bid submission. These tools will include a Medicare Plan Finder (MPF) summary table report that will be released in HPMS in May. Organizations and sponsors can upload their bid multiple times in HPMS prior to bid submission so that they can confirm that MPF data are being displayed accurately. Organizations and sponsors are encouraged to use this time prior to the submission deadline to verify their bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance action and will be suppressed in MPF until the first MPF update in November. In addition, CMS may issue more severe compliance actions such as warning letters and corrective action plans to organizations/sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice for CY 2016.

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

CMS may, under our regulatory authority at 42 C.F.R. §§ 422.510(a)(4)(xi) and 423.509(a)(4)(x), terminate the contracts of organizations that have failed to achieve a rating of three stars or better on their Part C or Part D performance in three consecutive years. Since CMS announced through rulemaking in 2012 that we would consider consistently low Star Ratings as a basis for terminating a Part C or Part D contract, a significant number of organizations have taken steps to improve the performance of their poor performing contracts. In other instances,

organizations have non-renewed low-rated contracts or consolidated their operations into different, higher-rated contracts. As a result, the overall quality of Medicare plan options available to beneficiaries continues to improve.

In the CY 2016 Call Letter, CMS announced that contracts that earned their third consecutive Part C or Part D rating of less than three stars with the release of the 2016 ratings in the fall of 2015 would receive non-renewal notices from CMS in February 2016 with an effective date of December 31, 2016, at 11:59 pm EST. We also announced that we would not calculate or publish 2017 Star Ratings associated with the non-renewed contracts.

CMS advises MAOs and PDP sponsors that we will conduct future star rating-based terminations according to a similar timeline. That is, CMS will issue contract non-renewal notices in February of each year, with an effective date of December 31st of the same year, to all contracts that meet the criteria for a star rating-based termination with the release of the set of star ratings issued in October of the preceding year. In March, following the issuance of the non-renewal notices, beneficiaries enrolled in plans offered under the non-renewed contracts will receive notices advising them that they will need to choose a new plan during the next annual election period to continue their Part C and Part D plan enrollment without interruption during the following benefit year. Finally, CMS will not calculate or publish Star Ratings for non-renewed contracts during the year in which CMS issues the non-renewal notice, so terminated contracts should not expect there to be an opportunity for CMS to reverse its determination based on the contract's improved Star Rating performance during its last year of operation.

***Enhancements to the 2017 Star Ratings and Beyond***

One of CMS' most important strategic goals is to improve the quality of care and health status of Medicare beneficiaries. For the 2017 Star Ratings, CMS continues to enhance the Star Ratings methodology so it further aligns with our policy goals. Our priorities include enhancing the measures and methodology to reflect the true performance of organizations and sponsors, ensuring stability due to the link to payment, and providing advance notice of future proposals. In this document, we describe the enhancements being proposed for the 2017 Star Ratings and beyond. CMS is not considering adding any new measures for 2017 Star Ratings. Except as noted below, we anticipate the methodology remaining the same as the 2016 Star Ratings.

For reference, the list of measures and a description of the methodology for the 2016 Star Ratings are included in the Technical Notes available on the CMS webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.
The cut points to determine star assignments for all measures and case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated for 2017 using the most current data available.

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

We appreciate the feedback we received from approximately 90 organizations to the November 12, 2015 Health Plan Management System (HPMS) memo, Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond.[21] The proposals below reflect those comments where appropriate. Requests for clarification and concerns about measure specifications have been passed along to measure developers and stewards, even if not specifically mentioned below. Also, CMS has posted a summary of the comments as well as the individual comments received on CMS.gov at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

### *A. Changes to Measures for 2017*

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

- If a specification change to an existing measure is announced in advance of the measurement period, the measure remains in the Star Ratings; it will not be moved to the display page.
- If the change announced during the measurement period significantly expands the denominator or population covered by the measure, the measure is moved to the display page for at least one year.
- If the change announced during the measurement period does not significantly impact the numerator or denominator of the measure, the measure will continue to be included in the Star Ratings (e.g., when during the measurement period additional codes are added that would increase the number of numerator hits for a measure).

The methodology for the following measures is being modified:

1. **Improvement measures (Part C & D).** While the methodology for incorporating measures into the calculation of the two improvement measures (one each for Part C and D) remains the same as in prior years, we have updated the measures used for each improvement measure to account for measures with at least two years of data. Please refer to Appendix 3 for updates to the measures to be used to calculate the 2017 improvement measures. If a contract's CAHPS measure score moved to very low reliability with the exclusion of the enrollees with less than 6 months of continuous enrollment for the 2015 survey administration, then the 2014 CAHPS measure score (used in 2015 Star Ratings) will be

[21] The Request for Comment can be found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf

used instead as the baseline for the 2017 improvement calculation for that measure. If the contract has missing 2015 CAHPS data due to very low reliability, we would use the 2014 CAHPS data only if there is a significant improvement from 2014 to 2016. This policy would affect very few contracts, but this would hold contracts harmless from missing data.

2. **Appeals Timeliness/Reviewing Appeals Decisions measures (Part C) and Appeals Upheld measure (Part D).** Currently, these measures include cases that are reopened and decided by April 1 of the following contract year. In some instances, appeals filed in the 4th quarter of the year and then subsequently reopened may not be determined by the Independent Review Entity (IRE) by April 1. We propose for the 2017 Star Ratings to modify these measure specifications so that if a reopening occurs and is decided prior to May 1, 2016, the reopened decision would be used. Reopenings decided on or after May 1, 2016 would not be reflected in these data, and the original decision result would be used.

3. **Contract Enrollment Data (Part C & D)**. Contract enrollment numbers are pulled from HPMS for the Part C and D "Complaints about the Health/Drug Plan" and the Part D "Appeals Auto-Forward" measures. Additionally, plan-level enrollment is pulled for the three Part C "Care for Older Adults" measures when the eligible population data are not included in the HEDIS submission. For these measures, twelve months of enrollment files are pulled from HPMS, and the average enrollment from those months is used in the measure calculations. In the Request for Comments, we discussed changing the twelve month period from January through December to February through January of the relevant measurement period. Further review of the enrollment data over the past five years has shown that new contracts have enrollment data showing in the January enrollment file that is not significantly different from subsequent months. Therefore, we are not proposing making this change to the enrollment data used in the Star Ratings.

4. **Transition from ICD-9 to ICD-10 (Part C & D).** The measure stewards, such as the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), have reviewed their measure specifications with diagnosis-related requirements to transition from ICD-9 to ICD-10.

   NCQA has incorporated the ICD-10 codes in the 2016 Healthcare Effectiveness Data and Information Set (HEDIS). During the transition period, both ICD-9 and ICD-10 codes will be used due to the look-back periods for some measures.

   The transition to ICD-10 is not relevant to PQA measures currently used in Star Ratings. We will review changes made by PQA as appropriate for current or future measures used by CMS.

5. **Appeals Upheld measure (Part D).** This measure shows how often an Independent Reviewer thought the drug plan's decision to deny an appeal was fair. For the 2016 Star

Rating Upheld measure, we excluded appeal cases for beneficiaries enrolled in hospice at any point during 2014. As noted in the 2016 Call Letter, this exclusion was only necessary for the 2016 measure as it is based on 2014 data that may have been affected by policy changes in 2014. CMS policy has not changed since 2014, so it is no longer necessary to exclude hospice appeal cases. This exclusion will not be continued for the 2017 Star Rating Appeals Upheld measure.

6. **Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D).** We will add a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score since exclusions are applied to the plan-reported MTM data.

   The CMR rate measure is an initial measure of the delivery of MTM services, and we continue to look forward to the development and endorsement of outcomes-based MTM measures as potential companion measures to the current MTM Star Rating. More information is provided later in this section about the Center for Medicare and Medicaid Innovation's Part D Enhanced MTM Model. Lastly, we will be implementing additional data integrity checks (discussed later in this section) to safeguard against inappropriate attempts to bias the data used for this measure.

### *B. Removal of Measures from Star Ratings*

1. **Improving Bladder Control (Part C).** This measure, collected through the Health Outcomes Survey (HOS), assesses the percentage of beneficiaries with urine leakage who discussed their problem with their provider and received treatment for the issue. NCQA made three changes to this measure. First, NCQA changed the denominator of both indicators to include all adults with urinary incontinence, as opposed to limiting the denominator to those who consider urinary incontinence to be a problem. This will remove a potential bias toward only sampling patients who were treated unsuccessfully. Second, NCQA changed the treatment indicator to assess whether treatment was discussed, as opposed to it being received. This will change the measure focus from receiving potentially inappropriate treatments, which often have adverse side effects, to shared decision making between the patient and provider about the appropriateness of treatment. Third, NCQA added an outcome indicator to assess how much urinary incontinence impacts quality of life for beneficiaries. Data from this outcome indicator will be analyzed further before any new measure (or measure specification change) is proposed as part of the Star Rating.

   These changes required revising the underlying survey questions in HOS. The revised questions were first collected in 2015. As a result of these changes, this measure will not be reported in the 2017 Star Ratings. The revised measure will be reported on the 2017 display page. The 2016 display measure uses data from the old questions.

2. ***High Risk Medication (Part D).*** The High Risk Medication (HRM) measure calculates the percent of Medicare Part D beneficiaries 65 and older who received two or more prescription fills for the same HRM drug with a high risk of serious side effects in the elderly. The measure is endorsed by the PQA and National Quality Forum (NQF), and the HRM rate is calculated using the PQA specifications and medication list based on American Geriatrics Society (AGS) recommendations. The AGS recently released the 2015 update of the Beers Criteria, which serve as the foundation for the AGS recommendations.

   The HRM measure will be removed from the Star Ratings and moved to the display measures for 2017. This proposal is based on a number of factors. While the AGS states that the criteria may be used as both an educational tool and quality measure, it further states that the intent is not to apply the criteria in a punitive manner. Specifically, the addition of a drug to the HRM list is not a contraindication to use, rather an encouragement to avoid use in the senior population without consideration of risks and benefits based on individual patient characteristics. This is a very difficult decisional balance to evaluate in a drug plan that does not have access to full clinical information. As the measure can be calculated only by using prescription drug event (PDE) data, medications cannot be included on the HRM List that have risks conditional on clinical factors that cannot be measured using PDE data alone. As a result, some "Avoid" medications are included in the measure, while others are not. This may create unintended consequences including the inappropriate encouragement of certain non-HRM medications, which may not be the best choice for an individual beneficiary's clinical circumstance.

   Lastly, because it is under direct provider control and should not be affected by non-clinical beneficiary characteristics, the HRM measure was not included in CMS' overall analysis to assess the impact of socio-economic status (SES) on the Star Ratings (discussed later in this draft Call Letter). However, our initial analysis found that after controlling for contract effects and dual eligible or low income subsidy status, there is a significant association between dual eligible/low income status and HRM use. This association remains after further controlling for age, sex, and race/ethnicity. We recommend that the measure developers further review this measure to better understand the associations.

   Avoiding potentially inappropriate medications in older adults remains important for quality of care for Medicare beneficiaries. Therefore, the HRM measure will move to the 2017 display page. We will continue to provide HRM measure reports to Part D sponsors on a monthly basis through the Patient Safety Analysis website, and we will continue to identify outliers.

   This measure may be considered again in the future for the Star Ratings. Measure specification updates endorsed by the PQA will be implemented by CMS with sufficient lead time ahead of formulary and bid deadlines. The PQA made two changes to the HRM

measure specifications. First, any patient with a hospice indicator at any point during the measurement year will be excluded from the denominator calculation. We propose to implement this change immediately for the 2017 display measure based on 2015 data. Second, the PQA revised the criteria to calculate the average dose for doxepin, reserpine, and digoxin. We propose to implement this change for the 2018 measure based on 2016 data. Any additional updates endorsed by the PQA by the 2017 formulary and bid deadlines in May and June 2016 may be considered for adoption in the 2019 measures (using 2017 data).

### *C. Data Integrity*

It is essential that the data used for CMS' Star Ratings are accurate and reliable. CMS' policy is to reduce a contract's measure rating to 1 star if it is determined that biased or erroneous data have been submitted. This would include cases where CMS finds mishandling of data, inappropriate processing, or implementation of incorrect practices by the organization/sponsor have resulted in biased or erroneous data. Examples would include, but are not limited to: a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract's failure to adhere to Plan Finder or PDE data requirements; a contract's errors in processing coverage determinations/exceptions or organization determinations found through program audits or other reviews; compliance actions due to errors in operational areas that would directly impact the data reported or processed for specific measures; or a contract's failure to pass Part C and D Reporting Requirements Data Validation related to organization/sponsor-reported data for specific measures.

CMS has taken several steps in the past years to protect the integrity of the data; however, we continue to identify new vulnerabilities where inaccurate or biased data could exist. We also must safeguard against the Star Ratings Program creating perverse incentives for sponsors. CMS program audits will soon include review of Part D sponsors' MTM programs, which will allow a more comprehensive assessment of Part D sponsors' MTM programs. More information will be released about the MTM audit criteria. Findings identified during pilots of these new MTM audit criteria would not be applied to Star Ratings. Once criteria are finalized, we would review and apply any relevant MTM program audit findings that could demonstrate systemic failures by sponsors that resulted in biased MTM data, outside of the Data Validation results. CMS is concerned about sponsor activities that may not be detected by Data Validation standards, such as attempts to restrict eligibility from their approved MTM programs, encouraging beneficiary opt-out of MTM programs within the first 60-days, or reporting CMRs that do not meet CMS' definition per guidance.

Data Validation standards primarily focus on compliance with CMS' reporting requirements, and CMS considers failing to meet these standards to represent systemic issues that would result in biased data. Data Validation element-level failures can indicate that incomplete or inaccurate data were reported for use in Star Ratings. It is possible for a sponsor to receive a passing score for a section, but have specific element-level failures that directly impact the validity of their

measure. For example, if the Data Validation found a sponsor's errors in the numbers of beneficiaries enrolled in the MTM, or receiving CMR, regardless of the overall MTM DV score, CMS would still have concerns about the accuracy of the sponsor's MTM CMR numerator and denominator.

CMS may perform additional audits or reviews to ensure the validity of data for specific contracts. Without rigorous validation of Star Ratings data, there is risk that CMS will reward contracts with falsely high ratings.

### *D. Impact of Socio-economic and Disability Status on Star Ratings*

A key goal of the MA and Part D programs is to achieve greater value and quality for all beneficiaries; therefore, an important corollary is that we do not distort quality signals in our measures, or mask true differences in quality of care. CMS continuously reviews the Star Ratings methodology to improve the process, incentivize plans, and provide information that is a true reflection of the performance and experience of the enrollees. The policies implemented must result in high quality of care and improved health outcomes for all of our beneficiaries, while acknowledging the unique challenges of serving traditionally underserved subsets of the population.

A number of MA organizations and PDP sponsors believe that enrollment of a high percentage of dual eligible (DE) enrollees and/or enrollees who receive a low income subsidy (LIS) limits their plans' ability to achieve high MA or Part D Star Ratings. CMS has responded to the concern from our stakeholders by comprehensively gathering information to determine if the Star Ratings are sensitive to the LIS/DE and disability status of a contract's enrollees. If adjustments are made to address this issue, they must be data driven. For example, if a disparity is due to challenges in serving disabled beneficiaries, rather than in serving LIS/DE beneficiaries, then the adjustment should clearly focus on disability status of beneficiaries. Similarly, unless our methods are transparent and open to input from a breadth of sources, MA organizations and Part D sponsors will not be able to easily translate our findings into actionable quality improvement steps.
With support from our contractors, CMS has undertaken research to provide scientific evidence as to whether MA organizations or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. In 2014, we issued a Request for Information to gather information directly from organizations to supplement the data that CMS collects, as we believe that plans and sponsors are uniquely positioned to provide both qualitative and quantitative information that is not available from other sources. In February and September 2015, we released details on the findings of our research.[22] We have also reviewed reports about the impact of socio-economic status (SES) on

[22] The February release can be found at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html

quality ratings, such as the report published by the National Quality Forum (NQF) posted at www.qualityforum.org/risk_adjustment_ses.aspx and both the Medicare Payment Advisory Commission's (MedPAC) *Report to the Congress: Medicare Payment Policy* posted at http://www.medpac.gov/documents/reports/mar2015_entirereport_revised.pdf and their recent presentation released on September 10th entitled *Factors Affecting Variation in Medicare Advantage Plan Star Ratings* posted at http://www.medpac.gov/documents/september-2015-meeting-presentation-factors-affecting-variation-in-medicare-advantage-plan-star-ratings.pdf. The IMPACT Act (P.L. 113-185) instructs the Office of the Assistant Secretary for Planning and Evaluation (ASPE) to conduct a study that examines the effect of individuals' SES on quality measures, resource use, and other measures for individuals under the Medicare program and report its findings to Congress by October 2016. Because ASPE's research agenda aligns closely with our goals, we have and will continue to work collaboratively with ASPE and other governmental agencies to broaden and expand the focus of the issue. We note that, as instructed by Congress in the IMPACT Act, ASPE is conducting further research in this area and may make recommendations for additional changes in the future. We look forward to ASPE's continued input.

CMS has also engaged measure developers, NCQA and the PQA, to examine their measure specifications used in the Star Ratings Program to determine if measure re-specification is warranted. The majority of measures used for the Star Ratings Program are consensus-based. As such, those measure scores cannot be adjusted for differences in enrollee case-mix unless required by the measure specification. Measure specifications can be changed only by the measure steward (the owner and developer of the measure). Measure re-specification is a multi-year process. For example, NCQA has a standard process for reviewing any measure and determining whether a measure requires re-specification. NCQA's re-evaluation process is designed to ensure any resulting measure updates abide by NCQA's desirable attributes of relevance, scientific soundness, and feasibility. Relevance describes the extent to which the measure captures information important to different groups, e.g., consumers, purchasers, policymakers. To determine relevance, NCQA assesses issues such as health importance, financial importance, and potential for improvement among entities being measured. Scientific soundness captures the extent to which the measure adheres to clinical evidence and whether its attributes are valid, reliable, and precise. Feasibility captures the extent to which a measure can be collected at reasonable cost and without undue burden. To determine feasibility, NCQA also assesses whether a measure is precisely specified and can be audited. The overall process for assessing the value of re-specification emphasizes multi-stakeholder input, use of evidence-based guidelines and data, and wide public input.

**CMS Research**

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The September release can be found at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf

As stated in the 2016 Final Call Letter, CMS believed additional research into the nature of the differential performance on a subset of measures was necessary before any interim or permanent changes in the Star Ratings measurements could be developed and implemented. The additional research conducted after the publication of the 2016 Final Call Letter allowed for further examination of LIS/DE differences ("effects") and their magnitude. Due to the considerable overlap between LIS/DE beneficiaries and disabled beneficiaries, the research was expanded to consider the possible role of disability status. The research considered the association between the performance on Star Ratings measures and enrollment of LIS/DE/disabled beneficiaries, and the variability across contracts of differences in performance on each measure to gain a better understanding of LIS/DE differences revealed in the preliminary research.[23]

The methodology employed permitted the estimation of within-contract differences associated with LIS/DE and/or disability. Within-contract differences are differences that may exist between subgroups of enrollees in the same contract (e.g., if LIS/DE enrollees within a contract have a different mean or average performance on a measure than non-LIS/DE enrollees in the same contract). These differences may be favorable or unfavorable for LIS/DE and/or disabled beneficiaries. Between-contract differences in performance associated with LIS/DE and/or disability status ("between-contract LIS/DE and/or disability disparities") are the possible additional differences in performance between contracts associated with the contract's proportion of LIS/DE and disabled enrollees that remain after accounting for within-contract disparities by LIS/DE and disability status. If LIS/DE and/or disabled beneficiaries are more or less likely than other beneficiaries to be enrolled in lower-quality contracts, then between-contract disparities may represent true differences between contracts in quality. Because of this possibility, between-contract disparities may not be appropriate for adjustment due to the risk of masking true differences in quality. Adjusting for within-contract disparities is an approach aligned with the consensus reflected in the NQF report on sociodemographic adjustment, which states that, "…*only the within-unit effects are adjusted for in a risk adjustment procedure because these are the ones that are related specifically to patient characteristics rather than differences across units*" (National Quality Forum, 2014). Our research focused on measuring within-contract differences in performance for LIS/DE and/or disabled compared to non-LIS/DE and non-disabled beneficiaries.

Our additional research findings were consistent with the preliminary results shared in the 2016 Final Call Letter. The research to date has provided scientific evidence that there exists a within-

[23] The research focused on a total of 16 clinical quality measures. A measure was *excluded* from analysis if the measure was already case-mix adjusted for SES (i.e., CAHPS and HOS measures), if the focus of the measurement was not a beneficiary-level issue but rather a plan-level issue (e.g., appeals, call center, Part D price accuracy), if the measure was scheduled to be retired or revised, or if the measure was applicable to only Special Needs Plans (SNPs) (i.e., SNP Care Management, Care for Older Adults measures).

contract LIS/DE and disability effect for a subset of the Star Ratings measures. The size of the effect differs across measures and is not exclusively negative.

CMS is firmly committed to building the foundation for a long-term solution that appropriately addresses the issue at hand and aligns with our policy goals. Any policy response must delineate the two distinct aspects of the LIS/DE and/or disability issue - quality and payment. The Star Ratings Program focuses on accurately measuring the quality of care provided, so any response must focus on enhancing the ability to measure actual quality differences among contracts. To address the LIS/DE and disability issue we must accurately address any sensitivity of the ratings to the composition of the beneficiaries enrolled in a contract at the basic building block of the rating system, the measure. CMS has encouraged the measure stewards to examine our findings and undertake an independent evaluation of the measures' specifications to determine if measure re-specification is warranted. Additionally, the payment response focuses on payment accuracy for beneficiaries with different dual statuses, differentiated by aged or disabled status, by improving the predictive performance of the CMS-HCC risk-adjustment model to take into account the unique cost patterns of each of these subgroups of beneficiaries. CMS is considering changes in the risk adjustment models used for payment and issued a separate Request for Comments on October 28, 2015 to obtain feedback on potential revisions. Based in part on the strong support we received to the Request for Comments, we have proposed revisions to the CMS-HCC risk adjustment models for Payment Year 2017 in the Advance Notice.

**Interim Analytical Adjustments**

While the measure stewards undertake a comprehensive review of their measures used in the Star Ratings Program and ASPE continues its work under the IMPACT Act, CMS has been exploring two options for interim analytical adjustments to address the LIS/DE and disability effect: (1) a Categorical Adjustment Index (CAI) and (2) Indirect Standardization (IS) as noted in the "Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond" released on November 12, 2015.[24] We believe the proposed methods, discussed briefly below and explained more fully during the User Call on December 3, 2015,[25] align with the goals of making adjustments that reflect the actual magnitude of the differences observed in the data, providing valid quality ratings to facilitate consumer choice, and providing incentives for MA and Part D quality improvement.

We recognize the need for an interim policy that is both transparent and feasible to implement pending any changes to measure specifications that may be made by the measure stewards. In

[24] The Request for Comment can be found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf

[25] The User Call slides can be found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Potential-Options-for-SES-and-Disability-Adjustments_120315.pdf

addition, the integrity of the Star Ratings and the core of its methodology must be maintained. Further, the adjustment must not result in unnecessary complexity and burden to plans and sponsors. CMS sought to develop a method to afford plans and sponsors the time needed to validate their data and not impinge on the time allotted for the plan preview period. Plans must feel confident in their ability to understand the methodology and reproduce their Overall and Summary Ratings.

The Categorical Adjustment Index (CAI) is a factor that would be added to or subtracted from a contract's Overall and/or Summary Star Rating to adjust for the average within-contract disparity; the adjustment factor varies by a contract's proportion of DE/LIS and disabled beneficiaries. The CAI approximates the effect of case-mix adjustment of contract performance scores for DE/LIS and disabled status. MA contracts would have up to three adjustments – one for the Overall Star Rating and one for each of the Summary Ratings (Part C and Part D). PDPs would have one adjustment for the Part D Summary Rating.

To calculate the CAI, first case-mix adjustment is applied to a subset of the Star Ratings measure scores using a beneficiary-level fixed-effects logistic regression model with contract intercepts and beneficiary-level indicators of LIS/DE and disability status. This type of adjustment is similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case mix adjustment, the only adjusters are LIS/DE and disability status. Adjusted measure scores are then converted to measure-level stars using the rating year measure cutoffs and used to calculate an Adjusted Overall and Summary Star Ratings. Unadjusted Overall and Summary Star Ratings are also determined per contract.

To determine the value of the CAI, contracts are first divided into an initial set of categories based on the combination of a contract's LIS/DE and disability proportions. For the adjustment for the Overall and Part C and D Summary Ratings for MA contracts, the initial groups would be formed by the deciles of LIS/DE and quintiles of disability, thus resulting in 50 initial categories. For PDPs, the initial groups would be formed using quartiles for both LIS/DE and disability. The mean differences between the Adjusted Overall or Summary Star Rating and the corresponding Unadjusted Star Rating for contracts in each initial category are determined and examined. The initial categories are collapsed to form final adjustment groups using criteria developed for the method and detailed later within this document. The CAI values are the mean differences between the Adjusted Overall or Summary Star Rating and the corresponding Unadjusted Star Rating for contracts within each final adjustment group. Separate CAI values are computed for the Overall and Summary Star Ratings, and the rating-specific CAI value would be the same for all contracts that fall within the same final adjustment category.

Indirect Standardization (IS), the alternative proposal for adjustment, would be applied to the same subset of the individual measures that are adjusted for the determination of the CAI. The focus of the adjustment is the within-contract LIS/DE and/or disability status difference in the

measure scores while allowing for the existence of true differences in quality by contract. The standardization would employ the current year's measure scores.

The methodology for IS includes the calculation of an expected measure score based on a contract's composition of LIS/DE and disabled beneficiaries using adjusted national means per selected measure. The ratio between a contract's actual (observed) and expected measure score is used to determine an adjusted measure score and likewise, an adjusted measure-level Star Rating. The conversion from an adjusted measure score to adjusted measure-level star would use cut points based on the adjusted scores. The adjusted measure-level stars are then used in conjunction with all other Star Ratings measures to arrive at the Adjusted Overall and Summary Star Ratings.

**Simulations**

Using the 2016 Star Rating's data, CMS simulated the change in the distribution of ratings to the Overall and Part C and D Summary Star Ratings for MA organizations and Part D Summary Rating for PDP contracts after the application of the CAI values and IS.

The measures selected for adjustment were determined by our research and include the measures that had the greatest differences in outcomes between LIS/DE and/or disability beneficiaries and non-LIS/DE and/or non-Disabled beneficiaries within the same contracts. The measures selected for adjustment include the following six Part C measures for MA (MA-only, MA-PD) and 1876 contracts: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, and Reducing the Risk of Falling. In addition, Medication Adherence for Hypertension (RAS antagonists) would be adjusted for MA-PDs and PDPs.[26]

Please note the general simulation results do not include contracts that exclusively serve Puerto Rico. The simulation results for Puerto Rico and a discussion of the LIS Indicator are presented in a separate section.

Below, we produce separate simulations of how both CAI and IS affect (i) the Overall Star Rating for MA-PDs; (ii) the Part C Summary Star Rating for MA-PDs; (iii) the Part D Summary Star Rating for MA-PDs; and (iv) the Part D Summary Star Rating for PDPs. Contracts will be able to review their simulation results in HPMS beginning on February 22, 2016.

**Simulations for MA contracts**

i. <u>Overall Star Rating</u>

*Categorical Adjustment Index (CAI)*

[26] The research showed that the median absolute difference in performance between LIS/DE and non-LIS/DE enrollees was greater than 5% for PDPs for Medication Adherence for Hypertension. It was slightly smaller for MA-PDs, but to apply consistent adjustments across MA-PDs and PDPs it is included for both delivery systems.

The simulation for the CAI used all reportable overall MA enrollment contract proportions for LIS/DE and disabled beneficiaries to determine the cutoffs for the initial categories.[27] Tables 1 and 2 provide the range of the percentages that correspond to the LIS/DE deciles and disability quintiles. The upper limit for each initial category is not included in that category, but rather the next higher category. For example, if a contract's percentage of LIS/DE beneficiaries is 12.60%, the contract's LIS/DE decile would be 3. The exceptions for the upper limit exclusion for a class are the tenth decile for LIS/DE and the fifth quintile for disabled. Both of these initial categories include the upper limit of the category of 100%.

**Table 1: Categorization of MA Contracts into Deciles of LIS/DE for Initial Categories for the Overall Summary Star Rating**

| LIS/DE Decile | Percentage of Contract's LIS/DE Beneficiaries |
|---|---|
| 1 | 0.00% to less than 8.94% |
| 2 | 8.94% to less than 12.60% |
| 3 | 12.60% to less than 15.70% |
| 4 | 15.70% to less than 19.00% |
| 5 | 19.00% to less than 23.90% |
| 6 | 23.90% to less than 30.37% |
| 7 | 30.37% to less than 46.30% |
| 8 | 46.30% to less than 73.90% |
| 9 | 73.90% to less than 99.00% |
| 10 | 99.00% to 100.00% |

**Table 2: Categorization of MA Contracts into Disability Quintiles for the Overall Summary Star Rating**

| Disability Quintile | Percentage of Contract's Disabled Beneficiaries |
|---|---|
| 1 | 0.00% to less than 9.00% |
| 2 | 9.00% to less than 13.10% |
| 3 | 13.10% to less than 18.86% |
| 4 | 18.86% to less than 26.50% |
| 5 | 26.50% to 100.00% |

The initial categories were collapsed to form the final adjustment categories in a manner that enforced monotonicity and ensured each category included at least 20 contracts to provide stability in the estimates. *In other words, initial categories were combined such that as the*

[27] The working definition for LIS/DE beneficiaries is defined as beneficiaries who qualify at any point in the measurement year for a low income subsidy through the application process and/or who are full or partial Dual (Medicare and Medicaid) beneficiaries. Disability status for beneficiaries is based on the Original Reason for Entitlement for Medicare.

*proportion of DE/LIS and disability beneficiaries within a contract increases, the adjustment (value of the CAI) does not decrease.* Table 3 provides the description of each of the final adjustment categories and the associated value of the CAI per category.

**Table 3: Final Simulated Adjustment Categories and Corresponding Values of the CAI for the Overall Star Rating**

| Final Adjustment Category | Description | CAI Value |
|---|---|---|
| 1 | %LIS/DE Decile 1, %Disability Quintile 1 | −0.016 |
| 2 | %LIS/DE Deciles 2-9, %Disability Quintile 1<br>%LIS/DE Deciles 1-6, %Disability Quintile 2 | −0.006 |
| 3 | %LIS/DE Deciles 1-5, %Disability Quintiles 3-5<br>%LIS/DE Decile 6, %Disability Quintile 3 | 0.002 |
| 4 | %LIS/DE Deciles 7-8, %Disability Quintiles 2-3 | 0.014 |
| 5 | %LIS/DE Decile 10, %Disability Quintiles 1-4<br>%LIS/DE Decile 9, %Disability Quintiles 2-4<br>%LIS/DE Deciles 6-8, %Disability Quintile 4 | 0.025 |
| 6 | %LIS/DE Deciles 6-8, %Disability Quintile 5 | 0.029 |
| 7 | %LIS/DE Decile 9, %Disability Quintile 5 | 0.055 |
| 8 | %LIS/DE Decile 10, %Disability Quintile 5 | 0.081 |

The CAI table would become part of the Technical Notes for the rating year.

The tables below show the number of contracts that achieve specified star ratings using both unadjusted and adjusted star ratings under each of the two interim analytical adjustments. The general format of the matrix that comprises Table 4 is used throughout this section. The cells that comprise the main diagonal of the matrix are shaded grey. Any contract that is counted in a cell on the main diagonal would not realize a change in its Star Rating after the application of the interim analytical adjustment. Any contract that is counted in a cell that lies above the main diagonal would realize an increase in its Star Rating after the application of the interim analytical adjustment. The cells directly above the main diagonal correspond to an increase of half-star after the application of the analytical adjustment and are shaded green. Any contract that is counted in a cell that lies directly below the main diagonal would realize a decrease in its Star Rating after the application of the interim analytical adjustment. The cells that lie directly below the main diagonal are shaded red. Further discussion of the movement of the contracts after the application of the adjustment is presented later within this section. Each table presented is specific to a particular rating (Overall, Part D Summary, or Part D Summary) and interim analytical adjustment (CAI or IS).

Table 4 details the movement of the Overall Star Rating with the application of the CAI as compared to the Unadjusted Overall Star Rating.

**Table 4: Comparison between Unadjusted Overall Star Rating and CAI-Adjusted Overall Star Rating**

| | Overall CAI-Adjusted Star Rating | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| ***Unadjusted Star Rating*** | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | *0* |
| *1.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | *0* |
| *2.0* | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | *1* |
| *2.5* | 0 | 0 | 0 | 9 | 1 | 0 | 0 | 0 | 0 | *10* |
| *3.0* | 0 | 0 | 0 | 0 | 67 | 5 | 0 | 0 | 0 | *72* |
| *3.5* | 0 | 0 | 0 | 0 | 0 | 133 | 3 | 0 | 0 | *136* |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 1 | 121 | 2 | 0 | *124* |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 66 | 0 | *66* |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | *12* |
| **CAI total/rating** | 0 | 0 | 1 | 9 | 68 | 139 | 124 | 68 | 12 | Total number of contracts 421 |

As shown in Table 5, the vast majority of contracts did not experience a change in their Overall Star Rating after applying the CAI. We note that many contracts have their Overall Rating reduced by a small amount by the CAI methodology, but that this ultimately did not affect their Overall Star Rating. A total of 12 contracts had a half-star change in their Overall Star Rating: 11 increased their Overall Rating by a half-star, and one decreased by a half-star. Of the contracts that received an increase in their Overall Star Rating, 10 enrolled a majority of LIS/DE beneficiaries and a variable proportion of disabled beneficiaries. The distribution of contracts that gain or lose stars could be different in future years depending on the proximity of the unrounded Star Rating to a particular cutoff. As detailed in the 2016 Star Rating Technical Notes available on the CMS webpage (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html), Overall and Summary Star Ratings are rounded following criteria to the nearest half-star.

**Table 5: Summary of Changes to Overall Star Rating under CAI**

| CAI vs Unadjusted Star Rating | Number of Contracts | Percent of Contracts |
|---|---|---|
| No Difference | 409 | 97.1% |
| Up By ½ Star | 11 | 2.6% |
| Down By ½ Star | 1 | 0.2% |

Table 6 summarizes the number of beneficiaries in contracts whose Overall Star Rating would have changed after the application of the CAI. In addition, the table summarizes the mean percentage of LIS/DE and disabled beneficiaries in the plans that realized a change in their Overall Rating. Based on the CAI simulation, there were 276,937 beneficiaries in contracts that

would receive an increase of half a star in their Overall Star Rating. The two contracts that had their scores change from 4.0 to 4.5 were almost exclusively serving vulnerable beneficiaries. The single contract that lost half a star was non-renewed in 2016. (The terminated contract was included in the simulation, because the data for the contract was reportable and included in the determination of measure cut points for the ratings year.) The contract whose rating decreased had the lowest percentage of LIS/DE and disabled beneficiaries of the affected contracts.

**Table 6: Change in Overall Star Rating for CAI – MA Contract Characteristics**

| Change in Overall MA Star Rating for CAI | Movement in Stars | Number of Contracts | Mean Percentage of LIS/DE | Mean Percentage of Disabled | Total Number of Beneficiaries Impacted (1/2016) |
|---|---|---|---|---|---|
| 2.5 to 3.0 | up | 1 | 82% | 50% | 10,171 |
| 3.0 to 3.5 | up | 5 | 85% | 38% | 212,949 |
| 3.5 to 4.0 | up | 3 | 71% | 51% | 26,470 |
| 4.0 to 4.5 | up | 2 | 100% | 29% | 27,347 |
| *4.0 to 3.5* | *down* | *1* | 18% | 12% | NA - contract inactive in 2016 |
| Total Number of Contracts | | 12 | Total Number of Enrollees | | 276,937 |

*Indirect Standardization (IS)*

The alternative interim analytical adjustment, IS, was applied using the 2016 Star Ratings data. The conversion from adjusted measure score to an adjusted measure-level Star Rating employed adjusted measure score cut points.

Table 7 details the movement of the Unadjusted Overall Star Rating under IS.

**Table 7: Comparison between Unadjusted Overall Star Rating and IS-Adjusted Overall Star Rating**

| | Overall Star Rating for IS-Adjusted Star | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *2.0* | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| *2.5* | 0 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 10 |
| *3.0* | 0 | 0 | 0 | 2 | 66 | 4 | 0 | 0 | 0 | 72 |
| *3.5* | 0 | 0 | 0 | 0 | 4 | 131 | 1 | 0 | 0 | 136 |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 9 | 110 | 5 | 0 | 124 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 56 | 0 | 66 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 10 | 12 |
| **IS total/rating** | 0 | 0 | 1 | 12 | 70 | 144 | 121 | 63 | 10 | Total number of contracts 421 |

As shown in Table 8, the majority of contracts did not experience a change in their Overall Star Rating using IS. A total of 37 contracts realized a half-star change in their Overall Star Rating. Approximately three-quarters of the impacted contracts experienced lower ratings, while a little over one-quarter of the 37 contracts that experienced a change gained half a star. Over half of the contracts that had their Overall Rating increase by half a star enrolled a majority of LIS/DE beneficiaries, while the other half of the contacts that realized a half-star increase did not. As with the CAI, the overall movement and number of contracts impacted by the application of IS can change from year to year and thus, the distribution of star increases and decreases as shown in Table 8 can vary in subsequent years.

**Table 8: Summary of Changes to Overall Star Rating under IS**

| IS vs Unadjusted Star Rating | Number of Contracts | Percent of Contracts |
|---|---|---|
| No Difference | 384 | 91.2% |
| Up By ½ Star | 10 | 2.4% |
| Down By ½ Star | 27 | 6.4% |

Using IS, 124,425 beneficiaries would be in contracts that received an increase of half a star and 715,786 beneficiaries would be in contracts that lost half a star. Table 9 summarizes the number of beneficiaries that would be in contacts whose Overall Rating changed. The contracts that experienced an increase to their Overall Rating tended to be the contracts that served a higher mean percentage of vulnerable beneficiaries as compared to the contracts that lost a half-star. However, two of the five contracts that had their Overall Rating change from 4.0 to 4.5 had very

low percentages of LIS/DE and disabled beneficiaries. One of the nine contracts whose score changed from 4.0 to 3.5 served almost exclusively LIS/DE beneficiaries. Three of the four contracts that experienced a change in their Overall Rating from 3.5 to 3.0 served a majority of LIS/DE beneficiaries.

**Table 9: Change in Overall Star Rating for IS – MA Contract Characteristics**

| Change in Overall MA Star Rating for IS | Movement in Stars | Number of Contracts | Mean Percentage of LIS/DE | Mean Percentage of Disabled | Total Number of Beneficiaries Impacted (1/2016) |
|---|---|---|---|---|---|
| 3.0 to 3.5 | up | 4 | 65% | 24% | 52,819 |
| 3.5 to 4.0 | up | 1 | 100% | 68% | 6,259 |
| 4.0 to 4.5 | up | 5 | 64% | 24% | 65,347 |
| *3.0 to 2.5* | *down* | 2 | 31% | 23% | 25,026 |
| *3.5 to 3.0* | *down* | 4 | 35% | 16% | 70,021 |
| *4.0 to 3.5* | *down* | 9 | 25% | 0% | 173,247 |
| *4.5 to 4.0* | *down* | 10 | 16% | 13% | 355,949 |
| *5.0 to 4.5* | *down* | *2* | 13% | 10% | 91,543 |
| Total Number of Contracts | | 37 | Total Number of Enrollees | | 840,211 |

ii. Part C Summary Rating

*CAI*

Tables 10 and 11 provide the range of the percentages that correspond to the LIS/DE deciles and disability quintiles for the initial categories for the determination of the CAI values for the Part C Summary Rating.

**Table 10: Categorization of MA Contracts into Deciles of LIS/DE for Initial Categories for the Part C Summary Adjustment**

| LIS/DE Decile | Percentage of Contract's LIS/DE Beneficiaries |
|---|---|
| 1 | 0.00% to less than 8.72% |
| 2 | 8.72% to less than 12.38% |
| 3 | 12.38% to less than 15.56% |
| 4 | 15.56% to less than 18.81% |
| 5 | 18.81% to less than 23.56% |
| 6 | 23.56% to less than 29.84% |
| 7 | 29.84% to less than 45.43% |
| 8 | 45.43% to less than 71.92% |
| 9 | 71.92% to less than 99.01% |
| 10 | 99.01% to 100.00% |

**Table 11: Categorization of MA Contracts into Disability Quintiles for the Part C Summary Adjustment**

| Disability Quintile | Percentage of Contract's Disabled Beneficiaries |
|---|---|
| 1 | 0.00% to less than 8.81% |
| 2 | 8.81% to less than 12.69% |
| 3 | 12.69% to less than 18.69% |
| 4 | 18.69% to less than 26.30% |
| 5 | 26.30% to 100.00% |

Table 12 provides the description of each of the final adjustment categories for the Part C Summary Rating and the associated value of the CAI for each final adjustment category.

**Table 12: Final Simulated Adjustment Categories and CAI Values for the Part C Summary Rating**

| Final Adjustment Category | Description | CAI Value |
|---|---|---|
| **1** | %LIS/DE Decile 1, %Disability Quintile 1 | −0.018 |
| **2** | %LIS/DE Deciles 2-8, %Disability Quintile 1<br>%LIS/DE Deciles 1-6, %Disability Quintile 2 | −0.002 |
| **3** | %LIS/DE Deciles 1-5, %Disability Quintiles 3-5<br>%LIS/DE Decile 6, %Disability Quintile 3 | 0.005 |
| **4** | %LIS/DE Deciles 7-8, %Disability Quintiles 2-3 | 0.011 |
| **5** | %LIS/DE Decile 9-10, %Disability Quintiles 1-3<br>%LIS/DE Deciles 6-10, %Disability Quintile 4 | 0.014 |
| **6** | %LIS/DE Deciles 6-8, %Disability Quintile 5 | 0.021 |
| **7** | %LIS/DE Decile 9, %Disability Quintile 5 | 0.033 |
| **8** | %LIS/DE Decile 10, %Disability Quintile 5 | 0.046 |

Table 13 details the movement of the Unadjusted Part C Summary Star Rating with the application of the CAI.

**Table 13: Comparison between Unadjusted Part C Summary Star Rating and CAI-Adjusted Part C Summary Star Rating**

| | Part C Summary Rating for CAI-Adjusted Star | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| *2.0* | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| *2.5* | 0 | 0 | 0 | 20 | 2 | 0 | 0 | 0 | 0 | 22 |
| *3.0* | 0 | 0 | 0 | 0 | 101 | 7 | 0 | 0 | 0 | 108 |
| *3.5* | 0 | 0 | 0 | 0 | 0 | 132 | 0 | 0 | 0 | 132 |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 0 | 91 | 0 | 0 | 91 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 60 | 0 | 60 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 6 | 8 |
| **CAI total/ratings** | 0 | 2 | 5 | 20 | 103 | 139 | 91 | 62 | 6 | Total number of contracts 428 |

As shown in Table 14, the vast majority of contracts did not experience a change in their Part C Summary Star Rating under the CAI. A total of 11 MA contracts realized a half-star change in their Part C Summary Star Rating, with nine contracts increasing by a half-star and two decreasing by a half-star. In general, the contracts that experienced an increase in their Part C Summary Rating were contracts that served a majority of vulnerable beneficiaries, with a third of the contracts serving almost exclusively LIS/DE beneficiaries. The two contracts that experienced a reduction in their rating had enrollment of a minimal percentage of LIS/DE and disabled beneficiaries. The overall movement and number of contracts impacted by the application of the CAI can change from year to year and thus, the distribution of star increases and decreases as shown in Table 14 can vary in subsequent years.

**Table 14: Summary of Changes to Part C Summary Star Rating under CAI**

| CAI vs Unadjusted Star Rating | Number of Contracts | Percent of Contracts |
|---|---|---|
| No Difference | 417 | 97.4% |
| Up By $^1/_2$ Star | 9 | 2.1% |
| Down By $^1/_2$ Star | 2 | 0.5% |

*IS*

Table 15 details the movement of the Unadjusted Part C Summary Star Rating under IS.

**Table 15: Comparison between Unadjusted Part C Summary Rating and IS-Adjusted Part C Summary Star Rating**

| | **Part C Summary Rating for IS-Adjusted Star** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| *2.0* | 0 | 0 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 5 |
| *2.5* | 0 | 0 | 0 | 18 | 4 | 0 | 0 | 0 | 0 | 22 |
| *3.0* | 0 | 0 | 0 | 0 | 104 | 4 | 0 | 0 | 0 | 108 |
| *3.5* | 0 | 0 | 0 | 0 | 1 | 129 | 2 | 0 | 0 | 132 |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 11 | 79 | 1 | 0 | 91 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 6 | 54 | 0 | 60 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 6 | 8 |
| **IS total/ratings** | 0 | 2 | 5 | 18 | 109 | 144 | 87 | 57 | 6 | Total number of contracts 428 |

As shown in Table 16, the majority of contracts did not experience a change in their Part C Star Rating under the IS. A total of 31 MA contracts realized a half-star change in their Part C Summary Star Rating, with about half of the impacted contracts experiencing an increase. Approximately half of the contracts that realized an increase in their rating served a majority of LIS/DE beneficiaries. One of the twenty contracts that experienced a decrease in their Part C Summary Rating had enrollments of LIS/DE beneficiaries of greater than 50%. The overall movement and number of contracts impacted by the application of IS can change from year to year and thus, the distribution of star increases and decreases as shown in Table 16 could vary in subsequent years.

**Table 16: Summary of Changes to Part C Summary Star Rating under IS**

| **IS vs Unadjusted Star Rating** | **Number of Contracts** | **Percent of Contracts** |
|---|---|---|
| No Difference | 397 | 92.8% |
| Up By ½ Star | 11 | 2.6% |
| Down By ½ Star | 20 | 4.7% |

iii. Part D Summary Rating for MA-PDs

*CAI*

Tables 17 and 18 provide the range of the percentages that correspond to the LIS/DE deciles and the disability quintiles for the initial categories for the determination of the CAI values for the Part D Summary Rating for MA-PDs.

**Table 17: Categorization of MA Contracts into Deciles of LIS/DE for Initial Categories for the Part D Summary Adjustment for MA-PDs**

| LIS/DE Decile | Percentage of Contract's LIS/DE Beneficiaries |
|---|---|
| 1 | 0.00% to less than 8.94% |
| 2 | 8.94% to less than 13.01% |
| 3 | 13.01% to less than 16.11% |
| 4 | 16.11% to less than 20.43% |
| 5 | 20.43% to less than 26.25% |
| 6 | 26.25% to less than 32.62% |
| 7 | 32.62% to less than 47.87% |
| 8 | 47.87% to less than 78.88% |
| 9 | 78.88% to less than 99.60% |
| 10 | 99.60% to 100.00% |

**Table 18: Categorization of MA Contracts into Disability Quintiles for the Part D Summary Adjustment for MA-PDs**

| Disability Quintile | Percentage of Contract's Disabled Beneficiaries |
|---|---|
| 1 | 0.00% to less than 9.39% |
| 2 | 9.39% to less than 13.58% |
| 3 | 13.58% to less than 19.95% |
| 4 | 19.95% to less than 29.71% |
| 5 | 29.71% to 100.00% |

Table 19 provides the description of each of the final adjustment categories for the Part D Summary Rating for MA-PDs and the associated values of the CAI for each final adjustment category.

**Table 19: Final Simulated Adjustment Categories and CAI Values for the Part D Summary Rating for MA-PDs**

| CAI Category | Description | CAI Value |
|---|---|---|
| 1 | %LIS/DE Deciles 1-5, %Disability Quintiles 1-2 | −0.007 |
| 2 | %LIS/DE Deciles 1-5, %Disability Quintiles 3-5 | −0.002 |
| 3 | %LIS/DE Deciles 6-10, %Disability Quintiles 1-3 | 0.001 |
| 4 | %LIS/DE Deciles 6-10, %Disability Quintile 4 | 0.027 |
| 5 | %LIS/DE Deciles 6-8, %Disability Quintile 5 | 0.052 |
| 6 | %LIS/DE Decile 9, %Disability Quintile 5 | 0.088 |
| 7 | %LIS/DE Decile 10, %Disability Quintile 5 | 0.092 |

Table 20 details the movement of the Unadjusted Part D Summary Rating for MA-PDs with the application of the CAI.

**Table 20: Comparison between Unadjusted Part D Summary Star Rating and CAI-Adjusted Part D Summary Star Rating for MA-PDs**

| | **Part D Summary Rating for CAI-Adjusted Star** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *2.0* | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| *2.5* | 0 | 0 | 0 | 10 | 1 | 0 | 0 | 0 | 0 | 11 |
| *3.0* | 0 | 0 | 0 | 0 | 28 | 6 | 0 | 0 | 0 | 34 |
| *3.5* | 0 | 0 | 0 | 0 | 0 | 117 | 9 | 0 | 0 | 126 |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 0 | 144 | 5 | 0 | 149 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 92 | 2 | 94 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 51 | 51 |
| **CAI total/ratings** | 0 | 0 | 0 | 11 | 29 | 123 | 153 | 97 | 53 | Total number of contracts 466 |

As shown in Table 21, the majority of contracts did not experience a change in their Part D Star Rating under CAI. All MA-PD contracts that realized change in their Part D Summary Star experienced a half-star increase in their Part D Summary Rating. Twenty of the twenty-four contracts whose Part D Summary Rating increased by a half-star had proportions of LIS/DE of greater than 50%. Ten of the contracts that realized a change in the Part D Summary Rating under CAI served a majority of disabled beneficiaries. The overall movement and number of

contracts impacted by the application of the CAI can change from year to year and thus, the distribution of star increases and decreases as shown in Table 21 can vary in subsequent years.

**Table 21: Summary of Changes to Part D Summary Star Rating under CAI for MA-PDs**

| CAI vs Unadjusted Star Rating | Number of Contracts | Percent of Contracts |
|---|---|---|
| No Difference | 442 | 94.8% |
| Up By ½ Star | 24 | 5.2% |
| Down By ½ Star | 0 | 0.0% |

*IS*

Table 22 details the movement of the Unadjusted Part D Summary Rating for MA-PDs under IS.

**Table 22: Comparison between Unadjusted Part D Summary Rating and IS-Adjusted Part D Summary Star Rating for MA-PDs**

| | Part D Summary Rating for IS-Adjusted Star | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *2.0* | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| *2.5* | 0 | 0 | 0 | 11 | 0 | 0 | 0 | 0 | 0 | 11 |
| *3.0* | 0 | 0 | 0 | 0 | 34 | 0 | 0 | 0 | 0 | 34 |
| *3.5* | 0 | 0 | 0 | 0 | 4 | 120 | 2 | 0 | 0 | 126 |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 9 | 138 | 2 | 0 | 149 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 83 | 0 | 94 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 11 | 40 | 51 |
| **IS total/ratings** | 0 | 0 | 1 | 11 | 38 | 129 | 151 | 96 | 40 | Total number of contracts 466 |

As shown in Table 23, a total of 39 contracts had a half-star change in their Overall Star Rating using IS: 4 increased their Part D Summary Rating by a half-star, and 35 decreased by a half-star. Three of the four contracts that realized an increase in their Part D Summary Rating served almost exclusively LIS/DE beneficiaries. The other contract that realized an increase in their Part D Summary Rating served a small percentage of LIS/DE beneficiaries. One contract that realized a decrease in their Part D Summary Rating had an enrollment of greater than 99% LIS/DE beneficiaries. The overall movement and number of contracts impacted by the application of IS can change from year to year and thus, the distribution of star increases and decreases as shown in Table 23 can vary in subsequent years.

**Table 23: Summary of Changes to Part D Summary Star Rating under IS**

| IS vs Unadjusted Star Rating | Number of Contracts | Percent of Contracts |
|---|---|---|
| No Difference | 427 | 91.6% |
| Up By ½ Star | 4 | 0.9% |
| Down By ½ Star | 35 | 7.5% |

**Simulations for PDP Contracts**

The summary of the PDP simulations excludes contracts that exclusively serve Puerto Rico; however, the same simulations for PDPs in Puerto Rico were completed and are discussed later in the Star Ratings section of the draft Call Letter.

iv. Part D Summary Rating

*CAI*

Tables 24 and 25 provide the range of the percentages that correspond to the LIS/DE and disability quartiles for the initial categories for the determination of the CAI values for the Part D Summary Rating for PDPs. Quartiles are used for both dimensions due to the limited number of PDPs as compared to MA contracts.

**Table 24: Categorization of PDP Contracts into LIS/DE Quartiles**

| LIS/DE Quartile | Percentage of Contract's LIS/DE Beneficiaries |
|---|---|
| **1** | 0.00% to less than 3.79% |
| **2** | 3.79% to less than 11.41% |
| **3** | 11.41% to less than 49.43% |
| **4** | 49.43% to 100.00% |

**Table 25: Categorization of PDP Contracts into Disability Quartiles**

| LIS/DE Quartile | Percentage of Contract's Disabled Beneficiaries |
|---|---|
| **1** | 0.00% to less than 5.37% |
| **2** | 5.37% to less than 9.98% |
| **3** | 9.98% to less than 28.32% |
| **4** | 28.32% to 100.00% |

Table 26 provides the description of each of the final adjustment categories for the Part D Summary Rating for PDPs and the associated value of the CAI per final adjustment category. Please note that the CAI values for the Part D Summary Rating for PDPs are different from the CAI values for the Part D Summary Rating for MA contracts. Categories were chosen to enforce monotonicity and to yield a minimum of 10 contracts per final adjustment category. There are three final adjustment categories for PDPs for the Part D Summary Rating.

**Table 26: Final Simulated Adjustment Categories and Corresponding Values of the CAI for PDPs**

| Final Adjustment Category | Description | CAI Value |
|---|---|---|
| **1** | %LIS/DE Quartiles 1 & 2<br>%LIS/DE Quartiles 3-4 & %Disability Quartiles 1-2 | −0.109 |
| **2** | %LIS/DE Quartile 3 & %Disability Quartiles 3-4<br>%LIS/DE Quartile 4 & %Disability Quartile 3 | −0.023 |
| **3** | %LIS/DE Quartile 4 & %Disability Quartile 4 | 0.127 |

Table 27 details the movement of the Unadjusted Part D Summary Rating for PDPs with the application of the CAI.

**Table 27: Comparison between Unadjusted Part D Summary Star Rating and CAI-Adjusted Part D Summary Star Rating for PDPs**

| | **Part D Summary Rating for CAI-Adjusted Star for PDPs** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *2.0* | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 2 |
| *2.5* | 0 | 0 | 0 | 5 | 1 | 0 | 0 | 0 | 0 | 6 |
| *3.0* | 0 | 0 | 0 | 0 | 13 | 3 | 0 | 0 | 0 | 16 |
| *3.5* | 0 | 0 | 0 | 0 | 2 | 12 | 0 | 0 | 0 | 14 |
| *4.0* | 0 | 0 | 0 | 0 | 0 | 3 | 10 | 0 | 0 | 13 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 9 | 0 | 11 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 2 |
| **CAI total/ratings** | 0 | 0 | 1 | 6 | 16 | 18 | 12 | 10 | 1 | Total number of contracts 64 |

As Table 28 shows, the majority of PDPs did not experience a change in their Part D Summary Star Rating. A total of 13 contracts had a half-star change in their Part D Rating: five contracts increased their Part D Summary Rating by a half-star, and eight contracts' Part D Ratings decreased by a half-star. All contracts that received an increase in their ratings had enrollment that include a majority of LIS/DE and a large percentage of disabled beneficiaries. In general, contracts that lost a half star were contracts with a low enrollment of LIS/DE and/or disabled beneficiaries. The overall movement and number of contracts impacted by the application of the CAI can change from year to year and thus, the distribution of star increases and decreases as shown in Table 28 can vary in subsequent years.

**Table 28: Summary of Changes to Part D Summary Star Rating using CAI for PDPs**

| CAI vs Unadjusted Star Rating | Number of Contracts | Percent of Contracts |
|---|---|---|
| No Difference | 51 | 79.7% |
| Up By ½ Star | 5 | 7.8% |
| Down By ½ Star | 8 | 12.5% |

Simulations of the application of the CAI resulted in a total of 2,117,550 beneficiaries in contracts that received an increase of half a star, and 818,431 beneficiaries in contracts that lost half a star. Table 29 summarizes the number of beneficiaries that would be in contacts whose Part D Summary Star Rating changed. The PDPs that experienced an increase in their Part D Summary Rating were the contracts that served a higher percentage of vulnerable beneficiaries as compared to the PDPs that lost a half-star.

**Table 29: Change in Part D Summary Rating for CAI – PDP Contract Characteristics**

| Change in Part D Star Rating for CAI | Movement in Stars | Number of Contracts | Mean Percentage of LIS/DE | Mean Percentage of Disabled | Total Number of Beneficiaries Impacted (1/2016) |
|---|---|---|---|---|---|
| 2.0 to 2.5 | up | 1 | 79% | 46% | 1,143 |
| 2.5 to 3.0 | up | 1 | 1% | 29% | 965,070 |
| 3.0 to 3.5 | up | 3 | 76% | 44% | 1,151,337 |
| *3.5 to 3.0* | *down* | 2 | 12% | 9% | 385,563 |
| *4.0 to 3.5* | *down* | 3 | 4% | 4% | 385,057 |
| *4.5 to 4.0* | *down* | 2 | 5% | 7% | 39,853 |
| *5.0 to 4.5* | *down* | *1* | 2% | 1% | 7,958 |
| Total Number of Contracts | | 13 | Total Number of Enrollees | | 2,935,981 |

*IS*

Table 30 details the movement of the Unadjusted Part D Summary Star Rating with the application of the IS for PDPs.

**Table 30: Comparison between Unadjusted Part D Summary Star Rating and IS-Adjusted Part D Summary Star Rating for PDPs**

| | **Part D Summary Rating for IS-Adjusted Star for PDPs** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Unadjusted Star Rating* | **1.0** | **1.5** | **2.0** | **2.5** | **3.0** | **3.5** | **4.0** | **4.5** | **5.0** | *Unadjusted total/rating* |
| *1.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *1.5* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| *2.0* | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 2 |
| *2.5* | 0 | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 6 |
| *3.0* | 0 | 0 | 0 | 0 | 16 | 0 | 0 | 0 | 0 | 16 |
| *3.5* | 0 | 0 | 0 | 0 | 2 | 12 | 0 | 0 | 0 | 14 |
| *4.0* | 0 | 0 | 0 | 0 | 2 | 0 | 10 | 1 | 0 | 13 |
| *4.5* | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 9 | 0 | 11 |
| *5.0* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 |
| **IS total/rating** | 0 | 0 | 1 | 7 | 20 | 12 | 12 | 10 | 2 | Total number of contracts 64 |

Table 31 shows the majority of PDPs did not experience a change in their Part D Summary Star Rating under IS. A total of six contracts had a half-star change (increase or decrease) in their Part D Summary Star Rating, and two contracts experienced a one-star decrease in their Part D Summary Star Ratings. The contracts that experienced an increase in their Part D rating had very different compositions of enrollees. One contract had the majority of enrollees classified as either LIS/DE or disabled, while the other contract served a minimal percentage of vulnerable beneficiaries. The overall movement and number of contracts impacted by the application of IS can change from year to year and thus, the distribution of star increases and decreases as shown in Table 31 could vary in subsequent years.

**Table 31: Summary of Changes to PDP Star Rating under IS**

| **IS vs 2016 Star Ratings** | **Number of Contracts** | **Percent of Contracts** |
|---|---|---|
| No Difference | 56 | 87.5% |
| Up By ½ Star | 2 | 3.1% |
| Down By ½ Star | 4 | 6.3% |
| Down by 1 Star | 2 | 3.1% |

The application of IS resulted in a total of 7,342 beneficiaries in contracts that received an increase of half a star and 425,416 beneficiaries in contracts that lost half a star and 83,124 beneficiaries in contrast that lost one star. Table 32 summarizes the number of beneficiaries that would be in contacts whose Part D Summary Star Rating changed. The one PDP that experienced an increase in their Part D Summary Rating from 2.0 to 2.5 served a higher percentage of vulnerable beneficiaries as compared to the other PDPs with changes. The contracts that experienced a decrease in their stars served a minimal percentage of LIS/DE/disabled beneficiaries.

**Table 32: Change in Part D Summary Star Rating for IS – PDP Contract Characteristics**

| Change in Part D Star Rating for IS | Movement in Stars | Number of Contracts | Mean Percentage of LIS/DE | Mean Percentage of Disabled | Total Number of Beneficiaries Impacted (1/2016) |
|---|---|---|---|---|---|
| 2.0 to 2.5 | up | 1 | 78% | 46% | 1,143 |
| 4.0 to 4.5 | up | 1 | 2% | 8% | 6,199 |
| *3.5 to 3.0* | *down* | 2 | 12% | 9% | 385,563 |
| *4.5 to 4.0* | *down* | 2 | 5% | 7% | 39,853 |
| *4.0 to 3.0* | *down* | 2 | 3% | 4% | 83,124 |
| Total Number of Contracts | | 8 | Total Number of Enrollees | | 515,882 |

**Summary and Policy Proposal**

The simulations suggest that there is less movement, in the Overall and Summary Star Ratings, with the application of the CAI compared to IS. The CAI adjustments result in modest negative adjustments for contracts that have low percentages of dual/disabled enrollees and larger positive adjustments for contracts with higher percentages of LIS/DE and disabled enrollees. By design, the values of the CAI are monotonic and thus, contracts with a larger percentage of vulnerable beneficiaries would realize more positive adjustments. The values of the CAI thus, align with the findings of our research. The changes that result due to the application of IS are not as consistent with the research findings. The application of IS affected some contracts in an unexpected direction, such that some contracts with high LIS/DE and disabled proportions received a negative adjustment, while some contracts with low enrollments of vulnerable beneficiaries experienced gains to their Star Ratings. The simulations confirm that, based on the 2016 Star Ratings, the CAI tends to increase the ratings for contracts with higher proportions of LIS/DE and disabled beneficiaries, while IS does not seem to do so as specifically and to the same degree as does the CAI.

After careful consideration of all input from our many stakeholders, comments received in response to this year's Request for Comments, evidence from multiple sources including our HHS partners and ASPE, findings from our internal research, and the simulation results, CMS

proposes to move forward with the proposed interim analytical adjustment of the CAI beginning with the 2017 Star Ratings.

**Methodology**

*This section provides further details of the methodology that was employed to determine the 2017 CAI values for the Overall and Summary Star Ratings.*

As discussed previously, the CAI is a factor that would be added to or subtracted from a contract's Overall and/or Summary Star Rating to adjust for the average within-contract disparity. Contracts would be categorized based on their percentages of LIS/DE and/or disabled beneficiaries, and the CAI value would be the same for all contracts within each final adjustment category. The CAI value is a star adjustment applied to a contract's Overall or Summary Star Rating whose value varies by the final adjustment category. MA plans would have up to three adjustments – one for the Overall Star Rating and one for each of the Summary Ratings (Part C and Part D). PDPs would have one adjustment for the Part D Summary Rating.

The CAI values would be computed by comparing the mean Overall and/or Summary contract Star Ratings derived from measure scores that are adjusted for LIS/DE and disability status to the mean Star Rating derived under the traditional methodology. The measures proposed for adjustment were determined by our research[28] and include the following six Part C measures for MA (MA-only, MA-PD) and 1876 contracts and one Part D measure: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, Reducing the Risk of Falling, and Medication Adherence for Hypertension (RAS antagonists).

The adjusted measure scores will be determined from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores by LIS/DE and disability status for MA or PDP contracts, without masking potential differences in quality across contracts. The models adjust for the average within-contract differences in measure scores by LIS/DE and/or disability status for MA and/or PDP contracts. The regression models quantify the relationship between the measure score of interest and LIS/DE and disability status, controlling for between-contract differences using contract fixed effects. The measure score adjustment is done without masking potential differences in quality between contracts. This approach approximates case-mix adjustment or patient-mix adjustment in a patient-level logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status, similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case-mix adjustment, the only adjusters are LIS/DE and disability status. Measure scores are adjusted first and then the adjusted measure score is

[28] The findings from the research can be found at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf

converted to a measure-level Star Rating using the measure thresholds for the given Star Ratings year. The unadjusted measure score cut points are employed in order to compare changes in measure stars using adjusted measure scores relative to unadjusted measure scores. Further, the CAI is applied to the Unadjusted Overall and Summary Star Ratings, again justifying the use of the unadjusted measure thresholds. Since the CAI will be added to the Unadjusted Overall Star Rating, the reward factor (formerly known as the I-factor) would be based on unadjusted scores. The Part C and D Improvement measures will use unadjusted measure scores for both years being compared.

Once the measures selected for adjustment have been converted to measure-level star ratings, the CAI values are determined using the following methodology:

*Note: In order to provide plans the values of the CAI for the Star Ratings year, the values for the CAI would be determined using the previous year's Star Ratings data.*

(1) Contracts are divided into an initial set of categories based on some combination of a contract's LIS/DE and disability proportions.[29] As done in the simulations, for the Overall Summary Star Rating and the Part C Summary Rating, 50 initial categories are formed corresponding to the 10 deciles of LIS/DE and the quintiles for disability. For the Part D Summary Star Rating adjustment for PDPs, the initial categories consist of the 16 combinations of LIS/DE quartile and disability quartile.

(2) The Adjusted Overall and Summary Star Ratings per contract are calculated using the adjusted measure-level stars of the measures selected for adjustment.

(3) For each contract and each rating type, the difference between the Adjusted Overall or Summary Star Rating and the corresponding Unadjusted Star Ratings is computed.

(4) Within each of the initial categories, the mean difference between the Adjusted Overall or Summary Star Rating and the corresponding Unadjusted Star Rating is determined.

(5) The mean differences for the initial categories in step (4) are examined and categories combined into final adjustment groups to ensure at least 20 MA contracts or 10 PDPs in each category and attain monotonicity with increasing proportions of LIS/DE and disability.

(6) Using the contracts that fall within the final adjustment groups, the mean difference between the Adjusted Overall or Summary Star Rating and the corresponding Unadjusted Star Rating is computed. The mean difference per final adjustment group is the CAI value for the group.

(7) Step 6 is repeated for each final adjustment group and the set of values for each group results in the CAI values.

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[29] A contract's proportion of LIS/DE and disabled beneficiaries will be based on enrollment during the measurement year.

(8) For each contract, the Adjusted Overall and/or Summary Star Rating is computed by adding the corresponding CAI value based on the contract's proportion of LIS/DE and disabled to a contract's Unadjusted Overall and/or Summary Star Rating. (There are separate CAI values for the Overall, Part C, and Part D Summary Ratings.)
The number of initial categories employed in the first step of the methodology will be determined based on the distribution of the composition of the contracts' enrollees. Each initial category does not need to contain the same number of contracts. The initial categories will be collapsed to form the final adjustment categories in a manner as to enforce monotonicity. In other words, initial categories are combined such that, as the proportion of LIS/DE or disability beneficiaries within a category increases and the other dimension does not decrease, the adjustment (value of the CAI) increases. It is possible that some initial categories will have only a small number of contracts or perhaps no contracts based on the distribution of the contracts' proportions for LIS/DE and disabled. Alternative initial groupings may be considered if numerous cells are underpopulated. The final adjustment categories will be created with a minimum number of 20 contracts per each final MA adjustment group and 10 contracts per each final PDP adjustment group. The guideline for the number of contracts per final adjustment groups is designed to maintain the stability of the estimates. If possible, final adjustment categories will be collapsed such that CAI values differ by at least 0.01 units in at least one of the two dimensions (LIS/DE and disability). (It may not always be possible to have final CAI category values differing by at least 0.01 units in at least one dimension given the goal of imposing monotonicity across both the DE/LIS and disability dimensions.)

The measure specification for every measure used in Star Ratings Program remains unchanged by the adjustment. The CAI is applied outside of the specification and is applied to each contract's current year Overall and/or Summary Star Ratings. Each contract within a given final adjustment group receives the same adjustment to its Overall and/or Summary Star Rating. The CAI values would be determined using the prior year's Star Rating data. For the 2017 Star Ratings, the CAI values would be based on the reportable values for the 2016 Star Ratings year using data from all contracts that meet reporting requirements. The percentage dual/LIS and disabled per contract will be determined using enrollment data from CY 2015. The CAI values would be available and released in the Final Call Letter. The values of the CAI would be presented in a series of four user-friendly tables – one each for the Overall and the Part C Summary Star Ratings, and two for the Part D Summary Star Ratings (one for MA-PDs and one for PDPs). The values for the index and all applicable rounding rules that would be employed would be detailed and available in the Medicare Part C & D Star Rating Technical Notes for the applicable year.

This simulation employed the 2016 Star Ratings data. Under our proposal, the simulation results would be the adjustments used for the 2017 Star Ratings. Tables 33, 34, 35 and 36 provide the CAI values for the 2017 Star Ratings.

**Table 33: 2017 MA Overall Star Rating CAI**

| Final Adjustment Category | Description | Percentage of Contract's LIS/DE Beneficiaries | Percentage of Contract's Disabled Beneficiaries | CAI Value |
|---|---|---|---|---|
| **1** | %LIS/DE Decile 1, %Disability Quintile 1 | 0.00% to 100.00% | 0.00% to 9.00% | −0.016 |
| **2** | %LIS/DE Deciles 2-9, %Disability Quintile 1<br>%LIS/DE Deciles 1-6, %Disability Quintile 2 | 8.94% to less than 99.0%<br>0.00% to less than 30.37% | 0.00% to 9.00%<br>9.00% to less than 13.1% | −0.006 |
| **3** | %LIS/DE Deciles 1-5, %Disability Quintiles 3-5<br>%LIS/DE Decile 6, %Disability Quintile 3 | 0.00% to less than 23.9%<br>23.9% to less than 30.37% | 13.1% to 100.0%<br>13.1% to less than 18.86% | 0.002 |
| **4** | %LIS/DE Deciles 7-8, %Disability Quintiles 2-3 | 30.37% to less than 73.9% | 9.00% to less than 18.86% | 0.014 |
| **5** | %LIS/DE Decile 10, %Disability Quintiles 1-4<br>%LIS/DE Decile 9, %Disability Quintiles 2-4<br>%LIS/DE Deciles 6-8, %Disability Quintile 4 | 99.0% to 100.0%<br>73.9% to less than 99.0%<br>23.9% to less than 73.9% | 0% to less than 26.5%<br>9.00% to less than 26.5%<br>18.86% to less than 26.5% | 0.025 |
| **6** | %LIS/DE Deciles 6-8, %Disability Quintile 5 | 23.9% to less than 73.9% | 26.5% to 100.0% | 0.029 |
| **7** | %LIS/DE Decile 9, %Disability Quintile 5 | 73.9% to less than 99.0% | 26.5% to 100.0% | 0.055 |
| **8** | %LIS/DE Decile 10, %Disability Quintile 5 | 99.0% to 100.0% | 26.5% to 100.0% | 0.081 |

**Table 34: 2017 MA Part C Summary Star Rating CAI**

| Final Adjustment Category | Description | Percentage of Contract's LIS/DE Beneficiaries | Percentage of Contract's Disabled Beneficiaries | CAI Value |
|---|---|---|---|---|
| **1** | %LIS/DE Decile 1, %Disability Quintile 1 | 0.00% to less than 8.72% | 0.00% to less than 8.81% | −0.018 |
| **2** | %LIS/DE Deciles 2-8, %Disability Quintile 1<br>%LIS/DE Deciles 1-6, %Disability Quintile 2 | 12.38% to less than 71.92%<br>0% to 29.84% | 0.00% to less than 8.81%<br>8.81% to 12.69% | −0.002 |
| **3** | %LIS/DE Deciles 1-5, %Disability Quintiles 3-5<br>%LIS/DE Decile 6, %Disability Quintile 3 | 0% to less than 23.56%<br>23.56% to less than 29.84% | 12.69 to100.00%<br>12.69% to less than 18.69% | 0.005 |
| **4** | %LIS/DE Deciles 7-8, %Disability Quintiles 2-3 | 29.84% to less than 71.92% | 8.81% to less than 18.69% | 0.011 |
| **5** | %LIS/DE Decile 9-10, %Disability Quintiles 1-3<br>%LIS/DE Deciles 6-10, %Disability Quintile 4 | 71.92% to100.0%<br>23.56% to100% | 0% to less than 18.69%<br>18.69% to less than 26.30% | 0.014 |
| **6** | %LIS/DE Deciles 6-8, %Disability Quintile 5 | 23.56% to less than 71.92% | 26.30% to100.0% | 0.021 |
| **7** | %LIS/DE Decile 9, %Disability Quintile 5 | 71.92% to less than 99.01% | 26.30% to100.0% | 0.033 |
| **8** | %LIS/DE Decile 10, %Disability Quintile 5 | 99.01% to100.0% | 26.30% to100.0% | 0.046 |

**Table 35: 2017 MA Part D Summary Star Rating CAI**

| Final Adjustment Category | Description | Percentage of Contract's LIS/DE Beneficiaries | Percentage of Contract's Disabled Beneficiaries | CAI Value |
|---|---|---|---|---|
| **1** | %LIS/DE Deciles 1-5, %Disability Quintiles 1-2 | 0.00% to less than 26.25% | 0.00% to less than 13.58% | −0.007 |
| **2** | %LIS/DE Deciles 1-5, %Disability Quintiles 3-5 | 0.00% to less than 26.25% | 13.58% or greater | −0.002 |
| **3** | %LIS/DE Deciles 6-10, %Disability Quintiles 1-3 | 26.25% or greater | 0.00% to less than 19.95% | 0.001 |
| **4** | %LIS/DE Deciles 6-10, %Disability Quintile 4 | 26.25% or greater | 19.95% to less than 29.71% | 0.027 |
| **5** | %LIS/DE Deciles 6-8, %Disability Quintile 5 | 26.25% to less than 78.88% | 29.71% or greater | 0.052 |
| **6** | %LIS/DE Decile 9, %Disability Quintile 5 | 78.88% to less than 99.60% | 29.71% or greater | 0.088 |
| **7** | %LIS/DE Decile 10, %Disability Quintile 5 | 99.60% or greater | 29.71% or greater | 0.092 |

**Table 36: 2017 PDP Part D Summary Star Rating CAI**

| Final Adjustment Category | Description | Percentage of Contract's LIS/DE Beneficiaries | Percentage of Contract's Disabled Beneficiaries | CAI Value |
|---|---|---|---|---|
| **1** | %LIS/DE Quartiles 1 & 2 | 0.00% to less than 11.41% | 0.00% to 100% | −0.109 |
| | %LIS/DE Quartiles 3-4 & %Disability Quartiles 1-2 | 11.41% to 100% | 0.00% to less than 9.98 | |
| **2** | %LIS/DE Quartile 3 & %Disability Quartiles 3-4 | 11.41% to less than 49.43% | 9.98% to 100% | −0.023 |
| | %LIS/DE Quartile 4 & Disability Quartile 3 | 49.43% to 100% | 9.98% to less than 28.32% | |
| **3** | %LIS/DE Quartile 4 & %Disability Quartile 4 | 49.43% to 100% | 28.32% to 100% | 0.127 |

**Additional response to address lack of an LIS indicator for enrollees in Puerto Rico**
Another issue we continue to examine is the manner to address the unique aspects of implementation of Medicare in Puerto Rico. Under statute, many Department of Health and Human Services' (HHS) programs, including Medicare and Medicaid, are implemented differently in Puerto Rico. In addition, Puerto Rico has a unique health care market with many low-income individuals in both Medicare and Medicaid and a complex legal history that affects the health care system in many ways. We are cognizant of the particular challenges in not only Puerto Rico, but in all territories without LIS and propose an additional analytical adjustment for contracts serving these areas exclusively to address the fact that the Part D low income subsidy (LIS) is not available there.

Representatives of and advocates for Puerto Rico and MA organizations have expressed additional concerns about the sensitivity of the Star Ratings. CMS has listened and is responding by considering two additional provisions in the 2017 Star Ratings to specifically address the concerns regarding quality ratings in Puerto Rico. CMS is proposing for contracts that are solely serving the population of beneficiaries in Puerto Rico: (1) the use of an LIS indicator that would be used in conjunction with the analytical adjustment and (2) a differentiated weighting scheme for the Part D medication adherence measures in the calculation of the Overall and Summary Star Ratings.

Notably, Puerto Rican beneficiaries are not eligible for LIS, which is an important element of the methodology for the analytical adjustment. (Beneficiaries in the 50 states and DC are eligible for LIS if their income is less than 150% of the Federal Poverty Level (FPL) and they meet the applicable resource requirement). To make the proposed analytical adjustment equitable, CMS is considering an additional adjustment for contracts in Puerto Rico to identify beneficiaries in

Puerto Rico's contracts whose incomes would result in an LIS designation in the 50 states and DC. Although LIS in the states depends on both income and resources, a data source for resource information for PR enrollees is not available. Thus, the simulations use only income information to simulate the LIS indicator. The value for the LIS indicator in Puerto Rico would then be used in the application of the analytical adjustment for the Overall and Summary Star Ratings. Currently, none of the territories, except Puerto Rico, have contracts that serve exclusively beneficiaries within the territory. The proposed changes discussed in this section would also apply to other territories without LIS if contracts serve exclusively beneficiaries in the territory.

In order to determine the LIS indicator for contracts in Puerto Rico, CMS must use a data source that is readily available at this time. For the 2017 Star Ratings, CMS proposes to employ the overall mean proportion of DE beneficiaries in Puerto Rico calculated using the rating year data and the mean proportion of beneficiaries at or below 150% of the FPL using the American Community Survey data for Puerto Rico. CMS has explored other sources of data for use in determining the LIS indicator for the upcoming rating year, but at this time no other source has been identified that can be employed. CMS will continue to explore sources for data to best estimate the LIS indicator for contracts in Puerto Rico. The data source for the LIS indicator must provide valid, reliable estimates for use in the Star Ratings. We encourage stakeholders in Puerto Rico to explore and suggest other data sources to determine the LIS indicator.

Having heard the voices of multiple stakeholders, including sponsors and beneficiaries in Puerto Rico, CMS proposes to move forward and implement the interim estimates for the LIS indicator instead of waiting for the availability of a different data source.

The contract-level modified LIS/DE proportion for Puerto Rico would be developed from two sources of information: (1) the overall proportion of beneficiaries in Puerto Rico with incomes less than 150% of the FPL and (2) each contract's proportion of DE beneficiaries. A linear regression model would be developed to predict the percentage of LIS in a contract using the percentage of DE using MA contracts in the 10 states with the highest poverty.[30] This model would then be adjusted for use in Puerto Rican contracts (i.e., contracts with a service area only in Puerto Rico) using Puerto Rico's mean percentage of DE and mean of LIS (using the percentage of Puerto Rico's population with incomes less than 150% of the FPL using the American Community Survey as the basis for the estimate). Using the model developed, each contract's proportion of DE beneficiaries in Puerto Rico would have a corresponding proportion

[30] The preliminary modelling suggested employing the 50 states and the District of Columbia results in very high accuracy in predicting contract-level LIS from contract-level DE. There is an insignificant impact on the model coefficients when restricting the data source to the lower-income subsets of states. CMS is proposing to use the percentage of DE using MA contracts in the 10 states with the highest poverty to create a contract-level measure of LIS/DE percentage to be used in the CAI.

of LIS to create a contract-level measure of LIS/DE percentage to be used in the CAI. We welcome comments on this proposed approach to approximate the percentage of LIS by contract in Puerto Rico, or other possible suggestions of ways to estimate this percentage.

CMS recognizes the additional challenge unique to Puerto Rico related to the medication adherence measures in the Star Ratings Program. It has been shown that beneficiaries' out-of-pocket costs may adversely affect medication adherence, which presents an additional barrier for Puerto Rican contracts serving beneficiaries whose incomes would result in an LIS designation in the states. In the past, one option considered was to reduce the weights of the three Part D Medication Adherence measures for Puerto Rican contracts. A prior proposal in the 2015 draft Call Letter to reduce the weight of the three Part D Medication Adherence measures to 1.5 as access measures for all Part D sponsors was not supported by the majority of commenters. In the 2015 Final Call Letter, CMS decided not to move forward with the proposal to reduce the weights of the adherence measures for all contracts.

We commend the Puerto Rican contracts on their improved performance overall across the 2016 Star Ratings and in particular the Part D Medication Adherence measures. This year, CMS is considering an additional option to the LIS/DE adjustment noted above, one that is similar to a previous proposal, but limited to MAOs and PDPs that operate solely in Puerto Rico or other non-continental territories in order to address the unique challenges of improving medication adherence in those areas. For the 2017 Star Ratings, CMS is proposing to reduce the weights of the three Part D Medication Adherence measures to zero for the calculation of the Overall and Summary Ratings, and retain the values and the associated weight of the three adherence measures for the calculation of the improvement factor.

The simulations for Puerto Rico employing the LIS Indicator and CAI, resulted in one contract realizing an increase in their Overall Star Rating by half a star, while with IS, one contract would experience a decline in their Overall Rating by half a star. There are no changes in the Part C or Part D Summary Ratings for PR contracts for the CAI simulation. For the IS simulation, one MA PR contract would experience a decline by half a star in their Part C Summary Rating and another MA contract would experience a decline by half a star in their Part D Summary Rating.

The simulations of the down weighting of the adherence measures for Puerto Rico resulted in four MA-PDs increasing by a half-star in their Overall Rating, independent of making a SES adjustment. With the down weighting of the adherence measures, one PDP increased one star in their Part D Summary Rating.

### *E. 2017 CMS Display Measures*

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that have been transitioned from the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed for informational purposes. Similar to the process used in 2016, organizations and sponsors will have the opportunity to preview their data for the

display measures prior to release on CMS' website. Data for measures moved to the display page will continue to be collected and monitored; poor scores on display measures may reveal underlying compliance and performance issues that are subject to enforcement actions by CMS. It is expected that all 2016 display measures will continue to be shown on CMS.gov in 2017. CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Other display measures may be provided as information only. Below are a number of revised or new measures for the 2017 display page.

1. **Timely Receipt of Case Files for Appeals (Part D) & Timely Effectuation of Appeals (Part D).** For the 2016 display measures, the data time frame for both measures was 01/01/2015 – 6/30/2015. CMS proposes to change the data time frame from the first six months of the current year to January 1 – December 31 of the previous year. For example, the 2017 display measures would be based on IRE data from January 1, 2015-December 31, 2015. This change will allow the appeal display measures to match the same timeframe used for the Part D Appeal Star Ratings measures.

2. **Medication Reconciliation Post Discharge (Part C)**. The Medication Reconciliation Post-Discharge (MRP) measure assesses the percentage of discharges from acute or non-acute inpatient facilities for members 66 years of age and older for whom medications were reconciled within 30 days of discharge. This measure has been collected in SNP HEDIS since 2008. NCQA made two changes: 1) expanded the coverage on this measure from Medicare SNPs only to all MA plans; and 2) expanded the age range to members 18 years and older. Both of these changes for HEDIS 2016 are seen as important steps to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. CMS is planning to include this measure on the 2017 display page and in the 2018 Star Ratings. Please refer to the NCQA HEDIS 2016 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications.

3. **Hospitalizations for Potentially Preventable Complications (Part C).** NCQA added to HEDIS 2016 a risk-adjusted measure of hospitalization for ambulatory care sensitive conditions based on the NQF-endorsed Prevention Quality Indicators (PQI), developed by AHRQ. This measure assesses the rate of hospitalization for complications of chronic and acute ambulatory care-sensitive conditions. The measure is therefore an important indicator of care coordination. CMS is planning to include this measure on the 2017 display page and is planning to include it in the 2018 Star Ratings. Please refer to the NCQA HEDIS 2016 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications.

4. **Statin Therapy for Patients with Cardiovascular Disease (Part C).** NCQA has added two sets of statin therapy measures to HEDIS aligned with the 2013 ACC/AHA blood cholesterol guidelines. These measures are focused on two of the major statin benefit groups described in the guidelines: patients with clinical atherosclerotic cardiovascular disease and patients with

diabetes. Since some of these HEDIS measures overlap with the measures developed by the PQA, CMS is planning to include only one of the HEDIS measures on the 2017 display page where we propose it remain for two years. After gaining experience with the new treatment guidelines and metric, we plan to include this measure in the 2019 Star Ratings. This measure focuses on statin therapy for patients with cardiovascular disease. It is the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year.

5. **Asthma Measures (Part C).** NCQA has expanded its asthma measures to include older adults. HEDIS 2016 includes two measures for older adults. Medication Management for People with Asthma is the percentage of members 5 to 85 years of age who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period (i.e., first prescription date through end of measurement year). The Asthma Medication Ratio is the percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. CMS is planning to include these on the 2017 and possibly 2018 display page and will consider these for inclusion in Star Ratings for future years.

6. **Statin Use in Persons with Diabetes (SUPD) (Part D).** This new PQA-endorsed measure, Statin Use in Persons with Diabetes (SUPD), calculates the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice according to the Enrollment Database (EDB) will be excluded from the denominator of the SUPD measure for the entire year. Part D sponsors have received year of service 2015 SUPD measure reports on a monthly basis through the Patient Safety Analysis website, and we will add the SUPD measure to the 2017 display page (using 2015 data) where we propose it remain for two years. After gaining experience with the new treatment guidelines and metric, we propose adding the SUPD measure to the 2019 Star Ratings (using 2017 data).

   Lastly, in January 2015, the PQA's Quality Metrics Expert Panel (QMEP) considered whether beneficiaries taking proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors should be excluded from the measure denominator. At this time, the QMEP decided not to exclude beneficiaries taking PCSK-9 inhibitors from SUPD measure denominator. It is our understanding that the PQA will review the measure specifications again when more information is available about this new therapeutic class.

***Forecasting to 2018 and Beyond***

The following describes changes to existing measures and potential new measures. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings.

***F. New Measures:***

See section E above which describes a number of new measures under consideration for the 2018 Star Ratings that will be reported as 2017 display measures. The following are additional measures under consideration for the Star Ratings or display measures for 2018 and beyond.

1. **Care Coordination Measures (Part C).** Effective care coordination contributes to improved health outcomes. CMS believes that 5-star contracts perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plan care coordination activities, however, is based largely on anecdote and discussions with high performing plans, as well as on data we collect from CAHPS surveys, which reflect enrollees' experiences with the care they receive.

   CMS is working to expand efforts in this area. To identify potential new care coordination measures, CMS is utilizing experts to conduct targeted research, extensive literature reviews, and data analysis, and to engage in discussions with expert panels and high performing plans. As part of this effort, we are considering various data sources; whether the measures should be focused on subgroups of MA enrollees or all MA enrollees; the activities that best represent care coordination such as ensuring seamless transitions across settings, appropriate follow up after inpatient and emergency department visits, communication across providers, and comprehensive assessments; as well as the relationship between the plan and provider in care coordination activities. NCQA, using administrative and medical record data, will begin testing the following proposed measures using 2015 data: primary care provider (PCP) notification of inpatient admissions, summary of care record in PCP chart, follow-up with PCP/specialist following hospital discharge or emergency department visit, and in the ambulatory setting whether there is a comprehensive assessment performed and documented by the PCP/specialist and whether there is a specialist visit summary in the PCP chart. Additionally, CMS has recently awarded another contract to develop care coordination measures using administrative data, including MA encounter data and Part D data. CMS continues to welcome comments on measures that could be developed using MA encounter data. We will provide updates to the industry as this work progresses.

2. **Depression Measures (Part C).** NCQA has adapted a provider-level depression outcome measure developed by Minnesota Community Measurement for use in HEDIS. Depression Remission or Response in Adolescents and Adults (DRR) uses a patient-reported outcome measure, the PHQ-9 tool, to assess whether patients with depression have achieved remission or have an improvement in their symptoms. The measure assesses the percentage of individuals age 12 and older with depression and an elevated PHQ-9 score (greater than 9) who achieve a PHQ-9 score of less than 5 at six months or have a 50% reduction in their

PHQ-9 score. This measure also uses a new data collection methodology for HEDIS, relying on data coming from electronic clinical data systems (e.g., EHRs, clinical registries, case management records). If approved, the new measure would be published in HEDIS 2017. CMS shared with NCQA comments received as part of our Request for Comments on this topic and will continue to monitor the development of this measure.

3. **Appropriate Pain Management (Part C).** NCQA is exploring opportunities to develop a new measure(s) focusing on appropriate pain management. The intent is to assess the quality of pain management and treatment. There is no definite timeline established for the development of this measure.

4. **Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D).** In the 2016 Call Letter, we noted that three opioid overutilization measures were in development by the PQA. We further stated that if these measures were endorsed by the PQA prior to the 2017 bid deadline in June 2016 that we may adopt them as future display measures or alternatively use them in the Overutilization Monitoring System (OMS). The measures were endorsed by the PQA in May 2015.

   PQA's three opioid measures examine multi-provider, high dosage opioid use among individuals 18 years and older without cancer and not in hospice care.

   Measure 1 (Opioid High Dosage): The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine equivalent dose (MED) for 90 consecutive days or longer.

   Measure 2 (Multiple Prescribers and Multiple Pharmacies): The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

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

   We tested the measures using the PQA specifications. We will develop new patient safety reports for the three opioid overutilization measures to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website, similar to the other patient safety measures. The website also includes the OMS. The reports will allow sponsors to track their performance over time and allow for contract level trending and outlier analyses. Reports will be distributed beginning with 2016 dates of service. After at least one year to gain experience with the measures and pending new guidelines (e.g., from CDC), we will consider adding these three measures to the 2019 Part D display page (using 2017 data). We do not

recommend adding these measures to the Star Ratings at this time due to concerns (1) about the current lack of consensus clinical guidelines for the use of opioids to treat chronic, non-cancer pain and potential exceptions due to medical necessity and (2) pending additional analysis on diagnosis data sources, such as newly available encounter data for Medicare Part C and resolving timing issues of RAPS file updates, which are used to identify exclusions for certain cancer conditions.

Additionally, NCQA is adapting the three opioid overuse measures developed by the PQA for potential use in HEDIS.

5. **Antipsychotic Use in Persons with Dementia (APD) (Part D).** CMS has been particularly concerned with the unnecessary use of antipsychotic drugs in nursing homes and, as a result, has pursued strategies to increase awareness of antipsychotic use in long term care settings. In 2013, we began to calculate a general atypical antipsychotic utilization rate, called *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes*, for inclusion in the Part D display measures. The average rates decreased from approximately 24.0% in 2011 to 21.4% in 2013.

   There continues to be increased attention on this important issue. The United States Government Accountability Office (GAO) released a report[31] in January 2015 describing the inappropriate use of antipsychotics in Part D beneficiaries with dementia, in both community (i.e., outside of nursing homes) and long-stay nursing home residents during 2012, with recommendations for CMS to address this problem. The GAO conducted this study due to concerns raised regarding the use of antipsychotic drugs to address the behavioral symptoms associated with dementia, the FDA's boxed warning that these drugs may cause an increased risk of death when used by older adults with dementia, and because the drugs are not approved for this use.

   In addition, the PQA endorsed the measure, *Antipsychotic Use in Persons with Dementia (APD).* This provides CMS with a new measure developed through a consensus process to monitor the inappropriate use of antipsychotics in both the nursing home and community settings across Medicare Part D plans.

   We tested this measure based on the PQA specifications. We calculated the APD measure rate in aggregate for all contracts, MA-PDs, and PDPs, and at the individual contract level, for all beneficiaries, community-only residents (never a nursing home resident), and both short-term and long-term nursing home residents that met the inclusion and exclusion criteria. Beneficiaries were identified as long-stay nursing home residents if they had stays greater than 100 cumulative days in a nursing home during the year based data in the Long

[31] Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings. http://www.gao.gov/products/*GAO-15-211*. *GAO-15-211*: Published: Jan 30, 2015. Publicly Released: March 2, 2015

Term Care Minimum Data Set (MDS). Each beneficiary was counted in only one category for the entire measurement period within a contract and not considered separately for time spent in different settings (e.g., a beneficiary who experienced both short-term and long-term nursing home stays was included only in the long-term category).

To identify the numerator and denominator populations, we used diagnosis data obtained from inpatient (IP), outpatient (OP), and carrier claims from the Common Working File (CWF) and RxHCCs from the RAPS. OP and Carrier claims are available for PDP contracts only. We also adjusted rates based on the number of months beneficiaries are enrolled in each Part D contract (i.e., member-years adjustment).

We conducted reliability testing using mixed effect logistic regression with varying intercept. The testing results indicate that the rate variations at the contract level are statistically significant, providing evidence that the measure is reliable.

A report, Antipsychotic Use in Part D Enrollees with Dementia, which summarizes the testing results, is posted on CMS.gov at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Antipsychotic-Use-in-Part-D-Enrollees-with-Dementia-v12092015.pdf.

We will develop new patient safety APD measure reports to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website beginning with year of service 2016. We also propose adding the overall APD measure plus breakout rates for community-only residents, short-term nursing home residents, and long-term nursing home stay residents to the 2018 Part D display measure set (using 2016 data) to continue to draw attention to the inappropriate use of antipsychotics in persons with dementia without an appropriate mental health diagnosis in both the community and nursing home settings. The APD measure will replace the *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes* display measure. However, we do not propose adding this measure to the Star Ratings pending additional research on diagnosis data sources, such as newly available encounter data for Medicare Part C and resolving timing issues of RAPS file updates.

***G. Changes to Existing Star Ratings and Display Measures and Potential Future Changes:***

*1.* **Colorectal Cancer Screening (Part C Star Rating)**. The Colorectal Cancer Screening (COL) measure assesses the percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer. This measure is based on the U.S. Preventative Services Task Force (USPSTF) guideline on colorectal cancer screening in adults age 50-75. NCQA is monitoring updates to the guideline as the USPSTF has recently released a draft recommendation statement. NCQA will consider revisions to the COL measure once the USPSTF final recommendation statement is published. It is anticipated that the final release of recommendations will not occur until late 2016.

2. **Fall Risk Management (Part C Star Rating).** The Fall Risk Management (FRM) measure, collected through the Health Outcomes Survey, consists of the following two indicators: 1) *Discussing Fall Risk* assesses the percentage of Medicare members 75 years of age and older or 65-74 years of age with a balance or walking problem or fall in the past 12 months who discussed falls or problems with balance or walking with their current practitioner; and 2) *Managing Fall Risk* assesses the percentage of Medicare members 65 years of age and older who had a fall or had problems with balance or walking in the past 12 months and received fall risk intervention from their current practitioner (defined as suggesting use of a cane or walker, a vision or hearing test, physical therapy or exercise, or taking of a postural blood pressure). NCQA is currently re-evaluating this measure to align with the most current U.S. Preventive Services Task Force (USPSTF) guidelines. NCQA is proposing to 1) revise the denominator in the Discussing Fall Risk indicator to include all Medicare members age 65 and older and 2) revise the numerator for the Managing Fall Risk indicator to include plan members who report having had an intervention. The survey question will list examples of interventions (such as use of vitamin D) to prompt survey respondents to recall if they received any fall risk management intervention from their provider. These proposed changes, if approved, would be published in HEDIS 2017 or HEDIS 2018.

3. **Pneumococcal Vaccination Status for Older Adults (Part C Display).** The Pneumococcal Vaccination Status for Older Adults (PNU) measure, collected through the Medicare CAHPS survey, assesses the percentage of Medicare members 65 years of age and older who have ever received a pneumococcal vaccination. In 2014, The Advisory Committee on Immunization Practices (ACIP) released new recommendations that all adults 65 years of age and older should receive sequential administration of both PCV13 and PPSV23. NCQA is considering changes to the measure to align with the most current guidelines. Specifically, they are evaluating the feasibility of developing a new measure of pneumococcal vaccination based on alternative data sources, such as administrative claims, state immunization registries and electronic health records. In the meantime they recommend the following wording changes to the existing CAHPS measure: "Have you ever had one or more pneumonia shots? Two shots are usually given in a person's lifetime and these are different from a flu shot. It is also called the pneumococcal vaccine". Pending OMB approval the new wording would be utilized for 2017 CAHPS implementation. This measure is on the CMS display page.

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

panel, and the opportunity for anyone to comment on the survey through multiple public comments period through the Federal Register.

The current MA & PDP CAHPS Survey includes the core CAHPS 4.0 Health Plan Survey. CMS conducted an experiment in 2015 to understand how CAHPS measures differ between 4.0 and 5.0, and based on the results we propose to update the survey for future years to reflect AHRQ's CAHPS 5.0 Health Plan Survey. The findings from the experiment suggest that these changes are associated with a small increase in scores for several evaluative MA measures. These small increases did not significantly differ across contracts. Since there are no longer fixed thresholds for Star Ratings and they are based on the actual distribution of scores, there should be no shifts in Star Ratings due to transition to the version 5.0 instrument compared to what would have been the case with 4.0. Every contract would have the same expected Star Rating whether version 4.0 or 5.0 is used, and the correlation between this year's Star Ratings and next year's Star Ratings should be the same regardless of whether 4.0 or 5.0 is used next year.

The 5.0 update applies recent improvements in survey design that resulted from development and testing of the Clinician & Group Surveys. The 5.0 version of the CAHPS Health Plan Survey incorporates some minor changes into the wording of core items, and a change in the placement of one core item that also resulted in the deletion of a screener item. The following are the changes in the 5.0 version of the Health Plan Surveys:

- **The items about access to urgent and non-urgent appointment items** were modified to ask respondents if they were able to get an appointment as soon as they needed, as opposed to as soon as they *thought* they needed. Non-urgent appointments are described as *a check-up or routine care* rather than *health care.* In addition, the phrase*, "…not counting the times you needed care right away"* was deleted from these questions. These revisions simplify the items and make them consistent with questions in other CAHPS surveys.

- **The item about how often it was easy to get appointments with specialists** was revised to ask respondents if they got an appointment to see a specialist as soon as they needed. This revision makes the item consistent with other CAHPS items that ask about access to care.

- **The item about how often it was easy to get care, tests, or treatment** was moved from the Your Health Plan section to the Your Health Care in the Last 6 Months section, because respondents had difficulty attributing this item to the health plan.

- **The screener item about getting care, tests, or treatment through the health plan** was deleted because the subsequent question was moved to an earlier section of the survey and no longer required a screener.

These changes would take effect for the 2017 CAHPS survey administration (used for 2018 Star Ratings) based on OMB approval. Since we are modifying question wording, we propose the following standard for deciding that a specification change has occurred for a CAHPS measure for the purposes of excluding it from the improvement measure calculation: (1) at least one item within the measure changed in wording, had a wording change in its screener, or had a wording change in the immediately preceding item, and (2) the measure score in version 5.0 was significantly different from the measure score in version 4.0 in the 5.0 experiment. Three MA measures met this standard: Getting Care Quickly, Customer Service, and Care Coordination. Thus, these three measures would be excluded from the Part C improvement measure for the 2018 Star Ratings.

We are also considering changing the sampling for CAHPS in future years when a contract is listed in HPMS as a consolidation between July of the prior year and January of the current year when the CAHPS sample is drawn. The sampling frame for the surviving contract would include the enrollees for all members of all contracts involved if two or more contracts consolidate under the same parent organization. We will continue to study this and would give advance notice before making any changes to the methodology.

*5.* **Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating).** Based on PQA specification change, the measure will exclude from the denominator those patients with one or more claims for sacubitril/valsartan. This exclusion will be applied for the 2017 Star Ratings.

*6.* **MPF Price Accuracy (Part D Star Rating).** As stated in the 2016 Call Letter, CMS is considering a few updates to this measure for the 2018 Star Ratings. The first proposed change is related to the method by which claims are excluded from the measure. Currently, the measure is limited to claims filled for 30-day supply at pharmacies reported by sponsors as retail only or retail and limited access only in their MPF Pharmacy Cost files. That is, claims that are not filled for exactly 30-day supply, or claims filled for 60 and 90 days' supply are excluded. Additionally, claims filled by retail pharmacies that are also long term care, mail order, or home infusion pharmacies are excluded. These restrictions result in the exclusion of many PDEs, thus potentially biasing the reliability of the measure.

We propose to include claims with 28-34 day supply, as we believe it would be appropriate to compare their PDE costs to MPF's fixed display of 1 month pricing. We also propose to include 60-62 and 90-93 day supply claims for a more comprehensive evaluation of PDE claims. Beginning with CY2015 MPF submissions, plans must provide brand and generic dispensing fees for 60 and 90 day supply claims in the Pharmacy Cost file. CMS can use these data, along with 60 and 90 day supply Pricing File data, to compare MPF and PDE costs.

Additionally, we propose to use the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims. CMS began requiring pharmacies to populate the Pharmacy Service Type field on all PDEs at the end of February 2013. We recommend expanding the retail claims identification process to include all PDEs that are from retail pharmacies according to the Pharmacy Cost data and have a Pharmacy Service Type of either Community/Retail or Managed Care Organization (MCO). Although some sponsors cited concern about the accuracy of these data as reported by pharmacists, Part D sponsors are ultimately responsible for the accuracy of their submitted PDE to CMS. According to PDE requirements, CMS expects "…sponsors and their network pharmacies to develop and implement controls to improve the accuracy of this information during 2013…" This methodology change would increase the number of PDEs eligible for inclusion in the Price Accuracy Scores while continuing to identify only retail claims.

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

By capturing the frequency of inaccuracy as well as the magnitude, the measure would better depict the reliability of a contract's MPF advertised prices. CMS is aware that while the MPF display is updated every two weeks, real time pricing, at the point of sale, can change as often as every day. Some sponsors have expressed concern that in order to perform well in the Price Accuracy measure, they cannot offer lower prices at point of sale in real time than the prices are displayed on MPF. We note that PDEs priced lower than MPF displayed pricing do not lower a contract's score in this measure. CMS' simulation of this proposal found little change in the range of contracts' accuracy scores. Other options we explored include measuring the magnitude of inaccuracy as a percentage cost difference, instead of the current measure's use of absolute cost difference. Testing however found this method may overstate small differences between PDE and MPF costs for low-cost claims. For example, when using percentage cost differences, a claim with a $2.00 PDE cost and a $1.00 MPF cost would be considered equally overpriced as a claim with a $200.00 PDE cost and a $100.00 MPF cost.

As noted in the 2016 Call Letter, we propose that these changes are implemented for the 2018 Star Ratings (using 2016 PDE and MPF data). We believe the proposed changes will

greatly improve the Price Accuracy Scores, making them a more comprehensive assessment of contracts' price reporting for Part D beneficiaries. For consistency, we propose these changes are also implemented for the 2018 display measure, Plan Submitted Higher Prices for Display on MPF.

*7.* **Drug-Drug Interactions (DDI) (Part D Display).** The PQA-endorsed DDI measure is currently a Part D display measure. This measure is defined as the percent of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or subsequent to the initial prescription.

The PQA has conducted an extensive review of the drug-drug pairs included in the DDI measure. They engaged a DDI expert panel convened by the University of Arizona on PQA's behalf, which completed the review, including a comparison to the DDI list developed for the Office of the National Coordinator for Health Information Technology (ONC). The Expert Panel's recommendations were reviewed by the PQA's Measure Update Panel for consideration by the PQA's Quality Metrics Expert Panel (QMEP). Next, the PQA will test the DDI measure specifications because there will be extensive changes. We will closely monitor any updates to this measure, test updated specifications when available, and propose changes in the future for the Part D display measure and patient safety reporting.

*8.* **Center for Medicare and Medicaid Innovation Model Tests.**

We note that some stakeholders (and commenters to the Request for Comments) have expressed concern regarding the potential for the improvements in quality resulting from the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced MTM Model test to adversely influence the Star Ratings of contracts ineligible to participate (or that include some PBPs ineligible to participate). As stated in the Request for Comments, the goal is to not penalize participants or non-participants in either model.

As the model tests are implemented, we will closely monitor performance trends of participating plans across individual measures and determine if any changes are warranted.

For the MA-VBID Model test, CMS is considering the exclusion of some of the model-participants' data when calculating measure-level cut points. We welcome any comments on this or other means of how to address any potential differences in performance between participating and non-participating plans.

The Part D plans participating in the Part D Enhanced MTM Model test will be waived from the MTM requirements under Section 1860D–4(c)(2) and 42 CFR 423.153(d) and the Part D Reporting Requirements for MTM. However, Part D sponsors will not be waived from establishing MTM programs in compliance with current requirements and reporting data for the remaining plans under each Part D contract. Therefore, the MTM Program CMR

Completion Rates will be calculated using available plan-reported data from the remaining plans under the Part D contract.

Some commenters have expressed concern that Enhanced MTM Model participants will sometimes be significantly advantaged or disadvantaged by the removal of the participating PBPs from the calculation of the CMR completion rate measure at the contract level, and have suggested the elimination of this measure for PDP contracts with model-participating plans. Some alternative possible options are to establish different cut points for model participants or to case mix adjust scores for the purpose of determining cut points. We are aware that the national scope of many PDP contracts must be taken into consideration in evaluating options for addressing potential differences in performance between participating and non-participating plans. We welcome comments on these or any other potential approaches to adjustments to the CMR completion rate percentage.

## *H. Measurement and Methodological Enhancements*

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. Feedback or recommendations can help CMS' continuing analyses, as well as our collaboration with measurement development entities such as NCQA and PQA. We welcome comments and input on issues not described in earlier sections.

Based on feedback received from the Star Ratings Request for Comments concerning our Call Center Monitoring methodology, CMS is considering whether to allow the interpreter an extra 60 seconds to address an introductory question that is asked prior to three specific plan benefit questions. Any changes made to the 2017 call center monitoring methodology would be announced in a fall 2016 HPMS memo.

Finally, we note that CMS has a rigorous Quality Assurance and Audit process over the test call process that involves multiple layers of review before, during and after each monitoring period. We encourage plans/sponsors to request and review their raw call data to validate the results. CMS believes that validation of the information by plans/sponsors is an important tool in our overall review of the monitoring contractor's performance, and we encourage plans/sponsors to contact CMS if they believe an error occurred.

### *Medicare Parts C & D Program Audits*

#### Proposed Release Date for the 2017 Part C and Part D Program Audit Protocols

Each year, the Medicare Parts C & D Oversight & Enforcement Group (MOEG) releases the Part C and Part D audit protocols to the industry in an effort to be as transparent as possible about our audit approach. We remain committed to continuous improvement in the development of our audit processes and protocols, and value the input and feedback of all sponsors and stakeholders. We have received feedback previously that sponsors would appreciate our audit protocols being

released well in advance of the audit year, to allow more time to implement the new protocols and prepare for audits.

Therefore, beginning with the 2017 audit protocols, we are planning to release the following year's protocols by the end of July, instead of mid-to-late fall. In other words, the 2017 protocols will be released in July of 2016. This release date should allow sponsors sufficient time to program their systems to pull accurate audit universes, conduct self-assessments, and prepare for an audit.

We recognize that by releasing the audit protocols in July, it will delay our ability to incorporate sponsors' feedback on protocols into the next year's versions. Instead, feedback gathered on 2016 protocols would be incorporated into the 2018 protocols. We welcome comments on the proposed July release date and the consequences of release on that timetable.

This new release cycle will have a particular impact on the two audit protocols that are being piloted in 2016, the Medication Therapy Management (MTM) and Provider Network Adequacy (PNA) protocols.

We gather feedback from sponsors who take part in an audit with pilot protocols and use their feedback and experience to evaluate if updates and changes are needed to our pilot protocols prior to finalizing them. Since we will begin the process of finalizing the 2017 protocols only a few months into the 2016 pilot audit period, we do not believe that we will have gathered enough feedback on the pilot protocols prior to the July release date. Therefore, we are proposing to extend the pilot of these protocols into 2017 in order to allow time to gather feedback and determine if revisions are needed to the pilot audit protocols.

As a reminder, sponsors subject to pilot protocols do not receive a score for the pilot, nor does it factor into their overall audit score. Finally, the results from the pilot audit protocol do not appear in the final audit report.

We would also like to acknowledge that the Provider Network Adequacy protocol will not be administered as a normal audit protocol and will not happen in conjunction with the remainder of our program audits. As mentioned in Section II of this document, wide scale monitoring efforts are underway with respect to network adequacy and provider directory. The Medicare Parts C & D Oversight and Enforcement Group (MOEG), in coordination with the Medicare Parts C & D Contract Administration Group (MCAG) are taking a comprehensive approach to monitor, audit and validate compliance with these requirements. Therefore, MOEG will be using the results of MCAG's monitoring each year to audit and validate correction of any deficiencies identified throughout the year. Those organizations who fail to correct and come into compliance with these requirements may be subject to possible enforcement action, including civil money penalties or enrollment sanctions.

### *Medicare Parts C & D Enforcement Actions*

#### Civil Money Penalty (CMP) Calculation Methodology

When CMS makes a determination that a plan sponsor's operational deficiencies adversely affected or had the substantial likelihood of adversely affecting enrollees, the agency imposes Civil Money Penalties (CMPs) in accordance with Subpart O of 42 C.F.R. §§ 422 and 423. A number of plan sponsors and industry groups have requested more information on the approach CMS uses to determine CMP amounts and how the impact of certain deficiencies are factored into a given CMP. In response to this interest, CMS plans to release a memo describing our interpretation of the applicable rules in a CMP Methodology by 2017, but will provide an opportunity for industry to comment before finalizing. This CMP methodology may be modified and republished on an as needed basis.

#### Compliance and Enforcement Actions Related to Part D Auto-Forwards

Part D plan sponsors are required to have procedures for making timely coverage determinations and redeterminations and for notifying enrollees of those decisions within the required adjudication timeframes. If notice of the decision is not provided within the required timeframe, the case must be automatically forwarded to the Part D Independent Review Entity (IRE). While all auto-forwarded cases represent non-compliance with CMS requirements for timely processing, of particular concern to CMS are plan sponsors with inordinately high levels of cases that are auto-forwarded throughout the plan year due to the plan sponsor's failure to meet the required adjudication timeframes. The requirements related to auto-forwarding untimely cases to the Part D IRE are set forth at 42 CFR Part 423, Subpart M and in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

The volume of cases auto-forwarded to the IRE has been significant and sustained over the past several years. CMS has been monitoring auto-forward rates with the expectation that there would be a meaningful reduction of this volume over time as Part D plan sponsors gained program experience. CMS is notifying Part D plan sponsors that in 2017 we will continue to increase the level and severity of the compliance and enforcement actions imposed on plans that substantially fail to comply with adjudication requirements for coverage determinations and redeterminations. CMS will use data to determine which plan sponsors are outliers with respect to untimely decisions and the corresponding rate at which cases are auto-forwarded to the Part D IRE. Pursuant to § 423.752(c)(1)(i), CMS has the authority to impose CMPs against sponsors that substantially fail to comply with the requirements related to coverage determinations, appeals and grievances in accordance with § 423.509(a)(4)(ii). A plan sponsor's inordinately high auto-forward rate is evidence of substantial failure to comply with the requirements to notify enrollees of coverage determination and redetermination decisions within the required timeframes. These failures adversely affect (or have the substantial likelihood of adversely

affecting) beneficiaries by causing inappropriate delays in accessing needed prescription drugs and/or financial hardship to beneficiaries.

**Enforcement Actions Related to One Third Financial Audit Findings**

Sections 1857(d)(1) and 1860D-12(b)(c) of the Social Security Act require the HHS Secretary to provide for the annual audit of the financial records of at least one-third of the Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs). The one-third financial audit program is designed to examine the health plans' financial records, internal controls over payment disbursements, Medicare utilization and costs, and the computation of Part C & D bids. Findings of noncompliance from these audits have identified significant financial errors, disallowed costs, and internal control weaknesses. While sponsors are required to put a corrective action in place and rectify their deficiencies, certain findings with adverse beneficiary impact, such as incorrect or increased cost-sharing or copayments for beneficiaries, warrant further enforcement actions. As a result, CMS is notifying Part C & D plan sponsors that starting with audits conducted in 2017 (based on CY 2015), we will begin to consider the findings of noncompliance from the one-third financial audits for potential enforcement actions, in accordance with 42 CFR §§422.752(c)(i) and 423.752(c)(i).

***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. In the CY 2016 Call Letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries.

Since the CY 2016 Call Letter, CMS has announced the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) Model tests, both scheduled to begin on January 1, 2017. These model tests are described below.

CMS continues to consider potential Innovation Center models in health plan design. We welcome stakeholder suggestions and input around potential approaches.

**Medicare Advantage Value-Based Insurance Design Model Test**

The MA-VBID Model test is an opportunity for MAOs to offer mandatory supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. Only those MAOs approved by CMS to participate in the model may do so, and only within PBPs accepted into the model test. The model will test whether these interventions can improve health outcomes and lower expenditures for Medicare Advantage enrollees. CMS is conducting the model test in seven states, and the application period for joining the model in CY 2017 closed last month.

### Part D Enhanced MTM Model

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

Stand-alone PDP basic plans that have applied and been approved to participate in the CMS Innovation Center's Enhanced MTM Model will offer MTM programs subject to the terms and conditions of the model test in the five selected Part D regions. All other Part D plans, including any ineligible plans offered by the PDP sponsors of participating plans, will remain subject to the current regulatory requirements for MTM programs and must include those costs in their 2017 Part D bids. None of the waivers or funding available to model-participating plans is applicable to the other ineligible plans offered by those PDP sponsors. A participating plan sponsor may use lessons learned from model beneficiary and provider engagement and intervention strategies to increase participation within its mandatory MTM programs in other plans, to the extent allowable outside of the model. For more information, please visit: https://innovation.cms.gov/initiatives/enhancedmtm/.

## Section II – Part C

### *Guidance on the Future of Provider Directory Requirements and Best Practices*

CMS wants to further emphasize the importance of providing accurate provider directories to MA enrollees. Inaccurate provider directories can impede access to care and bring into question the adequacy and validity of the MAO's network as a whole. In concert with previously released guidance, our focus remains making sure provider directories are accurate for Medicare beneficiaries and their caregivers who rely on them to make informed decisions regarding their health care choices.

CMS is aware of pilot programs being tested by some MAOs to use new technology to simplify the process of updating provider directories for physicians and other network participants. We are supportive of industry efforts to improve provider directories and encourage MAOs and providers to continue to work collaboratively to develop more effective and efficient methods of maintaining accurate provide directories. We see great potential with the use of technologies that capitalize on machine readable information. To foster the development of such technologies, we urge both industry and provider community to strive to provide data, including provider information on network participation, in a machine readable format. CMS has purposefully not prescribed the means by which MAOs must update their provider directories in order to allow innovation in this area such as updating provider directories by gathering a digital representation of provider participation and contact information directly from a provider's web page.

Preliminary data gathered by CMS, as well as continued stakeholder concerns, has intensified our concerns with provider directory accuracy. We will continue to aggressively identify and pursue instances of non-compliance by using a host of oversight methods. For example, with contractor support, we have developed a comprehensive process for monitoring provider directory accuracy, which is currently underway. The data collected through our monitoring activities could drive additional reviews of network adequacy, as well as future monitoring and/or audit-based activities. Moreover, identified areas of non-compliance may be subject to compliance and/or enforcement actions, including civil money penalties or enrollment sanctions.

CMS also remains committed to making provider directory requirements across CMS programs consistent. As such, the MA program is taking steps to harmonize the requirements and provide organizations that operate across multiple CMS programs consistency in the application of provider directory requirements.

Currently among MA, QHPs and the Medicaid managed care programs, MA provides the least prescriptive provider directory requirements. (See 42 C.F.R. §422.111(b)(3)(i) and explained in sections 60.4 and 100.4 of the Medicare Marketing Guidelines (https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2016-Medicare-Marketing-Guidelines-Updated.pdf). The MA program also has the fewest data elements required for its provider directory. In addition, both Medicaid and the QHPs have moved toward some level of machine readability for online provider directory content (see 45 C.F.R. 156.230(c) with additional guidance provided via Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces; and Proposed Medicaid Final Rule CMS–2390–P, 42 C.F.R. 438.10(h)(4)), while MA has not. The Office of Management and Budget (OMB) defines "machine readable" as a format in a standard computer language (not English text) that can be read automatically by a web browser or computer system.

Regulatory updates to § 422.111 would generally be needed to require MA organizations to issue provider directories that include the additional elements. CMS intends to propose such revisions in the future and encourages the inclusion of the elements listed below in provider directory requirements as a best practice and urges MAOs to incorporate them into their production of such directories in advance of future rulemaking.

The following are the provider directory data elements we believe are appropriate to use in current MAOs' provider directories:

- Machine readable content
- Provider medical group
- Provider institutional affiliation
- Non-English languages spoken by provider
- Provider website address
- Accessibility for people with physical disabilities

In addition, to further facilitate the ease with which enrollees' access providers, we encourage MAOs to also institute the best practice of incorporating a "warm transfer" policy to their customer service call centers. For enrollees calling to request help finding a provider, the CSR would close the call by calling the provider's office, establishing the need(s) of the enrollee, and transferring the enrollee to the provider's office to complete the appointment process.

***Overview of CY 2017 Benefits and Bid Review***

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

Medicare-Medicaid Plans in Capitated Financial Alignment Demonstrations are not subject to the review criteria summarized in the table below and benefits and benefit review guidance for these plans will be provided separately.

CMS makes all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expects all MAOs to submit their best, accurate, and complete bid(s) on or before the Monday, June 6, 2016 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 at any time prior to final approval will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of errors.

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

**Table 37. 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] Section 1876 Cost Plans and MA plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 CFR §§417.454(e) and 422.100(j)).

CMS has made changes to service category cost sharing amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) requirements for CY 2017 and have provided these changes in each applicable section below. Consistent with past years, MAOs must also address requirements implemented under the Affordable Care Act, such as the medical loss ratio and health insurance providers fee, and are expected to do so independently of our requirements for benefits or bid review. Therefore, we are not making specific adjustments or allowances for these changes in the benefits review requirements.

***Plans with Low Enrollment***

At the end of March, CMS will send affected MAOs a list of non-SNP plans that have fewer than 500 enrollees or fewer than 100 enrollees for SNP plans and that have been in existence for three or more years [as of March 2016 (three annual election periods)]. The notification represents

CMS' decision not to renew such plans under 42 CFR §422.506(b)(1)(iv) and (b)(2). 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 (such that the low enrollment plan still represents a viable plan option for enrollees).

Through return e-mail, MAOs must either (1) confirm that each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2017, or (2) provide a justification for renewal. If CMS does not find a unique or compelling reason that the low enrollment plan is a viable independent option for enrollees, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting business cases and the information required in those submissions will be included with the list of low enrollment plans sent to the MAO. Note: These requirements do not apply to Section 1876 cost plans, employer plans, or MA Medical Savings Account (MSA) plans.

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

***Meaningful Difference (Substantially Duplicative Plan Offerings)***

Pursuant to §422.254(a)(4), MAOs offering more than one plan in a given service area must guarantee the plans are substantially different so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs. For CY 2017, 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. For CY 2017, benefits and the reduction in cost sharing that are offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the meaningful difference evaluation. Documentation and instructions for the OOPC model are available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.

CMS considers HMO and HMO-POS as one plan type, unless the HMO-POS plan covers all Parts A and B services outside the network, in which case the HMO-POS plan is considered meaningfully different from the HMO plan. Consistent with CY 2016, this standard for evaluating meaningful difference will not include geographic or provider limitations on the out-of-network benefits. However, CMS in future years may consider HMO-POS plans

meaningfully different only if the plans do not place geographic or provider limitations on the out-of-network benefits.

For CY 2017, CMS will evaluate meaningful differences among CY 2017 non-employer and non-cost contractor plans offered by the same MAO, in the same county and, under the same contract, as follows:

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

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

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

4. The OOPC (Part C and Part D) PMPM estimate will be calculated for each plan. CMS considers a difference of at least $20.00 PMPM between the OOPC for each plan offered by the same MAO in the same county to be meaningful for purposes of applying the meaningfully different standard.

(CMS may conduct this evaluation at either the legal entity or parent organization level in future years.)

Note that plan characteristics such as premium, variations in provider networks, and/or serving different populations are not considered meaningfully different characteristics. CMS is maintaining the exclusion of premium from the criteria because the regulatory meaningful difference requirement is intended to be an objective measure of benefits between two plans; the inclusion of premium would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity. Network differences have also been excluded from our criteria because having a provider in one plan and not the other is not a change in benefit coverage.

CMS expects MAOs to submit CY 2017 plan bids that meet the meaningful difference standards, but will not prescribe how the MAOs should redesign benefit packages to achieve the differences. Furthermore, MAOs will have access to the necessary tools to calculate OOPC

estimates for each plan prior to bid submission. CMS will not approve plan bids that do not meet these standards.

CMS notes that meaningful difference will be evaluated based on the "as submitted formulary" prior to rebate reallocation, and "first approved formulary" following rebate reallocation. MAOs must follow the CY 2017 renewal/non-renewal guidance in the Final Call Letter to determine if their plans may be consolidated with other plans.

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

***Total Beneficiary Cost (TBC)***

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Act to deny MAO bids, on a case-by-case basis, if it determines the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next through the use of the TBC standard. A plan's TBC is the sum of the plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. By limiting excessive increases in the TBC from one year to the next, CMS is able to confirm enrollees who continue enrollment in the same plan are not exposed to significant cost increases. As in past years, CMS will evaluate TBC for non-employer plans (excluding D-SNPs). For CY 2017, benefits and cost sharing that are offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the TBC evaluation. The MA plans that are participating in the VBID model test will be evaluated under the TBC calculation, including plan premium and non-VBID benefits and cost sharing.

Under §422.254, CMS will reserve the right to further examine and request changes to a plan bid even if a plan's TBC is within the required amount. This approach not only protects enrollees from significant increases in cost sharing or decreases in benefits, but also confirms enrollees have access to viable and sustainable MA plan offerings.

CMS has focused on sharing information with and providing transparency to the MAOs as it relates to the TBC year-to-year evaluation. CMS is proposing to modify the payment adjustment in a different way than indicated in the CY 2016 Final Call Letter. Rather than "discounting" the plan-specific payment adjustment (including a coding intensity component), CMS proposes to eliminate the coding intensity adjustment factor. Since most of the ACA payment changes have been implemented, it is our expectation that MAOs are better positioned to share payment changes and provide affordable and effective benefits for beneficiaries. Going forward, the payment adjustment in the TBC calculation would account for changes in county benchmarks, quality bonus payment, and/or rebate percentages.

Consistent with past years, CMS will continue to incorporate the technical and payment adjustments described below and expect organizations to address other factors, such as risk adjustment model changes and payment of the health insurance provider's fee independently of our TBC requirement. As such, plans are expected to anticipate and manage changes in payment and other environmental factors to minimize changes in benefit and cost sharing over time. CMS also reminds MAOs that the Office of the Actuary extends flexibility on margin requirements so MAOs can satisfy the TBC requirement.

In mid-April, as in past years, CMS will provide plan specific CY 2016 TBC values and the following adjustments that are incorporated in the TBC calculation to account for changes from one year to the next:

- Technical Adjustments: (1) annual changes in OOPC model software and (2) maximum Part B premium buy-down amount change in the bid pricing tool, if applicable (no change for CY 2017).

- Payment Adjustments: (1) county benchmark, and (2) quality bonus payment and/or rebate percentages.

CMS will maintain the TBC change threshold at $32.00 PMPM for CY 2017. A plan experiencing a net increase in adjustments must have an effective TBC change amount below the $32.00 PMPM threshold to avoid denial of the bid under section 1854(a)(5)(C)(ii). Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the $32.00 PMPM threshold. In an effort to support plans that improve quality compensation and experience large payment adjustments, along with holding plans accountable for lower quality, CMS plans to apply the TBC evaluation as follows.

For CY 2017, the TBC change evaluation will be treated differently for the following specific situations:

- Plans with an increase in quality bonus payment and/or rebate percentage, and an overall payment adjustment amount greater than $32.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $32 PMPM) plus applicable technical adjustments.

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

- Plans with a star rating below 3.0 and an overall payment adjustment amount less than −$32.00 PMPM will have a TBC change threshold of $64.00 PMPM (i.e., 2 times TBC

change limit of $32.00) plus applicable technical adjustments.

- Plans not accounted for in the three specific situations above will be evaluated at the $32 PMPM limit, similar to last year.

CMS received feedback subsequent to last year's Call Letter suggesting that CMS make changes to the TBC evaluation for Special Needs Plans for End Stage Renal Disease (ESRD), which are subject to larger increases and/or decreases in payment amounts. To moderate potentially large payment changes and provide MAOs with the ability to maintain benefit stability year-to-year, while helping provide protection for this vulnerable beneficiary population, CMS is proposing to apply limits to the payment adjustment for ESRD plans as described below:

- Plans with an increase in the overall payment adjustment amount greater than $32.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $32 PMPM) plus applicable technical adjustments.

- Plans with a decrease in the overall payment adjustment amount less than -$32.00 PMPM will have a TBC change threshold of $64.00 PMPM (i.e., 2 times TBC change limit of $32.00 PMPM) plus applicable technical adjustments. That is, plans would not be allowed to make changes that result in greater than $64.00 worth of decreased benefits or increased premiums.

As indicated in the CY 2016 Final Call Letter, CMS proposed that each individual plan being consolidated into another plan must meet the TBC requirement on its own merit. For CY 2017, CMS will be moving forward with this proposal; therefore, organizations consolidating multiple plans into a single plan will no longer be permitted to use the enrollment-weighted average TBC change of the consolidating plans. This approach affords greater protection for beneficiaries and enrollees in non-renewing plans will be able to actively select another MA plan from the same or competing organization based on CMS non-renewal guidance.

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

***Maximum Out-of-Pocket (MOOP) Limits***

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

Table 38 below displays the CY 2017 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to Local PPOs and Regional PPOs. A

plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing. We chose to display the possible ranges of the MOOP amount within each plan type 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 38. CY 2017 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<br>$0 -$5,100 Combined | $3,401 - $6,700 In-network and<br>$3,401 - $10,000 Combined |
| Regional PPO | $0 - $3,400 In-network and<br>$0 - $5,100 Combined | $3,401 - $6,700 In-network and<br>$3,401 - $10,000 Combined |
| PFFS (full network) | $0 - $3,400 Combined | $3,401 - $6,700 Combined |
| PFFS (partial network) | $0 - $3,400 Combined | $3,401 - $6,700 Combined |
| PFFS (non-network) | $0 - $3,400 | $3,401 - $6,700 |

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

The Office of the Actuary conducts an annual analysis to help CMS determine the proposed MOOP amount. Since the MOOP requirement was finalized in §422.100(f)(4) and (5), a strict application of the 95th and 85th percentile would have resulted in MOOP limits fluctuating up and down year-to-year. CMS has exercised discretion to maintain stable MOOP limits from year-to-year, if the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages, and does not

discourage the adoption of the lower voluntary MOOP amount if the limit increases one year and then decreases the next. CMS expects to increase MOOP limits if a consistent pattern of increasing costs emerges over a period of time.

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

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

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis. CMS will apply this requirement separately to the following service categories for CY 2017: Inpatient, Skilled Nursing Facility (SNF), Durable Medical Equipment (DME), and Part B drugs. CMS will provide additional information and an illustrative comparison of service-level actuarial equivalent costs (as in past years) in the Final Call Letter.

***Part C Cost Sharing Standards***

For CY 2017, CMS will continue the current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower voluntary MOOP limit than is available to plans that adopt a higher, mandatory MOOP limit. Table 39 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans that we will not consider discriminatory or in violation of the applicable standards. CY 2017 bids must reflect enrollee cost sharing for in-network services no greater than the amounts displayed below. For LPPOs and RPPOs, these standards will be applied only to in-network services. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. Inpatient standards have been updated to reflect estimated changes in Original Medicare cost for CY 2017.

**Table 39. CY 2017 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 | $4,177 |
| Inpatient - 10 days | 1a | $2,471 | $1,977 |
| Inpatient - 6 days | 1a | $2,251 | $1,801 |
| Mental Health Inpatient - 60 days | 1b | $2,606 | $2,085 |
| Mental Health Inpatient - 15 days | 1b | $1,988 | $1,590 |
| Skilled Nursing Facility – First 20 Days[1] | 2a | $20/day | $0/day |
| Skilled Nursing Facility – Days 21 through 100[2] | 2a | $164.50/day | $164.50/day |
| Emergency Care/Post Stabilization Care | 4a | $75 | $75 |
| Urgently Needed Services[3] | 4b | $65 | $65 |
| Partial Hospitalization | 5 | $55/day | $55/day |
| Home Health | 6a | 20% or $35 | $0 |
| Primary Care Physician | 7a | $35 | $35 |
| Chiropractic Care | 7b | $20 | $20 |
| Occupational Therapy | 7c | $40 | $40 |
| Physician Specialist | 7d | $50 | $50 |
| Psychiatric and Mental Health Specialty Services | 7e and 7h | $40 | $40 |
| Physical Therapy and Speech-language Pathology | 7i | $40 | $40 |
| Therapeutic Radiological Services | 8b | 20% or $60 | 20% or $60 |
| DME-Equipment | 11a | N/A | 20% |
| DME-Prosthetics | 11b | N/A | 20% |
| DME-Medical Supplies | 11b | N/A | 20% |

| Cost Sharing Limits | | | |
|---|---|---|---|
| **Service Category** | **PBP Section B data entry field** | **Voluntary MOOP** | **Mandatory MOOP** |
| DME-Diabetes Monitoring Supplies | 11c | N/A | 20% or $10 |
| DME-Diabetic Shoes or Inserts | 11c | N/A | 20% or $10 |
| Dialysis Services | 12 | 20% or $30 | 20% or $30 |
| Part B Drugs-Chemotherapy[4] | 15 | 20% or $75 | 20% or $75 |
| Part B Drugs-Other | 15 | 20% or $50 | 20% or $50 |

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

[2] MA plans may have cost sharing for the first 20 days of a SNF stay. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).

[3] Emergency Care and Urgently Needed Care benefits are not subject to plan level deductible amount and/or out-of-network providers.

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

Please note that MAOs with benefit designs which use a coinsurance or copayment amount for which CMS does not have an established amount (e.g., coinsurance for inpatient or copayment for durable medical equipment) must submit documentation with their initial bid that clearly demonstrates how the coinsurance or copayment amount satisfies CMS service category requirements. This documentation must be submitted as part of supporting documentation for the Bid Pricing Tool as described in the Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2017, Appendix B-Supporting Documentation. CMS annually evaluates available Medicare data and other information to apply MA requirements in accordance with applicable law. Organizations are afforded the flexibility to design their benefits as they see fit so long as they satisfy Medicare coverage requirements.

As indicated in the table above, for SNF days 1 through 20, CMS will reduce the cost sharing limit for CY 2017 voluntary MOOP plans from $40 per day to $20 per day for beneficiary protection. In addition, we also intend to reduce the cost sharing limit from $20 per day to $0 per day for CY 2018 MA plans so that SNF cost sharing will align with Original Medicare for both voluntary and mandatory MOOP.

CMS has traditionally afforded MAOs greater flexibility in establishing Parts A and B cost sharing by adopting a lower, voluntary maximum out-of-pocket (MOOP) limit than is available

to plans that adopt a higher, mandatory MOOP limit. The number of MA plans with voluntary MOOPs has decreased significantly over the past several years which may call into question the value of allowing cost sharing flexibility and serve to minimize the impact of changes made to this policy. As a result, CMS intends to reduce or eliminate cost sharing flexibility in other service categories for voluntary MOOP plans, which would be accomplished over the next few years to minimize disruption to plans and enrollees.

CMS requests comments about whether current incentives should still be available to voluntary MOOP plans, and suggestions about other incentives to encourage MAOs to offer plans with a lower voluntary MOOP for enrollees. For example, flexibilities to highlight voluntary MOOP plans in marketing materials or a special indicator or priority sorting on Medicare Plan Finder. These types of marketing-related incentives may encourage plans and brokers to educate beneficiaries on the MOOP and its value to their overall financial protection should they experience large medical expenses during a plan year.

***Part C Optional Supplemental Benefits***

As part of our evaluation whether the bid and benefits are not discriminatory against enrollees with specific (or high cost) health needs, CMS will continue to review non-employer bid submissions to verify enrollees electing optional supplemental benefits are receiving reasonable value. As in CY 2016, CMS considers a plan to be not discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following thresholds: (a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15% and (b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by a percent of premium, is no greater than 30%.

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

***Plan Benefit Package (PBP) Updates and Guidance***

**Medical Services Performed in Multiple Health Care Settings**

In our continuing effort to avoid duplication of medical services entered in the PBP, CMS is offering additional guidance on how to place services that can be performed in different health care settings (e.g., physician office, outpatient hospital, and free standing facility) in the appropriate service category and correctly complete data entry within the PBP.

The outpatient hospital service category in the PBP has historically included a variety of services that may have their own dedicated PBP category. By including the same service in multiple locations throughout the PBP, we are concerned that marketing materials may be confusing and that CMS cost sharing requirements could be compromised. Based on the out-of-pocket cost

(OOPC) model methodology, including services with zero cost sharing for the minimum amount in a multiple service category will reduce the estimated out-of-pocket costs used by beneficiaries in comparing plans on Medicare Plan Finder and adversely affect CMS bid review for meaningful difference and Total Beneficiary Cost (TBC).

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

Another area of particular concern is Medicare-covered preventive services. All Medicare-covered zero dollar cost sharing preventive services must be included in PBP Service Category 14a and must not be included in any other service category (i.e., those benefits that are rated as A or B by the United States Preventive Services Task Force). For example, we do not expect to see a zero in the minimum data field in 9a (Outpatient hospital services) with a note that explains the zero dollar amount is for preventive services. All of the zero dollar Medicare-covered preventive services are to be placed in 14a only.

For CY 2016, plans were required to reflect cost sharing for the service categories listed in the table below appropriately within each designated service category:

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

In addition to the service categories listed above, plans must enter cost sharing for the service categories shown in the table below appropriately within each designated service category for CY 2017. These services should not be referenced in any other service category. We anticipate these changes will improve transparency and streamline the data entry so the cost sharing associated with those PBP service categories below reflects the services provided across a variety of healthcare settings.

| PBP Sec. B | Service Category |
|---|---|
| 7c | Occupational Therapy Services |
| 7g | Other Health Care Professional Services |
| 7i | Physical therapy and Speech Language Pathology Services |
| 8a | Outpatient Diagnostic Procedures and Tests and Lab Services |
| 8b | Outpatient Diagnostic and Therapeutic Radiological Services |
| 9a | Outpatient Hospital Services |
| 9b | Ambulatory Surgical Center Services (ASC) |

We continue to evaluate opportunities to streamline data entry and avoid duplication in the PBP and request comments for improving this process.

### Medicare-Covered Preventive Services

In previous years, MAOs were able to include non-zero dollar Medicare-covered preventive services in multiple service categories. CMS is modifying the PBP to rename B14a from "Medicare-covered Preventive Services" to "Medicare-covered Zero Dollar Preventive Services," and will create a new service category where all other Medicare-covered preventive services and any cost sharing (if applicable) can be identified clearly. This new services category will be B14e "Other Medicare-Covered Preventive Services," and will replace B14e "Diabetes Self-Management Training." PBP service category B14e "Other Medicare-Covered Preventive Services" will include cost sharing fields for the glaucoma screening benefit, diabetes self-management training, as well as up to five other optional Medicare-covered preventive services for which a copayment may be required that can be entered by the MAO.

## *Policy Updates*

### Tiered Cost Sharing of Medical Benefits

MAOs may choose to tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data. In addition to other standards for this plan design that are provided in the Medicare Managed Care Manual, Chapter 4, the tiered cost sharing must be applied so that all plan enrollees are charged the same cost sharing amount for any specific provider and all providers are available and accessible to all enrollees in the plan. For CY 2017, MAOs will be submitting tiering requests through an electronic mailbox. Details regarding the process will be provided in an HPMS memo in April.

### Cost Sharing /Bundling and Facility

CMS is concerned about the transparency of costs sharing for Medicare Advantage beneficiaries. Beneficiaries should be readily able to understand their cost sharing responsibilities. Specifically, MA plans should not unbundle Medicare services and establish multiple cost sharing for services.

For example, we are aware that in some cases an enrollee may receive a service in a facility setting that includes an additional facility fee that does not apply when the service is furnished in a physician’s office. While MA plans may have higher copays based on place of service, they should to the extent possible include the enrollee’s entire cost sharing responsibility in a single copay. This approach will make it easier for enrollees to understand and anticipate the cost sharing they will incur prior to receiving services. This is consistent with Medicare Advantage disclosure requirements at 42 CFR section 422.111(b)(2) which require that MA plans clearly and accurately disclose benefits and cost sharing. Accordingly, in situations where there is a difference in cost sharing based on place of service, those fees are to be combined (bundled) into

the cost sharing amount for that particular place of service and clearly reflected as a total copayment in appropriate materials distributed to beneficiaries.

Our goal is not to prevent appropriate cost sharing, but to ensure that cost sharing is transparent and meets CMS cost sharing standards.

**Interoperability-MA Plans and Contracted Providers**

Background

Interoperability is the ability of systems to exchange and use electronic health information from other systems without special effort on the part of the user.[32] The health care industry is moving towards interoperability because it promotes more effective exchange of health information, seamless care transitions, improved care coordination and enrollee health outcomes and enables providers and communities to deliver smarter, safer and more efficient care.

We believe that commercial payers as well as the Medicaid program have taken steps to promote interoperability across provider settings, and align with the Office of the National Coordinator for Health Information Technology (ONCHIT) standards for meaningful use and certified electronic health records (EHRs). CMS issued a Medicaid final rule on October 16, 2015 requiring eligible professionals to utilize certified technology to promote health information exchange as part of the Medicare and Medicaid EHR Incentive Program. This is a broader effort, however, to support delivery system reform and quality initiatives focused on patient outcomes.

In addition, §13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), requires that our contracts require MAOs to utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under § 3004 of the Public Health Services Act, as amended by § 13101 of the ARRA.

In alignment with the referenced legislation and Medicaid, CMS is currently exploring how best to encourage the adoption of technology that supports interoperability between Medicare Advantage (MA) plans and their contracted providers, and the need for rulemaking to require such adoption. CMS seeks comment from the industry regarding their experience with these activities, including barriers to successful adoption.

**Alternative Payment Models (APMs)**

Alternative Payment Models (APMs) are provider payment structures that incentivize health care quality, emphasize value over volume and care coordination activities. To help incentivize the transformation of our health care delivery system away from rewarding volume over value, the Administration has set a goal to have 30 percent of Medicare fee-for-service payments made based on APMs by the end of 2016 and 50 percent by the end of 2018.

In the Contract Year (CY) 2016 Call Letter, CMS indicated that we would reach out to MAOs to gain a better understanding of their use of provider incentives and value based contracting for physician services. Subsequently, CMS had conversations with a number of MAOs concerning

[32]Institute of Electrical and Electronic Engineers- http://www.ieee.org/200Bindex.html?WT.mc_id=mn_ieee

their use of alterative payment models. As a result of the high level of interest in the use of APMs and the long term HHS payment goals, CMS has added APM questions to the Part C reporting requirements. Specifically, CMS will ask MAOs to report on the proportion of payments made to providers based on the HHS developed four categories of value based payment: fee-for-service with no link to quality; fee-for-service with a link to quality; alternative payment models built on fee-for-service architecture; and population-based payment.

In order to maintain consistency with HHS goals of increasing the proportion of payment made based on quality and value, CMS will continue to support MAOs efforts to improve cost efficiency, reduce costs, and improve health outcomes through the use of APMs. In order to better support the continued implementation, growth, and sustainability of these models in Medicare Advantage, CMS is seeking comments from the industry regarding challenges and concerns associated with the use of APMs in Medicare Advantage.

**Connecting Beneficiaries to Care**

As a reminder, MA beneficiaries are entitled to an introductory "Welcome to Medicare" preventive visit within their first twelve months in Medicare. Each year thereafter, MA beneficiaries are then entitled to an Annual Wellness Visit (AWV). CMS recognizes the importance of yearly preventive visits to drive quality improvement in the care enrollees receive and is looking at ways in which MAOs can further engage enrollees and connect them to preventive and needed care. We welcome stakeholder suggestions and input around existing or potential approaches.

**Counseling and Related Support Services**

Recognizing that Alzheimer's disease and related dementias pose a serious and growing threat to Medicare beneficiaries and their families, CMS encourages MAOs to offer enrollees who are diagnosed with Alzheimer's or other related dementias innovative supplemental benefits that could enable their enrollees to remain in the community. Such benefits would provide a defined set of counseling and related supports to the enrollee or to the enrollee together with their informal (non-paid) caregivers. In designing their supplemental benefits, MAOs can take advantage of a variety of resources, including those provided by the Alzheimer's Association, and learning from models such as the New York University Caregiver Intervention (NYUCI) and the Department of Veterans' Affairs Resources for Enhancing Alzheimer's Caregivers Health (REACH) program.

**Prohibition on Billing Medicare-Medicaid Enrollees for Medicare Cost-Sharing**

We remind all Medicare Advantage (MA) plans of their obligation to protect dual eligible beneficiaries from incurring liability for Medicare cost-sharing. In July 2015, CMS released a study finding that confusion and inappropriate balance billing persist notwithstanding laws prohibiting Medicare cost-sharing charges for QMB beneficiaries, Access to Care Issues Among

Qualified Medicare Beneficiaries (QMB) ("Access to Care") https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf. These findings underscore the need to re-educate providers, plans, and beneficiaries about proper billing practices for dual eligible enrollees.

Under 42 CFR §422.504(g)(1)(iii), all MAOs --without exception-- must educate providers about balance billing protections applicable to dual eligible enrollees. Federal law bars Medicare providers from collecting Medicare Part A and Medicare Part B deductibles, coinsurance, or copayments from those enrolled in the Qualified Medicare Beneficiaries (QMB) program, a dual eligible program which exempts individuals from Medicare cost-sharing liability. (See Section 1902(n)(3)(B) of the Social Security Act, as modified by 4714 of the Balanced Budget Act of 1997). Balance billing prohibitions may likewise apply to other dual eligible beneficiaries in MA plans if the State Medicaid Program holds these individuals harmless for Part A and Part B cost sharing. See 42 CFR §422.504(g)(1)(iii). For more information about dual eligible categories and benefits, please visit: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/medicare_beneficiaries_dual_eligibles_at_a_glance.pdf.

In contracts with providers, MAOs must specify these balance billing prohibitions and instruct providers to either accept the MA payment as payment in full or bill the State for applicable Medicare cost-sharing for enrollees that are eligible for both Medicare and Medicaid. MA plans can find information about an enrollee's dual eligible status in the Monthly Membership Detail Data File. (See Appendix F.12, # 85 Dual Status Code in *the Plan Communications User Guide Appendices* at https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html).

In addition, CMS encourages MAOs to take affirmative steps to address common points of confusion among providers regarding balance billing. For example, we urge MAOs to explain that all MA providers-- not only those that accept Medicaid-- must abide by the balance billing prohibitions. Further, CMS suggests that plans clarify that balance billing restrictions apply regardless of whether the State Medicaid Agency is liable to pay the full Medicare cost sharing amounts. (Federal law allows State Medicaid Programs to reduce or negate Medicare cost-sharing reimbursements for QMBs in certain circumstances. See Section 1902(n)(3)(B) of the Social Security Act, as modified by 4714 of the Balanced Budget Act of 1997)).

Finally, to monitor provider compliance with balance billing rules and target provider outreach, CMS encourages MAOs to identify problem areas from plan grievance and CMS Complaint Tracking Module data. These steps will complement continued MAO efforts to remediate individual violations and clarify appropriate billing procedures.

**Medicare Advantage Organization Responsibilities for Clinical Trials**

We want to remind MAOs of their responsibilities regarding clinical trials. These responsibilities are also specified in Chapter 4 of the Medicare Managed Care Manual. While Original Medicare is generally responsible for payment of costs for most clinical trials, under NCD 310.1, MAOs are responsible for payment in the following instances:

- Category A and B investigational device exemption trials

  MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B investigational device exemption (IDE) studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A IDE studies and for routine care items and services, as well as the Category B device under study in Category B IDE studies.

  The local MAC(s) with jurisdiction over the Medicare Advantage plan's service area determines coverage of IDE studies.

- NCDs for clinical trials with coverage with evidence development

  In separate National Coverage Determinations (NCDs) requiring coverage with evidence development (CED), original Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines, for each NCD, that the significant cost threshold is exceeded for that item or service (see 42 CFR §422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html). Billing instructions are issued for each NCD.

In the case of IDE trials and clinical trials with CED, plans may cover these benefits as they do any other, that is, they may require pre-authorization and that enrollees follow all other plan rules.

In the case of clinical trials that are paid for by Original Medicare under NCD 310.1, we require MAOs, to provide coverage for: (1) services to diagnose conditions covered by clinical trial services, (2) most services furnished as follow-up care to clinical trial services and (3) services already covered by the MA organization. Should an MA plan beneficiary choose to participate in a clinical trial, he or she may remain in his or her MA plan while paying Original Medicare costs for a qualifying clinical trial.[33]

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[33] Clinical trials are covered under the Clinical Trials National Coverage Determination (NCD) (NCD manual, Pub. 100-3, Part 4, Section 310)

Please see section 10.7 of Chapter 4 of the Medicare Managed Care Manual for further information on MAO responsibilities for clinical trials.

***Dual-Eligible Special Needs Plans***

For CY 2017, we intend to continue our efforts to use administrative flexibilities to facilitate the integration of Medicare and Medicaid benefits by Dual-Eligible Special Needs Plans (D-SNPs) and improve the experience of care for dually-eligible Medicare-Medicaid enrollees in those plans. We will continue our work to improve marketing materials and model notices to better explain both the Medicare and Medicaid benefits provided by integrated D-SNPs. In addition, we propose the following policy clarifications that we believe will help D-SNPs deliver an array of benefits and services that meet the needs of Medicare-Medicaid enrollees and improve Medicare-Medicare enrollees' understanding of the coverage they receive.

**D-SNP Non-Renewals**

States that contract with D-SNPs to provide Medicaid benefits have an interest in providing D-SNP members in their states with accurate information regarding any changes to the delivery of their Medicaid benefits and facilitating the transition to new coverage that can accompany the nonrenewal or year-end termination of a D-SNP. A number of states therefore include in their MIPPA contracts with D-SNPs requirements that the plan inform the state about pending nonrenewals, service area reductions, or terminations so that the state can plan ahead for any outreach efforts to impacted D-SNP members in the state. While the MIPAA contract requirements are helpful for state planning purposes, we believe CMS can further assist states by providing notice to states in advance of any public announcement regarding nonrenewing or terminating D-SNPs that contract to provide Medicaid benefits to Medicare-Medicaid enrollees in these states. This would facilitate a more robust role for states in informing Medicare-Medicaid enrollees about how changes to their D-SNP coverage will impact delivery of their Medicaid benefits. This would build on our efforts in CY 2015 to include information on changes to Medicaid coverage in the integrated D-SNP nonrenewal notice. We seek comment from D-SNP sponsors and states on how best to implement this exchange of information with states on pending nonrenewals, service area reductions and terminations.

**D-SNP Model of Care**

An integrated D-SNP that provides Medicaid long-term services and supports must have a model of care (MOC) that incorporates provision of those services and their integration with the medical and prescription drug benefits the D-SNP provides under its Medicare contract (see §422.101(f)). States have the ability, through their contracting with D-SNP sponsors, to require that the D-SNP MOC fully integrates long-term services and supports and coordinates the provision of all Medicare and Medicaid services. We are interested in exploring ways for interested states to add specificity to existing elements that describe state requirements related to the management of long term services and supports to the CMS review criteria for D-SNP

MOCs. In addition, rather than having two separate and parallel processes for review of D-SNP MOCs—one by the state under the state contract and one by NCQA for Medicare approval— we would like to explore allowing states to review MOCs against their requirements concurrent with NCQA's review of MOCs in HPMS. This would leverage the current MOC review process and encompass delivery of both Medicare and Medicaid benefits. We note that the joint review process would not in any way change the current CMS requirements for review and approval of D-SNP MOCs by NCQA. This effort would build on a process successfully implemented in Minnesota under our Partnership to Align Administrative Functions for Improvements in Medicare-Medicaid Beneficiary Experience, as well as under the Financial Alignment Initiative for Medicare-Medicaid Plans. We seek comment on the potential benefits and operational challenges of a concurrent CMS-state MOC review, in particular from states that are potentially interested in participating in such a review process.

**Section III – Part D**

***Formulary Submissions***

**CY 2017 Formulary Submission Window**

The CY 2017 HPMS formulary submission window will open this year on May 16, 2016 and close at 11:59 pm PDT on June 6, 2016. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 6, 2016 in order for the formulary to be considered for review. The formulary used in a Part D plan is part of the plan's complete bid and therefore a failure to submit and link a formulary to each plan that uses a formulary by the June 6th deadline will result in denial of that bid submission.

**CY 2017 Formulary Reference File**

CMS will release the first CY 2017 Formulary Reference File (FRF) in March 2016. The March FRF release will be used in the production of the Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2016, in order to assist plan sponsors in satisfying meaningful difference and MA TBC requirements prior to bid submission. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

In May 2016, CMS is planning to provide a release of the 2017 FRF just prior to the June 6th formulary submission deadline. Given the limited timeframe between the May release of the 2017 FRF and the June 6th deadline, CMS is unable to accommodate an updated version of the 2017 OOPC model to incorporate the May FRF changes. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2017 FRF will not be included in the 2017 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 2017 FRF, since additional limitations will be imposed on the summer formulary update window.

Part D sponsors are reminded that they may enhance their formularies (i.e., add Part D drugs, reduce beneficiary cost-sharing, or remove utilization management edits) between the summer update window and the first HPMS submission of the upcoming plan year. Consistent with section 60.5 of the Medicare Marketing Guidelines, these enhancements must be included in the Part D sponsor's marketing materials and must be submitted during the next HPMS formulary submission window. Sponsors are encouraged to directly notify beneficiaries of formulary additions in a timely manner since in some cases, such as new generics, an earlier conversion could lead to better value for the beneficiary and potentially reduce program costs.

In an effort to better align plan sponsors' submission of quantity limits (QLs) with CMS' review, a new column will be added to the HPMS-posted FRF that indicates the unit for which sponsors must submit their QLs. While the vast majority of submitted QLs, such as those for solid oral dosage forms are straightforward, this additional information will be useful for products such as kits that contain prefilled syringes. The HPMS formulary submission will not be validated against this field. Rather, it will serve as a point of reference for CMS and Part D sponsors during the review of submitted QLs. Finally, we are evaluating the feasibility of including an informational column on the FRF that would periodically track price changes for FRF drugs.

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

Consistent with 42 CFR §423.153(b), CMS reminded sponsors in the 2015 Call Letter that they must establish utilization management controls, such as prior authorization (PA), in order to reduce costs and to prevent inappropriate utilization of prescribed medications under Part D. Currently, we permit Part D sponsors to implement point of sale (POS) PA edits to determine whether a drug is: 1) covered under Medicare Parts A or B; 2) being used for a Part D medically-accepted indication (MAI) (as defined in section 1860D-2(e)(4) of the Social Security Act); or 3) a drug, drug class, or has a 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., when used for cosmetic purposes or hair growth). While CMS allows sponsors to implement these PAs during transition (either for new enrollees into a plan or for current enrollees affected by formulary changes) to prevent Part D coverage for excluded drugs or for non-medically-accepted indications of Part D drugs, sponsors continue to be confused about which POS PA edits are permitted during transition. Section 30.4.8 of Chapter 6 of the Prescription Drug Benefit Manual (available at

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf) discusses edits for transition fills. The requirements for Part D sponsors to limit coverage to Part D drugs and Part D medically-accepted indications, assist in preventing over-utilization and under-utilization of prescribed medications, and utilize 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, POS PA edits for such purposes are appropriate even during transition.

The 2015 Call Letter encouraged sponsors to utilize PA for drugs that have a high likelihood of use for a non-medically-accepted indication. Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual discusses medically-accepted indication (available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf)

The 2015 Call Letter specified Transmucosal Immediate Release Fentanyl (TIRF) products and Cialis as examples of drugs that have a high likelihood of use for non-medically-accepted indications. Our guidance is focused on those drugs that pose the greatest risk for non-medically accepted indications, and, therefore, CMS does not expect to see POS PA edits during transition to determine the indication on most Part D drugs.

Coverage duration is a required component of criteria that are submitted to CMS as part of the formulary review process for PA approval. Sponsors often approve criteria for the duration of the plan year or for one calendar year from the initial approval date. Once a PA is approved, sponsors are not prohibited from utilizing "grandfathering" policies that allow beneficiaries to receive a drug from year to year without a requirement to satisfy the PA criteria in the future. In general, policies that facilitate appropriate access to medications for beneficiaries with chronic conditions are looked upon favorably by CMS. However, if such policies are implemented for products that have significant safety concerns and the high potential for non-MAI use (e.g., TIRF drugs), we expect sponsors to periodically confirm that beneficiaries continue to use these drugs for medically-accepted indications. This confirmation can be accomplished by establishing limits to the "grandfathering" processes for these drugs or through robust retrospective drug utilization review processes. This expectation would also apply to cases where members are moving across plans or when a new PBM is being utilized, for example.

***Medication Therapy Management (MTM)***

**Annual MTM Eligibility Cost Threshold**

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per §423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries

is specified as costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in §423.104(d)(5)(iv). The 2016 MTM program annual cost threshold is $3,507. The 2017 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2017 Call Letter.

**Annual MTM Submission and Approval Process**

A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The guidance memo for CY 2017 will be released approximately one month before the 2017 MTM program submission deadline. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Annually, Part D plan sponsors must submit an MTM program description to CMS through the Health Plan Management System (HPMS) for review and approval. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year.

Due to enhancements to the HPMS MTM submission module and expanded guidance and submission instructions over the years, MTM program submissions have increasingly high rates of initial approval. Beginning with the CY 2017 submissions, we propose to implement a modified annual MTM program review process and add attestations to the HPMS submission module as described below.

- All Part D sponsors will continue to submit an MTM program description through HPMS each year. Sponsors will continue to submit change requests throughout the year.
- Attestations of the Part D sponsor's compliance with Part D MTM program requirements will be added to the MTM submission module in HPMS.
- Sponsors must attest to meeting the MTM program requirements during the annual submission. Sponsors must re-attest when they submit change requests. The user completing the MTM submission and attestations in HPMS must have the authority to attest on behalf of the organization.
- A subset of MTM program submissions will be comprehensively reviewed:
  - Any new contracts;
  - Any contracts whose MTM submission failed initial review the prior year;
  - Any contracts that failed reporting requirements data validation or audit for MTM (when implemented);

- Any contracts that scored less than 3 stars on the MTM comprehensive medication review completion rate measure;
- A random sample of other program submissions.

We will continue to monitor beneficiary complaints, validation results of plan-reported MTM data, and CMS program audits of MTM programs.

**Submission Requirements for Enhanced MTM Model Participants**

The CMS Center for Medicare and Medicaid Innovation announced the Part D Enhanced MTM Model, an opportunity for stand-alone basic Prescription Drug Plans (PDPs) in selected regions to offer innovative MTM programs, aimed at improving the quality of care while also reducing costs. More information about the model test is available at https://innovation.cms.gov/initiatives/enhancedmtm/.

The Enhanced MTM Model test will begin January 1, 2017 with a five-year performance period. CMS will test the model in 5 Part D regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona). Eligible defined standard, actuarially equivalent, or basic alternative stand-alone PDPs in these regions, upon approval from CMS, can vary the intensity and types of MTM items and services based on beneficiary risk level and seek out a range of strategies to individualize beneficiary and prescriber outreach and engagement.

The current MTM requirements are waived for the PBPs approved to participate in the Enhanced MTM Model and data on participating PBPs must not be reported per the Part D Reporting Requirements under the current MTM program. This MTM data will instead be reported in accordance with model terms and conditions. CMS will notify the subset of plans that are NOT subject to current MTM requirements.

Plan sponsors with contracts that include PBPs that are not eligible to participate in the model must ensure that those non-participating plans comply with all standard MTM program requirements, including the submission of MTM program details in HPMS. More information will be provided in the annual MTM program guidance and submission instruction memo for CY 2017.

**Part D Reporting Requirements for MTM**

For monitoring purposes, Part D sponsors are responsible for reporting several data elements to CMS related to their MTM program per the Part D Reporting Requirements. Element X, "Topics discussed with the beneficiary during the comprehensive medication review (CMR), including the medication or care issue to be resolved or behavior to be encouraged", is suspended for the 2016 Part D Reporting Requirements until a more standardized set of data can be collected.

The industry, including the Pharmacy Quality Alliance (PQA) and the Academy of Managed Care Pharmacy (AMCP), is working on a framework to define drug therapy problems (DTPs). Sponsors should begin to develop the capacity to collect and report drug therapy problems using a standard framework and common terminology. We plan to propose new data elements for the Part D Reporting Requirements through the Paperwork Reduction Act (PRA) process as early as 2017 to capture drug therapy problems at the beneficiary-level using standard categories and definitions.

***Improving Clinical Decision-Making for Certain Part D Coverage Determinations***

The regulations for Part D coverage determinations prescribe that a plan sponsor must notify the enrollee of its decision no more than 72 hours from receipt of the request for standard requests for benefits, and no more than 24 hours from receipt of the request for expedited requests for benefits. For exception requests, the adjudication timeframe does not begin until the plan receives the prescriber's supporting statement. CMS established significantly shorter adjudication timeframes for Part D than for Medicare Advantage because the majority of Part D coverage requests involve prescription drugs an enrollee has not yet received, which increases the risk of adverse clinical outcomes if access to the drug is delayed. Enrollee access to drugs that require prior authorization (PA) or step therapy (ST) generally requires review by the plan sponsor to determine if the PA or step requirements have been satisfied (or if an exception request should be approved). The required adjudication timeframes for Part D coverage determinations are set forth at 42 CFR Part 423, Subpart M and in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

If a Part D plan is not able to obtain the information needed to approve coverage before the adjudication timeframe expires despite its outreach efforts, it must issue a denial notice and process new information received subsequent to the denial as a redetermination. Based on ten years of program experience, including plan audits, CMS has observed that when the 24 or 72 hour adjudication timeframe is impacted by a weekend or holiday (or both), the plan may be less likely to reach the prescriber to obtain necessary information before the adjudication timeframe expires. In these situations, CMS is concerned that expediency may occur at the expense of sound clinical decision-making, resulting in access delays for affected enrollees due to the need to go through the redetermination process which has longer maximum adjudication timeframes (72 hours from receipt of the request for expedited requests, and 7 days from receipt of the request for standard requests). A decision to deny the coverage request based solely on the lack of clinical information places the burden on the enrollee to request an appeal in order to have the request reviewed on its merits based on appropriate clinical documentation. We have additional concerns that not permitting Part D plans to extend the coverage determination timeframe in certain limited situations may result in increased program costs due to the fact that all redeterminations related to medical necessity must be made by a physician.

To address these concerns, CMS is contemplating rulemaking that would allow extensions to Part D adjudication timeframes in certain limited circumstances such as:

- The coverage determination level;
- Situations where the timeframe is impacted by a weekend or holiday;
- Requests for drugs that require PA or ST pursuant to the plan's CMS-approved formulary; and
- Cases where the plan does not have all necessary information from the prescriber required to make a clinically appropriate decision based on approved criteria.

Extensions would not be permitted for exception requests (including exceptions to PA or ST criteria), because our rules already provide for tolling the adjudication timeframe on the front-end until the plan receives the prescriber's supporting statement.

Any regulatory proposal would bear the following principles in mind:

- Because of the importance of timely processing of coverage requests, as described above, extensions in Part D should have a shorter maximum timeframe than MA extensions, which is up to 14 days.
- Extensions would be regulated in a manner similar to existing requirements for MA extensions in that they would be permitted only when justified in limited, non-routine circumstances as described above, and only when in the best interest of the enrollee.
- Written notification requirements to the enrollee would be established whenever an extension is taken.
- It would not be appropriate for a Part D plan to invoke an extension due to the plan's failure to conduct timely outreach as described in Chapter 18.

We are soliciting comments from stakeholders on the value of proposing regulatory changes that would permit Part D plans to extend the adjudication timeframe for certain coverage determination requests for drugs subject to PA or ST where: (1) the plan has been unable to obtain needed clinical information from the prescriber despite reasonable efforts to do so, and (2) the adjudication timeframe has been impacted by a weekend or holiday. We are particularly interested in hearing from physicians and other prescribers on potential benefits and drawbacks of such a change and any potential unintended consequences. We welcome additional suggestions from stakeholders on other potential changes related to this issue.

We note that any change to the Part D adjudication timeframes, including permitting the limited use of extensions, will require changes to the regulations in Subpart M as well as to the guidance in Chapter 18 of the Medicare Prescription Drug Benefit Manual. We will consider all

comments received as we determine appropriate next steps, including considering the feasibility of conducting a pilot to test potential changes that could improve the accuracy of clinical decision-making at the initial coverage decision, avoid potential delays in access to needed prescription drugs, and reduce costs associated with the Subpart M appeals process.

***Access to Preferred Cost-Sharing Pharmacies***

In the CY 2016 Call Letter, CMS announced several steps we would take to address low access to preferred cost sharing pharmacies (PCSPs). First, we announced that we would post information about 2016 PCSP access levels on the CMS website. Second, we announced that we would require plans who were outliers with respect to access to PCSPs to disclose that their plan's PCSP network offered lower access than other plans. Outliers were set at the bottom 10$^{th}$ percentile compared to all Part D plans in a given geographic type, using 2014 data. CMS required marketing materials to include specific disclaimer language for plans offering access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas. Finally, we announced that we would work with plans that were extreme outliers to address concerns about beneficiary access and marketing representations relating to preferred cost sharing. We worked with several such plans to either improve access or develop targeted marketing strategies to ensure that beneficiaries selecting these plans were aware of their status as extreme outliers.

CMS is pleased to note that plans increased PCSP access dramatically for 2016. As shown in the table below, the bottom 10$^{th}$ percentile of plans in 2016 offer access within two miles to 71% of urban beneficiaries, compared to 40% in 2014.

**Table 40. PCSP Access Rates for the Bottom 10$^{th}$ Percentile of Plans, 2014 through 2016**

| | 2014 | 2015 | 2016 | Convenient Access Standard for All Retail Pharmacies |
|---|---|---|---|---|
| **Urban Access Rate** | 40% | 62% | 71% | 90% |
| **Suburban Access Rate** | 87% | 92% | 95% | 90% |
| **Rural Access Rate** | 77% | 77% | 82% | 70% |

Because we believe the current policy is increasing access to PCSPs, we do not plan to make significant changes for 2017. Specifically, we will not change the outlier thresholds for 2017 to reflect the higher access levels achieved for 2016.

Therefore, CMS will continue its PCSP policy as announced in the 2016 Call Letter and implemented for the 2016 plan year. Plans that provide PCSP pharmacy access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas will be identified as outliers in 2017. Outlier plans will be

required to disclose in marketing materials, including websites, that their plans' PCSP networks offer lower access. Contract Year 2016 disclaimer language was announced in the June 24, 2015 HPMS memo "Marketing Disclaimer Language for Plans with Limited Access to Preferred Cost Sharing Pharmacies," and in the final "Medicare Marketing Guidelines" released on July 2, 2015. CMS continues to expect that plans will analyze their own 2016 and 2017 networks to determine whether they are below outlier thresholds. CMS will analyze preferred cost sharing pharmacy access on a quarterly basis and will remind plans of their outlier status periodically. CMS will also continue to work with extreme outliers to address concerns about beneficiary access and marketing representations related to preferred cost sharing. CMS will notify these plans in or around April 2016 that we plan to address 2017 PCSP access issues with them during bid negotiations. In 2016, most plans identified as extreme outliers opted to improve access rather than develop marketing plans to better inform beneficiaries of low PCSP access. We anticipate plans will take similar steps during 2017 negotiations.

Finally, although CMS will not post access information on the Medicare Plan Finder, we will continue to publish information about PCSP access levels annually on the CMS website at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html.

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

***Part D Benefit Parameters for Non-Defined Standard Plans***

Each year, in order to implement certain regulations, we set forth certain benefit parameters, which are based on updated data analysis, and therefore, are subject to change from year to year. Specifically, pursuant to § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package (other than defined standard) or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost sharing, formulary structure, or benefits offered; and, pursuant to 42 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. The benefit parameters for CY 2017 are set forth in Table 9 below. Adjustments to the Minimum Meaningful Difference and specialty tier thresholds are described below. The other cost sharing thresholds are established consistent with previous years methodology based on the 95th percentile of the CY 2016 Bid Data. For CY 2017, we will be maintaining the copayment cost sharing thresholds without the inflation adjustment.

**Tier Labeling and Composition**

We again remind sponsors that we expect Drug Tier Labels to be representative of the drugs that make up that tier. However, we have received a number of plan sponsors' comments via the 2016 Call Letter and in response to the Request for Comments on Non-Defined Standard Plan Tier Models for CY 2017, solicited through a HPMS memo in June 2015, recommending that

CMS provide a non-preferred drug tier option that will allow for a drug mix regardless of generic/brand status. Based on the comments received and as part of our continued efforts to provide tier label options that provide flexibility and transparency in benefit design, CMS included additional tier models for CY 2017 with a non-preferred drug tier option. The details of CY 2017 tier model options are included in the CY 2017 Plan Benefit Package Software and Formulary Submission PRA information collection request, now pending approval at the Office of Management and Budget, Office of Information and Regulatory Affairs. This information collection request is available on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html?DLPage=4&DLEntries=10&DLSort=1&DLSortDir=descending.

With the addition of a non-preferred drug tier, sponsors will have the option of selecting a non-preferred drug tier or non-preferred brand tier but not both. If sponsors continue to use a non-preferred brand tier, CMS will evaluate the brand/generic composition of that tier as part of the bid review process. Non-preferred brand tier outliers will be communicated for any plans that do not have a majority of brand drug products in that tier.

**Table 41. 2015 Prescription Drug Event Data**

| **2015 PDE Data** | **Average of % Beneficiary Cost Share** | | |
|---|---|---|---|
| | **Generic Drugs** | **Brand Drugs** | **All Drugs** |
| Non-Preferred Brand Total | 32.56% | 20.77% | 22.81% |
| **Plan w/ Copay** | **35.75%** | **19.90%** | **22.48%** |
| **Plan w/ Coinsurance** | **26.02%** | **22.72%** | **23.54%** |

CMS review of preliminary 2015 prescription drug event data (PDE) (Table 41.) showed that beneficiaries pay a lower cost share for generics in plans that have a coinsurance cost sharing structure (26.02%) for their non-preferred brand tier than in plans that use a copay cost-sharing structure (35.75%). Overall, on average for drugs on the non-preferred brand tier, there was no substantial difference in beneficiary cost sharing between plans that use a copay cost sharing structure and those that use coinsurance. However, based on industry comments received, it is our expectation that the new non-preferred drug tier likely will contain a greater proportion of generic drug products than the current non-preferred brand tier composition. While we appreciate that generic drug price increases are changing the paradigm, we also acknowledge that sponsors may include lower cost generics on the non-preferred drug tier in an effort to balance

the brand/generic drug composition of the tier and maintain actuarial equivalence. As cost trends in the Part D program are increasingly driven by high cost drugs it is important that we consider policy impacts on beneficiaries with lower overall drug costs. Although sponsors using a non-preferred drug tier have the option of choosing either copay or coinsurance cost sharing with the same thresholds as the non-preferred brand tier, CMS encourages Part D sponsors to consider using a coinsurance for the non-preferred drug tier instead of a copay. While there are advantages and disadvantages of copay/co-insurance cost-sharing structures, a coinsurance (versus copay) structure will provide a more equivalent benefit to those beneficiaries who use less expensive generic medications that are placed on a non-preferred drug tier. For example, if the non-preferred drug tier has a $100 copay, beneficiaries could be responsible for the full price of less expensive generic products that are placed on that tier. During the first year of implementation and until further notice, CMS will conduct an outlier test for those Part D sponsors who choose a copay for the non-preferred drug tier, to determine if beneficiaries will receive a benefit for the majority of drugs on this tier at the proposed copay. Moving forward, we will continue to evaluate the type and level of cost sharing that is most appropriate for this tier and that balances the Part D sponsor's ability to mix brand and generic drugs within a tier while maintaining transparency and a meaningful benefit offering for the beneficiaries who enroll in plans with non-preferred drug tiers.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 43 have been met, we will continue to rely on the FDA marketing status to identify formulary drugs as applicable or non-applicable. The maximum coinsurance of 60% applies to tiers that contain only applicable drugs. If non-applicable (i.e., generic) drugs or a combination of both generic and applicable drugs are on a tier, then the maximum coinsurance of 31% applies. We remind sponsors that when cost-sharing reductions beyond the standard benefit are offered through a supplemental Part D benefit, the plan liability is applied to applicable drugs for applicable beneficiaries before the manufacturer discount.

**Benefit Review**

We will continue to scrutinize the expected cost-sharing amounts incurred by beneficiaries under coinsurance tiers in order to more consistently compare copay and coinsurance cost sharing impacts. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty tiers that are greater than the standard benefit of 25%, we will compare the average expected cost-sharing amounts submitted by sponsors in the PBP to the established copay thresholds to determine whether the coinsurance values are discriminatory. (Please note that we will conduct the same cost-sharing analysis for the Select Care/Diabetic Drug Tiers, even though the maximum allowable coinsurance value is less than 25%. We will also continue to disallow incentives such as $0 or very low cost-sharing for 30 day supplies at mail service, unless offering the same cost sharing at the retail network.

Despite ACIP recommendations and Healthy People 2020 targets, adult immunization rates still remain low. We encourage Part D sponsors to consider offering $0 or low cost sharing for vaccines to promote this important benefit. While the inclusion of a dedicated vaccine tier or a Select Care/Select Diabetes tier that contains vaccine products as part of a 5 or 6 tier formulary structure is not a requirement, sponsors who choose to offer one of these formulary tiers must set the cost sharing at $0 for that tier. This policy is unchanged from CY 2016.

Over the last three years, we have seen a continuing decrease in the 95$^{th}$ percentile meaningful difference between basic and enhanced alternative (EA) plans which indicates there is a decreasing differential between basic and EA plan drug benefits. In order to continue to drive the participation of plans that provide distinct product offerings, CMS will use a meaningful difference threshold based on the 50$^{th}$ percentile for CY 2017 instead of the 95$^{th}$ percentile. As a result of the closing of the coverage gap, the change for CY 2017 to the 50$^{th}$ percentile is necessary to maintain an OOPC differential within the range of the original meaningful difference threshold. Specifically, the meaningful difference threshold will be based on the 50$^{th}$ percentile of the October CY 2016 Bid Data run through the CY 2016 OOPC MPF model which incorporates CY 2016 Formulary Data, 2010/11 MCBS Data, and FDA data for brand/generic determinations related to coverage gap cost-sharing estimates. In contrast to the continuing decrease in the 95$^{th}$ percentile meaningful difference between basic and EA plans, we have seen a continuing increase in year over year meaningful difference between EA to EA plans. The increase in meaningful difference between EA to EA plans makes it more challenging for plan sponsors to offer second EA plans. For CY 2017, we will also use the 50$^{th}$ percentile, instead of the 95$^{th}$ percentile, to establish the meaningful difference threshold between EA to EA plans to lessen the impact of EA to EA differences year over year and help maintain stability in the program.

Therefore, in 2017 the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $23 and the minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $34. As in the past, these meaningful difference requirements apply to all stand-alone PDPs, including those belonging to sponsors under a consolidation plan. We also continue to expect that the additional EA PDPs within a service area will have a higher value than the first EA plan and will include additional gap cost-sharing reductions for at least 10 percent of their formulary brand drugs**.**

In the CY 2012 Call Letter CMS explained that it does not believe that sponsors can demonstrate meaningful differences based on expected OOPCs between two stand-alone basic Part D benefit designs while maintaining both the statutory actuarial equivalence requirements and fulfilling the requirement to maintain cost effective drug utilization review programs. As we approach CY 2020 and the coverage gap closes, CMS does not believe that Part D sponsors can continue to maintain three plans (a basic and at most two EA plans) that will meet the meaningful difference test between all plans when the coverage gap is closed. Therefore, CMS encourages plan sponsors to consider the impact of the coverage gap closing on their current and future plan offerings to minimize future beneficiary disruption.

The methodology for developing the CY 2017 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 18, 2015 titled "Medicare Plan Finder (MPF) Plan Version (V1) of Out-of-Pocket Cost (OOPC) Model for CY 2016 and Updated Total Beneficiary Costs (TBC) Data Released on HPMS." Customary updates for utilization data, as well as PBP and formulary data used for CY 2017 bid submissions, are also included in the 2017 model.

In the 2016 Call Letter, we proposed instituting a Total Beneficiary Cost (TBC) measure for PDPs, similar to what has been in place for MAOs. The proposed change was intended to meet CMS's goals of establishing a more transparent and predictable process that beneficiaries can use to select plans that meet their health care needs, while also being protected from high or unexpected cost sharing. After completing analysis and engaging in discussions with stakeholders, CMS will not implement for CY 2017 an out-of-pocket cost (OOPC) or market basket approach to set thresholds for increases in cost-sharing and premiums whereby we would deny Part D plan bids with significant increases, pursuant to our authority in Section 3209 of the Affordable Care Act. Instead CMS will calculate and publish the Part D TBC to support transparency related to the out-of-pocket beneficiary costs year over year.

**Table 42. Benefit Parameters**

| | CY 2017 Threshold Values |
|---|---|
| Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1] | |
| Enhanced Alternative Plan vs. Basic Plan | $23 |
| Enhanced Alternative Plan vs. Enhanced Alternative Plan | $34 |
| Maximum Copay: Pre-ICL and Additional Cost- Sharing Reductions in the Gap (3 or more tiers) | S[2,3] |
| Preferred Generic Tier | <$20[4] |
| Generic Tier | $20 |
| Preferred Brand/Brand Tier | $47 |
| Non-Preferred Drug Tier | $100 |
| Non-Preferred Brand Tier | $100 |
| Injectable Tier | $100 |
| Select Care/Diabetic Tiers[5] | $11 |
| Maximum Coinsurance: Pre-ICL (3 or more tiers) | S[2,3] |
| Preferred Generic Tier | 25% |
| Generic Tier | 25% |
| Preferred Brand/Brand Tier | 25% |
| Non-Preferred Drug Tier | 50% |
| Non-Preferred Brand Tier | 50% |

| | CY 2017 Threshold Values |
|---|---|
| Injectable tier | 33% |
| Select Care/Diabetic Tiers[5] | 15% |
| Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs) [6] | S[3] |
| Preferred Generic Tier | 31% |
| Generic Tier | 31% |
| Preferred Brand/Brand Tier | 60% |
| Non-Preferred Drug Tier | 60% |
| Non-Preferred Brand Tier | 60% |
| Injectable Tier | 60% |
| Select Care/Diabetic Tiers[5] | 60% |
| Minimum Specialty Tier Eligibility | |
| 1-month supply at in-network retail pharmacy | $670 |

[1] The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 50th percentile of the October CY 2016 Bid Data run through the CY 2016 OOPC MPF model which incorporates CY 2016 Formulary Data, 2010/11 MCBS Data, and FDA data for brand/generic determinations related to coverage gap cost-sharing estimates. For each parent organization, any cost-sharing OOPC comparison between a basic plan and EA plan in the same region must meet the minimum Enhanced Alternative Plan vs. Basic Plan threshold. For each parent organization, any cost-sharing OOPC comparison between two EA plans in the same region must meet the threshold established annually by CMS.

[2] These thresholds are based on the 95th percentile of the CY 2016 Bid Data. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary.

[3] "S" in the above chart refers to "standard retail cost-sharing" at a network pharmacy. Standard retail cost-sharing (S) is cost-sharing other than preferred retail cost-sharing offered at a network pharmacy.

[4] Cost sharing for the Preferred Generic Tier need only be lower than that for the cost sharing of the Generic Tier. There is not a separate maximum cost share threshold for the Preferred Generic Tier.

[5] The Select Care Drug and Select Diabetic Drug Tiers must provide a meaningful benefit offering with low or $0 beneficiary cost-sharing for drugs targeting specific conditions (e.g., $0 tier for drugs related to diabetes and/or smoking cessation). The coinsurance threshold for these tiers is derived from an average expected copayment amount using PDE data for drugs submitted on preferred cost-sharing tiers. As noted earlier in this section, we continue to expect cost sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be $0.

[6] Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this gap benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier (partial tier coverage). If the additional gap cost- sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 31% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 50% manufacturer discount for applicable drugs.

### Specialty Tiers

Per 42 CFR 423.578 (a)(7), if a Part D plan sponsor maintains a formulary tier (the specialty tier) in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception. Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement. The current cost threshold of $600 was established in CY 2008.

In order to make sure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that meet the standards set forth in Section 30.2.4 of Chapter 6 of the Prescription Drug Benefit Manual. Part D sponsors offering prescription drug benefit plans with a specialty tier are limited to the defined standard cost-sharing of 25%, if the plan requires the standard deductible, and up to 33% cost-sharing if no deductible is required, or some percentage in-between dependent on a decreased deductible. 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.

As noted in the CY 2016 Call Letter, we continue to evaluate the specialty tier eligibility cost threshold. The current $600 threshold repeatedly identified outlier prescription drug event (PDE) data – less than one percent of 30 day equivalent fills exceeded $600. However, initial analyses of 2015 PDE indicate that this percentage now slightly exceeds one percent. This, coupled with the significant increase in the cost of Part D drugs since the last adjustment to the specialty tier

threshold, supports an increase in the specialty tier threshold for CY 2017. To adjust the threshold, we propose applying the annual percentage increase used in the Part D benefit parameter updates to the existing $600 threshold. Thus, for CY 2017, the specialty tier cost threshold will be $670. We may or may not increase the threshold on an annual basis moving forward. Annually, we will test the proposed increased threshold and continue to perform other analyses to assess whether threshold adjustments are necessary.

To support CMS's transparency initiatives, raise awareness, and educate beneficiaries on the cost of prescription drugs and their impact on the Part D program; CMS intends to add a hyperlink on the Medicare Plan Finder on Medicare.gov to the Medicare Drug Spending Dashboard, which is published on CMS.gov, and estimates implementation for 2017 Open Enrollment in Fall 2016.

**Generic Tier $0 Copay Plans**

Since the program began in 2006, use of lower cost generic alternatives by Medicare Part D enrollees has been high and steadily increasing as single source drugs lose patent exclusivity. However, low-income subsidy (LIS) enrollees continue to have lower use of generics compared to enrollees without income subsidies. Lower generic use is often attributed to the small differential between generic and brand drug copays legislatively mandated for LIS enrollees. Changes in copay to increase cost differential between brand and generic drugs for LIS beneficiaries requires Congressional authority; however, lowering the generic copay does not and in 2012, 685 or 21.1% of plans offered generic-tier $0-copay plans. Of those 685 plans, 265 were PDP plans and 420 were MA-PD plans. We, therefore, explored the impact of enrollment in generic-tier $0 copay plans on generic substitution rates between both LIS and Non-LIS enrollees compared to enrollment in generic-tier non-$0 copay plans.
Using 2012 prescription drug event data, our analysis found that generic substitution rates (GSR) for generic-tier $0 copay plans were 1.2 to 3.0 percentage points higher than in non-$0 copay plans. This finding held true for both Enhanced PDP and MA-PD plans, and PDP Basic plans for both LIS and non-LIS Part D populations. Within MA-PD Basic plans, GSR was not statistically different for LIS or non-LIS populations, but there were very few MA-PD generic-tier $0 copay basic plans. The lack of basic MA-PD plans is attributed to policy that does not require MA plans to offer a basic plan if they offer an EA plan without a monthly supplemental Part D premium in the same service area. Overall, if Part D enrollment were shifted from generic-tier non-$0 into $0 copay plans, generic use could potentially increase. Even small increases in generic use could mean significant savings to beneficiaries and to the Medicare Part D program. However, our analysis is not without limitations. A complete description of the study is found here: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html. At this time, CMS is providing these results as informational only and as an opportunity for further discussion on ways to increase generic use in Part D and in particular, the LIS population.

CMS has seen an increase in the number of plans with deductibles in 2016 compared to 2015. Some of these plans have a $0 cost share for generic drugs but require the beneficiary to meet a deductible prior to receiving generic medications for free. One option available to Part D sponsors is to provide first dollar generic coverage for medications on the $0 generic copay tier by exempting the $0 cost sharing tier from the deductible. CMS encourages plan sponsors to consider first dollar coverage for generic medications and other ways to increase generic use in the Part D program.

***Part D Employer Group Waiver Plans (EGWPs)***

Since January 1, 2014, supplemental benefits provided by employer group waiver plans (EGWPs) beyond the parameters of the defined standard benefit are always considered non-Medicare other health insurance (OHI). (See 77 Federal Register 22072 (April 12, 2012); and 80 Federal Register 7912 (February 12, 2015).) As a result of this change, we have continued to receive industry questions regarding the effect, if any, it had on other EGWP and Part D rules. The purpose of this guidance is to clarify CMS requirements for EGWPs with respect to some Part D rules involving plan design, formularies, and pharmacy networks that consistently have been the focus of these and other inquiries.

Section 1860D-22(b) of the Social Security Act gives CMS the authority to waive or modify Part D requirements that hinder the design of, offering of, or enrollment in EGWPs. All Medicare Part D requirements apply unless explicitly waived or modified by CMS, and the waivers are only available to those EGWPs that meet the circumstances and conditions imposed as part of those waivers. See 42 CFR §423.458(c)(3) and (4). In general, Part D sponsors cannot offer EGWPs with combined benefits (i.e., Part D plus employer OHI) with lesser value than the basic Part D benefit nor establish benefit designs that substantially discourage enrollment by certain Part D eligible beneficiaries. EGWPs must follow Part D rules in cases in which the provision of employer OHI is inextricably intertwined with drugs offered under the Part D benefit such that the two cannot be separated as a practical matter. (See also January 25, 2013 HPMS memo including Insurance Standards Bulletin Series guidance: "Because the Affordable Care Act has increased basic Part D benefits in the coverage gap, as of 2013 there will be very few claims that do not contain some basic Part D benefits and would not ultimately be governed (as a practical matter) by the Part D regulations.")

As conditions of the waivers identified below, we remind Part D sponsors of EGWPs of the following: (Please note that other conditions may attach to these waivers.)

**Waiver:** Part D sponsors offering EGWPs are not required to submit the same bid packages in their entirety as are Part D sponsors of individual plans. Prescription Drug Benefit Manual (PDBM), Ch. 12, EGWPs, §20.9. (For details, see 2016 HPMS Memo entitled "Release of the 2016 Plan Benefit Package and Bid Pricing Tool Software and Related Technical Bidding Guidance for Part D Employer/Union-Only Group Waiver Plans" (April 10, 2015).

- EGWP benefits (meaning, the Part D benefits, taking into consideration employer OHI) must continue to meet the following applicable actuarial standards in 42 CFR §423.104(e):
    - Deductible is limited to no greater than defined standard deductible;
    - Total Benefit is at least actuarially equivalent to the basic Part D benefit; and
    - Catastrophic Benefit is at least actuarially equivalent to the basic Part D catastrophic benefit.

      *See also* PDBM, Ch. 12, EGWPs, §20.9.
- Part D sponsors of EGWPs should take into consideration the annual established copay and coinsurance tier maximum thresholds for Part D plans when designing their tiered benefits to ensure they are not discriminating and discouraging certain beneficiaries from enrolling in the EGWP. *See* 2012 Final Call Letter, page 146 (April 4, 2011).

**Waiver:** EGWPs do not need to submit a unique formulary variation for each individual employer/union sponsored group health plan. PDBM, Ch. 12, EGWPs, §20.14.

- EGWPs that provide benefits with formularies will continue to:
    - Submit for CMS approval through the HPMS formulary module a base formulary, utilization management criteria, and transition policy that represents the minimum drug benefit upon which all other formulary variations in the same plan must be built. *See* 2015 Final Call Letter, page 127 (April 7, 2014). In other words, EGWPs cannot provide a formulary benefit that is less than what is included in the base formulary.
        - Submit a base formulary which has the fewest drugs and the most restrictive UM that any EGWP formulary variation will offer. For EGWPs with multi-tiered formularies, submit the maximum number of tiers that will be offered by any EGWP formulary variation in that same 800 series plan and ensure each drug is placed on the tier where it has the highest possible cost sharing of any formulary variation. *See* 2015 Final Call Letter, page 127 (April 7, 2014).
        - Assign all EGWP 800 series Part D plans to a formulary through the formulary crosswalk process. *See* Release of the Contract Year (CY) 2016 Bid Upload Functionality in HPMS (May 8, 2015 HPMS memo).
    - Only make enhancements to approved formularies (i.e., enrich formularies) that increase the value for any beneficiary who uses the drug(s). *See* 2015 Final Call

Letter, page 127 (April 7, 2014).

- Follow all applicable (that is, non-waived) CMS rules, including those found in PDBM, Chapter 6, Part D Drugs and Formulary Requirements, when restricting access (often referred to as making negative changes) to drugs covered under the Part D benefit that appear in any EGWP formulary (whether base or enriched). EGWPs restrict access when they, for instance, remove drugs; increase cost-sharing; and impose or make more restrictive existing prior authorization or step therapy requirements or quantity limits. *See* PDBM, Ch. 12, EGWPs, §§10.1, 20.14. To provide further clarification, please note:

  - When required by the circumstances of the negative change, we would require EGWPs to, for instance, provide notice of the changes; exempt affected enrollees from the proposed change for the plan year; update formularies and other applicable beneficiary communications; and process enrollee requests for exceptions.

  - EGWPs making negative changes to drugs on the base formulary must request CMS approval through the HPMS negative change request (NCR) module. In contrast, when an EGWP adds drugs to enhance the base formulary, CMS does not require the sponsor to submit the additional drugs in HPMS for CMS approval. *See* PDBM, Ch. 12, EGWPs, §20.14. Subsequently, if an EGWP wanted to make a negative change to a drug that was not included in the base formulary, as a matter of operations, it would not be possible for the EGWP to submit a negative change request for that drug through HPMS. Therefore, while we continue to expect EGWPs to follow all other applicable rules regarding negative changes to drugs included under the Part D benefit that appear on an enriched EGWP formulary, we do not expect them to submit such changes to the HPMS NCR module.

***Improving Drug Utilization Review Controls in Medicare Part D***

In the Final 2013 Call Letter and supplemental guidance, CMS described a medication safety approach by which sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications.[34] In July 2013, CMS launched the Overutilization Monitoring System (OMS) to help oversee sponsors' compliance with this CMS overutilization guidance.

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

CMS continues to focus on and expect sponsors to further reduce opioid and acetaminophen (APAP) overutilization in the Medicare Part D program. In this section, we describe the results of Part D sponsors' implementation of improved drug utilization controls to prevent overutilization and improve medication use since January 2013. We also solicit comments and suggestions about the new proposals described below to reduce the unsafe overutilization of medications by Part D beneficiaries.

- Timeliness of beneficiary-level opioid point of sale (POS) edit submissions to the Medicare Advantage and Prescription Drug System;
- Discontinuation of OMS APAP Reporting through the OMS;
- Changes to the OMS opioid overutilization methodology;
- Formulary-level cumulative morphine equivalent dose (MED) POS edits;
- Soft formulary-level opioid POS edit following initiation of buprenorphine addiction therapy;
- Access to medication-assisted treatment for opioid addiction;
- Elimination of utilization management processes that may lead to inappropriate use of methadone in pain management.

In addition, the Enhancements to the 2017 Star Ratings and Beyond section of the draft 2017 Call Letter discusses proposed implementation of three new PQA-endorsed opioid overutilization measures.

**New Expectation for Entering Opioid Point of Sale Claims Edit Information in the Medicare Advantage and Prescription Drug System (MARx)**

CMS enhanced MARx in February 2014 to automate the process by which sponsors notify other sponsors about their beneficiary-level opioid POS edit decisions. Sponsors enter information in MARx when they have made a decision to implement a beneficiary-level opioid POS claim edit. MARx then alerts a new sponsor when a beneficiary identified in this manner by the previous sponsor enrolls in the new sponsor's plan. The new sponsor then has the capability to contact the prior sponsor using the Part D Sponsor Overutilization Contact List found on the CMS webpage, Improving Drug Utilization Controls in Part D at https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html. To facilitate data sharing between Part D sponsors, CMS has expected sponsors to submit POS edit notifications into MARx in a timely manner which we are now specifying as within seven (7) days of the date on the beneficiary's written advance notice. CMS expects sponsors to submit implementations, terminations, and modifications of such POS edits within seven (7) days of the event. As of

December 15, 2015, CMS has received 2,400 contract-beneficiary-level opioid POS edit notifications through MARx for 2,233 unique beneficiaries.

### Results of Overutilization Policy

Part D sponsors have had a significant impact on reducing overutilization of opioids and APAP. From 2011 through 2015, there was a 47% decrease or 13,753 fewer Medicare Part D beneficiaries identified as potential opioid overutilizers (i.e., beneficiaries with at least 90 consecutive days with greater than 120 mg MED daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims). This represents a 57% decrease in the share of beneficiaries using opioids who are identified as potential opioid overutilizers (see Table 43).

**Table 43. OMS Part D Potential Opioid Overutilization Rates, 2011 – 2015***

| Year | Total Part D Enrollees | Total Part D Enrollees Utilizing Opioids | % Part D Enrollees Utilizing Opioids | Total Beneficiaries with at Least 90 Consecutive Days >120 mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims | Difference Year-to-Year | Share of Opioid Utilizers Flagged as Outliers | Difference in Share Year-to-Year |
|---|---|---|---|---|---|---|---|
| 2011 | 31,483,841 | 10,049,914 | 31.9% | 29,404 | | 0.29% | |
| 2013 | 37,842,632 | 11,794,908 | 31.2% | 25,347 | − 4,057 *47% decrease* | 0.21% | −0.08% *57% decrease* |
| 2014 | 39,982,962 | 12,308,735 | 30.8% | 21,838 | − 3,509 | 0.18% | −0.04% |
| 2015 | 41,835,016 | 12,510,448 | 29.9% | 15,651 | − 6,187 | 0.13% | −0.05% |

*Table 43 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. For these opioid utilization comparisons, CMS used OMS methodology and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.

The number of beneficiaries identified annually as potential APAP overutilizers from 2011 to 2015, based on the CMS definition in the OMS, decreased by 94%, from 76,681 to 4,539 (See Table 44).

**Table 44. OMS Part D Potential APAP Overutilization Rates, 2011-2015***

| Year | Total Part D Enrollees | Total Part D Enrollees Utilizing APAP | % Part D Enrollees Utilizing APAP | Total Beneficiaries with Daily APAP Dose Exceeding 4 g for 30 or More Days Within Any Six-month Period with at Least One Day Exceeding 4 g Within the Most Recent Calendar | Difference Year-to-Year | Share of APAP Utilizers Flagged as Outliers | Difference in Share Year-to-Year |
|---|---|---|---|---|---|---|---|
| 2011 | 31,483,841 | 9,449,693 | 30.0% | 76,581 | | 0.81% | |
| 2013 | 37,842,632 | 10,591,651 | 28.0% | 26,122 | −50,459 | 0.25% | −0.56% |
| 2014 | 39,982,962 | 10,845,499 | 27.1% | 6,286 | −19,836 | 0.06% | −0.19% |
| 2015 | 41,835,016 | 10,712,430 | 25.6% | 4,539 | −1,747 | 0.04% | −0.02% |

*For these APAP utilization comparisons, CMS used OMS methodology and PDE TAP Data. For 2011, PDE TAP Data were processed through 13AUG2012; subsequent year analyses used PDE TAP data processed with cut-off dates in the early January of the following year.

### *Updates to Overutilization Policy for Contract Year (CY) 2017*

#### Discontinuation of APAP Reporting through the OMS

Since the annual number of APAP overutilizers has decreased dramatically since 2011, we propose to discontinue the reporting of APAP overutilization tickets in the OMS beginning with the April 2016 OMS reports.

However, we will continue to monitor APAP overuse. As stated in the 2016 Call Letter, we will begin reporting the High APAP Daily Dose Rate for CY 2016 at the contract level for informational purposes. The High APAP Daily Dose Rate will be defined as the number of APAP days exceeding a 4 g daily dose (DD) per 1,000 APAP user days. Daily dose will be rounded to the nearest tenth using standard rounding methodology. We will also identify outliers at the contract level, and we propose new outlier response requirements beginning in 2017 similar to the process used for the Patient Safety measure reports. Therefore, we propose adding this metric into Patient Safety reporting, not to the OMS, as originally described in the 2016 Call Letter. Both the Patient Safety reporting and the OMS are available within the Patient Safety website.

#### Opioids

#### Compliance Activities and Changes to the OMS Opioid Overutilization Methodology

Since the OMS was launched in July 2013, CMS has used the following criteria to identify potential opioid overutilizers:

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

In the 2015 Call Letter, we described our concern that some sponsors' internal criteria or processes to identify and address potential opioid overutilization may be insufficient. For the January 2014 OMS reports, 67% of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria (OMS response code BSC). CMS also announced that beginning January 2015, sponsors' internal opioid criteria for retrospective identification of egregious patterns of opioid overutilization and subsequent case management should be no less restrictive than 120 mg MED daily dose over at least 90 consecutive days. Other criteria, such as the number of prescribers and pharmacies, could vary from CMS specifications. Sponsors may also vary the measurement period, and most sponsors look back 90 to 120 days. Continued review of sponsors' responses to the OMS in 2015 suggested potential noncompliance with CMS guidance.

In light of this, we performed additional outreach to assess compliance with CMS guidance by select Part D sponsors who were identified as outliers based on their APAP and opioid responses to the OMS.

CMS contacted Part D sponsors at the parent organization level to obtain information about their overutilization criteria and case management programs, and for the sponsors to explain their responses to specific tickets received through the OMS. Overall, we found that sponsors were generally compliant with CMS guidelines.

Based on our analysis of the information from this effort, we identified opportunities to potentially modify the OMS opioid overutilization criteria in the future (as early as 2018) to reduce the number of tickets for which sponsors repetitively submit response codes BSC (No further review planned: Beneficiary did not meet the sponsor's internal criteria) and BOR (Beneficiary-level POS edit determined not necessary: Beneficiary's overutilization resolved).

Ideas include to:

- Shorten the measurement period from 12 months to 6 months; and
- Use average MED rather than a count of 90 consecutive days of high MED.

The revised 'Overutilization of Opioids' criteria would be:

> Use of opioids with an average daily MED exceeding 120 mg for an episode of at least 90 days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 6 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

The average MED is calculated by summing each PDE's MED and dividing this sum by the duration of the opioid episode in days. An opioid episode consists of at least two opioid PDE fills. The episode duration is the number of days between the first and last opioid PDE during the measurement period plus the last PDE's days supply plus 1 day (end-date). If the end-date is beyond the last day of the measurement period, the quantity is multiplied by the percent of the days supply that occurs during the measurement period, and the end-date becomes the last calendar day of the measurement period.

By allowing gaps between prescription fills and days supply in the calculation, the average MED per 90-day episode methodology may identify more beneficiaries who are chronic users of high opioid doses than the consecutive days method. Shortening the measurement period from 12 months to the most recent 6 months may better identify current potential overutilization and reduce the number of repeat cases reported by the OMS. We are analyzing the impact of these potential revisions in identifying potential opioid overutilizers.

In addition, CMS is investigating how prescribers are counted in the OMS opioid overutilization criteria. We are analyzing the feasibility of grouping NPIs (National Provider Identifiers) within a clinical practice as reported in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) rather than count unique NPIs, which would reduce false positives in the group practice setting. Suggestions include grouping based upon Tax ID number (TIN), Employer ID number (EIN), or primary location address. Identifying common clinical practice groups based on prescribers whose NPIs are associated only with one primary location TIN or a single EIN could prevent mis-matching of prescribers who participate in multiple clinical practices. This conservative grouping methodology resulted in a 4.8% decrease in the number of potential opioid overutilizers that would have been identified by the OMS in the October 2015 cycle.

These analyses are in the preliminary stage, and we welcome feedback from sponsors for our analyses. We also solicit comments on the proposed revisions to the OMS opioid overutilization criteria, on alternative ways to count prescribers, and considerations for implementation by sponsors. We may consider changes to guidance and the opioid overutilization criteria beginning in 2018 based on experience from compliance activities, additional analyses, and the upcoming CDC guideline (as described further below).

Other findings and takeaways from our compliance activities include:

- Sponsors should review repeat OMS response replies. For example, instead of resubmitting the BSC response code repeatedly for the same case, sponsors may confirm medical necessity with the prescribers. The DMN (Determined Medically Necessary) response code triggers the OMS exception logic for one year.
    - Although several morphine equivalent conversion factors exist, CMS encourages

sponsors to use the CDC morphine milligram equivalent (MME[35]) conversion factors within their opioid overutilization programs. The MME conversion table is available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html) which contains information to help Part D sponsors create or revise their programs to address the unsafe use of opioid pain medications.

We thank the sponsors that participated in this outreach effort. We were not only able to assess potential non-compliance, but we gained information on ways to improve our guidance and overutilization methodology.

**CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017**

Although the overutilization of opioids has decreased in Part D as discussed above, CMS has indicated on multiple occasions that we believe Part D sponsors should implement formulary-level cumulative opioid edits at POS to prospectively prevent opioid overutilization. Industry reaction has consistently been that such edits are premature due their complexity. As described in the final CY 2016 Call Letter, we commenced a pilot project in 2015 to assess the feasibility and impact of such POS edits.

Through the pilot project, we noted that Part D sponsors demonstrated that they can effectively implement soft and hard formulary-level cumulative MED edits at POS while blocking the edit for beneficiaries with known exceptions. The sponsors evaluated their own data when developing edit specifications and exclusion criteria to identify potential opioid overutilization while maintaining access to opioids when needed for their enrollees.

- A soft edit was piloted by one sponsor to identify potential overutilization before reaching the OMS threshold. The edit was designed to identify beneficiaries who were receiving more than 100 mg MED per day for at least 60 days over a 6-month measurement period with more than two prescribers and more than two pharmacies for their opioid prescriptions. Exclusion criteria included cancer, hospice care, and prior determinations of medical necessity. The results from this pilot showed that the edit was not arduous from an operations perspective, was inexpensive to implement and was not disruptive. Pharmacists submitted appropriate override codes when re-submitting rejected claims. No complaints were received from providers or members. The soft edit worked as expected to identify, delay or stop potential opioid overutilization before the majority were identified by the OMS.

[35] Note: CDC's terminology, morphine milligram equivalents (MME), is equal to morphine equivalent dose (MED) in milligrams as used by CMS. Often calculated as a daily dose.

- Two sponsors applied a hard POS edit for opioid use that exceeds 200 mg MED daily. The edit excluded quantities allowed during the refill grace period, beneficiaries enrolled in hospice or with a cancer diagnosis, and prior coverage determinations of medical necessity. Resolving the edit required a prior authorization or coverage determination at the plan level. The edit did not include criteria for exceeding a certain number of opioid prescribers, and one sponsor did report that a notable number of cases were approved (i.e., overturned). However, the sponsor believed that the edit was worthwhile - prescribers were engaged, and prescriptions were changed. Formal complaints have not been noted from beneficiaries, pharmacies, or prescribers.

Therefore, CMS expects sponsors who adjudicate pharmacy claims at POS to implement formulary-level cumulative MED POS edits effective January 1, 2017. PACE organizations who do not adjudicate claims at POS are exempt from this expectation. In order to minimize claim rejections on false positives, we propose that sponsors implement both soft and hard cumulative MED POS edits.

For CY 2017, we expect sponsors' Pharmacy and Therapeutics (P&T) committees to develop the specifications for the soft and hard[36] cumulative MED POS edits. At this time, CMS requests comments from sponsors on our proposed parameters for formulary-level, cumulative MED POS edits, including alternative thresholds, criteria to reduce false positives, and methods to assure prompt access to prescribed opioids when determined medical necessary.

The proposed parameters are:

- Soft edits that can be overridden at the pharmacy level when a prescription claim will result in the beneficiary's active or overlapping opioid prescriptions reaching or exceeding a certain daily cumulative MED threshold. This threshold may be set at 90 mg to 120 mg MED. The soft-edit rejection can be overridden by the pharmacist submitting appropriate NCPDP Professional Pharmacy Service codes.

- Hard edits for daily cumulative MED threshold at or above 200 mg MED.

For both soft and hard edits, sponsors should minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills (e.g., based on early refill allowances) or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeals

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

processes. If sponsors decide to include a provider count criterion in the soft or hard edit specifications, we recommend two prescribers of the active opioid prescriptions as the threshold. We do not recommend a consecutive high-MED days criterion because it would not prevent beneficiaries from reaching high opioid doses.

Prior to implementing soft and hard cumulative formulary MED thresholds at POS, the sponsor's CY 2017 formulary submission must reflect these edits. In addition to the HPMS formulary submission, plan sponsors must submit detailed operational information by the CY 2017 formulary submission deadline. The documentation must contain at a minimum the MED level being utilized for each edit and a written description of the program's mechanics, including the mechanism by which the edits would be resolved. This information must be submitted via e-mail to partdformularies@cms.hhs.gov with a subject line of "Cumulative MED – [applicable FID number]."

**Concurrent Use of Opioids and Buprenorphine**

As described in the 2016 Call Letter, we investigated the concurrent use of buprenorphine and opioids in Part D as a potential new measure for the OMS as informational only. Currently, the formulations of buprenorphine sublingual (SL) and buprenorphine-naloxone SL film or tablets are only approved by the Food and Drug Administration (FDA) for the treatment of opioid addiction and not for the treatment of pain. Because buprenorphine effectively blocks the analgesic properties of other opioids used to treat acute pain, it generally prevents the use of other opioids as an adjunctive treatment for pain syndromes.

An analysis of PDE data from April 1, 2014 through March 31, 2015 identified over 24,500 Medicare Part D beneficiaries with concurrent buprenorphine buccal formulation and opioid use, including over 20% with 30 or more concurrent opioid days. CMS believes there are additional opportunities for improvements through drug utilization management. Therefore, we expect sponsors to implement a soft formulary-level POS edit when an opioid prescription is presented following the initiation of buprenorphine addiction therapy. At this time, we will not include a measure of concurrent use of opioids and buprenorphine in the OMS, but we will continue to monitor utilization trends. For additional guidance in the use of buprenorphine in the treatment of addiction refer to http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

**Access to Medication-Assisted Treatment**

Despite efforts such as those outlined above, opioid addiction continues to be a significant public health concern. In October 2015, the President issued a Memorandum to Federal Departments and Agencies to identify barriers to medication-assisted treatment (MAT) for opioid use disorders and develop action plans to address these barriers. In response, CMS will use available vehicles to inform physicians, MA organizations and Part D sponsors about MAT coverage, including clarifying that MA plans have the same obligation to cover addiction treatment as is

available under Original Medicare and that Part D plans must ensure access to MAT that are covered under Medicare Part D. Currently only buprenorphine, buprenorphine/naloxone, and naltrexone are covered Part D drugs when used for medication-assisted treatment (MAT) of opioid addiction. Under current methadone is not covered by Part D for substance abuse treatment because it does not meet the Part D requirement that it "may be dispensed only upon a prescription" since it cannot be dispensed upon a prescription at a pharmacy when used for this purpose. The agency seeks comment on whether this statutory requirement is a barrier to treatment. It is critical that Medicare beneficiaries who are in need of these therapies have appropriate access to these drugs in Part D. Given the requirements imposed by the Drug Addiction Treatment Act of 2000 and Risk Evaluation and Mitigation Strategy for buprenorphine-containing products for MAT, Part D sponsors should not impose prior authorization criteria that simply duplicate these requirements. When prior authorizations are utilized, Part D sponsors must also carefully consider approval durations so as to not subject beneficiaries who are in need of these therapies to unnecessary hurdles. Part D formulary and plan benefit designs that hinder access, either through overly restrictive utilization management strategies or high cost-sharing, will not be approved.

**A Note about the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain**

The CDC is preparing a guideline for opioid prescribing to assist primary care providers in delivering safer, more effective chronic pain management for patients with pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline, which is expected to be released in early 2016, is being developed through a rigorous scientific process using subject matter experts, the most recent scientific evidence, and public comment. Topics include 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use, including the use of opioids in patients age 65 and older. In the draft guideline, CDC identified 50 mg MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing dosage to 90 MME per day. The draft guideline also presented tapering methodology for long-term, high opioid dose users, which may be useful to reduce high opioid doses. We encourage sponsors' P&T committees to carefully review and consider CDC's recommendations, and to share the CDC guideline with opioid prescribers. The draft CDC Guideline for Prescribing Opioids for Chronic Pain may be found on the CDC website at http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

During 2016, we will consider potential revisions to CMS overutilization guidance and the OMS opioid overutilization methodology based on the CDC guideline, for presentation in the 2018 Call Letter. In addition, we will consider recommendations set forth in the guideline during the CY 2017 formulary and benefits review. For example, CDC notes that methadone has been associated with a disproportionately high number of overdose deaths relative to its prescribing

frequency for pain management. As a result, the draft guideline states that methadone should not be used as a first line agent for pain management when an extended-release/long-acting opioid is indicated, and that only providers who are familiar with the complexities of methadone's pharmacokinetic and pharmacodynamics properties should prescribe it for pain. Part D sponsors should evaluate their utilization management strategies and eliminate processes that may lead to inappropriate utilization of methadone in pain management. Submitted Part D benefit packages and formularies will be reviewed to ensure that methadone is not the sole preferred opioid analgesic within a plan design.

***Point of Sale Pilot***

In the final 2016 Call Letter, CMS committed to conducting a pilot to help identify options for resolving certain point of sale (POS) claim rejections without the enrollee having to request a coverage determination from the plan. We began this pilot in the summer of 2015. Participation was limited to a small number of Part D plans and PBMs, and included both large and small organizations, as well as stand-alone Part D and MA-PD plans, in an effort to ensure the pilot would be representative of the entire Part D program.

Pilot participants were asked to develop a proactive process that is initiated without any action on the enrollee's part in response to a claim that rejects at the POS. Participants were also asked to identify 5 to 10 target drugs for the pilot that are Part D drugs not on the plan's formulary or formulary drugs subject to approved step therapy or prior authorization requirements. Participants met regularly with CMS throughout the testing period, first to share details of their proactive process and list of target drugs, then to provide updates and narratives for individual test cases. We recommended that each participant work on about 20 cases for the pilot and provide the following:

- A narrative for each test case and basic data reporting;
- Burden and resources involved, including time commitments, need for clinical staff, operational constraints and resource limitations;
- Lessons learned—the pros and cons of proactively responding to rejected claims, what worked and what didn't as testing progressed;
- How the pilot process compares with the coverage determination process (similarities and differences);
- Other ideas that may help address POS issues without the enrollee having to initiate the coverage determination process; and
- How the participant organization might operationalize a similar process in response to a potential policy change and any challenges that may be encountered in implementing such a process on a broader scale.

We indicated during the CMS Compliance Conference in June 2015 that we would provide additional information in the CY 2017 Call Letter. CMS is analyzing the final reporting from pilot participants to determine if there are any best practices or other operational changes plans could make related to POS rejections for the 2017 plan year. Some of the areas CMS may explore are based on the pilot experience could include:

- How CMS and Part D plans could reduce the volume of rejected claims on the front end

by resolving certain issues before the prescription is sent to the pharmacy, such as:

- Encouraging electronic prescribing, particularly electronic prior authorization, or other efficiencies in the PA process for a subset of drugs where the information needed to satisfy the PA may be obtained in a streamlined manner;
- Making formularies more accessible to prescribers earlier in the process

- How plans could employ proactive processes to resolve certain POS issues without the enrollee having to request a coverage determination, such as:
  - Identifying an appropriate subset of rejected claims to target proactive outreach efforts;
  - Designing outreach processes in a way that maximizes value while managing plan, pharmacy and prescriber resources, and program costs.

We welcome feedback from Part D plans and other stakeholders on these issues, and expect to provide additional information in the final Call Letter.

***Extended Days' Supply and First Fill Quantity Limits***

Part D sponsors that offer an extended (2 or 3 month) days' supply are not required to uniformly apply this benefit across each tier. Sponsors must indicate in the plan benefit package (PBP) if an extended days' supply for a given tier applies across an entire tier, or applies only to a subset of drugs on a tier. Currently there is no process for sponsors to indicate which specific drugs on a partial extended days' supply tier qualify for extended days' supplies verses those drugs that do not.

In an effort to increase transparency, beginning in CY 2017, sponsors that indicate a partial extended days' supply tier within their PBP will be required to submit the specific drugs not available as extended days' supply as an HPMS supplemental file. This file ("Non-Extended Day Supply") includes the RXCUIs that will not be available as an extended day's supply during initial formulary submission and as necessary during formulary update window submissions. Detailed submission guidance will be provided during the formulary submission training at a later date.

We understand many plans offer beneficiaries 2 or 3 month supplies of medications as a convenient and potentially cost saving option. However, consistent with good medical practice, it can often be appropriate for the prescriber to follow up sooner with a patient starting a new therapy. This is especially true in the case of complex therapies or drugs with a narrow therapeutic index or a high risk of side effects. With any multi-day fill there is the potential that a patient's dose may change or he or she discontinue therapy due to side effects, adverse reactions, or lack of clinical response. In these cases, the remaining amount of medication is often wasted if

the beneficiary does not continue on the original drug. The potential for drug waste is especially pronounced when starting on a new drug therapy, as the effectiveness and tolerability are unknown for the patient. Dispensing a 2 or 3 month supply as a first fill to a patient who is naïve to therapy may result in excessive waste, as well as unnecessary expense, if the patient ultimately does not use the full amount dispensed.

Starting in 2017, plan sponsors will now also have the option to indicate in the PBP at the tier level if any drugs are available for an extended days' supply on all but the first fill. This change allows sponsors to designate drugs where they will only cover up to a one month supply the first time the drug is filled, providing an opportunity to limit drug waste when a new therapy is not working for the patient or has adverse effects.. While some prescribers may choose to schedule another visit with a patient beginning a complex therapy to determine the need for adjustments or discontinuation of therapy, Part D sponsors may not require such a step or a new prescription for the second fill to be covered for the extended days' supply. After the first one month supply, the change to extended days' supply should be seamless for the beneficiary.

The specific drugs will not be included in an HPMS supplemental file for 2017. Therefore, sponsors should make clear in beneficiary materials information about first fill quantity limits and which drugs are affected.

***Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy***

Many Part D sponsors contract with mail order pharmacies to offer beneficiaries an alternative way to fill prescriptions under the Part D benefit, often at much lower cost sharing than is available at network retail pharmacies. While mail order pharmacies make up a relatively small percentage of total prescriptions filled under the Part D program, we are committed to ensuring consistent and reliable beneficiary access to medications, regardless of what type of pharmacy fills the prescription.

One aspect of providing consistent access includes responding to urgent medication needs. Various scenarios can result in a beneficiary running out or having only a small amount of a medication remaining, such that a standard mail order fill may arrive too late to avoid a gap in therapy. As stated in §423.120, a Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering mail order, provided the requirements assuring pharmacy access are met. In our experience, under such circumstances some Part D sponsors direct their enrollees to retail pharmacies to obtain a needed medication. Other sponsors provide rush orders (e.g., next day delivery) from mail order pharmacies to supply the medication.

CMS has received beneficiary complaints about mail order pharmacies indicating that they will rush ship an urgently needed order, but the order does not arrive when promised or at all, potentially resulting in gaps in therapy. To protect beneficiaries from inconsistent or unreliable practices that may jeopardize timely access to medications, CMS expects Part D sponsors to

work with their mail order pharmacies to develop and implement protocols for providing access to urgently needed medications. Further, beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials. Having established protocols and beneficiary information in place can streamline how sponsors respond to such needs.

***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 2017 COB user fee will be collected at a monthly rate of $0.116 for the first 9 months of the coverage year (for an annual rate of $0.087 per enrollee per month) for a total user fee of $1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2017 bids.

In contract year 2017, we will use the COB user fees for activities including:

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

***Part D Low Enrollment***

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. While we are particularly concerned with plans that have fewer than 500 enrollees, we urge sponsors to voluntarily withdraw or consolidate any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html to determine if any of their plans meet this criterion. By April 2016, we will notify plans with less than 1,000 enrollees of available options for consolidation/withdrawal options. We reserve the right to require low enrollment plans to consolidate/withdraw in the future based on the marketplace at that time to ensure that all Part D plans offered in the marketplace are attractive to beneficiaries and do not add to their confusion in selecting a plan best suited to their prescription drug coverage needs.

## Section IV – Medicare-Medicaid Plans

### *Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2017*

This section provides an overview of the contract year (CY) 2017 Medicare requirements and timeframes for Medicare-Medicaid Plans (MMPs). We will also provide guidance in the Final CY 2017 Call Letter about which provisions in other sections apply to MMPs. Finally, we remind MMPs of the policy regarding the use of past performance information for determining eligibility for receipt of passive enrollment.

Annual submission timelines for MMPs are aligned with the standard Medicare Advantage (MA) and Part D annual schedule, as detailed in this Call Letter. As is the case for other MA and Part D plans, MMPs must submit a formulary, medication therapy management (MTM) program, and plan benefit package (PBP).

In addition to the requirements for MA-PD plans and PDPs, MMPs must also submit:

- On an annual basis, information to ensure the plan has a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid service providers, including long-term supports and services.
- If applicable based on the approval period given to the most recent model of care (MOC) submission, a MOC that meets CMS's requirements for SNPs, as well as any applicable state requirements.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 45 below catalogues previously released guidance for MMPs or guidance that may be of particular interest to MMPs. CMS will release updated or new guidance as necessary; where more recent guidance exists or is released for topics that appear in previously released documents, MMPs should use the most recent document.

**Table 45: Previously Released Guidance**

| Topic | Link to document |
|---|---|
| MMP Enrollment and Disenrollment Guidance | https://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf |
| Additional State-specific Enrollment Guidance | https://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html |
| State-specific Marketing Guidance | https://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html |
| Waiver of Part D LIS Cost-Sharing Amounts | https://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf |
| Past Performance Review Methodology Updates for CY 2017 | https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html |

**Network Adequacy Determinations**

MMPs will be required to resubmit their network information in September 2016 to ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. MMPs may assess the Medicare portion of their networks at any time using the plan-only upload functionality in the HPMS Network Management Module (NMM). The current reference file that provides the MMP standards is available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html as well as on the reference page within the NMM. CMS will release additional guidance on the submission process, including how MMPs will be able to submit exception requests in the summer of 2016.

**Model of Care (MOC)**

As discussed in January 14, 2016 HPMS memorandum, "Changes to Special Needs Plans and Medicare-Medicaid Plan Model of Care Submissions and Updates in the Health Plan

Management System for CY 2017," we strongly encourage MMPs to avail themselves of the new off-cycle update process, as MMPs' MOC submissions preceded the development of three-way contract requirements on care management and care coordination under each demonstration. Submission of changes through this process, as outlined in that memorandum and other guidance from CMS, will allow MMPs to align their current MOCs with all relevant demonstration requirements.

**Formulary and Supplemental Drug Files**

Each contract year, MMPs must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. For CY 2017 formulary approval, MMPs must submit: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2016 Part D formulary application guidance; and (2) an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs. MMPs must submit their base formularies no later than **June 6, 2016**. Supplemental formulary files are due in HPMS on **June 10, 2016 at 11:59 a.m. EST**.

All MMPs must submit an ADD file which can only contain non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. CMS will work with states to provide ADD file guidance to MMPs by May 2016. This guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). It is at the states' discretion whether to require their plan applicants to include one proxy NDC or multiple NDCs on the ADD file for each covered product.

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

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

CMS will release a CY 2017 formulary training video for plans in mid-to-late March 2016.

**Plan Benefit Package (PBP)**

MMPs' plan benefit packages (PBPs) are reviewed annually to ensure that MMPs accurately describe the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits. CMS will launch the HPMS PBP module on April 8, 2016, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2017. In addition, CMS will release an online training module on the CY 2017 PBP software for plans on April 8, 2016.

MMPs must submit their integrated PBPs to CMS no later than June 6, 2016 (11:59 p.m. PST). Non-timely submission of a PBP is considered a plan notice of non-renewal. In addition, to the PBP, MMPs are required to submit the following as part of a complete bid submission:

- Service Area Verification
- Plan Crosswalk (NOTE: This is only for renewing contracts in CY2017)
- Formulary Crosswalk

CMS will work with states to issue PBP guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits by the time the PBP module is launched in April 2016. The PBP review will be conducted jointly between CMS and states to ensure the data entry is consistent with minimum coverage and cost sharing requirements under Medicaid, Medicare Parts A, B, and D, and each state's demonstration.

As part of our demonstration implementation activities, the Medicare-Medicaid Coordination Office, in partnership with the Center for Medicare, has provided additional flexibility to MMPs with respect to PBP corrections after the time of final PBP approval. This flexibility has been necessary to accommodate mid-year legislative changes to Medicaid benefits, as well as the timing of payment rate finalization.

The following policies apply to MMP changes to PBPs:

- CMS will approve MMPs' requests to make PBP revisions to add or remove plan-offered supplemental benefits between the time of the release of the National Average Monthly Bid Amount in early August and sign-off of PBPs in HPMS in late August 2016. This will allow plans to accommodate any benefit changes in their required documents (including the Annual Notice of Change, Evidence of Coverage/Member Handbook, and Summary of Benefits) during the Annual Election Period.
- Rate-related PBP corrections to supplemental benefits are permissible during the Center for Medicare's annual correction window in September 2016 (see the calendar in this Call Letter for more information), but only for purposes of adding supplemental benefits to PBPs. MMPs that elect to correct their PBPs must work with their contract management team on an appropriate member communication strategy (e.g., addenda or errata sheets for materials that have already been mailed to members; updates to other materials for current and prospective members). In addition, there will be no compliance penalty for a PBP correction provided an MMP meets these conditions.
- Any PBP corrections after the Center for Medicare's annual correction window in September 2016 will be considered on a case-by-case basis. PBP corrections due to plan error will be subject to compliance action, regardless of whether they are positive or negative changes.

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

Our policy regarding the use of past performance information is articulated in previous guidance memoranda, including – most recently – in the February 23, 2015 HPMS memorandum, "Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2016." MMPs should refer to that guidance for additional information regarding the impact of sanctions, treatment of new legal entities, and eligibility for passive enrollment after effectuation of the three-way contract.

**Appendix 1 – Contract Year 2017 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals (Updated)**

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 6, 2016). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products because the individual plan is being non-renewed. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal of the plan by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with regulatory requirements, CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance, Chapter 3 of the Prescription Drug Benefit Manual and annual summer CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2017 is summarized below and defined in Appendix 2. These are the same options that existed in CY 2016. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

Please note, Medicare Advantage Organizations should reference Chapter 4, Chapter 16a, and Chapter 16b of the Medicare Managed Care Manual for Contract Year 2017 guidance on renewals and non-renewals.

### *1. New Plan Added*

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

### *2. Renewal Plan*

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

### *3. Consolidated Renewal Plan*

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

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

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

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

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

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

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

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

***5. Terminated Plan (Non-Renewal)***

A PDP sponsor may elect to terminate a current PBP for the following contract year and must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) by June 6, 2016. CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan, which includes the sponsor's basic plan if that is the only plan available. However, as stated in the CY 2015 Call Letter, CMS reminds sponsors that we do not intend to approve bids under which a PDP sponsor would propose to non-renew its current basic plan in a PDP region, thus disenrolling all the plan's current members at the end of the year, and offer a brand new basic plan during the upcoming benefit year. In a situation where enrollees are crosswalked to a comparable plan, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period, as well as information about alternative options.

***6. Consolidated Plans Under a Parent Organization***

For purposes of ensuring compliance with transition requirements following an acquisition or merger under our significant differences policy, or to make plan transitions following a novation,

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

**Appendix 2 – Contract Year 2017 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 2017 that is not linked to a 2016 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 2016 PBP in CY 2017. The same PBP ID number and benefit design (basic or enhanced alternative) must be retained in order for all current enrollees to remain in the same PBP in CY 2016. | HPMS Plan Crosswalk Definition: A 2017 plan that links to a 2016 plan and retains all of its plan service area from 2016. The 2017 plan must retain the same plan ID as the 2016 plan. HPMS Plan Crosswalk Designation: Renewal Plan | The renewal PBP ID must remain the same so that current enrollees will remain in the same PBP ID. The PDP sponsor does not submit enrollment transactions for current enrollees. | No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2017. 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 2016 into a single renewal PBP for CY 2017. The PDPsponsor must designate which of the renewal PBP IDs will be retained in CY 2016 after consolida-tion. | HPMS Plan Crosswalk Definition: Two or more 2016 plans that merge into one 2017 plan. The 2017 plan ID must be the same as one of the consolidatin g 2016 plan IDs.<br><br>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 2017. | 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 2016 prescription drug PBP in CY 2017 andexpands 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 2017. | HPMS Plan Crosswalk Definition: A 2017 800-series plan that links to a 2016 800-series plan and retains all of its plan service area from 2016, but also adds one or more new regions. The 2017 plan must retain the same plan ID as the 2016 plan. HPMS Plan Crosswalk Designa-tion:<br><br>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 2017. 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 2016 PBP. | HPMS Plan Crosswalk Definition:<br>A 2016 plan that is no longer offered in 2017.<br>HPMS Plan Crosswalk Designation: Terminated Plan | CMS expects the sponsor to crosswalk theaffected enrollees into the most comparable plan. The PDP sponsor does not submit disenrollment transactions.<br>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 theservice area. |

| | | | | | | |
|---|---|---|---|---|---|---|
| 6 | Consolidated Plans across Contracts under the Same Parent Organization | A parent organization merges two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk. | Exceptions Crosswalk Request: Sponsors must submit an exceptions request to CMS, which will complete the crosswalk on behalf of the sponsor<br>HPMS Plan Crosswalk Designa-tion: The plan being crosswalk-ed must be marked as a terminated plan in the HPMS crosswalk.<br>The remaining 2017 plan must be active and contain the applicable service area from the terminated plan being crosswalked. | PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. CMS will effectuate this renewal option and HPMS will record the merger of two or more whole PBPs. The PDP sponsor does not submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidatio n. | No enrollment election for current enrollees to remain enrolled in the renewal PBP in 2017. New enrollees must complete enrollment request. | Current enrollees are sent a standard ANOC. |

**Appendix 3 – Improvement Measures (Part C & D)**

| Part C or D | Measure | Measure Type | Weight | Improvement Measure |
|---|---|---|---|---|
| C | Breast Cancer Screening | Process Measure | 1 | Yes |
| C | Colorectal Cancer Screening | Process Measure | 1 | Yes |
| C | Annual Flu Vaccine | Process Measure | 1 | Yes |
| C | Improving or Maintaining Physical Health | Outcome Measure | 3 | No |
| C | Improving or Maintaining Mental Health | Outcome Measure | 3 | No |
| C | Monitoring Physical Activity | Process Measure | 1 | Yes |
| C | Adult BMI Assessment | Process Measure | 1 | Yes |
| C | Special Needs Plan (SNP) Care Management | Process Measure | 1 | Yes |
| C | Care for Older Adults – Medication Review | Process Measure | 1 | Yes |
| C | Care for Older Adults – Functional Status Assessment | Process Measure | 1 | Yes |
| C | Care for Older Adults – Pain Assessment | Process Measure | 1 | Yes |
| C | Osteoporosis Management in Women who had a Fracture | Process Measure | 1 | Yes |
| C | Diabetes Care – Eye Exam | Process Measure | 1 | Yes |
| C | Diabetes Care – Kidney Disease Monitoring | Process Measure | 1 | Yes |
| C | Diabetes Care – Blood Sugar Controlled | Intermediate Outcome Measure | 3 | Yes |
| C | Controlling Blood Pressure | Intermediate Outcome Measure | 3 | Yes |
| C | Rheumatoid Arthritis Management | Process Measure | 1 | Yes |
| C | Reducing the Risk of Falling | Process Measure | 1 | Yes |
| C | Plan All-Cause Readmissions | Outcome Measure | 3 | Yes |
| C | Getting Needed Care | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Getting Appointments and Care Quickly | Patients' Experience and Complaints Measure | 1.5 | Yes |

| Part C or D | Measure | Measure Type | Weight | Improvement Measure |
|---|---|---|---|---|
| C | Customer Service | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Rating of Health Care Quality | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Rating of Health Plan | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Care Coordination | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Complaints about the Health Plan | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Members Choosing to Leave the Plan | Patients' Experience and Complaints Measure | 1.5 | Yes |
| C | Beneficiary Access and Performance Problems | Measures Capturing Access | 1.5 | No |
| C | Health Plan Quality Improvement | Improvement Measure | 5 | No |
| C | Plan Makes Timely Decisions about Appeals | Measures Capturing Access | 1.5 | Yes |
| C | Reviewing Appeals Decisions | Measures Capturing Access | 1.5 | Yes |
| C | Call Center – Foreign Language Interpreter and TTY Availability | Measures Capturing Access | 1.5 | Yes |
| D | Call Center – Foreign Language Interpreter and TTY Availability | Measures Capturing Access | 1.5 | Yes |
| D | Appeals Auto–Forward | Measures Capturing Access | 1.5 | Yes |
| D | Appeals Upheld | Measures Capturing Access | 1.5 | Yes |
| D | Complaints about the Drug Plan | Patients' Experience and Complaints Measure | 1.5 | Yes |
| D | Members Choosing to Leave the Plan | Patients' Experience and Complaints Measure | 1.5 | Yes |
| D | Beneficiary Access and Performance Problems | Measures Capturing Access | 1.5 | No |
| D | Drug Plan Quality Improvement | Improvement Measure | 5 | No |
| D | Rating of Drug Plan | Patients' Experience and Complaints Measure | 1.5 | Yes |
| D | Getting Needed Prescription Drugs | Patients' Experience and Complaints Measure | 1.5 | Yes |

| Part C or D | Measure | Measure Type | Weight | Improvement Measure |
|---|---|---|---|---|
| D | MPF Price Accuracy | Process Measure | 1 | No |
| D | Medication Adherence for Diabetes Medications | Intermediate Outcome Measure | 3 | Yes |
| D | Medication Adherence for Hypertension (RAS antagonists) | Intermediate Outcome Measure | 3 | Yes |
| D | Medication Adherence for Cholesterol (Statins) | Intermediate Outcome Measure | 3 | Yes |
| D | MTM Program Completion Rate for CMR | Process Measure | 1 | Yes |