February 15, 2013

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

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter

In accordance with Section 1853(b)(2) of the Social Security Act (the 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 2014. The following information is also included: preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2014, changes in payment methodology for CY 2014 for Part D benefits, and annual adjustments for CY 2014 to the Medicare Part D benefit parameters for the defined standard benefit. For 2014, CMS will announce the MA capitation rates on the first Monday in April 2013, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Attachment I shows the preliminary estimates of the national per capita MA growth percentage and the national Medicare fee-for-service growth percentage, which are key factors in determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2014 governing payment for original Medicare benefits and rebates. Attachment III sets forth the changes in payment methodology for CY 2014 for Part D benefits. Attachment IV presents the annual adjustments for CY 2014 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 2014 Call Letter for Medicare Advantage (MA) organizations; section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including both employer/union-only group health plans (EGWPs) and direct contract plans. The Call Letter contains information these plan sponsor organizations will find useful as they prepare their bids for the new contract year.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2014@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 1, 2013, release of the final Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern Standard Time on Friday, March 1, 2013.

/ s /
Jonathan Blum
Director
Center for Medicare
/ s /
Paul Spitalnic, A.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2014 ADVANCE NOTICE
TABLE OF CONTENTS

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2014 5
Section A. MA Growth Percentage 5
Section B. FFS Growth Percentage 6

Attachment II. Changes in the Part C Payment Methodology for CY 2014 8
Section A. MA Benchmark, Quality Bonus Payments and Rebate 8
Section B. IME Phase Out 11
Section C. ESRD State Rates 12
Section D. Clinical Trials 12
Section E. Location of Network Areas for PFFS Plans in Plan Year 2015 12
Section F. Calculation of Fee for Service Rates 13
Section G. Recalibration and Clinical Update of the CMS-HCC Risk Adjustment Model 16
Section H. Medicare Advantage (MA) Enrollee Risk Assessments 22
Section I. Adjustment for MA Coding Pattern Differences 23
Section J. Normalization Factors 23
J1. Normalization for the CMS-HCC Model (aged/disabled beneficiaries enrolled in MA plans or PACE organizations) 23
J2. Normalization Factor for the ESRD Dialysis Model 24
J3. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model 25
Section K. Frailty Adjustment 25
Section L. Medical Loss Ratio (MLR) Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs 26

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2014 28
Section A. Part D Benefit Administration and Prescription Drug Event (PDE) Reporting 28
A1. Applicable Beneficiary and Plan Dispensing/Vaccine Administration Fee Liability on: a) Applicable Drug Claims that Straddle the Coverage Gap; and b) Applicable Drug Coverage Gap Claims under EA Plans offering Part D Supplemental Coverage in the Gap 28
A2. Beneficiary and Plan Negotiated Price Cost Component Liability 34
A3. Other Health Insurance (OHI) including Employer Group Waiver Plans (EGWPs) 38
A4. Enhanced Alternative Plan Mapping Rule 4 39
Section B. Update of the Rx-HCC Model 40
Section C. Payment Reconciliation 41
Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2014 43

Section E. Medical Loss Ratio (MLR) Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs 47

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2014 48
Section A. Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary 48
Section B. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average) 49
Section C. Calculation Methodology 49
Section D. Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries 51
Section E. Retiree Drug Subsidy Amounts 53

Attachment V. Preliminary CMS-HCC and Rx-HCC Risk Adjustment Factors 54
Table 1. Preliminary CMS-HCC Model Community and Institutional Relative Factors for the CMS-HCC Risk Adjustment Model 55
Table 2. Preliminary CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees 60
Table 3. Preliminary CMS-HCC Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs) 61
Table 4. Preliminary Disease Hierarchies for the CMS-HCC Model 62
Table 5. Comparison of Current and Revised CMS-HCC Risk Adjustment Model HCCs 63
Table 6. Preliminary CMS RxHCC Model Relative Factors for Continuing Enrollees 70
Table 7. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Non-Low Income 74
Table 8. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Low Income 75
Table 9. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Institutional 76
Table 10. Preliminary List of Disease Hierarchies for the Revised CMS RxHCC Model 77

Attachment VI. 2014 Call Letter 78

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2014

The Affordable Care Act establishes a new blended benchmark as the MA county rate, effective in CY 2012 under which county rates are determined by blending two components: an applicable amount (the pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a specified amount (a new Affordable Care Act rate set under section 1853(n)(2) of the Act).

For 2014, the rate established under section 1853(k)(1) is the greater of: 1) the county's 2014 FFS rate or 2) the 2013 applicable amount increased by the CY 2014 national per capita MA growth percentage. For 2014, the "specified amount" will be based on a percentage of the 2014 FFS rate.

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 2014 is -2.3 percent. This estimate reflects an underlying trend change for CY 2014 in per capita costs of -3.2 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.

We appreciate that plans are facing several legislatively mandated changes affecting payment for 2014, and this may present challenges for plans. We solicit comment on suggestions to address these challenges within the parameters of current law. In addition, we solicit comment on ways to modify requirements to improve opportunities for administrative efficiencies while improving delivery of care.

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

Table I-1. National Per Capita MA Growth Percentage – Aged/Disabled

	Aged+Disabled
2014 Trend Change	-3.2%
Revision to CY 2013 Estimate	4.4%
Revision to CY 2012 Estimate	-1.5%
Revision to CY 2011 Estimate	-1.4%
Revision to CY 2010 Estimate	-0.4%
Revision to CY 2009 Estimate	-0.1%
Revision to CY 2008 Estimate	0.2%
Revision to CY 2007 Estimate	-0.2%
Revision to CY 2006 Estimate	0.0%
Revision to CY 2005 Estimate	0.0%
Revisions to CY 2004 Estimate	0.0%
Total Change	-2.3%

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding. Health Information Technology (HITECH) and electronic health record (EHR) incentive payments are excluded from the calculation of the adjusted average per capita cost.

Section B. FFS Growth Percentage

The Affordable Care Act requires that the specified amount of the Medicare Advantage benchmark amounts be calculated as a percentage of the county FFS amounts. Table I-2 below provides the current estimate of the increase in the Aged/Disabled FFS United States per capita cost (USPCC), which will be used for the county FFS portion of the benchmark. The percentage increase in the FFS USPCC is shown as the current projected FFS USPCC for 2014 divided by projected FFS USPCC for 2013.

Table I-2 also shows the increase in the FFS USPCC for dialysis-only ESRD. Statewide dialysis-only ESRD rates are determined by applying a historical average geographic adjustment to a projected FFS dialysis-only ESRD USPCC. Beginning with 2013 rates, we will be using a 5-year average of State data to determine the average geographic adjustment, similar to the method used to determine the geographic adjustments for non-ESRD rates.

Table I-2 – Increase in the FFS USPCC Growth Percentage

	Aged/Disabled	ESRD
Current projected 2014 FFS USPCC	$751.75	$7207.44
Prior projected 2013 FFS USPCC	$767.99	$7218.90
Percent increase	-2.1%	-0.2%

These estimates are preliminary and could change when the final rates are announced on April 1, 2013 in the final Announcement of Calendar Year (CY) 2014 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 1, 2013 final Announcement.

Attachment II. Changes in the Part C Payment Methodology for CY 2014

Section A. MA Benchmark, Quality Bonus Payments and Rebate

New Methodology for County Rates

The Affordable Care Act established a new methodology for calculating MA county rates, effective 2012, and required a blended benchmark to be used during a transition period. Beginning with CY 2012, and throughout the transition period, county rates are determined by blending two components: an applicable amount (the pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a specified amount (a new Affordable Care Act rate set under section 1853(n)(2) of the Act). Section 1853(n)(4) of the Act requires that the blended benchmark be capped at the level of the 1853(k)(1) applicable amount.

Section 1853(c)(1)(D)(ii) requires CMS to rebase the county fee-for-service (FFS) rates, which form the basis of the specified amount, periodically, but not less than once every three years. When the rates are rebased, CMS updates its estimate of each county's FFS costs using more current FFS claims information. CMS plans to rebase the county FFS rates for 2014.

Applicable Amount

The applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1). For 2014, it is the greater of: 1) the county's 2014 FFS rate or 2) the 2013 applicable amount increased by the CY 2014 National Per Capita Medicare Advantage Growth Percentage.

Specified Amount

The specified amount is based upon the following formula:

(2014 FFS rate minus IME phase-out amount) × (applicable percentage + applicable percentage quality increase)

Section 1853(n)(2)(C) requires CMS to determine applicable percentages for a year based on county FFS rate rankings for the previous year that was a rebasing year. To determine the CY 2014 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2013 FFS costs, because 2013 is the most recent FFS rate rebasing year prior to 2014. 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.

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 the applicable percentage for the previous year and 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 third quartile to the second quartile, the applicable percentage would be 103.75 percent for the year of the change – the average of 107.5 percent and 100 percent.

Quality Bonus Payment Demonstration/Applicable Percentage Quality Increase

The Affordable Care Act provides for CMS to make quality bonus payments (QBPs) to MA organizations that meet quality standards measured under a five-star quality rating system. As announced in the final 2012 Announcement, CMS is conducting a nationwide three-year demonstration in effect from 2012 to 2014 to test an alternative method for determining QBPs. The demonstration tests whether providing scaled bonuses to MA organizations with three or more stars leads to more rapid and larger year-to-year quality improvements in quality scores. During this demonstration, for contracts at or above three stars, QBPs will be computed along a scale; the higher a contract's star rating, the greater the QBP percentage.

Under the demonstration, the QBP percentage for each star rating is as follows:

Stars Rating	QBP Percentage for 2012/2013	QBP Percentage for 2014
Less than 3 stars	0%	0%
3 stars	3%	3%
3.5 stars	3.5%	3.5%
4 stars	4%	5%
4.5 stars	4%	5%
5 stars	5%	5%

Qualifying County Bonus Payment

Beginning with payment year 2012, the Affordable Care Act extends a double quality percentage point increase to a qualifying plan located in a "qualifying county." Under the demonstration a qualifying plan is a plan that has a quality rating of three stars or higher. (An MA plan's star rating is the rating assigned to its contract.) Section 1853(o)(3)(B) 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 subsection (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 beneficiaries residing in the county enrolled in a MA plan; and 3) has average FFS county spending for 2014 that is less than the national average FFS spending for 2014. The 2014 FFS rates are not available at the time this Advance Notice is published. The FFS rates and the national average FFS spending amount will be published in the final 2014 Announcement.

CMS will publish a complete list of qualifying counties in the final 2014 Announcement. The listing will contain all counties that meet all three criteria as stated in Section 1853(o)(3)(B) of the Act. Two of the three elements for determining a qualifying county 1) 2004 urban floors (Y/N for each county), and 2) 2009 Medicare Advantage penetration rates (%) can be found at the CMS website at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html.

Affordable Care Act County Rates Transitional Phase-In

The blend of the Specified Amount and Applicable Amount used to create the county rates, as discussed above, will be phased in on a transitional basis beginning in 2012 and ending in 2017. In 2012, each county was assigned to one of three transition periods - two, four, or six years. CMS determined a county's specific transition period by calculating the difference between the county's Projected 2010 Benchmark Amount and 2010 applicable amount. The Projected 2010 Benchmark Amount was a one-time only calculation, which has been employed solely for the purpose of assigning each county its appropriate transition period, in accordance with the Affordable Care Act.

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

Blended Benchmark Calculations.

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

Table II-2. Blended Benchmark Calculations

	Two Year County Blend		Four Year County Blend		Six Year County Blend	
Year	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%

Rebate and Quality Bonus.

Under section 1854(b)(1)(C) of the Affordable Care Act, the level of rebate is tied to the level of the plan's star rating. The Affordable Care Act stipulates that by 2014, new rebate percentages will apply, based on a plan's star rating, as shown in Table II-3.

Table II-3. Determination of MA Plan Beneficiary Rebate Amounts

Star Rating	2014
4.5+ Stars	70%
3.5 to <4.5 stars	65%
< 3.5 stars	50%

A new contract under a new parent organization will be treated as having a star rating of 3.5 stars. This specific provision for the determination of star levels for new plans is for purposes of determining the rebate level only, and not for other payment purposes. There is no exception for low enrollment plans in 2014, and they will be treated as having a star rating of 3 stars.

Section B. IME Phase Out

Section 161 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to phase out indirect medical education (IME) amounts from MA capitation rates. 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 2014, we will first calculate the 2014 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 2014 rates. The absolute effect of the IME phase-out on

each county will be determined by the amount of IME included in the initial FFS rate. By statute, the maximum reduction for any specific county in 2014 is 3% of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2014 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section C. ESRD State Rates

In developing the 2014 ESRD Medicare Advantage rates, we obtain the FFS dialysis reimbursement and enrollment data by each state for the years 2007 – 2011. For each year, we compute the per capita costs by state. The geographic indices for each state are calculated by dividing the state per capita cost by the total per capita cost of the nation. The average geographic adjustment (AGA) by state is determined. The AGA is the 5-year weighted average of the geographic indices, which is standardized by dividing by the 5-year average risk scores. We calculated the 2011 FFS ESRD dialysis United States per capita cost (USPCC) based on the 2011 data above, and using trend factors, develop the prospective 2014 FFS ESRD dialysis USPCC. The 2014 ESRD dialysis rates by state are determined by multiplying the 2014 FFS ESRD dialysis USPCC by the state AGA. The 2014 ESRD dialysis rate is adjusted by removing the direct graduate medical expenses (GME) and gradually removing the indirect medical expenses (IME).

Section D. Clinical Trials

In 2014, we will continue the policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Section E. Location of Network Areas for PFFS Plans in Plan Year 2015

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 Social Security Act) must meet the access standards described in section 1852(d)(4)(B) of the Social Security Act through signed contracts with providers. These PFFS plans may not meet access standards by establishing payment rates that are not less than the rates that apply under Original Medicare and having providers deemed to be contracted as described in 42 CFR 422.216(f).

Network area is defined in section 1852(d)(5)(B) of the Social Security 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 Social Security 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 2015 in the final *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.* We will also include the list on the CMS website at http://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html. We will use January 1, 2013 enrollment data to identify the location of network areas for plan year 2015.

Section F. Calculation of Fee for Service Rates

Under the Affordable Care Act, the specified amount of the Medicare Advantage (MA) county benchmarks is based on FFS costs. In 2014, some counties will be completely based on the specified amount, some will be 75 percent based on the specified amount, and others will be 50 percent based on the specified amount. Approximately twenty-one percent of MA enrollees are in counties in which the 2014 rate will be based entirely on the specified amount (these are also called 'two-year counties' because the phase-in for these counties is two years). See Table II-4 below. The other portion of the rate is what would have been paid based on pre-ACA requirements, or the applicable amount (also called the pre-ACA rate).

Table II-4 Distribution of Enrollees by County Type

County Type	2014 Specified Amount	2014 Applicable Amount	MA Enrollment in County Type (based on July 2011)
Two-year	100%	0%	21%
Four-year	75%	25%	47%
Six-year	50%	50%	32%

For the four and six-year counties, the 2014 rate will be partially based on what would have been paid had the ACA not been passed (also called the pre-ACA rate).

The FFS cost for each county is a product of 1) the national FFS rate, or United States per-capita cost (USPCC), and 2) a county-level geographic index called the average geographic adjustment (AGA). For 2014, we are considering refinements to the AGA methodology, as discussed below.

Background

As noted above, the FFS cost for each county is a product of 1) the national FFS rate, or USPCC, and 2) a county-level geographic index called the average geographic adjustment (AGA). The USPCC represents the projected average per-beneficiary cost for all non-ESRD beneficiaries enrolled in Medicare FFS. The FFS USPCC is determined on a current law basis and reflects the anticipated effects of all legislation, regulation, and sub-regulatory policies affecting the payment year. The AGA measures the per capita FFS cost in each county relative to the FFS USPCC. In previous years, CMS has calculated each AGA using five years of historical claims data for each

county. Under this methodology, the AGA has been based on a five-year rolling average of historical per capita FFS cost in each county relative to the national cost. For example, the AGAs used to calculate the 2013 FFS rates were based on the average FFS cost in each county during the period 2006-2010. This rolling average approach has been used to smooth experience, lessen year-to-year fluctuation in the rates, and to enhance the statistical credibility of the historical claims experience. For 2014, CMS will use five years of FFS data, from 2007 to 2011, to estimate each county AGA.

AGA Methodology for 2014

In the first step, for 2014, CMS will add 2011 cost and enrollment data, and drop 2006 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 2007-2011.

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

Item	Description of Adjustment
Hospice	Exclusion of hospice costs
Cost plan	Exclusion of FFS claims paid on behalf of cost plan enrollees
Puerto Rico	Only include claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment

CMS described our rationale for making these adjustments (hospice, cost plan, and Puerto Rico), beginning with the 2009 claims data, on page 14 of the Advance Notice of Methodological Changes for Calendar Year 2012 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, published on February 18, 2011. CMS also noted at that time that we planned to transition this change over a five year period by using this adjustment in each new claim year estimated, and as a result, CMS did not make these changes in the 2007 and 2008 FFS claims data.

As in prior years, CMS will also make additional adjustments to the FFS rates for certain items. These adjustments are made after the AGA is calculated:

Item	FFS Rate Adjustment
Direct Graduate Medical Education	Removed from FFS county rates, (as per Section 1853(c)(1)(D)(i) of the Social Security Act)
Indirect Medical Education	Removed from FFS county rates, as per phase-out schedule in MIPPA
Credibility	For counties with less than 1,000 members, blend county experience with that of others in the market area
VA-DOD	Apply a cost ratio (an increase to claim costs) to counties with significant Tricare enrollment in the Uniformed Services Family Health Plan.

In order to more accurately estimate the AGAs, CMS is considering a new, third step in the AGA calculation to adjust the historical data to reflect more current FFS pricing rules. We are considering this refinement because AGAs based exclusively on historical claims experience do not take into account changes in payment indices from the historical year to the contract year. For example, the contract year 2014 MA ratebook will be based on FFS spending for 2007 through 2011, which represents a 3-to-7 year lag from the historical to the projected period. These historical data do not incorporate more current FFS reimbursement rules and other policy changes that may have differential geographic effects.

In this step that we are contemplating, CMS would apply a pricing adjustment to the claims; in effect, we would re-price the claims. More specifically, if we were to adopt this approach, we would re-price the inpatient, hospital outpatient, skilled nursing facility, and home health claims to reflect the most current wage indices, and we would re-price physician claims with the most current Geographic Practice Cost Index. For example, CMS would use the FY 2013 wage index to re-price the 2007-2011 FFS inpatient claims. This potential approach would take into account the requirement in the ACA that wage index adjustments are budget neutral on a national basis.[1]

For FY 2012, hospital and physician spending represented 70 percent of the total Medicare FFS spending, while skilled nursing facility (SNF) and home health costs account for an additional 14 percent of the spending. The structure of the major FFS payment systems is similar in that there are both resource and geographic components. The key pricing elements for the five largest payment categories are shown below.

[1] "For example, the portion of the 2007 inpatient claims tied to the wage index for a given county would be repriced by multiplying the 2007 claims for that county by the ratio of the 2013 Wage Index to the 2007 Wage Index.

Provider Category	Resource index	Geographic index
Inpatient Hospital	Diagnosis Related Groups (MS-DRGs)	Hospital Wage Index
Physician	Relative Value Units (RVUs)	Geographic Practice Cost Indexes (GPCIs)
Outpatient Hospital	Ambulatory Payment Classifications (APCs)	Hospital Wage Index
Skilled Nursing (SNF)	Resource Utilization Groups (RUGs)	Hospital Wage Index
Home Health	Home Health Resource Groups (HHRGs)	Hospital Wage Index

We believe focusing on the five largest payment systems in the FFS sector would be an appropriate way to estimate the AGAs.

As part of this third step, CMS would also recalculate home health claims to account for the outlier payment policy that went into effect in 2010. Beginning with FY 2010, outlier payments to home health providers are limited to 10 percent of the base payments to each provider. This policy, which is now law due to ACA section 3131, has a variable impact by county.

In the fourth and final step, the average of the five-year geographic indices, based on the adjusted claims data, would be divided by the average five-year risk score for the county in order to develop the AGA. This step is unchanged from previous years, and would be undertaken even if CMS did not pursue the third step in the process (the re-pricing of the claims) for 2014.

CMS is considering making the refinements to the calculation of FFS rates as outlined in the third step in the AGA calculation described above. CMS recognizes that these changes 1) may have disparate geographic impacts, and 2) represent a significant change from the existing methodology that we have used to set FFS rates. Therefore, CMS requests comment on appropriate methodologies for calculating the FFS rates. Specifically, CMS would appreciate comments on alternative approaches to this issue, as well as any comments on the potential impacts of the proposed changes. In addition, we request comment on the timeframe for implementation of such refinements including whether such refinements should be implemented for 2014 or a future year, as well as options for phasing-in this change over a multi-year period.

Section G. Recalibration and Clinical Update of the CMS-HCC Risk Adjustment Model

In 2014, CMS will implement an updated version of the CMS-HCC risk adjustment model, including the coefficients for the community, institutional, new enrollee, and C-SNP new enrollee segments of the model. The 2014 model will encompass updates to (1) the data years used to recalibrate the model and (2) a clinical revision of the diagnoses included in each hierarchical condition category (HCC). We propose to use this updated CMS-HCC model in Part C payment for aged/disabled beneficiaries enrolled in MA plans and PACE organizations.

CMS recalibrated the CMS-HCC risk adjustment model using 100 percent fee-for-service (FFS) claims for the years 2010 and 2011. Specifically, 2010 diagnoses were used to predict 2011 expenditures.

In addition to using more recent data years in recalibrating the model, the new CMS-HCC model will reflect a clinical update that involved reviewing all ICD-9 diagnoses codes. In consultation with a panel of outside clinicians, CMS reviewed and grouped clinically similar ICD-9 codes into diagnosis groupings, which are used as the building blocks of the condition categories. These diagnosis groupings were then mapped to condition categories based on similar clinical characteristics and cost implications. Both the panel of clinicians and analyses of cost data informed CMS' creation of condition categories.

We estimated coefficients for condition categories and demographic factors by regressing the total expenditure for A/B benefits 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, Medicaid status, disability status) in predicting FFS per capita costs.

Changes to the condition categories, such as additions, deletions, and revisions, are based on each condition category's ability to predict costs for Medicare Parts A and B benefits. Condition categories that do not predict costs well – because the coefficient is small, the t-value is low, a small number of beneficiaries with a certain condition results in an unstable coefficient, or the condition does not have well-specified diagnostic coding – are not included in the model. There were no changes in the demographic factors used in the CMS-HCC model.

In a final step, hierarchies were imposed on the condition categories, assuring that more advanced and costly forms of a condition are reflected in a higher coefficient. Hierarchies also ensure that double credit is not given when a beneficiary develops a more severe form of a condition. For example, if a beneficiary has diagnoses that map to both Chronic Kidney Disease (CKD), Severe (Stage 4) (HCC 137) and CKD, Stage 5 (HCC 136), then this beneficiary's risk score will reflect CKD, Stage 5 and not CKD, Severe (Stage 4).

In order to use the risk adjustment model to calculate risk scores for payment, we create relative factors for each demographic factor and HCC in the model. We do this by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year (that is, the "denominator year"). For 2014, CMS used the predicted per capita costs for 2012, adjusted for model phase in (see Phase in of New Model discussion below). The relative factors are used to calculate risk scores for individual beneficiaries. The denominator, which is used to create relative factors for all segments of the CMS-HCC model, is $9,050.01.

Differences between the current model and the revised model will occur for several reasons. Changes in the marginal cost attributable to an HCC, relative to changes in the average cost, can alter the relative factor associated with that HCC. Similarly, changes in the marginal cost

attributable to an HCC, relative to changes in the marginal costs attributable to all other HCCs, can also result in changes in the relative factor associated with that HCC. In addition, changes in the relative factors will result from changes in the assignment of ICD-9 codes to HCCs, as well as the addition or deletion of HCCs to the model.

The updated model, including both recalibrating the model on more current data and incorporating the clinical update, results in more appropriate relative weights for the HCCs in the model because they reflect more recent coding and expenditure patterns in FFS Medicare, as well as newly constructed HCCs that are now possible as a result of ICD-9 codes that have been introduced since the original CMS-HCC model was created. Beneficiary risk scores or plan average risk scores may change depending on each individual beneficiary's combination of diagnoses.

Changes to HCCs in the Model

The 2014 model has 79 HCCs, up from 70. The increase in HCCs is a result of new HCCs added to the model and the splitting of several existing HCCs.

HCCs added to the model:

Two new HCCs related to metabolic disorders were added: "Other significant endocrine and metabolic disorders" and "Morbid obesity."

In addition, we have added "Fibrosis of the Lung and Other Chronic Lung Disorders" and "Exudative Macular Degeneration."

Changes to existing HCCs:

A number of diseases that are currently included in HCCs with other related conditions have been broken out into their own HCCs. These conditions include quadriplegia, cerebral palsy, amyotrophic lateral sclerosis (ALS) and other motor neuron disease, and atherosclerosis of the extremities with ulceration or gangrene. Additional conditions that have been broken out into separate HCCs are pressure ulcers and kidney disease. Two HCCs for pressure ulcers with the highest severity are included in the model.

Renal failure is broken out into "Acute Renal Failure" and different severity levels of chronic kidney disease (CKD).

The 2014 model consolidates the diabetes HCCs in the current model as follows: diabetes with acute complications, diabetes with chronic complications, and diabetes without complications.

In addition, due to concerns about the specificity of coding, dementia HCCs are not included in the 2014 model. Also, we have removed the lower severity pressure ulcer HCCs now that there is more experience with coding those diagnoses, and we are able to differentiate the coefficients among these HCCs.

However, we are concerned about the high rate of coding of other HCCs by MA organizations, relative to FFS providers, given that the coefficients are calibrated on FFS data. Therefore, in addition to the changes mentioned above, we also made changes to several other HCCs to address MA coding intensity.

- Since the clinically-revised model allowed us to better estimate marginal costs for a wider range of renal disease (specifically, the current HCC131 renal failure is split among a range of acute and chronic kidney conditions), we removed the lower-severity kidney disease HCCs, including Chronic Kidney Disease (CKD) stage 3, CKD stages 1-2, or unspecified; unspecified renal failure; and nephritis.

- We restructured polyneuropathy (HCC 75 in the new model) to remove diabetic neuropathy. Diabetic neuropathy is still mapped to diabetes with Chronic Complications (HCC18), while other diagnoses were moved to non-payment HCCs. The remaining diagnoses remain in HCC75 as "Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy."

- The "Renal*Congestive Heart Failure" (CHF) interaction term has been modified in that "renal disease" now encompasses all the kidney-related HCCs in the revised model.

We are proposing all of the changes noted above and request comment on the overall model and the changes to various HCCs.

For a list of HCCs in the proposed model, please see Table 5 in Attachment V.

Disease interactions: The coefficients for the community model continue to have six disease interactions, the net result of the following changes: three disease interactions were removed, three were added, two were retained, and one was modified.

- The disease interactions retained from the current model are: Diabetes*Congestive Heart Failure (CHF) and CHF* Chronic Obstructive Pulmonary Disease (COPD)
- The Renal*CHF interaction term has been modified in that "renal disease" now encompasses all the kidney-related HCCs in the revised model.
- The disease interactions that were removed are: Diabetes* Cardiovascular Disease (CVD), COPD*CVD* Coronary Artery Disease (CAD), and Renal Failure*CHF*Diabetes.
- New disease interaction terms are: Sepsis*Cardiorespiratory failure, Cancer*Immune Disorders and COPD*Cardiorespiratory Failure.

The institutional set of coefficients now has twelve disease interactions instead of five. It retains two interactions from the current model – Diabetes*CHF and CHF* COPD – and adds ten new disease interaction terms:

- COPD*Cardiorespiratory failure

- Sepsis*Pressure Ulcer
- Sepsis*Artificial Openings for Feeding or Elimination
- Artificial Openings for Feeding or Elimination*Pressure Ulcer
- COPD*Aspiration and Specified Bacterial Pneumonias
- Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer
- Sepsis*Aspiration and Specified Bacterial Pneumonias
- Schizophrenia*COPD
- Schizophrenia*CHF
- Schizophrenia*Seizure Disorders and Convulsions

Disabled interactions: The community set of coefficients retains all five existing disabled-disease interactions and adds two additional disabled-disease interactions: Disabled*Chronic Pancreatitis, and Disabled*Complications of Specified Implanted Device or Graft.

The institutional set of coefficients retains one of the four disabled-disease interactions – Disabled*Opportunistic infections – and adds five new disabled-disease interactions:

- Disabled*CHF
- Disabled*Pressure Ulcer
- Disabled*Chronic Ulcer of the Skin, Except Pressure Ulcer
- Disabled*Bone/Joint Muscle Infections/Necrosis
- Disabled*Multiple Sclerosis

CMS continues to include Medicaid as a demographic factor in the CMS-HCC risk adjustment model, which incorporates attributes of Title XIX eligible beneficiaries, including low-income status.

New enrollee segments

The new enrollee segment of the CMS-HCC model is used in Part C payment for beneficiaries enrolled in MA plans or PACE organizations who do not have adequate diagnoses to calculate a risk score. CMS considers a beneficiary without 12 months of Part B in the data collection year as a new enrollee. The new enrollee segment of the CMS-HCC model comprises demographic factors: age, sex, Medicaid status, and originally disabled status. To date, for each beneficiary who is a new enrollee, we have calculated their new enrollee risk score by adding up the relative factors for their applicable demographic characteristics. When we have published these new enrollee models, we have created tables showing every combination of new enrollee risk scores across these demographic characteristics.

In the updated model that we are implementing for 2014, we have estimated each of these possible risk scores individually. For example, we directly estimate the risk score for a specific new enrollee type, such as female 70-74, Medicaid, and originally disabled. This approach results in better specified risk scores for new enrollees because the marginal relative cost

attributed to Medicaid status is now reflected independently for each age and sex cell, rather than adding the age/sex factor to a separately estimated Medicaid factor.

New Enrollee Risk Scores for Chronic SNPs

For 2014, CMS will update the model used to create new enrollee risk scores for new enrollees in chronic SNPs. Beginning in 2011, in accordance with Section 3205 of the Affordable Care Act, CMS implemented a model designed to pay new enrollees in chronic SNPs based on the full risk of C-SNP enrollees, given that these beneficiaries must have certain conditions to be enrolled in these plans. New enrollee risk scores are used for those beneficiaries who do not have 12 months of Part B and, therefore, for whom CMS cannot calculate a full risk score. 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' risk.

The C-SNP new enrollee model is built upon the CMS-HCC model, detailed within this section. The C-SNP new enrollee factors were developed by first calculating an average risk score for continuing enrollees in chronic SNPs using the regular 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 will 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.

Phase in of New Model

Based on our analysis of the impact of the revised CMS-HCC risk adjustment model on MA contracts, the average MA risk score under the revised model would be lower than the average MA risk scores under the 2013 model. The main cause of this change in risk score is the differential coding between MA and FFS. Although the model is calibrated to retain an average 1.0 risk score in FFS, MA plans tend to code at higher rates those HCCs that experienced reductions in their relative value in this new model. To provide for a transition from the 2013 model to the revised model, we propose to implement the revised model over a multi-year period. Specifically, beginning in 2014, we propose to implement the coefficients of the revised model, but to transition over a multi-year period to the revised model denominator. Under this transition, for 2014, the denominator would be reduced by 2.5%, such that the average MA risk score would approximate the average MA risk score under the model used in 2013. In subsequent years, the denominator would be incrementally adjusted to provide for a multi-year transition to the revised model denominator.

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 score. Table 4 provides the

updated hierarchies for the revised HCCs, and Table 5 provides a comparative list of current and revised HCCs.

Section H. Medicare Advantage (MA) Enrollee Risk Assessments

MA enrollee risk assessments are used to assess the overall health of the beneficiary, make diagnoses, and identify gaps in care. These evaluations are generally initiated by Medicare Advantage (MA) organizations through outreach to the MA enrollee, for example, via postcards and phone calls. MA organizations have been using enrollee risk assessments for a number of years and these assessments can contribute to improved care by promoting wellness and prevention. Frequently, they are conducted in the beneficiary's home, but they may also occur at the provider's clinic or office.

MA enrollee risk assessments are also used as a tool to identify enrollee diagnoses that can be submitted to CMS for the purpose of risk adjusted payment. CMS is concerned that these risk assessments could be used as a vehicle for collecting risk adjustment diagnoses without follow-up care or treatment being provided to the beneficiary by the plan. The purpose of risk adjustment is to measure health status that is related to plan liability and in the case of these assessments, it is not clear that there is plan liability associated with the provision of treatment. This contributes to increased risk scores and differences in coding patterns between MA and FFS. In order to be acceptable for risk adjusted payments, the risk assessment must be conducted as a face-to-face encounter by a provider that is an acceptable risk adjustment provider type (e.g., a physician or nurse practitioner), and be documented in a medical record in order to meet risk adjustment rules. Examples of diagnoses that could be identified include chronic conditions, such as diabetes and vascular disease.

These MA enrollee risk assessments are often referred to as Health Risk Assessments (HRAs), and they may be associated with an Annual Wellness Visit (AWV). As of 2011, Fee-For-Service Medicare is required to provide AWVs as a benefit to beneficiaries. The AWV is intended to improve patient care through the identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions. MA organizations are also required to provide beneficiaries with AWVs, with an HRA component, as part of the benefit package.

The Centers for Medicare & Medicaid Services strongly encourages the use of such tools for wellness and prevention efforts. However, CMS also wants to ensure that payments to MA organizations are accurate, that treatment for identified conditions is done when appropriate, and that costs are reflective of treatment. Therefore, CMS will be implementing a data collection and analysis effort in 2013 of diagnoses that are associated with an MA enrollee risk assessment. Beginning with 2013 dates of service, when reporting risk adjustment diagnoses to CMS, MA organizations will be required to flag those diagnoses collected in an MA enrollee risk

assessment. In addition, CMS will be considering different approaches for ensuring the accuracy and completeness of this risk assessment information.

To better ensure that our payments to plans reflect diagnoses for which there has been an associated treatment or that have been diagnosed by a treating provider, for payment year 2015, CMS is considering excluding, for risk adjustment payment purposes, the diagnosis data collected from MA enrollee risk assessments that are not confirmed by a subsequent clinical encounter by a provider type that has been approved for risk adjustment purposes. We invite comment on this proposal.

Section I. Adjustment for MA Coding Pattern Differences

We have updated the MA coding adjustment factor for 2014 to 4.91%.

Section J. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

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

Below are the preliminary normalization factors for each model. Values are carried to additional decimal places and may not agree to the rounded values presented below. The final normalization factors will be published in the final 2014 Announcement, to be released April 1, 2013.

J1. Normalization for the CMS-HCC Model (aged/disabled beneficiaries enrolled in MA plans or PACE organizations)

The preliminary 2014 Part C normalization factor is 1.026.

To calculate the normalization factor for the CMS-HCC risk adjustment model, CMS used the risk adjustment model to be implemented in 2014 to calculate five years of risk scores for the FFS population. For the 2014 normalization factor, CMS used risk scores from 2008 to 2012 to calculate an annual trend, which was then compounded for two years to adjust for two years of FFS risk score growth, i.e., from the denominator year of 2012 to the payment year of 2014.

The Part C normalization factor is used to normalize the following risk scores: aged/disabled community, aged/disabled institutional, aged/disabled new enrollee, and C-SNP new enrollee. The trend is calculated on the population of FFS beneficiaries.

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

2008: 0.947
2009: 0.963
2010: 0.978
2011: 0.987
2012: 1.000

The linear annual trend over these five years (2008-2012) is 0.013. This annual trend is applied for the years between the denominator year (2012) and the payment year (2014) by taking it to the second power. The normalization factor is obtained as follows: $(1.013)^2 = 1.026$.

J2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2014 normalization factor for the ESRD dialysis model is 1.039.

To calculate the normalization factor for the CMS-HCC ESRD dialysis model, CMS uses the ESRD risk adjustment model to be implemented in 2014 and calculates five years of dialysis risk scores for the FFS population. For the 2014 normalization factor, CMS used risk scores from 2008 to 2012 to calculate an annual trend. The 2014 factor will adjust for five years of risk score growth, i.e., from the denominator year of 2009 to the payment year of 2014.

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

2008: 0.994
2009: 1.000
2010: 1.006
2011: 1.013
2012: 1.027

The linear annual trend over these five years (2008-2012) is .008. This annual trend is applied for the years between the denominator year (2009) and the payment year (2014) by taking it to the fifth power. The normalization factor is obtained as follows: $1.008^5 = 1.039$.

Normalization Factor for Functioning Graft

The preliminary 2014 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is 1.085, which will adjust for risk score growth over the five years from the denominator year of 2009 to the payment year of 2014.

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

2008: 0.977
2009: 1.000
2010: 1.016
2011: 1.032
2012: 1.043

The linear annual trend over these five years (2008-2012) is 0.017. This annual trend is applied for the years between the denominator year (2009) and the payment year (2014) by taking it to the fifth power. The normalization factor is obtained as follows: $1.017^5 = 1.085$.

J3. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The preliminary 2013 normalization factor for the RxHCC model is 1.029.

To calculate the normalization factor for the RxHCC risk adjustment model, CMS used the risk adjustment model to be implemented in 2014 and calculated 5 years of risk scores for the population of Medicare beneficiaries enrolled in Part D plans. For the 2014 normalization factor, CMS used risk scores from 2007-2011 to calculate an annual trend, which was then compounded for three years, to adjust for three years of Part D risk score growth, i.e, from the denominator year of 2011 to the payment year of 2014.

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

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

2007: 0.964
2008: 0.970
2009: 0.981
2010: 0.995
2011: 1.000

The linear annual trend over these five years (2007-2011) is 0.010. This annual trend is applied for the years between the denominator year (2011) and the payment year (2014) by taking it to the third power. The normalization factor is obtained as follows: $1.010^3 = 1.029$.

Section K. Frailty Adjustment

<u>Frailty Adjustment for Programs of All Inclusive Care for the Elderly (PACE) organizations and FIDE SNPs.</u>

CMS is required by law to ensure that payments to PACE organizations reflect the frailty of the PACE population, and may 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 appropriately updated whenever the CMS-HCC model is updated. Since CMS is updating the CMS-HCC model for 2014, we have also updated the current frailty adjustment factors for 2014. Further, since we will use the same CMS-HCC model for PACE and for MA plans (including FIDE SNPs), we will use the same frailty factors to pay both PACE organizations and FIDE SNPs in 2014.

In updating the frailty factors, we again used data on limitations on Activities of Daily Living (ADLs) that were collected between February 2008 and August 2008 by the FFS Consumer Assessment of Healthcare Providers and Systems (CAHPS). CAHPS data is similar to the Health Outcomes Survey (HOS), in that they both collect ADL information via mail surveys with telephone follow-up.

MA organizations that are planning to sponsor a FIDE SNP, and that wish to receive frailty payments in 2014, will need to have contracted with a vendor to field the 2013 Health Outcomes Survey (HOS) at the PBP level if CMS is to be able to calculate a frailty score for any FIDE SNP that exists at a sub-contract level (or at the contract level, but has less than 500 enrollees). To determine whether a FIDE SNP has a similar average level of frailty as PACE, FIDE SNP frailty scores will be compared with PACE frailty in the same manner as for 2013.

Table II-1 below presents the preliminary recalibrated frailty factors for CY 2014. Due to the new model, the preliminary recalibrated frailty factors for CY 2014 for ADLs 5-6 have increased from 0.380 in CY 2013 to 0.446 in CY 2014.

Table II-1. Preliminary Recalibrated Frailty Factors for CY 2014

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

Section L. Medical Loss Ratio (MLR) Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Section 1103 Affordable Care Act amended section 1857(e) of the Social Security Act to add new medical loss ratio (MLR) requirements, beginning with CY 2014. The proposed policy to

implement MLR requirements will be published as a notice of proposed rulemaking in the Federal Register.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2014

Section A. Part D Benefit Administration and Prescription Drug Event (PDE) Reporting

CMS's goal is to establish one clear set of standards that all Part D plans can implement so that we can ensure: 1) uniform treatment of beneficiary liability across all Part D plans; 2) accurate calculation of the coverage gap discount amount, and 3) consistency of benefit administration across all phases of the benefit. In working with industry to prepare for benefit changes resulting from the Affordable Care Act of 2010 and the upcoming change to the regulatory definition of Part D supplemental benefits, we believe there is a need for additional guidance relating to:

A1. Applicable Beneficiary and Plan Dispensing/Vaccine Administration Fee Liability on
   a) Applicable Drug Claims that Straddle the Coverage Gap (applicable to all Part D plans) and
   b) Applicable Drug Coverage Gap Claims for Enhanced Alternative (EA) Plans offering Part D Supplemental Coverage in the Gap;

A2. Beneficiary and Plan Negotiated Price Cost Component Liability (applicable to all Part D plans);

A3. Other Health Insurance (OHI) including Employer Group Waiver Plans (EGWPs) (applicable to all Part D plans); and

A4. Enhanced Alternative Plan Mapping Rules.

A1. Applicable Beneficiary and Plan Dispensing/Vaccine Administration Fee Liability on: a) Applicable Drug Claims that Straddle the Coverage Gap; and b) Applicable Drug Coverage Gap Claims under EA Plans offering Part D Supplemental Coverage in the Gap.

In the 2013 Advance and Final Rate Notices, respectively, CMS proposed and adopted the policy that plans and beneficiaries will share dispensing/vaccine administration fee liability on coverage gap claims for applicable drugs. Specifically, the beneficiary liability for such fee(s) on a coverage gap claim will be determined by applying the beneficiary's coverage gap coinsurance to the dispensing fee and the plan liability will be calculated as the balance. In 2013, this means that the beneficiary will pay 47.5% of the dispensing fee and the plan will pay 52.5% on coverage gap claims without supplemental coverage in the gap.

However, in working through examples with industry to illustrate how to apply the policy to applicable drug coverage gap straddle claims and coverage gap claims under EA plans with Part D supplemental coverage in the gap, it became clear that more detailed guidance would be needed before implementing the provision. As a result, we delayed implementation of policy changes for applicable drug coverage gap straddle claims for all plan types and coverage gap claims under EA plans with Part D supplemental coverage in the gap for 2013. We now seek comments on the following potential new policies we are considering for CY2014:

a) Coverage Gap Straddle Claims

Applicable to all Part D plans

CMS is considering a policy that would always include the dispensing/vaccine administration fee within the negotiated price to the greatest extent possible. In effect, this policy would maintain the current policy that the dispensing/vaccine administration fee for any coverage gap straddle claim is included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold to the greatest extent possible. We believe this is the most beneficiary friendly approach that ensures uniform treatment of beneficiary liability across all Part D plans and the accurate calculation of the coverage gap discount amount.

The following two examples demonstrate how this proposed policy would be implemented for PDE reporting.

Example 1 – Defined Standard Benefit

When claim adjudication begins, the TGCDC Accumulator is $6,924.52 and the TrOOP Accumulator is $4,720.75. The plan offers a defined standard benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee. The dispensing fee will be placed in the catastrophic coverage phase of the benefit.

PDE Fields	Claim Total
Total Gross Covered Drug Cost Accumulator	$6,924.52
True Out of Pocket Accumulator	$4,720.75
Beginning Benefit Phase	G
Ending Benefit Phase	C
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	Drug Cost within each phase	Ingredient cost paid	Dispensing fee
Coverage Gap	$30.00	$30.00	$0.00
Catastrophic Coverage Phase	$172.00	$170.00	$2.00
Total	$202.00	$200.00	$2.00

PDE Reporting of Coverage Gap PDEs with no Part D supplemental coverage in the gap:

1. **Determine the costs that fall in the Coverage Gap:** $30.00
2. **Determine Discount Eligible Cost:** $30.00
3. **Calculate Gap Discount:** $30.00 × 50% = $15.00
4. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 × 47.5% = $14.25
5. **Calculate Covered Portion of Plan Paid Cost-sharing:** $30.00 × 2.5% = $.75

   In the catastrophic phase, Covered D Plan Paid (CPP) amount is the lesser of (1) 95% of the drug cost in the catastrophic phase or (2) the amount representing drug cost in the catastrophic phase - $6.60. In this example, the CPP is $163.40.

6. **Determine beneficiary liability for cost falling outside of the Coverage Gap:** The beneficiary pays the greater of 5% of the drug cost in the catastrophic phase or $6.60. In this example, the beneficiary pays $8.60.

	Pt. Pay Amount	Reported Gap Discount	CPP
Coverage Gap	$14.25	$15.00	$0.75
Catastrophic Coverage	$8.60	$0.00	$163.40
PDE Fields	$22.85	$15.00	$164.15

Example 2 – EA Benefit

When claim adjudication begins, the TGCDC Accumulator is $6,700.00 and the TrOOP Accumulator is $4,720.00. The plan offers an enhanced alternative benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee. There is a 30% co-insurance in the coverage gap.

PDE Fields	Claim Total
Total Gross Covered Drug Cost Accumulator	$6,700.00
True Out of Pocket Accumulator	$4,720.00
Beginning Benefit Phase	G
Ending Benefit Phase	C
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	Drug Cost within each phase	Ingredient cost paid	Dispensing fee
Coverage Gap	$100.00	$100.00	$0.00
Catastrophic Coverage Phase	$102.00	$100.00	$2.00
Total	$202.00	$200.00	$2.00

PDE Reporting of Coverage Gap PDEs for EA plans with supplemental gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $100.00
2. **Determine Plan liability:** $100.00 − $30.00 = $70.00
3. **Determine Discount Eligible Cost:** $100.00 − $70.00 = $30.00
4. **Calculate Gap Discount:** $30.00 × 50% = $15.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 − $15.00 = $15.00
6. **Determine CPP and Non-covered Plan Paid Amount (NPP):**

   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax
   2.5% × $100.00 = $2.50
   The dispensing fee is not included in the coverage gap.
   NPP in the coverage gap is $100.00 − ($15.00 + $15.00 + $2.50) = $67.50
   Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
   The CPP amount is the lesser of 95% of the drug cost in the catastrophic phase or Drug cost in the catastrophic phase - $6.60. The CPP in the catastrophic phase is $102 − $6.60 = $95.40.
   NPP in the catastrophic phase is $0.00

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:**

   In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.

8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:**

In the catastrophic phase, the beneficiary pays the greater of $6.60 or 5% of the drug cost in the catastrophic phase. In this example, the beneficiary pays $6.60.

	Pt. Pay Amount	Reported Gap Discount	CPP	NPP
Coverage Gap	$15.00	$15.00	$2.50	$67.50
Catastrophic Coverage	$6.60	$0.00	$95.40	$0.00
PDE Fields	$21.60	$15.00	$97.90	$67.50

b) Coverage Gap Claims under EA plans with Part D supplemental coverage in the gap

We are considering implementing the policy originally adopted in the Final Rate Notice for CY 2013 that specified the dispensing/vaccine administration fee liability on applicable drug coverage gap claims under EA plans with Part D supplemental coverage in the gap would be commensurate with the coinsurance percentage. For example, if the coinsurance percentage under the benefit is 25%, the beneficiary will pay 25% of the dispensing/vaccine administration fee and the plan will pay 75% of the dispensing/vaccine administration fee. The manufacturer discount would be calculated as 50% of the beneficiary coinsurance percentage as applied to the coverage gap negotiated price (as defined in 42 CFR § 423.2305).

Similarly, if the EA plan has a fixed copay, then the beneficiary liability for the dispensing/vaccine administration fee would be commensurate with the percentage of total Part D claim cost attributed to the before-discount copay. For example, if the copay under the benefit is $25 and the total Part D claim cost is $100 ($98 ingredient cost and $2 dispensing fee), then the beneficiary will pay 25% of the dispensing fee and the plan will pay 75% of the dispensing fee. The manufacturer discount would be calculated as 50% of the result (copay minus 25% of dispensing fee). Therefore, the manufacturer would pay $12.25, the beneficiary would pay $12.75 and the plan would pay $75.00.

This approach to applicable drug coverage gap claims under EA plans aligns with our shared responsibility approach on applicable drug coverage gap claims under basic benefits that is needed to correctly implement 1860D-2(b)(2)(D) of the Social Security Act. Moreover, it is consistent with the proposed proportional plan and beneficiary liability for other negotiated price cost components discussed in Section B. of Attachment III and, therefore, will help ensure uniform treatment of beneficiary liability across all Part D plans.

The following example demonstrates how this proposed policy would be implemented for PDE reporting for EA plans with supplemental coverage in the gap.

When claim adjudication begins, the TGCDC Accumulator is $3,000.00 and the TrOOP Accumulator is $1,110.00. The plan offers an enhanced alternative benefit. The claim falls in the coverage gap phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee. There is a 30% co-insurance in the coverage gap.

PDE Fields	Claim Total
Total Gross Covered Drug Cost Accumulator	$3,000.00
True Out of Pocket Accumulator	$1,100.00
Beginning Benefit Phase	G
Ending Benefit Phase	G
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

PDE Reporting of Coverage Gap PDEs for EA plans with supplemental gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $202.00
2. **Determine Plan liability:** $202.00 − $60.60 = $141.40
3. **Determine Discount Eligible Cost:** The beneficiary pays 30% of the ingredient cost and 30% of the dispensing fee within the gap. The discount eligible cost is the drug cost in the gap minus plan and beneficiary liability for the dispensing fee. In this example, the discount eligible cost is $202 − $141.40 − $0.60 = $60.00
4. **Calculate Gap Discount:** $60.00 × 50% = $30.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $60.00 − $30.00 = $30.00
6. **Determine CPP and NPP amounts:**

   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax plus 52.5% of the dispensing fee in the gap
   2.5% × $200.00 = $5.00
   52.5% × $2.00 = $1.05
   NPP is $202.00 − ($30.60 + $30.00 + $6.05) = $135.35

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:**

   The beneficiary pays 30% of the dispensing fee falling within the gap. The beneficiary liability for the dispensing fee is $0.60

	Pt. Pay Amount	Reported Gap Discount	CPP	NPP
PDE Fields	$30.60	$30.00	$6.05	$135.35

A2.Beneficiary and Plan Negotiated Price Cost Component Liability

Applicable to all Part D plans

In the Advance Notice for CY 2013, we proposed that plan and beneficiary liability for each cost component of the negotiated price be calculated proportional to plan and beneficiary liability for the entire negotiated price in all phases of the benefit. The reasons for doing so included ensuring a level playing field, uniform treatment of beneficiary liability across all Part D plans, and consistency of benefit administration across all phases of the benefit. For example, if a claim is adjusted post-point-of-sale to eliminate one price component, such as sales tax or dispensing fee, there would be one consistent basis for reimbursing the beneficiary. In light of technical challenges we did not change existing policy for CY 2013.

We again are considering a policy for CY 2014 that makes beneficiary and plan liability for each cost component of the negotiated price proportional to the beneficiary and plan liability for the entire negotiated price when the claim falls squarely in one phase of the Part D benefit. For example, if a beneficiary has a 25% coinsurance on a claim in the initial coverage phase with a $100 negotiated price that includes a $2 dispensing fee and $5 sales tax, the beneficiary would be responsible for 25% of the ingredient cost, 25% of the dispensing fee and 25% of the sales tax, and the plan would be responsible for the remainder of each cost component.

However, if a claim straddles benefit phases, we are considering adopting one of two options for determining beneficiary and plan's negotiated price cost component liability and seek comments on each option:

a) Implement the policy proposed in the Advance Notice for CY 2013 and adopted in the Final Rate Notice for CY 2013 that each cost component of the negotiated price, except for dispensing and vaccine administration fees that would be subject to the coverage gap straddle claim policy proposed in section A1(a) of Attachment III, be calculated proportional to beneficiary and plan liability for the entire negotiated price in all phases of the benefit. Under this policy, a plan could either apply programming logic that calculates the proportional liability of each cost component in each phase or alternatively calculate the proportional liability based upon the aggregate beneficiary/plan liability for the claim. Either methodology would take into account the differing proportional liability in each phase of the benefit and would ensure that plan could consistently determine individual negotiated price cost component liability when necessary. Note that this policy would not change the existing straddle claim rules described in current PDE guidance (April 26, 2007 HPMS memorandum titled, "A Q and A that addresses claims straddling co-payment benefit phases" and rules and examples provided in the 2011 PDE Participant Guide).

   The following example demonstrates how this proposed policy would be implemented for PDE reporting.

When claim adjudication begins, the TGCDC Accumulator is $6,700.00 and the TrOOP Accumulator is $4720.00. The plan offers an enhanced alternative benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee and $10.00 sales tax. There is a 30% co-insurance in the coverage gap.

PDE Fields	Claim Total
Total Gross Covered Drug Cost Accumulator	$6,700.00
True Out of Pocket Accumulator	$4720.00
Beginning Benefit Phase	G
Ending Benefit Phase	C
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	Drug Cost within each phase	Percentage of drug cost (excluding dispensing fee) within each phase	Ingredient cost paid	Dispensing fee	Sales tax
Coverage Gap	$100.00	50.00%	$95.00	$0.00	$5.00
Catastrophic Coverage Phase	$102.00	50.00%	$95.00	$2.00	$5.00
Total	$202.00	100%	$190.00	$2.00	$10.00

PDE Reporting of Coverage Gap PDEs for EA plans with supplemental gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $100.00
2. **Determine Plan liability:** $100.00 − $30.00 = $70.00
3. **Determine Discount Eligible Cost:** $100.00 − $70.00 = $30.00. The $30.00 co-insurance contains ($28.50 ingredient cost and $1.50 sales tax)
4. **Calculate Gap Discount:** $30.00 × 50% = $15.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 − $15.00 = $15.00. The beneficiary pays $14.25 in ingredient cost and $0.75 in sales tax.
6. **Determine CPP and NPP amounts:**

Determine CPP and NPP in the Coverage Gap phase:

CPP is 2.5% of the ingredient cost and sales tax
2.5% × $100.00 = $2.50

The dispensing fee is not included in the coverage gap.
NPP is $100.00 − ($15.00 + $15.00 + $2.50) = $67.50
Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
The plan amount is the lesser of 95% of the drug cost in the catastrophic phase or Drug cost in the catastrophic phase - $6.60. In this example, the CPP in the catastrophic phase is $95.40.
NPP in the catastrophic phase is $0.00

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:**

   In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.

8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:**

   In the catastrophic phase, the beneficiary pays the greater of $6.60 or 5% of the drug cost in the catastrophic phase. In this example, the beneficiary pays $6.60.

	Pt. Pay Amount	**Reported Gap Discount**	**CPP**	**NPP**
Coverage Gap	$15.00	$15.00	$2.50	$67.50
Catastrophic Coverage Phase	$6.60	$0.00	$95.40	$0.00
PDE Fields	$21.60	$15.00	$97.90	$67.50

b) Implement a new policy that each negotiated price cost component must be included entirely in one phase of the benefit to the greatest extent possible. For the dispensing fee, this phase would always be below the ICL or above the annual out-of-pocket threshold to the greatest extent possible. For all other cost components, this phase would be the first phase in which the cost component would be less than the amount remaining in the phase. While this approach does not provide for claim-level proportionate liability for each cost component, it does provide a level playing field, uniform treatment across all Part D plans, and consistency of benefit administration across all phases of the benefit without changing the existing straddle claim rules described in current PDE guidance (April 26, 2007 HPMS memorandum titled, "A Q and A that addresses claims straddling co-payment benefit phases" and rules and examples provided in the 2011 PDE Participant Guide). We believe either approach would resolve the issue of inconsistent treatment of negotiated price cost component liability across Part D plans when it arises, for example, in the context of beneficiary reimbursement. However, initial feedback CMS received on these two approaches was more supportive of option a) because option b): 1) only works when the cost components other than dispensing fee are less than the threshold dollar amount remaining in the phase whereas option a) has no such limitation, and 2) is more confusing and consequently increases the likelihood of implementation errors. We are interested in receiving additional comments in support of or against each specific proposal.

The following example demonstrates how this proposed policy would be implemented for PDE reporting.

When claim adjudication begins, the TGCDC Accumulator is $6,700.00 and the TrOOP Accumulator is $4720.00. The plan offers an enhanced alternative benefit. The claim begins in the coverage gap and ends in the catastrophic coverage phase. The beneficiary purchases a brand drug that cost $202.00, which includes a $2.00 dispensing fee and $10.00 sales tax. There is a 30% co-insurance in the coverage gap.

PDE Fields	**Claim Total**
Total Gross Covered Drug Cost Accumulator	$6,700.00
True Out of Pocket Accumulator	$4720.00
Beginning Benefit Phase	G
Ending Benefit Phase	C
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

Distribution of Drug Cost across benefit phases

Benefit Phase	**Drug Cost within each phase**	**Ingredient cost paid**	Dispensing fee	**Sales tax**
Coverage Gap	$100.00	$90.00	$0.00	$10.00
Catastrophic Coverage Phase	$102.00	$100.00	$2.00	$0.00
Total	$202.00	$190.00	$2.00	$10.00

PDE Reporting of Coverage Gap PDEs for EA plans with supplemental gap coverage:

1. **Determine the costs that fall in the Coverage Gap:** $100.00
2. **Determine Plan liability:** $100.00 − $30.00 = $70.00
3. **Determine Discount Eligible Cost:** $100.00 − $70.00 = $30.00. The $30.00 co-insurance contains $27.00 in ingredient cost and $3.00 in sales tax
4. **Calculate Gap Discount:** $30.00 × 50% = $15.00
5. **Determine Beneficiary cost-sharing in the Coverage Gap:** $30.00 − $15.00 = $15.00 The beneficiary pays $13.50 in ingredient cost and $1.50 in sales tax.
6. **Determine CPP and NPP amounts:**

   Determine CPP and NPP in the Coverage Gap phase:
   CPP is 2.5% of the ingredient cost and sales tax

2.5% × $100.00 = $2.50
The dispensing fee is not included in the coverage gap.
NPP is $100.00 − ($15.00 + $15.00 + $2.50) = $67.50
Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
The plan amount is the lesser of 95% of the drug cost in the catastrophic phase or Drug cost in the catastrophic phase - $6.60. In this example, the CPP in the catastrophic phase is $95.40.
NPP in the catastrophic phase is $0.00

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:**

   In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.

8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:**

   In the catastrophic phase, the beneficiary pays the greater of $6.60 or 5% of the drug cost in the catastrophic phase. In this example, the beneficiary pays $6.60.

	Pt. Pay Amount	**Reported Gap Discount**	**CPP**	**NPP**
Coverage Gap	$15.00	$15.00	$2.50	$67.50
Catastrophic Coverage Phase	$6.60	$0.00	$95.40	$0.00
PDE Fields	$21.60	$15.00	$97.90	$67.50

A3. Other Health Insurance (OHI) including Employer Group Waiver Plans (EGWPs)

Applicable to all Part D plans

EGWPs currently provide additional coverage as either 1) Medicare Part D supplemental benefits, reported on PDEs as Non Covered Plan Paid Amount (NPP) or 2) Non-Medicare OHI, reported on PDEs as patient liability reduced by other payer (PLRO). Beginning in 2014, all additional coverage provided by EGWPs will be considered OHI and reported as PLRO.

It is our understanding that there are two PDE reporting methods currently being used by Part D sponsors when OHI results in beneficiary cost-sharing that is greater than it would be under the Part D plan benefit. Under one method, sponsors cap the patient pay amount, low-income cost-sharing subsidy (LICS) amount, and TrOOP amount based upon their Part D plan benefit and report PLRO as zero. In other words, OHI is not reported on the PDE when it increases beneficiary cost-sharing above the Part D plan benefit.

Under the second method, if the OHI increases the amount the patient pays at the pharmacy then the Patient Pay Amount on the PDE reflects what the patient pays at POS and PLRO is negative. For example, the beneficiary purchases a $100.00 drug in the intial coverage phase. Under the OHI, the beneficiary pays $30.00. In the defined standard benefit, the beneficiary would pay $25.00 and the plan would pay $75.00. The PLRO is determined by subtracting $30.00 from $25.00, which is -$5.00. The Patient Pay Amount on the PDE would be $30.00.

If the beneficiary is LICS then the Part D sponsor applies the LICS formula rules, which are published in our technical assistance training guide. With this method, LICS is calculated and capped based upon the Part D plan benefit and patient pay is adjusted based upon the OHI. PLRO is still determined using the same formula in which the OHI patient pay is subtracted from the original patient pay amount. The PLRO amount is negative and the patient pay amount is adjusted based upon the OHI. For EGWPs providing additional coverage as OHI, LICS is capped based upon the defined standard benefit. If the patient pay amount under the OHI is greater than the Part D plan benefit, PLRO is negative and the patient pay is updated to reflect the patient pay amount under OHI. For example, a low income beneficiary purchases a brand drug in the initial coverage phase. The low income beneficiary is a category two low income beneficiary in which the co-pay for a brand drug is $3.50. The cost of the drug is $100.00. In the initial coverage phase, a non-low income beneficiary would pay $25.00 for this drug.

The LICS amount is the difference between the non-low income beneficiary amount ($25.00) and the category two co-pay amount ($3.50), which is $21.50. The beneficiary has OHI in which the co-pay is $40.00. To determine PLRO, the OHI patient pay amount ($40.00) is subtracted from the original patient pay amount ($3.50). The PLRO amount is −$36.50.

Beginning in 2014, we are considering requiring all Part D sponsors, including EGWP sponsors, use only the second method and apply LICS formula rules. We believe the PDE should reflect actual point-of-sale incurred costs, and we need to know whether EGWP sponsors are providing creditable coverage and to what extent secondary payers are diminishing the value of the Part D benefit. We seek comments to identify questions and issues with implementing this policy.

A4.Enhanced Alternative Plan Mapping Rule 4

Currently, under EA Mapping Rule 4, if the YTD Gross Covered Drug cost is greater than the estimated total covered Part D spending at the Out-of-Pocket threshold but True Out-of-Pocket (TrOOP) cost is less than or equal to the Out-of-Pocket (OOP) threshold, the Part D plan maps 15% of the ingredient cost, sales tax, and any fees falling within this rule (dispensing fee or vaccine administration fee) to covered plan paid amount (CPP).

As a result of the Affordable Care Act changes to the Defined Standard Benefit that began closing the coverage gap for non-applicable drugs in 2011 and begins closing the coverage gap for applicable drugs in 2013, CMS has been asked if EA Mapping Rule 4 will change. After considering these questions and reconsidering the justification for Mapping Rule 4 in light of the

coverage gap changes, CMS is considering eliminating EA Mapping Rule 4 beginning in 2014. We believe that EA sponsors are already being paid for the additional 15% through supplemental beneficiary premiums and question why we should continue to credit this amount as CPP. Consequently, EA plans would always use EA Mapping Rule 3 to map to the basic Part D benefit when a beneficiary has drug spend above the initial coverage limit but TrOOP is less than or equal to the OOP threshold. We seek comment on this potential policy change, including any justification for maintaining EA Mapping Rule 4.

Section B. Update of the Rx-HCC Model

For 2014, CMS has recalibrated the RxHCC risk adjustment model using diagnosis data from 2010 FFS claims and 2011 expenditure data from Prescription Drug Event (PDE) data. The updated model reflects the 2014 benefit structure.

To be included in the model estimation sample, beneficiaries must be (1) fee-for-service beneficiaries who are both entitled to Part A and enrolled in Part B in the base year (2010), and (2) entitled to Part D and enrolled in a PDP for at least one month in the prediction year (2011).

Prior to recalibrating the RxHCC model, CMS made adjustments to the 2011 PDE data to approximate the 2014 benefit structure. The adjustments to the PDE data are similar to those made for the 2013 RxHCC model in that we incorporated the payment year plan liability in the gap. For 2014, plan liability for non-LIS beneficiaries in the gap will be 28% for non-applicable (generic) drugs and 2.5% plan liability for applicable (brand) drugs in the coverage gap. In addition, we made assurances that all PDEs were mapped to the defined standard benefit across all phases of the Part D benefit. All other things being equal, the impact of increased plan liability as a result of the cost sharing reduction for non-applicable drugs and applicable drugs will result in differential risk score changes for LIS and non-LIS beneficiaries. This is because plan liability for non-LIS populations, relative to LIS populations, will increase.

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 status, disability status).

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

We created relative factors by dividing all the dollar coefficients by the average per capita predicted expenditure for a specific year. The denominator for the revised RxHCC risk adjustment model was developed using data from Medicare beneficiaries enrolled in both MAPDs and PDPs. We do this in order to set the average RxHCC risk score to 1.0 for the

enrolled population. We used a denominator of average per capita costs for 2011 to create the relative factors for the model. The denominator, which is used to create relative factors for all segments of the model, is $1,182.35.

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 aged-disabled model.

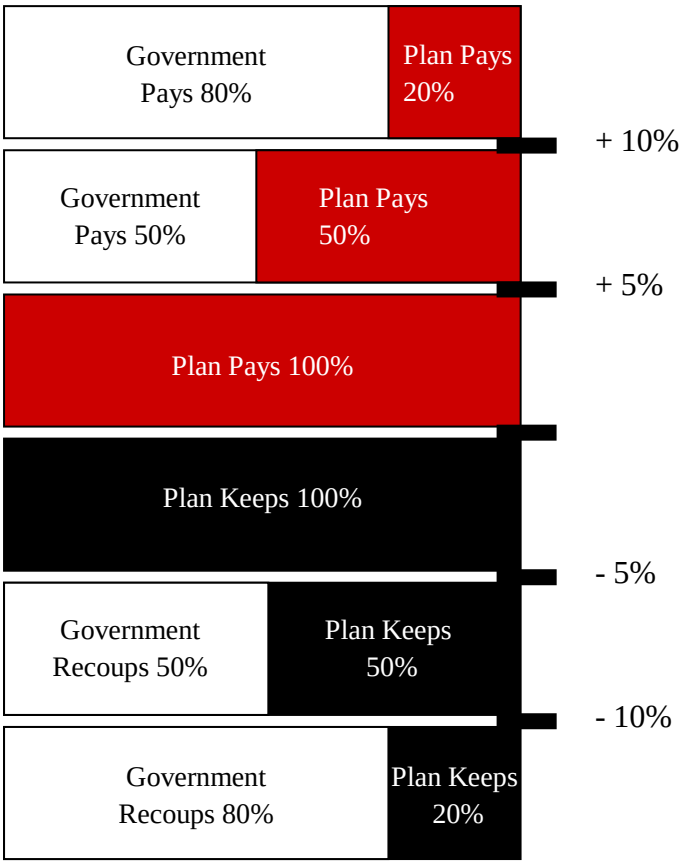
Section C. Payment Reconciliation

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

CMS has evaluated the risk sharing amounts provided by CMS for 2007 – 2011 to assess whether they have decreased or stabilized. A steady decline or stabilization in the Part D risk sharing amounts would suggest that Part D sponsors have significantly improved in their ability to predict Part D expenditures. However, CMS has found that risk sharing amounts continue to vary significantly for Part D sponsors. In addition, the aggregate risk sharing amount paid by CMS varies significantly from year to year. Therefore, CMS will apply no changes to the current risk percentages for contract year 2014. We will continue to evaluate the risk sharing amounts each year to determine if higher risk percentages should be applied for Part D risk sharing.

Thus, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2013. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2014. The payment adjustments for the first and second corridors are 50% and 80%, respectively. Please see Figure 1 below which illustrates the risk corridors for 2014.

Figure 1. Part D Risk Corridors for 2014



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% of the target amount), the Part D sponsor pays 100% 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% of the target amount), the government pays 50% and the plan pays 50%. For the portion of the plan's AARCC that exceeds the second threshold upper limit, the government pays 80% and the plan pays 20%.

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% of the target amount), the plan keeps 100% 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% of the target amount), the government recoups 50% of the difference between the first threshold lower limit and the plan's AARCC. The plan would keep 50% of the difference between the first threshold lower limit and the plan's AARCC as well as 100% 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% of the difference between the plan's AARCC and the second threshold lower limit as well as 50% of the difference between the first and second threshold lower limits. In this case, the plan would keep 20% of the difference between the plan's AARCC and the second threshold lower limit, 50% of the difference between the first and second threshold lower limits, and 100% of the difference between the target amount and the first threshold lower limit.

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2014

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit (ICL), annual out-of-pocket (OOP) threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries.

Accordingly, the actuarial value of the drug benefit reflects the changes in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. The Part D benefit parameters are updated using two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

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

i. the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit;
ii. minimum copayments for costs above the annual out-of-pocket threshold;
iii. maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
iv. the deductible for partial low-income subsidy (LIS) eligible enrollees; and
v. maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

<u>Updates to Part D Benefit Parameters</u>

The benefit parameters listed above will be updated by −4.03% for 2014 as summarized by Table III-1 below. This update reflects the 2013 annual percentage trend of −2.76% as well as a multiplicative update of -1.31% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be updated by −4.03% from their 2013 values.

Updates to Co-Payments for Certain Full Benefit Dual Eligible Individuals

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 1.96% for 2014 as summarized in Table III-1 below.

This increase reflects the 2013 annual percentage trend in CPI of 1.80%, as well as a multiplicative update of 0.16% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase in the CPI.

Determining Total Covered Part D Spending at Out-of-Pocket Threshold

Each year, CMS releases the Total Covered Part D Spending at the Out-of-Pocket Threshold, which is the amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit. Due to reductions in beneficiary cost sharing for drugs in the coverage gap phase for applicable (that is non-LIS) beneficiaries per section 1860D-2, the total covered Part D spending may be different for applicable and non-applicable (that is 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 (that is LIS) beneficiary to attain the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement, this amount may be higher. This amount is calculated based on 100% cost sharing in the deductible and coverage gap phases and 25% in the initial coverage phase.

- 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 (that is non-LIS) beneficiary to attain the out-of-pocket threshold in the defined standard benefit. If the beneficiary has additional prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement, this amount may be higher. This amount is estimated based on 100% beneficiary cost sharing in the deductible phase, 25% in the initial coverage phase, and in the coverage gap, 72% for non-applicable (generic) drugs and 97.5% for

applicable (brand) drugs. Please see Attachment IV for additional information on the calculation of the estimated total covered Part D spending for applicable beneficiaries.

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

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

Annual Percentage Increases

	Annual percentage trend for 2013	Prior year revisions	Annual percentage increase for 2013
Applied to all parameters but (1)	−2.76%	−1.31%	−4.03%
CPI (all items, U.S. city average): Applied to (1)	1.80%	0.16%	1.96%

Part D Benefit Parameters

	2013	2014
Standard Benefit		
Deductible	$325	$310
Initial Coverage Limit	$2,970	$2,850
Out-of-Pocket Threshold	$4,750	$4,550
Total Covered Part D Spend at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,733.75	$6,455.00
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,938.69	$6,690.77
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) [category code 3]	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (2)	$1.10	$1.20
Other (2)	$3.50	$3.60
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $8,580 (individuals) or ≤ $13,620 (couples) (6)[category code 1]		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,300 (individual) or $26,580 (couples)(6)(category code 4)		
Deductible	$66.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Retiree Drug Subsidy Amounts		
Cost Threshold	$325	$310
Cost Limit	$6,600	$6,350

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) For beneficiaries who are not considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are not eligible for the coverage gap program, this is the amount of total drug spending required to reach the out-of-pocket threshold in

the defined standard benefit. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.
(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are eligible for the coverage gap discount program, this is the estimated average amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.
(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (couple) was not receiving home and community-based services qualify for zero cost-sharing as of January 1, 2013, as specified by the Secretary.
(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2013 values of $66.14, $1.16, and $3.49, respectively.
(6) The actual amount of resources allowable will be updated for contract year 2014.

Section E. Medical Loss Ratio (MLR) Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Section 1103 Affordable Care Act amended section 1857(e) of the Social Security Act to add new medical loss ratio (MLR) requirements, beginning with CY 2014. Because section 1860D-12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e), these MLR requirements also apply to the Part D program. The proposed policy to implement MLR requirements will be published as a notice of proposed rulemaking in the Federal Register.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2014

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2014, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

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

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

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

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

Deductible: From $325 in 2013 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,970 in 2013 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,750 in 2013 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2013, and rounded to the nearest multiple of $0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2013, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $66[2] in 2013 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.65 per generic or preferred drug that is a multi-source drug, and $6.60 for all other drugs in 2013, and rounded to the nearest multiple of $0.05.

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

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.15 per generic or preferred drug that is a multi-source drug, and $3.50 for all other drugs in 2013[3], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

Section C. Calculation Methodology

Annual Percentage Increase

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

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2013 value of $66.14.

[3] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2013 values of $1.16 per generic or preferred drug that is a multi-source drug, and $3.49 for all other drugs.

program data. For the 2014 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August2012 - July2013}{August2011 - July2012} = \frac{\$2{,}807.26}{\$2{,}887.05} = 0.9724$$

In the formula, the average per capita cost for August 2011 – July 2012 ($2,887.05) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2012 – July 2013 ($2,807.26) is calculated based on actual Part D PDE data incurred from August – December, 2012 and projected through July, 2013.

The 2014 benefit parameters reflect the 2013 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table IV-1.

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

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	7.31%	7.30%
2008	5.97%	5.92%
2009	4.25%	4.25%
2010	3.08%	3.09%
2011	2.44%	2.45%
2012	2.27%	2.46%
2013	3.31%	1.83%

Accordingly, the 2014 benefit parameters reflect a multiplicative update of -1.31% for prior year revisions. In summary, the 2014 parameters outlined in Section A are updated by -4.03% for 2014 as summarized by Table IV-2.

Table IV-2. Annual Percentage Increase

Annual percentage trend for July 2013	−2.76%
Prior year revisions	−1.31%
Annual percentage increase for 2014	−4.03%

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

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

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2014, the September 2013 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2013 CPI based on the projected amount included in the President's FY2014 Budget.

The September 2012 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2014 is calculated as follows:

$$\frac{\text{Projected September 2013 CPI}}{\text{Actual September 2012 CPI}} \; or \; \frac{235.567}{231.410} = 1.0180$$

(Source: President's FY2014 Budget and Bureau of Labor Statistics, Department of Labor)

The 2014 benefit parameters reflect the 2013 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2012 annual percentage increase. The 2013 parameter update reflected an annual percentage trend in CPI of 1.83%. Based on the actual reported CPI for September 2012, the September 2012 CPI increase is now estimated to be 2.00%. Thus, the 2014 update reflects a multiplicative 0.16% correction for prior year revisions. In summary, the cost sharing items outlined in Section B are updated by 1.96% for 2014 as summarized by Table IV-3.

Table IV-3. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2013	1.80%
Prior year revisions	0.16%
Annual percentage increase for 2013	1.96%

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

For 2014, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $6,690.77. It is calculated as the ICL plus 100% beneficiary cost sharing divided by the weighted gap coinsurance factor. The factor is calculated assuming 100% cost sharing in the deductible phase, 25% in the initial coverage phase and in the coverage gap, 72% for non-applicable (generic) drugs and 97.5% for applicable (brand) drugs. In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.26% of the gross covered brand

drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 52.5% reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.13% to 97.37% 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:

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad \textit{or} \quad \$2{,}850 + \frac{\$3{,}605.00}{93.861\%} = \$6{,}690.77$$

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

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

OOP threshold – OOP costs up to the ICL *or* $4,550 − $945.00 = $3,605.00

Weighted gap coinsurance factor is calculated as follows:

(Brand GDCB % for non-LIS × 97.37% cost sharing for applicable drugs) + (Generic GDBC % for non-LIS × 72% cost sharing for non-applicable drugs)

or

(86.2% × 97.37%) + (13.2% × 72%) = 93.861%

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to applicable (brand) drugs as reported on the 2012 PDEs.

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

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

  or

  97.37% = [(99.74% × 97.5%) + (0.26% × 47.5%)]

- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to non-applicable (generic) drugs as reported on the 2012 PDEs.

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

Section E. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $320 and $6,500, respectively, for plans that end in 2012, and as $325 and $6,600, respectively, for plans that end in 2013. For 2014, the cost threshold is $310, and the cost limit is $6,350.

Attachment V. Preliminary CMS-HCC and Rx-HCC Risk Adjustment Factors

Table 1. Preliminary CMS-HCC Model Community and Institutional Relative Factors for the CMS-HCC Risk Adjustment Model 55
Table 2. Preliminary CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees 60
Table 3. Preliminary CMS-HCC Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs) 61
Table 4. Preliminary Disease Hierarchies for the CMS-HCC Model 62
Table 5. Comparison of Current and Revised CMS-HCC Risk Adjustment Model HCCs 63
Table 6. Preliminary CMS RxHCC Model Relative Factors for Continuing Enrollees 70
Table 7. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Non-Low Income 74
Table 8. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Low Income 75
Table 9. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Institutional 76
Table 10. Preliminary List of Disease Hierarchies for the Revised CMS RxHCC Model 77

Table 1. Preliminary CMS-HCC Model Community and Institutional Relative Factors for the CMS-HCC Risk Adjustment Model

Variable		Community	Institutional
Female			
0-34 Years		0.201	1.198
35-44 Years		0.211	0.973
45-54 Years		0.270	0.938
55-59 Years		0.334	1.005
60-64 Years		0.402	1.010
65-69 Years		0.295	1.268
70-74 Years		0.357	1.174
75-79 Years		0.448	1.059
80-84 Years		0.553	0.945
85-89 Years		0.694	0.857
90-94 Years		0.835	0.723
95 Years or Over		0.861	0.546
Male			
0-34 Years		0.124	1.191
35-44 Years		0.127	0.916
45-54 Years		0.186	0.933
55-59 Years		0.275	0.975
60-64 Years		0.319	1.108
65-69 Years		0.295	1.423
70-74 Years		0.365	1.467
75-79 Years		0.454	1.426
80-84 Years		0.557	1.360
85-89 Years		0.700	1.283
90-94 Years		0.869	1.102
95 Years or Over		1.054	0.972
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.155	0.069
Medicaid_Female_Disabled		0.087	0.069
Medicaid_Male_Aged		0.181	0.069
Medicaid_Male_Disabled		0.088	0.069
Originally Disabled_Female		0.245	0.014
Originally Disabled_Male		0.167	0.014
Disease Coefficients	**Description Label**		
HCC1	HIV/AIDS	0.482	1.951
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.548	0.589
HCC6	Opportunistic Infections	0.451	0.353
HCC8	Metastatic Cancer and Acute Leukemia	2.546	1.233
HCC9	Lung and Other Severe Cancers	0.997	0.691
HCC10	Lymphoma and Other Cancers	0.689	0.422
HCC11	Colorectal, Bladder, and Other Cancers	0.325	0.303
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.158	0.203
HCC17	Diabetes with Acute Complications	0.378	0.486

Variable		Community	Institutional
HCC18	Diabetes with Chronic Complications	0.378	0.486
HCC19	Diabetes without Complication	0.121	0.186
HCC21	Protein-Calorie Malnutrition	0.731	0.409
HCC22	Morbid Obesity	0.374	0.594
HCC23	Other Significant Endocrine and Metabolic Disorders	0.251	0.289
HCC27	End-Stage Liver Disease	0.947	1.110
HCC28	Cirrhosis of Liver	0.409	0.359
HCC29	Chronic Hepatitis	0.257	0.359
HCC33	Intestinal Obstruction/Perforation	0.318	0.394
HCC34	Chronic Pancreatitis	0.293	0.098
HCC35	Inflammatory Bowel Disease	0.310	0.326
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.510	0.349
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.383	0.360
HCC46	Severe Hematological Disorders	1.165	0.814
HCC47	Disorders of Immunity	0.534	0.532
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258	0.168
HCC54	Drug/Alcohol Psychosis	0.431	0.055
HCC55	Drug/Alcohol Dependence	0.431	0.055
HCC57	Schizophrenia	0.503	0.319
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.339	0.319
HCC70	Quadriplegia	1.265	0.667
HCC71	Paraplegia	1.078	0.552
HCC72	Spinal Cord Disorders/Injuries	0.522	0.287
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.982	0.376
HCC74	Cerebral Palsy	0.046	-
HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	0.418	0.308
HCC76	Muscular Dystrophy	0.579	0.220
HCC77	Multiple Sclerosis	0.570	-
HCC78	Parkinson's and Huntington's Diseases	0.708	0.178
HCC79	Seizure Disorders and Convulsions	0.291	0.147
HCC80	Coma, Brain Compression/Anoxic Damage	0.585	0.106
HCC82	Respirator Dependence/Tracheostomy Status	1.558	1.814
HCC83	Respiratory Arrest	0.822	1.198
HCC84	Cardio-Respiratory Failure and Shock	0.338	0.453
HCC85	Congestive Heart Failure	0.377	0.235
HCC86	Acute Myocardial Infarction	0.282	0.528
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.264	0.528
HCC88	Angina Pectoris	0.145	0.485
HCC96	Specified Heart Arrhythmias	0.302	0.269
HCC99	Cerebral Hemorrhage	0.347	0.221

Variable		Community	Institutional
HCC100	Ischemic or Unspecified Stroke	0.325	0.221
HCC103	Hemiplegia/Hemiparesis	0.596	0.062
HCC104	Monoplegia, Other Paralytic Syndromes	0.406	0.062
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.449	0.908
HCC107	Vascular Disease with Complications	0.420	0.308
HCC108	Vascular Disease	0.306	0.110
HCC110	Cystic Fibrosis	0.427	0.373
HCC111	Chronic Obstructive Pulmonary Disease	0.355	0.373
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.281	0.266
HCC114	Aspiration and Specified Bacterial Pneumonias	0.689	0.292
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.205	0.292
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.208	0.443
HCC124	Exudative Macular Degeneration	0.343	0.171
HCC134	Dialysis Status	0.488	0.521
HCC135	Acute Renal Failure	0.488	0.521
HCC136	Chronic Kidney Disease (Stage 5)	0.230	0.521
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.230	0.302
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.551	1.076
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.371	0.446
HCC161	Chronic Ulcer of Skin, Except Pressure	0.549	0.318
HCC162	Severe Skin Burn or Condition	0.422	0.336
HCC166	Severe Head Injury	0.585	0.106
HCC167	Major Head Injury	0.167	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.509	0.233
HCC170	Hip Fracture/Dislocation	0.458	-
HCC173	Traumatic Amputations and Complications	0.272	0.125
HCC176	Complications of Specified Implanted Device or Graft	0.580	0.535
HCC186	Major Organ Transplant or Replacement Status	0.913	0.528
HCC188	Artificial Openings for Feeding or Elimination	0.667	0.609
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.798	0.480
Disease Interactions			
CANCER_IMMUNE	Cancer*Immune Disorders	0.971	-
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.265	0.226
CHF_RENAL	Congestive Heart Failure*Renal Disease	0.325	-
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.467	0.518
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.187	0.194
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.219	-

Variable		Community	Institutional
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	-	0.289
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	-	0.507
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	-	0.327
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	-	0.217
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	-	0.399
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	-	0.463
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	-	0.567
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	-	0.347
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer		0.536
Disabled/Disease Interactions			
DISABLED_HCC6	Disabled, Opportunistic Infections	0.462	-
DISABLED_HCC34	Disabled, Chronic Pancreatitis	0.562	-
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	-	0.393
DISABLED_HCC46	Disabled, Severe Hematological Disorders	1.381	-
DISABLED_HCC54	Disabled, Drug/Alcohol Psychosis	0.339	-
DISABLED_HCC55	Disabled, Drug/Alcohol Dependence	-	-
DISABLED_HCC77	Disabled, Multiple Sclerosis	-	0.417
DISABLED_HCC85	Disabled, Congestive Heart Failure	-	0.452
DISABLED_HCC110	Disabled, Cystic Fibrosis	2.476	-
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	-	0.441
DISABLED_HCC176	Disabled, Complications of Specified Implanted Device or Graft	0.516	-
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer	-	0.277

Notes:

1. The denominator is $9050.01.
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Opportunistic Infections = HCC 6.
   Cancer = HCCs 8-12.
   Diabetes = HCCs 17, 18, 19.
   Bone/Joint/Muscle Infections/Necrosis = HCC 39.
   Immune Disorders = HCC 47.
   Schizophrenia = HCC 57.
   Multiple Sclerosis = HCC 77.
   Seizure Disorders and Convulsions = HCC 79.
   Cardiorespiratory Failure = HCCs 82-84.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Aspiration and Specified Bacterial Pneumonias = HCC 114.
   Renal Disease = HCCs 134-137.
   Pressure Ulcer = HCCs 157-158. HCCs 159-160 are no longer included in the pressure ulcer interaction terms.
   Chronic Ulcer of Skin, except Pressure = HCC 161.
   Artificial Openings for Feeding or Elimination = HCC 188.

Sources:

RTI International analysis of 2010-2011 Medicare 100% data and RTI International analysis of 2010-2011 Medicare 100% institutional sample.

Table 2. Preliminary 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	0.694	0.935	-	-
35-44 Years	0.848	1.119	-	-
45-54 Years	0.931	1.284	-	-
55-59 Years	0.995	1.356	-	-
60-64 Years	1.151	1.470	-	-
65 Years	0.523	1.057	1.198	1.529
66 Years	0.516	1.005	1.259	1.683
67 Years	0.549	1.005	1.259	1.683
68 Years	0.584	1.005	1.259	1.683
69 Years	0.643	1.005	1.259	2.171
70-74 Years	0.690	1.009	1.259	2.171
75-79 Years	0.879	1.188	1.259	2.171
80-84 Years	0.997	1.469	1.259	2.171
85-89 Years	1.268	1.657	1.259	2.171
90-94 Years	1.268	1.657	1.259	2.171
95 Years or Over	1.268	1.657	1.259	2.171
Male				
0-34 Years	0.432	0.792	-	-
35-44 Years	0.625	1.049	-	-
45-54 Years	0.816	1.321	-	-
55-59 Years	0.866	1.503	-	-
60-64 Years	0.906	1.574	-	-
65 Years	0.527	1.192	0.895	1.641
66 Years	0.535	1.084	0.957	1.641
67 Years	0.595	1.238	0.957	2.218
68 Years	0.663	1.238	1.275	2.218
69 Years	0.696	1.238	1.275	2.218
70-74 Years	0.803	1.238	1.275	2.218
75-79 Years	1.062	1.423	1.275	2.218
80-84 Years	1.336	1.787	1.275	2.218
85-89 Years	1.545	1.938	1.275	2.218
90-94 Years	1.545	1.938	1.275	2.218
95 Years or Over	1.545	1.938	1.275	2.218

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 denominator is $9050.01.

Table 3. Preliminary 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	1.343	1.523	-	-
35-44 Years	1.343	1.523	-	-
45-54 Years	1.504	1.902	-	-
55-59 Years	1.594	2.027	-	-
60-64 Years	1.697	2.100	-	-
65 Years	0.998	1.626	1.793	2.249
66 Years	0.998	1.626	1.793	2.249
67 Years	1.078	1.669	1.788	2.272
68 Years	1.078	1.669	1.788	2.272
69 Years	1.078	1.669	1.788	2.272
70-74 Years	1.267	1.821	1.987	2.509
75-79 Years	1.503	2.024	2.102	2.631
80-84 Years	1.709	2.218	2.393	2.804
85-89 Years	1.943	2.467	2.393	2.804
90-94 Years	1.943	2.467	2.393	2.804
95 Years or Over	1.943	2.467	2.393	2.804
Male				
0-34 Years	1.389	1.396	-	-
35-44 Years	1.389	1.396	-	-
45-54 Years	1.475	1.841	-	-
55-59 Years	1.602	2.037	-	-
60-64 Years	1.641	2.048	-	-
65 Years	1.022	1.717	1.716	2.251
66 Years	1.022	1.717	1.716	2.251
67 Years	1.086	1.774	1.774	2.331
68 Years	1.086	1.774	1.774	2.331
69 Years	1.086	1.774	1.774	2.331
70-74 Years	1.309	2.002	1.944	2.486
75-79 Years	1.534	2.094	2.064	2.707
80-84 Years	1.796	2.328	2.318	2.708
85-89 Years	2.067	2.590	2.318	2.708
90-94 Years	2.067	2.590	2.318	2.708
95 Years or Over	2.067	2.590	2.318	2.708

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 2010-2011 Medicare C-SNP community continuing enrollees.

Table 4. Preliminary Disease Hierarchies for the CMS-HCC Model

Hierarchical Condition Category (HCC)	If the HCC Label is listed in this column…	…Then drop the HCC(s) listed in this column
	Hierarchical Condition Category (HCC) Label	
8	Metastatic Cancer and Acute Leukemia	9,10,11,12
9	Lung and Other Severe Cancers	10,11,12
10	Lymphoma 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 HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 135 rather than HCC 136.

Table 5. Comparison of Current and Revised CMS-HCC Risk Adjustment Model HCCs

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
HCC	**Description**	**HCC**	**Description**	**HCC**	**Description**	**Category Short Name**
HCC1	HIV/AIDS	HCC1	HIV/AIDS	HCC1	HIV/AIDS	Infection
HCC2	Septicemia/Shock	HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	
HCC5	Opportunistic Infections	HCC6	Opportunistic Infections	HCC6	Opportunistic Infections	
HCC7	Metastatic Cancer and Acute Leukemia	HCC8	Metastatic Cancer and Acute Leukemia	HCC8	Metastatic Cancer and Acute Leukemia	Neoplasm
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	HCC9	Lung and Other Severe Cancers	HCC9	Lung and Other Severe Cancers	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	HCC10	Lymphoma and Other Cancers	HCC10	Lymphoma and Other Cancers	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	HCC11	Colorectal, Bladder, and Other Cancers	HCC11	Colorectal, Bladder, and Other Cancers	
		HCC12	Breast, Prostate, and Other Cancers and Tumors	HCC12	Breast, Prostate, and Other Cancers and Tumors	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	HCC17	Diabetes with Acute Complications	HCC17	Diabetes with Acute Complications	Diabetes
HCC16	Diabetes with Neurologic or Other Specified Manifestation	HCC18	Diabetes with Chronic Complications	HCC18	Diabetes with Chronic Complications	
HCC17	Diabetes with Acute Complications	HCC19	Diabetes without Complication	HCC19	Diabetes without Complication	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation					
HCC19	Diabetes without Complication					
HCC21	Protein-Calorie Malnutrition	HCC21	Protein-Calorie Malnutrition	HCC21	Protein-Calorie Malnutrition	Metabolic
		HCC22	Morbid Obesity	HCC22	Morbid Obesity	
		HCC23	Other Significant Endocrine and Metabolic Disorders	HCC23	Other Significant Endocrine and Metabolic Disorders	
HCC25	End-Stage Liver Disease	HCC27	End-Stage Liver Disease	HCC27	End-Stage Liver Disease	Liver
HCC26	Cirrhosis of Liver	HCC28	Cirrhosis of Liver	HCC28	Cirrhosis of Liver	
HCC27	Chronic Hepatitis	HCC29	Chronic Hepatitis	HCC29	Chronic Hepatitis	
HCC31	Intestinal Obstruction/Perforation	HCC33	Intestinal Obstruction/Perforation	HCC33	Intestinal Obstruction/Perforation	Gastrointestinal
HCC32	Pancreatic Disease	HCC34	Chronic Pancreatitis	HCC34	Chronic Pancreatitis	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
HCC33	Inflammatory Bowel Disease	HCC35	Inflammatory Bowel Disease	HCC35	Inflammatory Bowel Disease	
HCC37	Bone/Joint/Muscle Infections/Necrosis	HCC39	Bone/Joint/Muscle Infections/Necrosis	HCC39	Bone/Joint/Muscle Infections/Necrosis	Musculoskeletal
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	
HCC44	Severe Hematological Disorders	HCC46	Severe Hematological Disorders	HCC46	Severe Hematological Disorders	Blood
HCC45	Disorders of Immunity	HCC47	Disorders of Immunity	HCC47	Disorders of Immunity	
		HCC48	Coagulation Defects and Other Specified Hematological Disorders	HCC48	Coagulation Defects and Other Specified Hematological Disorders	
HCC51	Drug/Alcohol Psychosis	HCC54	Drug/Alcohol Psychosis	HCC54	Drug/Alcohol Psychosis	Substance Abuse
HCC52	Drug/Alcohol Dependence	HCC55	Drug/Alcohol Dependence	HCC55	Drug/Alcohol Dependence	
HCC54	Schizophrenia	HCC57	Schizophrenia	HCC57	Schizophrenia	Psychiatric
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	HCC58	Major Depressive, Bipolar, and Paranoid Disorders	HCC58	Major Depressive, Bipolar, and Paranoid Disorders	
HCC67	Quadriplegia, Other Extensive Paralysis	HCC70	Quadriplegia	HCC70	Quadriplegia	Spinal
HCC68	Paraplegia	HCC71	Paraplegia	HCC71	Paraplegia	
HCC69	Spinal Cord Disorders/Injuries	HCC72	Spinal Cord Disorders/Injuries	HCC72	Spinal Cord Disorders/Injuries	
HCC70	Muscular Dystrophy	HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	Neurological
HCC71	Polyneuropathy	HCC74	Cerebral Palsy	HCC74	Cerebral Palsy	
HCC72	Multiple Sclerosis	HCC75	Polyneuropathy	HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	
HCC73	Parkinson's and Huntington's Diseases	HCC76	Muscular Dystrophy	HCC76	Muscular Dystrophy	
HCC74	Seizure Disorders and Convulsions	HCC77	Multiple Sclerosis	HCC77	Multiple Sclerosis	
HCC75	Coma, Brain Compression/Anoxic Damage	HCC78	Parkinson's and Huntington's Diseases	HCC78	Parkinson's and Huntington's Diseases	
		HCC79	Seizure Disorders and Convulsions	HCC79	Seizure Disorders and Convulsions	
		HCC80	Coma, Brain Compression/Anoxic Damage	HCC80	Coma, Brain Compression/Anoxic Damage	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
HCC77	Respirator Dependence/Tracheostomy Status	HCC82	Respirator Dependence/Tracheostomy Status	HCC82	Respirator Dependence/Tracheostomy Status	Arrest
HCC78	Respiratory Arrest	HCC83	Respiratory Arrest	HCC83	Respiratory Arrest	
HCC79	Cardio-Respiratory Failure and Shock	HCC84	Cardio-Respiratory Failure and Shock	HCC84	Cardio-Respiratory Failure and Shock	
HCC80	Congestive Heart Failure	HCC85	Congestive Heart Failure	HCC85	Congestive Heart Failure	Heart
HCC81	Acute Myocardial Infarction	HCC86	Acute Myocardial Infarction	HCC86	Acute Myocardial Infarction	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	
HCC83	Angina Pectoris/Old Myocardial Infraction	HCC88	Angina Pectoris	HCC88	Angina Pectoris	
HCC92	Specified Heart Arrhythmias	HCC96	Specified Heart Arrhythmias	HCC96	Specified Heart Arrhythmias	
HCC95	Cerebral Hemorrhage	HCC99	Cerebral Hemorrhage	HCC99	Cerebral Hemorrhage	Cerebrovascular Disease
HCC96	Ischemic or Unspecified Stroke	HCC100	Ischemic or Unspecified Stroke	HCC100	Ischemic or Unspecified Stroke	
HCC100	Hemiplegia/Hemiparesis	HCC103	Hemiplegia/Hemiparesis	HCC103	Hemiplegia/Hemiparesis	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	HCC104	Monoplegia, Other Paralytic Syndromes	HCC104	Monoplegia, Other Paralytic Syndromes	
HCC104	Vascular Disease with Complications	HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	Vascular
HCC105	Vascular Disease	HCC107	Vascular Disease with Complications	HCC107	Vascular Disease with Complications	
		HCC108	Vascular Disease	HCC108	Vascular Disease	
HCC107	Cystic Fibrosis	HCC110	Cystic Fibrosis	HCC110	Cystic Fibrosis	Lung
HCC108	Chronic Obstructive Pulmonary Disease	HCC111	Chronic Obstructive Pulmonary Disease	HCC111	Chronic Obstructive Pulmonary Disease	
HCC111	Aspiration and Specified Bacterial Pneumonias	HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	HCC114	Aspiration and Specified Bacterial Pneumonias	HCC114	Aspiration and Specified Bacterial Pneumonias	
		HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	Eye
		HCC124	Exudative Macular Degeneration	HCC124	Exudative Macular Degeneration	
HCC130	Dialysis Status	HCC134	Dialysis Status	HCC134	Dialysis Status	Kidney
HCC131	Renal Failure	HCC135	Acute Renal Failure	HCC135	Acute Renal Failure	
HCC132	Nephritis	HCC136	Chronic Kidney Disease (Stage 5)	HCC136	Chronic Kidney Disease (Stage 5)	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
		HCC137	Chronic Kidney Disease, Severe (Stage 4)	HCC137	Chronic Kidney Disease, Severe (Stage 4)	
		HCC138	Chronic Kidney Disease, Moderate (Stage 3)			
		HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)			
		HCC140	Unspecified Renal Failure			
		HCC141	Nephritis			
HCC148	Decubitus Ulcer of Skin	HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	Skin
HCC149	Chronic Ulcer of Skin, Except Decubitus	HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	
HCC150	Extensive Third-Degree Burns	HCC161	Chronic Ulcer of Skin, Except Pressure	HCC161	Chronic Ulcer of Skin, Except Pressure	
		HCC162	Severe Skin Burn or Condition	HCC162	Severe Skin Burn or Condition	
HCC154	Severe Head Injury	HCC166	Severe Head Injury	HCC166	Severe Head Injury	Injury
HCC155	Major Head Injury	HCC167	Major Head Injury	HCC167	Major Head Injury	
HCC157	Vertebral Fractures w/o Spinal Cord Injury	HCC169	Vertebral Fractures without Spinal Cord Injury	HCC169	Vertebral Fractures without Spinal Cord Injury	
HCC158	Hip Fracture/Dislocation	HCC170	Hip Fracture/Dislocation	HCC170	Hip Fracture/Dislocation	
HCC161	Traumatic Amputation	HCC173	Traumatic Amputations and Complications	HCC173	Traumatic Amputations and Complications	
HCC164	Major Complications of Medical Care and Trauma	HCC176	Complications of Specified Implanted Device or Graft	HCC176	Complications of Specified Implanted Device or Graft	Complications
HCC174	Major Organ Transplant Status	HCC186	Major Organ Transplant or Replacement Status	HCC186	Major Organ Transplant or Replacement Status	Transplant
HCC176	Artificial Openings for Feeding or Elimination	HCC188	Artificial Openings for Feeding or Elimination	HCC188	Artificial Openings for Feeding or Elimination	Openings
HCC177	Amputation Status, Lower Limb/Amputation Complications	HCC189	Amputation Status, Lower Limb/Amputation Complications	HCC189	Amputation Status, Lower Limb/Amputation Complications	Amputation
Community Model Interactions						
D_HCC5	Disabled_Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections	**Disabled/ Disease Interactions**
D_HCC44	Disabled_Severe Hematological Disorders	D_HCC34	Disabled, Chronic Pancreatitis	D_HCC34	Disabled, Chronic Pancreatitis	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
D_HCC51	Disabled_Drug/Alcohol Psychosis	D_HCC46	Disabled, Severe Hematological Disorders	D_HCC46	Disabled, Severe Hematological Disorders	
D_HCC52	Disabled_Drug/Alcohol Dependence	D_HCC54	Disabled, Drug/Alcohol Psychosis	D_HCC54	Disabled, Drug/Alcohol Psychosis	
D_HCC107	Disabled_Cystic Fibrosis	D_HCC55	Disabled, Drug/Alcohol Dependence	D_HCC55	Disabled, Drug/Alcohol Dependence	
		D_HCC110	Disabled, Cystic Fibrosis	D_HCC110	Disabled, Cystic Fibrosis	
		D_HCC176	Disabled, Complications of Specified Implanted Device or Graft	D_HCC176	Disabled, Complications of Specified Implanted Device or Graft	
INT1	DM_CHF	SEPSIS_ CARD_ RESP_FAIL	Sepsis*Cardiorespiratory Failure	SEPSIS_ CARD_ RESP_FAIL	Sepsis*Cardiorespiratory Failure	**Disease Interactions**
INT2	DM_CVD	CANCER_ IMMUNE	Cancer*Immune Disorders	CANCER_ IMMUNE	Cancer*Immune Disorders	
INT3	CHF_COPD	DIABETES_ CHF	Diabetes*Congestive Heart Failure	DIABETES_ CHF	Diabetes*Congestive Heart Failure	
INT4	COPD_CVD_CAD	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	
INT5	RF_CHF	CHF_ RENAL	Congestive Heart Failure*Renal Disease	CHF_RENAL	Congestive Heart Failure*Renal Disease	
INT6	RF_CHF_DM	COPD_ CARD_ RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	COPD_ CARD_ RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	
Institutional Model Interactions						
D_HCC5	Disabled_Opportunistic Infections	D_HCC85	Disabled, Congestive Heart Failure	D_HCC85	Disabled, Congestive Heart Failure	**Disabled/ Disease Interactions**
D_HCC44	Disabled_Severe Hematological Disorders	D_PRESSURE_ ULCER	Disabled, Pressure Ulcer	D_PRESSURE_ ULCER	Disabled, Pressure Ulcer	
D_HCC51	Disabled_Drug/Alcohol Psychosis	D_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	D_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	
D_HCC52	Disabled_Drug/Alcohol Dependence	D_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	D_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	
D_HCC107	Disabled_Cystic Fibrosis	D_HCC77	Disabled, Multiple Sclerosis	D_HCC77	Disabled, Multiple Sclerosis	

V12 Model (with 70 HCC's)		V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
		D_HCC6	Disabled, Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections	
DM_CHF1	Diabetes_Congestive Heart Failure	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	**Disease Interactions**
DM_CVD_	Diabetes_Cerebrovascular Disease	COPD_CARD_ RESP_FAIL	Chronic Obstructive Pulmonary Disease *Cardiorespiratory Failure	COPD_CARD_ RESP_FAIL	Chronic Obstructive Pulmonary Disease *Cardiorespiratory Failure	
CHF_COPD	Congestive Heart Failure_Chronic Obstructive Pulmonary Disease	SEPSIS_ PRESSURE_ ULCER	Sepsis*Pressure Ulcer	SEPSIS_ PRESSURE_ ULCER	Sepsis*Pressure Ulcer	
COPD_CVD_ CAD_	Chronic Obstructive Pulmonary Disease_Cerebrovascular Disease_Coronary Artery Disease	SEPSIS_ARTIF_ OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	SEPSIS_ARTIF_ OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	
RF_CHF1	Renal Failure_Congestive Heart Failure	ART_OPENINGS_ PRESSURE_ ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	ART_OPENINGS_ PRESSURE_ ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	
RF_CHF_DM	Renal Failure_Congestive Heart Failure_Diabetes	DIABETES_CHF	Diabetes*Congestive Heart Failure	DIABETES_CHF	Diabetes*Congestive Heart Failure	
		COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	
		ASP_SPEC_ BACT_PNEUM_ PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	ASP_SPEC_ BACT_PNEUN PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	
		SEPSIS_ASP_ SPEC_BACT_ PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	SEPSIS_ASP_ SPEC_BACT_ PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	
		SCHIZOPHRENIA_ COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	SCHIZOPHRENIA _COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	
		SCHIZOPHRENIA_ CHF	Schizophrenia* Congestive Heart Failure	SCHIZOPHRENIA _CHF	Schizophrenia*Congestive Heart Failure	

V12 Model (with 70 HCC's)	V21 Model (revised; with 83 HCCs)		V22 Model (with 79 HCCs)		
	SCHIZOPHRENIA_ SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	SCHIZOPHRENIA _SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	

Source: RTI International.

Table 6. Preliminary CMS RxHCC Model Relative Factors for Continuing Enrollees

Continuing Enrollee (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.164	-	0.453	1.720
35-44 Years		-	0.359	-	0.656	1.682
45-54 Years		-	0.470	-	0.746	1.509
55-59 Years		-	0.499	-	0.746	1.467
60-64 Years		-	0.488	-	0.719	1.408
65-69 Years		0.331	-	0.522	-	1.455
70-74 Years		0.326	-	0.537	-	1.388
75-79 Years		0.329	-	0.531	-	1.318
80-84 Years		0.337	-	0.526	-	1.255
85-89 Years		0.337	-	0.501	-	1.177
90-94 Years		0.325	-	0.465	-	1.067
95 Years or Over		0.283	-	0.385	-	0.887
Male						
0-34 Years		-	0.165	-	0.476	1.657
35-44 Years		-	0.309	-	0.612	1.593
45-54 Years		-	0.422	-	0.678	1.521
55-59 Years		-	0.437	-	0.668	1.406
60-64 Years		-	0.439	-	0.634	1.329
65-69 Years		0.353	-	0.431	-	1.363
70-74 Years		0.346	-	0.460	-	1.318
75-79 Years		0.325	-	0.451	-	1.268
80-84 Years		0.302	-	0.451	-	1.217
85-89 Years		0.279	-	0.427	-	1.170
90-94 Years		0.269	-	0.418	-	1.080
95 Years or Over		0.265	-	0.413	-	0.949
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.054	-	0.110	-	0.047
Originally Disabled_Male		-	-	0.097	-	0.047
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	2.129	2.715	2.429	2.756	1.220
RXHCC5	Opportunistic Infections	0.105	0.082	0.072	0.079	0.054
RXHCC8	Chronic Myeloid Leukemia	2.811	3.045	3.196	3.819	1.686
RXHCC9	Multiple Myeloma and Other Neoplastic Disorders	1.738	2.179	1.466	1.811	0.695
RXHCC10	Breast, Lung, and Other Cancers and Tumors	0.130	0.167	0.200	0.239	0.065

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
RXHCC11	Prostate and Other Cancers and Tumors	0.011	0.021	0.072	0.030	0.026
RXHCC14	Diabetes with Complications	0.276	0.211	0.344	0.341	0.289
RXHCC15	Diabetes without Complication	0.184	0.151	0.255	0.261	0.204
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.402	1.012	0.358	0.815	0.115
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.056	0.074	0.021	0.065	0.066
RXHCC20	Thyroid Disorders	0.046	0.093	0.056	0.110	0.047
RXHCC21	Morbid Obesity	0.045	-	0.038	0.026	0.094
RXHCC23	Disorders of Lipoid Metabolism	0.101	0.097	0.150	0.181	0.078
RXHCC25	Chronic Viral Hepatitis	0.138	0.171	0.285	0.190	0.016
RXHCC30	Chronic Pancreatitis	0.113	0.061	0.055	0.065	0.041
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.060	0.056	0.055	0.065	0.041
RXHCC32	Inflammatory Bowel Disease	0.289	0.216	0.210	0.397	0.122
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.088	0.074	0.136	0.151	0.069
RXHCC38	Aseptic Necrosis of Bone	0.063	0.115	0.061	0.196	0.122
RXHCC40	Psoriatic Arthropathy	0.338	0.460	0.736	1.252	0.558
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.161	0.210	0.222	0.420	0.103
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.133	0.210	0.165	0.255	0.101
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.042	0.126	0.121	0.156	-
RXHCC47	Sickle Cell Anemia	0.111	0.244	0.043	0.614	0.320
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.259	0.389	0.316	0.321	0.343
RXHCC49	Immune Disorders	0.183	0.211	0.198	0.226	0.148
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.030	0.027	0.025	0.087	0.025
RXHCC54	Alzheimer`s Disease	0.453	0.229	0.245	0.151	-
RXHCC55	Dementia, Except Alzheimer`s Disease	0.232	0.127	0.100	0.020	-
RXHCC58	Schizophrenia	0.341	0.429	0.551	0.861	0.341
RXHCC59	Bipolar Disorders	0.301	0.310	0.355	0.564	0.291
RXHCC60	Major Depression	0.254	0.275	0.316	0.401	0.237
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.156	0.183	0.181	0.384	0.163
RXHCC62	Depression	0.118	0.142	0.122	0.215	0.134
RXHCC63	Anxiety Disorders	0.041	0.080	0.083	0.176	0.110

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
RXHCC65	Autism	0.156	0.260	0.406	0.509	0.163
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.062	0.260	0.403	0.325	-
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.022	0.100	0.271	0.231	-
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	0.022	0.018	0.134	0.097	-
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.187	0.266	0.175	0.404	0.052
RXHCC72	Spinal Cord Disorders	0.058	0.112	0.046	0.050	-
RXHCC74	Polyneuropathy	0.083	0.167	0.084	0.154	0.079
RXHCC75	Multiple Sclerosis	0.858	1.384	0.837	2.004	0.327
RXHCC76	Parkinson`s Disease	0.378	0.442	0.240	0.224	0.154
RXHCC78	Intractable Epilepsy	0.196	0.408	0.161	0.632	0.033
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.108	0.094	0.054	0.172	-
RXHCC80	Convulsions	0.049	0.053	0.040	0.121	-
RXHCC81	Migraine Headaches	0.096	0.167	0.122	0.126	0.102
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.073	0.143	0.103	0.130	0.110
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.248	0.513	0.303	0.458	0.128
RXHCC87	Congestive Heart Failure	0.152	0.081	0.257	0.116	0.127
RXHCC88	Hypertension	0.143	0.067	0.244	0.113	0.076
RXHCC89	Coronary Artery Disease	0.180	0.097	0.169	0.066	0.031
RXHCC93	Atrial Arrhythmias	0.069	0.039	0.017	-	0.021
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.078	0.017	0.058	-	-
RXHCC98	Spastic Hemiplegia	0.159	0.187	0.070	0.133	0.035
RXHCC100	Venous Thromboembolism	-	0.035	-	0.088	0.022
RXHCC101	Peripheral Vascular Disease	0.054	0.051	0.102	0.060	-
RXHCC103	Cystic Fibrosis	0.237	1.285	0.272	1.778	0.163
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.237	0.135	0.272	0.230	0.163
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.127	0.135	0.108	0.230	0.038
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	-	0.011	-	-	0.020

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
RXHCC111	Diabetic Retinopathy	0.124	0.074	0.104	0.071	0.074
RXHCC113	Open-Angle Glaucoma	0.189	0.153	0.232	0.188	0.179
RXHCC120	Kidney Transplant Status	0.191	0.191	0.254	0.271	0.192
RXHCC121	Dialysis Status	0.131	0.196	0.240	0.522	0.203
RXHCC122	Chronic Kidney Disease Stage 5	0.111	0.126	0.138	0.156	0.104
RXHCC123	Chronic Kidney Disease Stage 4	0.111	0.126	0.124	0.156	0.104
RXHCC124	Chronic Kidney Disease Stage 3	0.090	0.126	0.101	0.156	0.062
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.039	0.060	0.034	0.060	0.030
RXHCC126	Nephritis	0.039	0.060	0.034	0.060	0.030
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.043	0.056	0.016	0.044	0.023
RXHCC145	Pemphigus	0.182	-	0.154	0.205	0.048
RXHCC147	Psoriasis, Except with Arthropathy	0.111	0.149	0.232	0.384	0.169
RXHCC156	Narcolepsy and Cataplexy	0.373	0.437	0.389	0.640	0.285
RXHCC166	Lung Transplant Status	0.825	0.747	0.891	1.017	0.199
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.552	0.255	0.437	0.326	0.199
RXHCC168	Pancreas Transplant Status	0.191	0.191	0.254	0.229	0.192
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	1.071
NonAged_RXHCC58	NonAged * Schizophrenia	-	-	-	-	0.306
NonAged_RXHCC59	NonAged * Bipolar Disorders	-	-	-	-	0.207
NonAged_RXHCC60	NonAged * Major Depression	-	-	-	-	0.117
NonAged_RXHCC61	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.101
NonAged_RXHCC62	NonAged * Depression	-	-	-	-	0.086
NonAged_RXHCC63	NonAged * Anxiety Disorders	-	-	-	-	0.015
NonAged_RXHCC65	NonAged * Autism	-	-	-	-	0.101
NonAged_RXHCC75	NonAged * Multiple Sclerosis	-	-	-	-	0.710
NonAged_RXHCC78	NonAged * Intractable Epilepsy	-	-	-	-	0.107
NonAged_RXHCC79	NonAged * Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	-
NonAged_RXHCC80	NonAged * Convulsions	-	-	-	-	-

Note: The 2011 denominator of $1,182.35 used to calculate the 2013 RxHCC model factors is the national predicted average annual cost under the model.

Source: RTI Analysis of 100% 2011 PDE, 2010 Carrier NCH, 2010 Inpatient SAF, 2010 Outpatient SAF, 2011 HPMS, 2011 CME, 2010-2011 Denominator, and Part D Final Intermediate File.

Table 7. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Non-Low Income

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.488	0.524	-	-
35-44 Years	0.747	0.758	-	-
45-54 Years	0.943	1.166	-	-
55-59 Years	1.023	1.354	-	-
60-64 Years	1.047	1.389	-	-
65 Years	0.587	1.391	1.018	1.391
66 Years	0.630	1.391	1.018	1.391
67 Years	0.641	1.391	0.803	1.391
68 Years	0.663	1.391	0.803	1.391
69 Years	0.668	1.391	0.803	1.391
70-74 Years	0.642	1.391	0.642	1.391
75-79 Years	0.627	1.391	0.627	1.391
80-84 Years	0.515	1.391	0.515	1.391
85-89 Years	0.429	1.391	0.429	1.391
90-94 Years	0.231	1.391	0.231	1.391
95 Years or Over	0.231	1.391	0.231	1.391
Male				
0-34 Years	0.301	0.524	-	-
35-44 Years	0.586	0.758	-	-
45-54 Years	0.811	1.036	-	-
55-59 Years	0.862	1.226	-	-
60-64 Years	0.954	1.367	-	-
65 Years	0.632	1.450	0.918	1.450
66 Years	0.686	1.450	0.757	1.450
67 Years	0.696	1.450	0.757	1.450
68 Years	0.714	1.450	0.757	1.450
69 Years	0.713	1.450	0.757	1.450
70-74 Years	0.693	1.450	0.693	1.450
75-79 Years	0.636	1.450	0.636	1.450
80-84 Years	0.510	1.450	0.510	1.450
85-89 Years	0.379	1.450	0.379	1.450
90-94 Years	0.200	1.450	0.200	1.450
95 Years or Over	0.200	1.450	0.200	1.450

Notes:

1. The Part D Denominator used to calculate relative factors is $1,182.35. 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% 2011 PDE, 2010 Carrier NCH, 2010 Inpatient SAF, 2010 Outpatient SAF, 2011 HPMS, 2011 CME, 2010-2011 Denominator, and Part D Final Intermediate File.

Table 8. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Low Income

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.965	1.570	-	-
35-44 Years	1.342	1.707	-	-
45-54 Years	1.400	1.817	-	-
55-59 Years	1.316	1.817	-	-
60-64 Years	1.249	1.803	-	-
65 Years	1.025	1.817	1.148	1.817
66 Years	0.719	1.817	0.822	1.817
67 Years	0.719	1.817	0.822	1.817
68 Years	0.719	1.817	0.822	1.817
69 Years	0.719	1.817	0.822	1.817
70-74 Years	0.733	1.817	0.798	1.817
75-79 Years	0.766	1.817	0.798	1.817
80-84 Years	0.824	1.817	0.824	1.817
85-89 Years	0.805	1.817	0.805	1.817
90-94 Years	0.682	1.817	0.682	1.817
95 Years or Over	0.682	1.817	0.682	1.817
Male				
0-34 Years	0.849	1.668	-	-
35-44 Years	1.171	1.740	-	-
45-54 Years	1.190	1.748	-	-
55-59 Years	1.087	1.635	-	-
60-64 Years	0.991	1.672	-	-
65 Years	0.835	1.553	0.887	1.553
66 Years	0.515	1.553	0.584	1.553
67 Years	0.515	1.553	0.584	1.553
68 Years	0.515	1.553	0.584	1.553
69 Years	0.515	1.553	0.584	1.553
70-74 Years	0.552	1.553	0.579	1.553
75-79 Years	0.576	1.553	0.576	1.553
80-84 Years	0.576	1.553	0.576	1.553
85-89 Years	0.576	1.553	0.576	1.553
90-94 Years	0.613	1.553	0.613	1.553
95 Years or Over	0.613	1.553	0.613	1.553

Notes:

1. The Part D Denominator used to calculate relative factors is $1,182.35. 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% 2011 PDE, 2010 Carrier NCH, 2010 Inpatient SAF, 2010 Outpatient SAF, 2011 HPMS, 2011 CME, 2010-2011 Denominator, and Part D Final Intermediate File.

Table 9. Preliminary CMS RxHCC Model Relative Factors for New Enrollees, Institutional

Variable	Baseline – Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.160	2.476
35-44 Years	2.160	2.476
45-54 Years	2.293	2.476
55-59 Years	2.058	2.476
60-64 Years	2.022	2.476
65 Years	2.126	2.476
66 Years	1.931	2.476
67 Years	1.931	2.476
68 Years	1.931	2.476
69 Years	1.931	2.476
70-74 Years	1.718	2.476
75-79 Years	1.606	2.476
80-84 Years	1.557	2.476
85-89 Years	1.274	2.476
90-94 Years	1.274	2.476
95 Years or Over	1.274	2.476
Male		
0-34 Years	2.175	2.316
35-44 Years	2.404	2.316
45-54 Years	2.193	2.316
55-59 Years	1.955	2.316
60-64 Years	1.932	2.316
65 Years	1.915	2.316
66 Years	1.769	2.316
67 Years	1.769	2.316
68 Years	1.769	2.316
69 Years	1.769	2.316
70-74 Years	1.708	2.316
75-79 Years	1.667	2.316
80-84 Years	1.566	2.316
85-89 Years	1.410	2.316
90-94 Years	1.410	2.316
95 Years or Over	1.410	2.316

Notes:

1. The Part D Denominator used to calculate relative factors is $1,182.35. 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% 2011 PDE, 2010 Carrier NCH, 2010 Inpatient SAF, 2010 Outpatient SAF, 2011 HPMS, 2011 CME, 2010-2011 Denominator, and Part D Final Intermediate File.

Table 10. Preliminary List of Disease Hierarchies for the Revised CMS RxHCC Model

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is listed in this column…	…Then drop the RxHCC(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
8	Chronic Myeloid Leukemia	9,10,11,48,50
9	Multiple Myeloma and Other Neoplastic Disorders	10,11,48,50
10	Breast, Lung, and Other Cancers and Tumors	11
14	Diabetes with Complications	15
18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	19
30	Chronic Pancreatitis	31
40	Psoriatic Arthropathy	41,42,147
41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	42
47	Sickle Cell Anemia	50
48	Myelodysplastic Syndromes, Except High-Grade	50
54	Alzheimer's Disease	55
58	Schizophrenia	59,60,61,62,63,65,66,67,68
59	Bipolar Disorders	60,61,62,63
60	Major Depression	61,62,63
61	Specified Anxiety, Personality, and Behavior Disorders	62,63
62	Depression	63
65	Autism	61,62,63,66,67,68
66	Profound or Severe Mental Retardation/Developmental Disability	67,68
67	Moderate Mental Retardation/Developmental Disability	68
78	Intractable Epilepsy	79,80
79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	80
86	Pulmonary Hypertension and Other Pulmonary Heart Disease	87,88
87	Congestive Heart Failure	88
103	Cystic Fibrosis	104,105
104	Chronic Obstructive Pulmonary Disease and Asthma	105
120	Kidney Transplant Status	121,122,123,124,125,126,168
121	Dialysis Status	122,123,124,125,126
122	Chronic Kidney Disease Stage 5	123,124,125,126
123	Chronic Kidney Disease Stage 4	124,125,126
124	Chronic Kidney Disease Stage 3	125,126
125	Chronic Kidney Disease Stage 1, 2, or Unspecified	126
166	Lung Transplant Status	167,168
167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	168

Source: RTI International.

Attachment VI. 2014 Call Letter

2014 Announcement
Table of Contents

Attachment VI: Call Letter 2014 80
Section I – Parts C and D 81
Annual Calendar 81
Plan Corrections 86
Incomplete Bid Submissions 87
Formulary Submission Deadline 88
Star Ratings Changes 89
Plan/Sponsor Continuity of Operations (COOP) 105
Revisions to Good Cause Processes 106
Year 7 Agent/Broker Compensation Guidance 106
Capitated Financial Alignment Demonstrations 107
Section II – Part C 108
Benefit Flexibility for Certain Special Needs Plans 108
SNP Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) Requirements 110
Updates to the Qualification Process for Fully Integrated Dual Eligible (FIDE) Special Needs Plans 110
Supplemental Benefits Guidance 111
Rewards and Incentives Programs for Medicare Advantage Organizations 112
Provider / Beneficiary "Shared Decision Making" 112
Inappropriate shifting of drug coverage from Medicare Part B to Part D 113
Plans with Low Enrollment 114
Overview of CY 2014 Benefits Bid Review 114
Meaningful Difference (Duplicative Plan Offerings) 115
Total Beneficiary Cost (TBC) 117
Maximum Out of Pocket (MOOP) Limits 118
Transferability of an MA enrollee's annual contribution toward their maximum out-of-pocket cost sharing limit (MOOP) 119
Service Category Cost-Sharing Requirements 120
Part C Optional Supplemental Benefits 121
Part C Crosswalks: Segmentation 122
Exceptions to Policies Permitting Plans to Limit Durable Medical Equipment to Certain Brands and Manufacturers 122
Cost Plan Competition Requirements 123
Expanding use of the Blue Button Initiative 123
Medicare Advantage Part C EOB 124

Summary of Benefits (SB) Update 124
PBP Notes Update for CY 2014 125
Section 6055 of the Internal Revenue Code. 126
Section III – Part D 126
Payment for Hospice and ESRD Beneficiaries under Part D 126
Daily Cost-Sharing Requirements 129
Hospital Outpatient Drug Supplies During Observation Services....129
Withdrawal of Part D Bids after CMS Approval....131
Inappropriate Use of Prior Authorization (PA) Forms 132
Auto-Ship Refill Programs in Part D....133
Incremental Fills of Schedule II Controlled Substances Prescriptions....134
Real-time, Direct Access to Systems that Adjudicate Claims and Process Appeals and Grievances....134
Applicability of Rewards and Incentives in Part D 135
Payment of Extemporaneous Compounds from Compounding Pharmacies....136
Million Hearts™ Initiatives....137
Expansion of Part D Policy on Improving Utilization Review Controls....139
Drug Class Quantity Limits 139
Change in Part D Barbiturate Coverage....140
Part D Benefit Parameters for Non-Defined Standard Plans....141
Employer Group Waiver Plan (EGWP) Supplemental Prescription Drug Benefits....144
PDE Guidance on Post-Point-Of-Sale Claim Adjustments 145
Post Point-of-Sale Per Claim Administrative Fees....148
Medication Therapy Management....148
Antipsychotic Data....154
Improvements to the Prescription Drug Plan Information Files....156
Coordination of Benefits (COB) User Fee....156
Part D Low Enrollment....156
Preferred / Non-Preferred Pharmacy Networks....157
Appendix 1 – Additional Gap Coverage....158
Appendix 2 – Contract Year 2014 Guidance for Prescription Drug Plan (PBP) Renewals and Non-Renewals 161
Appendix 3 – Contract Year 2014 Guidance for Prescription Drug Plan (PBP) Renewals and Non-Renewals - Table 166
Appendix 4 – Contract Year 2014 Guidance for PDP PBP Renewal Option 6 Special Disenrollment Model Notice....172
Appendix 5 - Summary of Comments to the Request for Comments on the 2014 Star Ratings and Beyond....174

Attachment VI: Call Letter 2014

How to Use This Call Letter

The 2014 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs) and Part D sponsors need to take into consideration in preparing their 2014 bids.

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

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

If you have questions concerning this Call Letter, please contact: Vanessa Sammy at Vanessa.Sammy@cms.hhs.gov (Part C issues) and Stephanie Hammonds at Stephanie.Hammonds@cms.hhs.gov (Part D issues).

Section I – Parts C and D

Annual Calendar

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

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
January 10, 2013	Release of the 2014 MAO/MA-PD/PDP/Service Area Expansion Applications.	✓	✓	✓
January 9 & 16, 2013	Industry training on 2014 Applications.	✓	✓	✓
February 21, 2013	2014 Applications are due to CMS.	✓	✓	✓
Late February 2013	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓		
March 1, 2013	CMS releases guidance concerning updates to Parent Organization designations in HPMS.	✓	✓	✓
March 1, 2013	Initial Submission deadline for risk adjustment data with dates of service January 1, 2012 through December 31, 2012.	✓		✓
March 4, 2013	D-SNP deadline to notify CMS of intent to offer additional supplemental benefits as a result of meeting the qualifying criteria.	✓		
March 15, 2013	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2013).	✓	✓	
Mid-Late March, 2013	Release of CY 2014 Formulary Training Video	✓	✓	
March 22, 2013	Release of the of the Fiscal Soundness Module in HPMS.	✓	✓	
Early April 2013	CY 2014 Out-of-pocket cost (OOPC) estimates for each plan and an OOPC model in SAS will be made available to MAOs to download from the CMS website that will assist plans in meeting meaningful difference and MA total beneficiary cost requirements prior to bid submission.	✓	✓	
Early April, 2013	Information about renewal options for contract year 2014 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
April 2013	Conference call with industry to discuss the 2014 Call Letter.	✓	✓	✓
April 2013	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	
April 1, 2013	2014 Final Call Letter released. Announce CY 2014 MA Capitation Rates and MA and Part D Payment Policies. *(Applies to Part C and Part D Sponsors only)*	✓	✓	✓

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
April 3, 2013	Industry training on CY 2014 Formulary Submission	✓	✓	
April 5, 2013	Release of the 2014 Plan Benefit Package (PBP) online training module	✓	✓	✓
April 5, 2013	Release of the 2014 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓
April 2013	Medicare Advantage and Part D Spring Conference.	✓	✓	
April 22, 2013	Release of the 2014 Medication Therapy Management (MTM) Program Submission Module in HPMS.		✓	
April/May, 2013	CMS contacts Medicare Advantage Organizations (MAO) and PDPs with low enrollment plans.	✓	✓	✓
May, 2013	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2013 will be available for all organizations.	✓	✓	
May 2013	Release of Medicare Marketing Guidelines for CY 2014.	✓	✓	✓
May 2, 2013	CMS strongly encourages MA, MA-PD and PDP plans to notify us of its intention to non-renew a county(ies) for individuals, but continue the county(ies) for "800 series" EGWP members, convert to offering employer-only contracts, or reduce its service area at the contract level, by May 2, 2013. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓
May 6, 2013	2014 MTM Program submission deadline.		✓	
May 10, 2013	Release of the 2014 Bid Upload Functionality in HPMS	✓	✓	✓
May 13, 2013	Release of Health Plan System (HPMS) Formulary Submission Module	✓	✓	
May 31, 2013	2014 Formulary Submissions due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Transition Attestations due to CMS PA/ST Attestations due to CMS P&T Attestations due to CMS	✓	✓	
Late May/Early June, 2013	Release of the 2014 Medicare Marketing Guidelines in HPMS (Chapter 3 of the Medicare Managed Care Manual/Chapter 2 of the Prescription Drug Benefit Manual)	✓	✓	✓
Late May/June, 2013	CMS sends qualification determinations to applicants based on review of the 2014 applications for new contracts or service area expansions.	✓	✓	
Late May/June to Early September, 2013	CMS completes review and approval of 2014 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	✓
May 31, 2013	Release of the 2012 DIR Submission Module in HPMS.	✓	✓	

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
May 31, 2013	Sponsors may begin to upload agent/broker compensation information in HPMS.	✓	✓	✓
May 31, 2013	Release of the 2014 Marketing Module in HPMS.	✓	✓	✓
June 3, 2013	Deadline for submission of CY 2014 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2014 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Voluntary Non-Renewal. Deadline for MA plans, MA-PD plans, PDPs and Medicare cost-based contractors and cost-based sponsors to submit a contract non-renewal, service area reduction notice to CMS for CY 2014. 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 2014.	✓	✓	✓
June 7, 2013	Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS.	✓	✓	✓
June 7, 2013	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)*	✓	✓	
June 24, 2013	Release of the CY 2014 Summary of Benefits (SB) hard copy change request module in HPMS.	✓	✓	
Late June, 2013	Non-Renewal. CMS sends an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓
June 30, 2013	Final date to submit CY 2013 marketing materials to ensure timely CMS review and approval. NOTE: Sponsors may continue to submit CY 2013 file and use materials as these may be filed in HPMS five calendar days prior to their use.	✓	✓	✓
Early July, 2013	2014 Plan Finder pricing test submissions begin	✓	✓	✓
July1, 2013	All Dual Eligible SNPs are required to have a contract with the State Medicaid Agency.	✓	✓	✓
July 5, 2013	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓		
July 31, 2013	2014 MTM Program Annual Review completed.		✓	
Mid-Late July, 2013	CY 2014 Limited Formulary Update Window	✓	✓	
Late July, 2013	Submission deadline for agent/broker compensation information via HPMS.		✓	

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
Late July/Early August, 2013	CMS encourages cost-based plans to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Plan Finder" and the *Medicare & You* handbook. SBs must be submitted by this date to be assured of being included.	✓	✓	✓
Early August, 2013	CMS releases the 2014 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.			✓
Early August, 2013	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓
August 1, 2013	Plans are expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓
August 1, 2013	CMS informs currently contracted organizations of its decision to not renew of a contract for 2014.		✓	
August 22-26, 2013	First CY 2014 preview of the 2014 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	
August 28 – August 30, 2013	First CY 2014 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
Late August 2013	Contracting Materials submitted to CMS.	✓	✓	✓
End of August/Early September 2013	Plan preview periods of star ratings in HPMS.	✓	✓	✓
September 6, 2013	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2012 through June 30, 2013.	✓	✓	
Mid-September 2013	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓
Mid- September 2013	All 2014 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓		✓
September 10 - September13, 2013	Second CY 2014 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
September 16 – 30, 2013	CMS mails the 2014 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
September 30, 2013	CY 2014 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by September 30. Plans have the option to include Pharmacy/Provider directories in this mailing. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies with the ANOC/EOC to ensure current member receipt by September 30. Note: With the exception of the ANOC/EOC, LIS Rider, directories, and abridged or comprehensive formularies, no additional materials may be sent prior October 1.	✓	✓	✓
October 1, 2013	Organizations may begin marketing their CY 2014 plan benefits. Note: Once an organization begins marketing CY 2014 plans, the organization must cease marketing CY 2013 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2013 materials upon request, conduct one-on-one sales appointments and process enrollment applications.	✓	✓	✓
October 1, 2013	Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS. Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request any SB hard copy change.	✓	✓	✓
October 1, 2013	Tentative date for 2014 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
October 2, 2013	The final personalized beneficiary non-renewal notification letter must be received by PDPs, MA plan, MA-PD plans, and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2013.	✓	✓	✓
October 10, 2013	Star ratings go live on medicare.gov.	✓	✓	✓
October 15, 2013	Part D sponsors must post PA and ST criteria on their websites for the 2014 contract year.	✓	✓	
October 15, 2013	2014 Annual Election Period begins. All organizations/sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓	

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
November 9, 2013	Notices of Intent to Apply (NOIA) for CY 2015 due for MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	
Late November, 2013	Display measures data are posted in HPMS for plan preview.	✓	✓	✓
Late November, 2013	2014 Readiness Assessment due to CMS	✓	✓	✓
November – December, 2013	CMS issues "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	
December 1, 2013	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.	✓	✓	✓
December 1, 2013	Cost-based plans must publish notice of non-renewal.			✓
December 7, 2013	End of the Annual Election Period.	✓	✓	
Mid- December, 2013	Display measures data on CMS.GOV updated.	✓	✓	✓
2014				
January 1, 2014	Plan Benefit Period Begins	✓	✓	✓
January 1 – February 14, 2014	MA Annual 45-Day MA Disenrollment Period (MADP).	✓		
Early January 2014	Release of CY 2015 MAO/MA-PD/PDP/SAE/EGWP applications.	✓		
Mid-January, 2014	Industry training on CY 2015 applications.	✓	✓	✓
January 31, 2014	Final Submission deadline for risk adjustment data with dates of service January 1, 2012 through December 31, 2012.	✓	✓	✓
Late February 2014	Applications due for CY 2015.	✓		✓
March 7, 2014	Initial Submission deadline for risk adjustment data with dates of service January 1, 2013 through December 31, 2013	✓	✓	✓
September 5, 2014	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2013 through June 30, 2014	✓		✓

Plan Corrections

CMS expects that requests for MA, cost plan and PDP corrections for CY 2014 will be minimal. As required by 42 CFR §§422.254, 423.265(c)(3) and 423.505(k)(4), submission of the final actuarial certification and the bid attestation serves as documentation that the final bid submission has been verified and is complete and accurate at the time of submission. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation.

After bids are approved, CMS will not reopen the submission gates to correct errors identified by the plan until the plan correction window in September. The plan correction window will be open from mid – September to October 1, 2013. Only changes to the PBP that are supported by the BPT are allowed during the plan corrections period.

CMS has determined that given the limited timeframe for review of the corrected PBP in relation to the initial posting of plan data in Medicare Plan Finder (MPF), the affected plans will be suppressed in MPF for the initial release until the bid is corrected and approved, and the MPF is updated for the second release in early November. Please also be advised that an organization requesting a plan correction will receive a corrective action warning letter. An organization that received a warning letter for CY 2013 may receive a corrective action plan if it requests a plan correction for CY 2014.

Incomplete Bid Submissions

Per Sections 1854(a)(1)(A) and 1860D-11(b) of the Social Security Act, initial bid submissions for all Part C and Part D plans are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY2014, the bid submission deadline is June 3, 2013 at 11:59 PM Pacific Daylight Time.

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

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

Organizations are responsible for ensuring complete and accurate bids are submitted by the June deadline. This year, CMS is making clear that all components required for an organization's bid must be submitted by the deadline to constitute a complete submission. If any one of the required components are not submitted by the deadline, the bid submission will be considered incomplete and will not be accepted by CMS absent extraordinary circumstances. This requirement is consistent with previous years (please refer to HPMS Memo "Release of Contract Year (CY) 2013 Bid Upload Functionality in HPMS," dated May 11, 2012.)

The Health Plan Management System (HPMS) Bid Upload functionality, made available each May, allows all Organizations to submit each required component of their bids well in advance of the deadline and reporting tools track those components which were successfully submitted and which are still outstanding. Given the resources available to organizations to monitor and verify the status of bid submissions, CMS expects that all components of a bid will be 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 may give consideration to late submissions in rare situations if the late submission is the result of a technical issue beyond the Organization's control. All Organizations should ensure that appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that are preventing the bid from proceeding to desk review.

Formulary Submission Deadline

In the December 19, 2012 HPMS memo entitled "CY 2014 Formulary Submission Deadline," CMS announced that the CY 2014 Health Plan Management System (HPMS) formulary submission window will be open later this year than in past years, from 12:00 am PDT on May 13, 2013 to 11:59 pm PDT on May 31, 2013. In addition, CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of May 31, 2013 in order for it to be considered for review.

The decision to change the CY 2014 formulary submission window and deadline was made after consideration was given to the valuable feedback CMS received from Part D plan sponsors with respect to the proposed changes. We have evaluated the impact of the formulary submission deadline date change with respect to Formulary Reference File (FRF) release dates, formulary submission windows, and the Part D out-of-pocket cost (OOPC) analyses. Consistent with years past, CMS intends to provide the first release of the CY 2014 FRF in March 2013. The March FRF release will be used in the production of the OOPC model tool, scheduled to be released in April 2013, in order to assist plan sponsors in meeting meaningful difference and MA total beneficiary cost 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.

Based on plan sponsor feedback, CMS is planning to provide a May 2013 release of the 2014 FRF just prior to the new formulary submission deadline. In their comments, sponsors cited the advantage of having the most up-to-date FRF information available to them at the time of their formulary submission as the basis for their support of having an additional FRF release prior to the formulary submission deadline. Given the limited timeframe between the May release of the 2014 FRF and the new formulary submission deadline, CMS will be unable to accommodate an updated version of the 2014 OOPC model to incorporate the May FRF changes, as noted above. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2014 FRF will not be included in the 2014 OOPC model.

While CMS will continue to offer a summer formulary update, formulary changes 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 FRF 2014, since additional limitations will be imposed on the summer formulary update window, as noted in the December 19, 2012 HPMS Memo entitled "CY 2014 Formulary Submission Deadline."

Star Ratings Changes

For the 2014 Star Ratings, CMS is making a few enhancements to the current methodology to further align it with our policy goals. In this section, we describe the enhancements being considered for the 2014 Star Ratings and unless noted below, we do not anticipate the methodology changing from the 2013 Star Ratings. The 2013 methodology document (Technical Notes) can be found at www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ PerformanceData.html under the 2013 Plan Ratings link. The star cut points for all measures and case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated with the most current data available.

In November 2012, CMS sent out a Request for Comments to Part C and D sponsors, stakeholders, and advocates that described CMS' proposed methodology for the 2014 Star Ratings and beyond for Medicare Advantage (MA) and Prescription Drug Plans. The purpose of this comment period was to provide plans and advocates with additional notice of the methodology so that CMS could identify any needed changes in advance of the Call Letter. We received approximately 80 comment letters. Appendix 5 contains a summary of the comments received and CMS' responses. We have incorporated this feedback in developing the enhancements proposed in this draft Call Letter. Based on the feedback received, while we are proposing changes to methodologies on current measures, we are proposing no new measures for 2014. We welcome additional feedback that has not been already submitted to CMS by your organization.

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

Changes to the Methodology of Current Measures

CMS is proposing to modify the methodology for the following measures:

- *Call Center – Foreign Language Interpreter and TTY Availability (Part C and D). Affects Puerto Rico Plans only.* Recognizing that Spanish is the predominant language in Puerto Rico, beginning in 2013 CMS is proposing to measure English as a foreign language for contracts for which Puerto Rico is the exclusive service area. We are proposing to replace "non-English language" with "foreign language" in the metric to reflect this change.

- *Quality Improvement (Part C and D).* CMS' methodology currently includes a hold harmless provision for contracts with overall ratings of 4 or more stars that would have their overall rating decreased with the addition of the improvement measure(s). CMS is proposing to modify the methodology so contracts are also held harmless if their individual measure stars are 5 stars in the two years being evaluated for improvement. That is, if a contract receives 5 stars in an individual measure for the two years being measured, and demonstrates a statistically significant decline (at the 0.05 significance level) on the eligible measure, then this measure will not be included in the contract's improvement measure calculation. Contracts must have data for at least half of the eligible measures used to calculate the improvement score to be eligible for the improvement measure. Measures that are held harmless as described here will be included in the count of eligible measures used to determine eligibility for the measure. Improvement scores of 0 (equivalent to no net change on the eligible measures included in the improvement calculation) will receive 3 stars when assigning the star ratings for the improvement measure.

- *High-Risk Medication Use (Part D).* This measure is based on the Pharmacy Quality Alliance (PQA) -endorsed Use of High-Risk Medications in the Elderly (HRM) measure. The HRM measure is defined as the percentage of Medicare Part D enrollees 65 years or older who received two or more fills of at least one HRM (i.e., the same HRM drug) during the measurement year. CMS is proposing that the following clarification be made to the measure's technical notes: *This measure calculates the percentage of Medicare Part D beneficiaries 65 years or older who received two or more prescription fills for <u>the same HRM drug</u> with a high risk of serious side effects in the elderly*. CMS' methodology already takes into account 2 or more fills for the same HRM (active ingredient); please refer to the Report User Guide on the Patient Safety Analysis Website for more information.

  The PQA updated the HRM measure specifications and National Drug Code (NDC) list as a result of the American Geriatrics Society (AGS) recommendations to the Beers List. CMS evaluated the new HRM list, and there is approximately 50% overlap in drugs that are included on both the prior HRM drug list and the updated list. CMS provided notice in the 2013 Call Letter that it would evaluate implementing this new list on either CY2012 or CY2013 PDE data, for the 2014 or 2015 Star Ratings, to determine when these revised specifications would become effective. CMS proposes the following, which is a change from what was initially proposed:

  - The original PQA HRM list (i.e. the one used for the 2013 Star Ratings) will continue to be applied to calculate the HRM measure for the 2014 Star Ratings using 2012 Prescription Drug Event (PDE) data.

- The updated PQA HRM list, based on the AGS recommendations to the Beer's List, will be applied to calculate the HRM measure for the 2015 Star Ratings using 2013 PDE data.

- Since CMS began using the updated PQA HRM medication list to calculate the 2012 HRM rates provided to contracts via the Patient Safety Analysis Website in August 2012, CMS will redesign the reports to also include 2012 HRM rates using the original PQA HRM list. The timing for the revised reports is still being determined. We also anticipate releasing 2013 reports by May of 2013.

Part D coverage of barbiturates (used in the treatment of epilepsy, cancer, or a chronic mental health disorder) and benzodiazepines began in January 2013. The updated PQA HRM list includes barbiturates, not benzodiazepines. Therefore, the measure calculation will reflect Part D coverage changes, and Part D covered barbiturates would be included in the calculation for the 2015 Star Ratings using the 2013 PDE data. We expect that a pre-determined 4-star threshold will not be set for this measure for several years, and that this measure will continue to be excluded from the Improvement measure, given the continued specification changes. CMS will continue to base star cutpoints on statistical analyses and the relative ranking of contracts' scores.

- *Medication Adherence for Diabetes Medications (Part D).* This measure is currently defined as the percent of Medicare Part D beneficiaries 18 years or older who adhere to their prescribed drug therapy across four classes of oral diabetes medications: biguanides, sulfonylureas, thiazolidinediones, and DiPeptidyl Peptidase (DPP)-IV Inhibitors. Per PQA-endorsed specifications, beneficiaries who have one or more prescriptions for insulin in the measurement period are excluded. CMS is proposing to adopt PQA's changes to this measure's specifications for the 2015 Star Ratings (using 2013 PDE data), specifically the addition of two additional drug classes to the numerator and denominator (meglitinides and incretin mimetic agents). We also propose renaming the measure to: *Medication Adherence for Diabetes Medications*. The new proportion of days covered (PDC) calculation would determine if the beneficiary is covered by at least one drug from any of the six classes of diabetes drugs. CMS will determine if these changes are significant, and if so, this would necessitate the suspension of a pre-established 4-star threshold (if established for 2014 Star Ratings). We would also like to note that for the Medication Adherence measures for Diabetes, Hypertension, and Cholesterol, we will continue to use a slightly modified PDC calculation to adjust for overlapping prescriptions for the same drug using generic name (ingredient name). PQA's specifications use Generic Code Numbers (GCNs) (which includes strength). Considering medication adherence is measured using claim fill dates and days supply as a proxy for utilization, there are some scenarios where using GCN may be too restrictive. For this reason, we will continue to use the broader interpretation of the PDC calculation using generic name.

- *Rounding of measure data.* CMS proposes to round measure data and cut points used for CMS' Star Ratings (including Part D Patient Safety measures) to whole numbers, in order to avoid small differences in decimal values that result in differences in performance ratings, except for the following measures: Part C and D Complaints about the Health and Drug Plan measures, Health and Drug Plan Quality Improvement measures, and Part D Appeals Auto-Forward. For the measures rounded to whole numbers, we will use standard rounding rules where raw measure scores that end in less than 0.50 are rounded down and raw measure scores that end in 0.50 or more are rounded up. The Complaints measures are rounded to two decimal points, the Improvement measures are rounded to three decimal points and Part D Appeals Auto-forward is rounded to one decimal point. The rounding discussed here does not apply to the overall and summary ratings.

Other Changes

As usual, CMS expects to update existing measures with current specifications or underlying data. For example, CMS will refresh analyses to include updated NDC lists provided by the PQA for the respective patient safety measures. These changes are typically reflected in ongoing information shared with Plans, e.g., Patient Safety Website reports, prior to the release of Star Ratings. Beginning with the 2015 Star Ratings and Display measures (using 2013 PDE data), we will implement the PQA's specification change to account for obsolete NDCs. NDCs will be included in the measure calculation if the obsolete date is within the period of measurement (measurement year). Other updates to CMS' monitoring and audit protocols may be reflected as well.

Four Star Thresholds

Similar to 2013, CMS will continue to apply previously established 4-star thresholds, unless significant changes have been made to a measure's technical specifications. There are no measures for 2014 Star Ratings that have significant technical changes that would necessitate a change from the current 4-star thresholds. The current cut-points for all other measures can be found in the Technical Notes available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html under the 2013 Plan Ratings link.

CMS proposes to set 4-star thresholds for all measures that have been part of the Star Ratings for at least two years based on the historical data. The table below lists the 2014 proposed new 4-star thresholds for Part C and D measures:

Table 1: Proposed new 4-star thresholds

Measure	MA-only	MA-PDs	PDPs
Adult BMI assessment	≥ 61%	≥ 61%	-
COA – medication review	≥ 81%	≥ 81%	-
COA – functional status assessment	≥ 75%	≥ 75%	-
COA – pain screening	≥ 56%	≥ 56%	-
Plan all-cause readmissions	≤ 11%	≤ 11%	-
Complaints about the Plan	≤ 0.19	≤ 0.19	≤ 0.19
Beneficiary Access and Performance Problems	> 60	> 60	> 60
Members Choosing to Leave the Plan	≤ 10%	≤ 10%	≤ 10%
Medication Adherence for Diabetes Medications	-	≥ 76%	≥ 77%
Medication Adherence for Hypertension (RAS antagonists)	-	≥ 77%	≥ 79%
Medication Adherence for Cholesterol (Statins)	-	≥ 72%	≥ 74%

CMS has emphasized the importance of supporting the Million Hearts™ initiative. A number of measures in the Star Ratings are consistent with this aim, as they monitor cardiovascular care, blood pressure, and medication adherence. High quality in these measures is expected to reduce risks for heart attack, hypertension, kidney disease, and stroke for Medicare beneficiaries. For the 2015 Star Ratings, we are proposing to raise the 4-star thresholds for the following measures that are relevant to Million Hearts™ to encourage quality improvement by plans on these six measures:

Cardiovascular Care – Cholesterol Screening (Part C)
Controlling Blood Pressure (Part C)
Diabetes Treatment (Part D)
Medication Adherence for Diabetes Medications (Part D)
Medication Adherence for Hypertension (RAS antagonists) (Part D)
Medication Adherence for Cholesterol (Statins) (Part D)

The proposed 4-star thresholds are as follows beginning with the 2015 Star Ratings. For all measures we have set a 2 percentage point increase. For these measures we have seen in the trend data increases in performance so this change reflects continuous improvement in these areas.

Table 2: Revised thresholds for 2015 Star Ratings

Measure	Revised 4-star Threshold
Cardiovascular Care- Cholesterol Screening	≥ 87%
Controlling Blood Pressure	≥ 65%
Diabetes Treatment	MA-PDs ≥ 87%; PDPs ≥ 84%
Medication Adherence for Diabetes Medications	MA-PDs ≥ 78%; PDPs ≥ 79%
Medication Adherence for Hypertension (RAS antagonists)	MA-PDs ≥ 79%; PDPs ≥ 81%
Medication Adherence for Cholesterol (Statins)	MA-PDs ≥ 74%; PDPs ≥ 76%

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

In constructing Star Ratings for public reporting and the Quality Bonus Payment (QBP) program, a key concern is the possibility of generating Star Ratings that do not reflect a contract's "true" performance. This possibility is called the risk of "misclassifying" a contract (e.g., scoring a "true" 4-star contract as a 3-star contract). Beginning with the 2015 Star Ratings, CMS is proposing to include low-enrollment contracts in the Star Rating program. The change discussed here becomes more critical in 2015 since the risk of performance misclassification for all contracts increases when including low-enrollment contracts.

To address this issue, CMS has been evaluating several analytic strategies in order to determine an approach to mitigate the risk of misclassification. After evaluating these strategies, CMS is considering changing the way MA, MA-PD, and PDP ratings are calculated. Instead of basing the overall star calculation on an average of star ratings for each individual measure (e.g., 1-5 stars), CMS proposes beginning with the 2014 Star Ratings to calculate star ratings by using the individual measure scores themselves (e.g., percent, rate, or score), which are more precise reflections of the performance data than the measures' star ratings, and result in lower misclassification rates of overall contract performance. For example, suppose Contract A scored 47% and Contract B scored 63% on Breast Cancer Screening. Both of these contracts would receive 2 stars for the measure although they had a 16 percentage point difference in performance. For calculation of these contracts' overall and/or summary rating, we propose using the individual measure scores, which would preserve this 16-point difference in performance (instead of the 2-star rating which does not preserve this difference). Information about the relative differences in contracts' performances on each measure is accounted for in the overall and summary rating calculations.

In order to calculate an overall and/or summary composite score that is on the scale of the stars (which ranges from 1 to 5 possible stars), each individual measure raw score must be rescaled prior to calculating a weighted average using the existing weights. For each measure, this rescaling produces a continuous score between 0 and 5. These rescaled scores can be interpreted as follows: measure scores from 0 through 1 correspond to '1-star scores,' scores greater than 1 but not greater than 2 correspond to '2-star scores,' and so on. The lowest-scoring contract will

have a rescaled score of 0, and the highest-scoring contract will have a rescaled score of 5. If the measure has a fixed 4-star threshold, the threshold is rescaled to a score of 3, so that rescaled scores between 3 and 4 correspond to '4-star scores.'

Below are two examples of rescaling the original measure scores to the scale of the measure stars, one with a fixed 4-star threshold and the other without a fixed threshold.

For the first example, suppose that the lowest-scoring contract on Breast Cancer screening had a score of 20%, and the high-scoring contract had a score of 90%. The 4-star threshold for this measure is 74%. The scaled score for each contract is calculated as follows:

- First, rescale the raw scores that are below the 4-star threshold. For each contract with a raw score less than 74%, the scaled score equals:

  scaled score = 3×(raw score − 20%)/(74% − 20%)

  so for a contract with raw score 50%, the scaled score would be …

  scaled score = 3×(50% − 20%)/(74% − 20%) = 1.667.

- Second, rescale the raw scores that are at or above the 4-star threshold. For each contract with a raw score greater than or equal to 74%, the scaled score equals:

  scaled score = 2×(raw score − 74%)/(90% − 74%) + 3

  so for a contract with raw score 85%, the scaled score would be …

  scaled score = 2×(85% − 74%)/(90% − 74%) + 3 = 4.375.

For the second example, suppose that the lowest-scoring contract on Care for Older Adults Medication Review had a score of 25%, and the high-scoring contract had a score of 85%. This measure has no fixed 4-star threshold. The scaled score for each contract is calculated as follows:

scaled score = 5×(raw score − 25%)/(85% − 25%)

so for a contract with a raw score 70%, the scaled score would be …

scaled score = 5×(70% − 25%(/(85% − 25%) = 3.75

Please note that the scaled score used has up to 3 decimal points for this calculation.

Finally, the 0-5 continuous weighted average of the individual measure scaled scores (i.e., the final composite score) is translated into an overall star rating of 1 to 5 stars, in ½ star increments. To do this, the 0-5 continuous scores are rounded up to the nearest half star to assign the final star. In other words, in the last step of the star calculation, the contracts with a final composite score greater than 4.5 will be assigned 5 stars, contracts with a score between 4.00 and 4.50 will be assigned 4.5 stars, and so on.

Low Performer Icon

CMS currently assigns the Low Performer Icon (LPI) to contracts receiving less than 3 stars for their Part C or Part D summary ratings for the last 3 consecutive years. Concerns have been raised by stakeholders over this definition, specifically that an MA-PD contract under the current definition may switch back and forth from poor performance in Part C to poor performance in Part D from year to year and these contracts will not receive the LPI for poor performance. For example, under the current methodology, a contract can avoid being assigned the LPI if they previously had three years of low performance (less than 3 stars) on Part C but raised it to 3 stars in the current year, although they may have one or more years of low performance on Part D. In order to avoid providing potentially misleading information to beneficiaries, as well as creating inequality in CMS' monitoring and outreach activities for LPI contracts, CMS proposes assigning the LPI to any MA-PD contract receiving 2.5 stars or lower for any combination of their Part C or their Part D summary ratings for three consecutive years. Contracts are responsible for providing adequate care and services across both C and D. This change will encourage consistent improvement in the quality of care across all of the C and D measures for MA-PD contracts.

Weighting Categories of Measures

We are planning to keep the same weighting categories used for the 2013 Star Ratings, in which outcome and intermediate outcome measures are 3 times the weight of process measures, while patient experience and access measures are 1.5 times the weight of process measures. We plan to assign new Star Ratings measures a weight of "1" in the first year, and then the weight in the second year would depend on the weighting category. The following tables list the proposed 2014 Star Ratings measures and their weighting categories.

Table 3: Part C Measure Weights

Measure Name	Weighting Category	Part C Summary	MA-PD Overall
Breast Cancer Screening	Process Measure	1	1
Colorectal Cancer Screening	Process Measure	1	1
Cardiovascular Care – Cholesterol Screening	Process Measure	1	1
Diabetes Care – Cholesterol Screening	Process Measure	1	1
Glaucoma Testing	Process Measure	1	1
Annual Flu Vaccine	Process Measure	1	1
Improving or Maintaining Physical Health	Outcome Measure	3	3
Improving or Maintaining Mental Health	Outcome Measure	3	3
Monitoring Physical Activity	Process Measure	1	1
Adult BMI Assessment	Process Measure	1	1

Measure Name	Weighting Category	Part C Summary	MA-PD Overall
Care for Older Adults – Medication Review	Process Measure	1	1
Care for Older Adults – Functional Status Assessment	Process Measure	1	1
Care for Older Adults – Pain Screening	Process Measure	1	1
Osteoporosis Management in Women who had a Fracture	Process Measure	1	1
Diabetes Care – Eye Exam	Process Measure	1	1
Diabetes Care – Kidney Disease Monitoring	Process Measure	1	1
Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	3
Diabetes Care – Cholesterol Controlled	Intermediate Outcome Measure	3	3
Controlling Blood Pressure	Intermediate Outcome Measure	3	3
Rheumatoid Arthritis Management	Process Measure	1	1
Improving Bladder Control	Process Measure	1	1
Reducing the Risk of Falling	Process Measure	1	1
Plan All-Cause Readmissions	Outcome Measure	3	3
Getting Needed Care	Patients' Experience and Complaints Measure	1.5	1.5
Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	1.5
Customer Service	Patients' Experience and Complaints Measure	1.5	1.5
Overall Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	1.5
Overall Rating of Plan	Patients' Experience and Complaints Measure	1.5	1.5
Care Coordination	Patients' Experience and Complaints Measure	1.5	1.5
Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	1.5
Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	1.5

Measure Name	Weighting Category	Part C Summary	MA-PD Overall
Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	1.5
Health Plan Quality Improvement	Outcome Measure	3	3
Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5	1.5
Reviewing Appeals Decisions	Measures Capturing Access	1.5	1.5
Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	1.5

Table 4: Part D Measure Weights

Measure Name	Weighting Category	Part D Summary	MA-PD Overall
Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	1.5
Appeals Auto–Forward	Measures Capturing Access	1.5	1.5
Appeals Upheld	Measures Capturing Access	1.5	1.5
Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1.5	1.5
Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	1.5
Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	1.5
Drug Plan Quality Improvement	Outcome Measure	3	3
Rating of Drug Plan	Patients' Experience and Complaints Measure	1.5	1.5
Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1.5	1.5
MPF Price Accuracy	Process Measure	1	1
High Risk Medication	Intermediate Outcome Measure	3	3
Diabetes Treatment	Intermediate Outcome Measure	3	3
Medication Adherence for Diabetes Medications	Intermediate Outcome Measure	3	3

Measure Name	Weighting Category	Part D Summary	MA-PD Overall
Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	3
Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	3

Integrity of Star Ratings

The data used for CMS' Star Ratings must be accurate and reliable. CMS has taken several steps in the past years to protect the integrity of the data; however we continue to guard against new vulnerabilities when inaccurate or biased data are included. CMS' policy is to reduce a contract's measure rating to 1 star if it is identified that biased or erroneous data have been submitted by the plan or identified by CMS. This would include cases where CMS finds plans' mishandling of data, inappropriate processing or implementation of incorrect practices 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 data requirements; a contract's errors in processing of coverage determinations and exceptions; compliance actions taken against the contract due to errors in operational areas that would directly impact the data reported or processed for specific measures; and a contract's failure to pass data validation directly related to data reported for specific measures.

Disaster Implications

The effects of Hurricane Sandy were significant for Medicare beneficiaries in a number of areas, as well as the Parts C and D organizations that provide important medical care and prescription drug coverage for them. After the storm, plans raised concerns that their Star Ratings could be adversely affected by the disruption in medical and drug services. As referenced in the November 7, 2012 HPMS memo on "Reminder of Pharmacy and Provider Access during a Federal Disaster or Other Public Health Emergency Declaration," areas potentially impacted would be those found at the Disaster Federal Register Notice section on Federal Emergency Management Agency's (FEMA's) web site (http://www.fema.gov/news/disasters.fema).

As announced by CMS in the December 10, 2012 HPMS memorandum, affected plans were to contact CMS through the Part C and D Star Ratings mailboxes if they believed their operations and/or clinical care experienced major issues as a result of the storm that would impact their Star Ratings measures. Plans that contacted CMS about storm-related issues related to Star Ratings measures have been contacted by CMS. However, if you experienced a problem which was reported to CMS and have not received a response, please contact CMS immediately. If you have experienced a problem and have not reported it to CMS yet, please contact us by February 28, 2013 through PartCRatings@cms.hhs.gov and/or PartDmetrics@cms.hhs.gov.

Measures Being Removed from Star Ratings and New Measures for the Display Page

Display measures on http://www.cms.gov are not part of the Star Ratings. These may be 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 only. CMS will give advance notice if we are moving display measures to the Star Ratings. Similar to the 2013 display page, plans have the opportunity to preview their data on the display measures prior to release on CMS' website. Data on measures moved to the display page will continue to be collected and monitored, and poor scores on display measures are subject to compliance actions by CMS.

CMS is considering transitioning the Enrollment Timeliness, Getting Information from Drug Plan, and Call Center—Pharmacy Hold Time measures from the Star Ratings to the 2014 display page. The Enrollment Timeliness measure is being moved to the display page due to the lack of variation in the scores across contracts with the scores being skewed very high. Getting Information from Drug Plan is being moved to the display page since there is little variation in the scores across contracts with the scores being skewed very high. The Call Center—Pharmacy Hold Time is being moved to the display page since sponsors' performances have been consistently high for several years.

We are planning on introducing the following measures to the 2014 display page in preparation for them potentially being included as new 2015 Star Rating measures:

- *Pharmacotherapy Management of COPD Exacerbation (PCE) (Part C).* The percentage of COPD exacerbations for members 40 years of age and older who had an acute inpatient discharge or emergency department encounter on or between January 1–November 30 of the measurement year and who were dispensed appropriate medications. This measure includes two rates: 1) Dispensed a systemic corticosteroid within 14 days of the event; and, 2) Dispensed a bronchodilator within 30 days of the event. See HEDIS 2012 Technical Specifications, Volume 2 for more information about data specifications. Analysis of submitted data suggests that there is little missing data for this measure.

- *Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (Part C).* We are considering adding the percentage of adolescent and adult members with a new episode of alcohol or other drug (AOD) dependence who received: 1) Initiation of AOD Treatment—the percentage of members who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis; 2) Engagement of AOD Treatment—the percentage of members who initiated treatment and who had two or more additional services with a diagnosis of AOD within 30 days of the initiation visit. See HEDIS 2012 Technical Specifications, Volume 2 for more information about data specifications. The

measure used would focus on the 18+. Analysis of submitted data suggests that there is little missing data for this measure.

- *HEDIS Scores for Low Enrollment Contracts (Part C).* As a precursor to including low enrollment contracts in the 2015 Star Ratings, CMS will publish HEDIS scores for low enrollment contracts as part of the 2014 display page. Contracts with less than 1,000 enrollees are first submitting HEDIS data to CMS in the summer of 2013. These data will be analyzed and presented on the display page prior to these data becoming part of the Star Ratings in 2015.

- *Variation of MPF Price Accuracy (Part D).* The current MPF Price Accuracy star rating measure compares a Prescription Drug Event (PDE) unit cost to the corresponding advertised Medicare Plan Finder's (MPF) unit cost, and does not account for instances where the PDE unit cost is lower than the MPF unit cost. CMS is interested in evaluating these instances and determining if there are potentially discriminatory pricing intended to dissuade certain patient populations from joining a plan. Incorporation of this information into the current MPF Price Accuracy measure may occur for 2015.

We are also planning to continue displaying the following measures on the 2014 display page in preparation for the possibility of adding them to the 2015 Star Ratings measures:

- *Special Needs Plan (SNP) Care Management measure (Part C SNPs).* This measure captures the completion of initial and annual standardized health risk assessments among SNPs. See http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/PartCTechSpecs_Oct11.pdf for more information about data specifications.

- *Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).* This measure is based on the PQA-endorsed measure, Completion Rate for Comprehensive Medication Review (CMR), which measures the percentage of beneficiaries who met eligibility criteria for the Medication Therapy Management (MTM) program and who received a CMR. Based on comments received, we propose keeping this measure as a Display Measure for 2014 (using validated 2012 beneficiary-level plan-reported MTM data collected as part of the Part D reporting requirements). For 2014, it would continue to be defined as the percent of non-Long Term Care (non-LTC) MTM program enrollees who received a CMR. The denominator is the number of non-LTC beneficiaries who were at least 18 years or older as of the beginning of the reporting period and who were enrolled in the MTM program for at least 60 days during the reporting period. The numerator is the number of beneficiaries from the denominator who received a CMR during the reporting period.

LTC beneficiaries are excluded from this measure calculation using the plan-reported LTC enrollment element, in which plans indicate for each beneficiary eligible for MTM if the beneficiary was a LTC resident for the entire time they were enrolled in MTM during the reporting period. CMS has conducted additional testing and has concerns about the accurate exclusion of MTM program enrollees based on plan-reported LTC status. CMS' initial attempts to validate the plan-reported LTC status of MTM program enrollees against data on nursing home stays from the Minimum Data Set (MDS) found that approximately 25% of MTM program enrollees reported by plans as LTC beneficiaries for the entire time they were enrolled in MTM were reported in MDS as never being a LTC resident (conversely, 75% of MTM program enrollees reported as LTC beneficiaries were reported in MDS as being a LTC resident). In contrast, CMS found plans' reporting of beneficiaries as not being enrolled in LTC, or with unknown LTC status matched MDS records. As a result of these findings, CMS is concerned that there is a risk of plans incorrectly reporting a beneficiary as being a LTC resident in order to exclude them from the CMR completion rate calculation when a CMR was not delivered in order to improve their rates. This would prevent accurate comparisons of plans' MTM programs by CMS. CMS already provides plans with a long term care institutional indicator to assist in identifying beneficiaries with SNF or other LTC status and believes that this data source is preferable to plan-reported data. To better meet plan's needs, CMS will begin providing the long term care institutional indicator report on a quarterly basis in 2013 (exact dates for distribution to be determined). CMS is also considering continued use of plan-reported LTC status, but to only exclude those MTM enrollees from the denominator for the 2014 Display Measure reported as LTC residents if LTC status is verified in MDS.

Beginning in 2013, LTC beneficiaries are no longer exempt from the CMR requirement, and sponsors are required to offer CMRs to all beneficiaries enrolled in the MTM program at least annually regardless of setting. In the HPMS memo dated April 10, 2012 titled *CY 2013 Medication Therapy Management Program Guidance and Submission Instructions*, CMS provided additional definition and guidance for the delivery of CMRs. Also, as of January 1, 2013, an individualized, written summary in CMS' standardized format must be provided following each CMR. The provision of the written summary in the standardized format requires certain minimum service levels and will help further standardize the delivery of CMRs across sponsors. For these reasons, CMS proposes adding this measure to the Star Ratings in 2015 using 2013 data with the inclusion of LTC beneficiaries in the measure calculation. CMS will also explore if further refinement of the measure calculation is warranted considering the targeting criteria and size of the MTM eligible population may significantly vary by plan sponsor. Sponsors should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs and who they must offer a CMR. We are seeking comments on possible ways to weight or factor the percent of the Part D

sponsors' enrollment population that is eligible for their MTM program into the measure calculation for a more fairer comparison.

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

- *Drug-Drug Interactions Measure (Part D).* This measure is adapted from the PQA Drug-Drug Interactions measure. It is defined as the percent of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or subsequent to the initial prescription. The PQA reviewed and updated the list of drug-drug interactions. We propose to continue to use the current PQA DDI measure list for the 2014 Display Measure (using 2012 PDE data) and to test and implement the updated PQA DDI measure list for the 2015 Display Measure (using 2013 PDE data). The changes made to the DDI list include:
    - Delete the DDIs - carbamazepine and propoxyphene; tamoxifen and SSRIs; warfarin and cimetidine; warfarin and fibrates (fenofibrate, fenofibric acid, gemfibrozil).
    - Add the DDIs - carbamazepine and clarithromycin, erythromycin and telithromycin.

It is expected that all other 2013 display measures will continue to be shown on http://www.cms.gov.

Forecasting to 2015 and Beyond

Potential new measures we are considering proposing for 2015 include:

- *Disenrollment Reasons*. CMS will be implementing PDP and MA Plan Disenrollment Reasons survey in 2013. A random sample of voluntary disenrollees at each contract will be surveyed as close as possible to the actual disenrollment. In the previous pilot testing of this survey, beneficiaries frequently cited the following reasons for disenrollment: financial reasons, prescription drug benefits and coverage, patient experience with regard to prescription drugs, patient experience with regard to health plan, and coverage of doctors and hospitals. The primary reasons for disenrollment may be considered for new measure(s) to be included in Star Ratings in the future. This is similar to the disenrollment reasons information that CMS used to make publicly available for health plans prior to 2006 when the reasons for disenrollment were linked to the disenrollment rates information. CMS will be providing reports back to contracts with results for their enrollees with comparisons to state, region, and national estimates. The primary purpose of the plan reports is to assist MA and PDP contracts with quality improvement efforts, and to that end, we will provide both summary measures and drill-down item information.

Changes to Measure Specifications or Calculations

- *Breast Cancer Screening for HEDIS 2014*. The National Committee for Quality Assurance is considering making the following modifications to this measure:
    - Raising the denominator upper age to 74 years;
    - Stratifying the measure into two age group-based rates: 40-49 years and 50-74 years; and
    - Changing the numerator time frame from 24 months to 30 months.

  NCQA encourages health plans to provide feedback on the proposed changes through the NCQA public comment website available in February of 2013.

- *HOS Calculations.* The Star Ratings incorporate health outcome measures from the Health Outcomes Survey (HOS). CMS is exploring alternative scoring approaches such as a model that combines multiple health dimensions into a score from 0 to 1, where 0 represents death and 1 represents optimum functioning. Work is underway to assess reliability and validity of the model. CMS will provide plans with additional details on this model as they become available in the fall of 2013. If the additional work proves successful, CMS would consider adding the measure derived from this model to the 2015 display page and potentially to Star Ratings in subsequent years.

Measures for Informational Purposes Only

We are considering introducing the following measures to the 2014 display page for informational purposes only (i.e., they would not have an effect on Star Ratings).

- *CAHPS measures about contact from a doctor's office, health plan, pharmacy, or prescription drug plan*. For example, measures include questions that ask about reminders for appointments, tests or treatment, to get a flu shot or other immunization, or screening tests such as breast cancer or colorectal cancer screening; follow up after a hospital stay; reminders to fill or refill a prescription, and to ensure medications are taken as directed.

- *Use of Highly Rated Hospitals.* Using the Hospital Value-based Purchasing scores, develop an enrollment weighted measure of hospital utilization. Inclusion of this measure on the display page is pending ongoing analysis.

- *CAHPS – Complaint Resolution*. CMS is interested in using beneficiaries' responses regarding their satisfaction with the resolution of their complaints as a new display measure for informational purposes. This information would complement the information currently available on complaint rates.

Additional measures under consideration for the future include:

- *CAHPS – Health Information Technology – EHR measures*. There are many local, regional, and national initiatives to accelerate the adoption of electronic health records which will result in changes in terms of how care is delivered. Given this significant change in the healthcare delivery system, it is important to assess the use of electronic health records from the perspective of patients. CMS is considering adding a small set of questions to the CAHPS survey to obtain information on the use of electronic health records from the patient perspective. CMS is currently exploring modifying for the health plan setting a subset of questions that have previously been developed for the Clinician & Group CAHPS Survey that focus on:

    - Use of a computer or handheld device during office visits
    - Use of a computer or handheld device to look up test results or other information about patient during office visits
    - Use of a computer or handheld device to show patient information
    - Use of a computer or handheld device to order prescription medicines
    - Whether patient found provider's use of a computer or handheld device helpful
    - Whether patient found it harder or easier to talk to provider when provider used computer or handheld device

  If CMS goes forward with these items, they would be implemented in the 2014 CAHPS survey. CMS recognizes that this is an evolving area so initially these measures would be collected and fed back to plans as part of their annual CAHPS Plan Reports for quality improvement.

Plan/Sponsor Continuity of Operations (COOP)

We are considering developing proposed regulations that would establish COOP requirements for MA organizations and Part D sponsors to help ensure the continuity of essential functions, operational areas, and critical IT support systems.

In the wake of Hurricane Sandy, it became clear that some plans, particularly some with operational centers and/or IT resources physically located in the affected areas, did not have consistent continuity plans or back-up systems/processes to ensure ongoing operations and the coordinated deployment of critical staff to back-up locations.

We believe that establishing a COOP framework, including a core set of minimum requirements, will assist organizations and sponsors in the event of future disruptions, as well as help ensure that critical Medicare benefits continue to be delivered. Examples of minimum requirements contained in typical COOP plans include:

- Security and availability of mission critical data and IT systems
- Establishment of a chain of command
- Procedures for staff and downstream contractor notification and activation of the COOP
- Attainment of operational capability within 12 hours.

CMS is requesting comments from MA organizations and Part D sponsors on establishing a COOP framework of minimum requirements intended to help ensure beneficiaries will continue to have access to coverage and care. We are specifically interested in feedback regarding those key operations that must remain available or be recoverable within 12 hours and which systems and other IT support hardware should be considered mission essential. Comments will be considered for future rulemaking on this topic.

Revisions to Good Cause Processes

In April, 2011, we published final regulations to allow reinstatement into a Medicare Advantage (MA) or Part D plan when an individual is disenrolled for failure to pay premiums or the Part D income related monthly adjustment amount (Part D-IRMAA), but is determined to have good cause (75 FR 21456). We published coordinating regulations in April, 2012, to extend the same rights to beneficiaries enrolled in cost plans (77 FR 22096). We defined good cause as an unexpected and unforeseen circumstance that prevented the individual from making timely payment. For plan year 2012, CMS established a process for receiving good cause requests, making determinations, and communicating with plans on payments to meet the requirements for reinstatement.

During 2012, CMS received helpful feedback about the process from plans and sponsors. We used this information to adjust communication materials to streamline the process and lessen the number of CTM complaints that plans received for potential disenrollment errors. CMS is now contemplating options to further improve and streamline the good cause review process. For example, we are considering expanding the plan's role in the process to include accepting requests and gathering information about these cases prior to submitting the requests to CMS for good cause determinations. While we are considering options for additional plan involvement, responsibility for making the final determination of good cause will remain with CMS.

CMS is requesting comments from MA organizations and Part D sponsors on ways we might improve the process to receive and review good cause requests for reinstatement. Comments will be considered for future guidance and possible future rulemaking.

Year 7 Agent/Broker Compensation Guidance

Section 1851(j)(2) of the Social Security Act gives the Secretary the authority to establish limitations on agent and broker compensation so as to create incentives for them to enroll individuals into Medicare Advantage plans intended to best meet the individuals' health care needs. Section 1860D-4(l) extends these same limitations to the Part D program. The implementing regulations found at 42 C.F.R. §422.2274 and §423.2274 establish the limitations on compensation including: the definition of total compensation amount, the 6-year compensation cycle, initial and renewal compensation amounts, and rules for when and how compensation is paid. The Medicare Marketing Guidelines (section 120) provide sub-regulatory guidance for plans to operationalize the regulatory requirements.

While CMS established a 6-year compensation requirement for MA organizations and PDP sponsors to pay independent agents/brokers, it was silent about what plans may do after the 6-year cycle expires. We are now approaching the end of the first 6-year cycle, and a number of plans have asked us whether they can continue to pay agents/brokers beyond the 6-year cycle. As an interim step, we have advised MA organizations and PDP sponsors in our MMG (section 120.4.3) that they can, at their own discretion, continue to pay renewal compensation beyond the six years.

We are concerned that agents/brokers may have an incentive to move beneficiaries to another plan after year 6 in order to start a new 6-year compensation cycle. As a result, we intend to propose rules in 2013 (for the 2015 contract year) addressing agent/broker compensation requirements, including allowing MA organizations and PDP sponsors to continue to pay agents/brokers compensation at an amount up to the renewal amount for years seven and beyond.

Capitated Financial Alignment Demonstrations

CMS is working to improve the quality of care that individuals dually eligible for Medicare and Medicaid (Medicare-Medicaid enrollees) receive by expanding access to seamless, integrated programs. CMS will test two financial alignment models with States across the country – a capitated approach (the Capitated Financial Alignment Demonstration) using health plans (Medicare-Medicaid Plans, or MMPs) as the delivery vehicle for integrated care, and a managed fee-for-service approach.

Annual Low Income Beneficiary Reassignment

While each participating State's demonstration model may be different, generally, under the capitated model, certain beneficiaries who would have otherwise been reassigned under CMS's annual reassignment process to a Part D plan may instead be passively enrolled into an MMP. However, if a beneficiary is not passively enrolled, but instead is included in the CMS reassignment to a new PDP effective January, 2014 (for example, if CMS and a state implement a demonstration on a date other than January, 2014), the individual will not be eligible for passive enrollment into an MMP until January, 2015.

In addition to those individuals who would have been otherwise included in Part D reassignment in 2014, other Medicare and Medicaid enrollees may be passively enrolled into an MMP including beneficiaries currently enrolled in other Medicare health or drug plans that would not be part of the reassignment process. Please refer to http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html for more information about the demonstrations.

CMS will provide additional information about the states in which we will implement a demonstration in 2014.

Auto and Facilitated Assignment

New Medicare-Medicaid beneficiaries may be auto enrolled into an MMP instead of a Part D sponsor in some demonstration states. CMS will provide additional information when this policy is finalized.

Enrollment

While certain Medicare-Medicaid beneficiaries may be offered passive enrollment into an MMP, beneficiaries may opt out of enrollment at any time and an MMP may not lock enrollees into its plan. Beneficiaries may use any of the existing election periods available to them as outlined in MA and PDP guidance to elect other Medicare coverage options.

Marketing

MAOs and PDPs operating in prospective demonstration areas must ensure that their agents, brokers, contracted providers, and/or plan representatives do not distribute marketing materials that are materially inaccurate, misleading, or otherwise make material misrepresentations about the possible impacts of the demonstration on Medicare Advantage (MA) plans and Prescription Drug Plan (PDP) Medicare-Medicaid enrollees.

CMS and States will monitor enrollments and disenrollments for both evaluation purposes and for compliance with applicable marketing and enrollment laws regulations and CMS policies, for the purposes of identifying any inappropriate or illegal marketing practices. As part of this analysis, CMS and States will monitor any unusual shifts in enrollment by individuals identified for passive enrollment into a particular MMP to an MA plan operated by the same parent organization. If those shifts appear to be due to inappropriate or illegal marketing practices, CMS and the State may discontinue further passive enrollment into an MMP. Any illegal marketing practices will be referred to appropriate agencies for investigation.

Section II – Part C

Benefit Flexibility for Certain Special Needs Plans

Regulations at 42 CFR §422.102(e) allow dual eligible special needs plans (D-SNPs) that meet a high standard of integration and minimum performance and quality-based standards to offer supplemental benefits beyond those currently permitted for MA plans. Such D-SNPs must meet the established standards for a high level of integration of services, but are not required to meet the definition of a fully integrated dual eligible SNP (FIDE SNP), as defined in 42 CFR §422.2 of the MA program regulations. Below, we remind MA plans of those qualifying criteria for CY2014. Additional information, including the qualifying criteria listed below and the list of applicable benefits may also be found in the updated Medicare Managed Care Manual Chapter 16b – Special Needs Plans that will be issued in early Spring2013.

(a) Contract Design Requirements for Plans to Qualify for Benefits Flexibility

In order to meet the minimum contract requirements for the purposes of qualifying for benefits flexibility in CY 2014, the D-SNPs must:

- Be a specialized MA plan for special needs individuals described in section 1859(b)(6)(B)(ii) of the Act;
- Be operational in CY 2014, and have operated in CY 2013;
- Facilitate access to all covered Medicare benefits and all Medicaid benefits covered in the State Medicaid plan;
- Have a current, capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long term care benefits and services, when such coverage is consistent with State policy;
- Coordinate delivery of covered Medicare and Medicaid primary, acute, and long term care services throughout its entire service area; and
- Possess a valid contract arrangement with the State, in accordance with CMS policy and the requirements at 42 C.F.R. §422.107.

We will apply these contract design requirements at the individual SNP plan (i.e., SNP plan benefit package) level.

(b) Qualifying Standards for Benefits Flexibility Eligibility

The D-SNP must:

(1) have received a 3-year approval of its model of care most recently reviewed by the National Committee for Quality Assurance (NCQA); and

(2) Either be in a contract with a 3 star (or higher) overall (i.e., Parts C and D) rating for CY 2013 on the Medicare Plan Finder website; or if the D-SNP is part of a contract that does not have sufficient enrollment to generate a star rating, the ratings will be based upon CY 2013 SNP plan-level HEDIS measures.

(3) In addition, the D-SNP must not be a poor performer, i.e., not be part of a contract with a score of 2 points or more on either the Part C or the Part D portion of the 2014 application cycle past performance review methodology.[4]

[4] The 2014 past performance methodology is described in our "2014 Application Cycle Past Performance Review Methodology Update" memo issued via the Health Plan Management System (HPMS) on January 17, 2013. The past performance methodology analyzes the performance of MA and Part D contracts in 11 distinct performance categories, assigning negative points to contracts with poor performance in each category. The analysis uses a 14-month look-back period; thus, for example, the 2014 application cycle analysis looks at performance from January 1, 2012 through February 28, 2013. While this analysis is done at the contract level, the results are rolled up to the legal entity level for purposes of denying applications based on past performance. We propose to use the contract-level results for purposes of the SNP quality formula.

As a condition of offering any of the additional supplemental benefits, we are requiring qualified D-SNPs to attest, at the time of bid submission, that the additional supplemental benefit(s) they describe in the plan benefit package (PBP) do not inappropriately duplicate an existing service(s) that enrollees are eligible to receive under a waiver, the State Medicaid plan, Medicare Part A or B, or through the local jurisdiction in which they reside. Additionally, qualified D-SNPs that elect to offer additional supplemental benefits must specifically describe the benefit(s) each enrollee would receive in the individualized care plan and track progress on certain goals (e.g., keeping beneficiaries in the community and out of institutions) in their MOCs. The D-SNP must submit to CMS portions of its MOC annually to document the new supplemental benefit(s) they would be offering under this benefit flexibility. CMS will include those D-SNPs in MOC implementation reviews/audits.

D-SNPs that believe they meet the qualifying criteria set forth above, and that wish to offer additional supplemental benefits will be required to notify us of their intent by March 4, 2013. We will review those requests and notify each plan about whether or not it will be eligible to offer additional benefits. We will provide qualified D-SNPs with additional operational guidance on bid submission and benefits requirements at that time. D-SNPs should not discuss the specifics of their proposed benefits in their requests. Rather, qualified D-SNPs would include their specific proposed benefits as a part of their PBPs during bid submission, and we will approve D-SNPs' specific new supplemental benefits, as appropriate.

Plans that wish to be considered for participation in this initiative must send their participation requests via email to: snp_mail@cms.hhs.gov.

SNP Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) Requirements

FIDE SNPs must mail CY 2014 Annual Notice of Change (ANOC) with the Summary of Benefits (SB) for member receipt by September 30, 2013 and then send the Evidence of Coverage (EOC) for member receipt by December 31, 2013. Dual eligible SNPs that send a combined, standardized ANOC/EOC for member receipt by September 30, 2013 are not required to send an SB to current members; however, the SB must be made available upon request.

Updates to the Qualification Process for Fully Integrated Dual Eligible (FIDE) Special Needs Plans

For CY 2014, D-SNPs that wish to be reviewed as a Fully Integrated Dual Eligible (FIDE) Special Needs Plan (SNP) must attest that they would like to be reviewed as a FIDE SNP and complete and upload the FIDE SNP Contract Review Matrix (found in the CY 2014 SNP Proposal). Plans should use this matrix to identify where each FIDE SNP element is met within their State Medicaid Agency Contract (SMAC). The matrix will be used to assist CMS in reviewing the SMAC to determine whether a D-SNP qualifies as a FIDE-SNP under 42 CFR § 422.2, i.e., that the D-SNP: 1) provides dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization; 2) has a capitated contract with a

State Medicaid Agency that includes coverage of specified primary, acute, and long term care benefits and services consistent with State policy; 3) coordinates the delivery of covered Medicare and Medicaid health and long term care services using aligned care management and specialty care network methods for high-risk beneficiaries: and 4) employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, enrollment, communications, grievance and appeals, and quality improvement. CMS will issue a written determination to the D-SNPs that wish to be reviewed as FIDE SNPs that indicates whether or not they qualify.

Supplemental Benefits Guidance

Pap Smear /Pelvic Exam

In the draft call letter for CY 2013, we proposed to require that MA plans and section 1876 cost contractors adhere to the schedule used under Original Medicare for providing $0 cost share preventive services, with two exceptions: additional sessions of smoking and tobacco cessation counseling and medical nutrition therapy as supplemental benefits. Thus, MAOs would not have been allowed to offer other preventive services (e.g., annual screening Pap smears/pelvic exams) as supplemental benefits. Rather, MAOs must adhere to the Medicare Part B benefits schedule, under which certain preventive services, including screening Pap smears/pelvic exams are covered at $0 cost share every two years. Ultimately, however, we decided to continue to allow MA plans to continue to offer annual screening Pap smear/pelvic exams as a supplemental benefit, because we were sensitive to plans' concerns that they not withdraw such services without time to educate enrollees about their reasons for doing so. We encouraged plans to prepare for the probability that such annual screening services may not be allowed as supplemental benefits in future years.

For CY 2014, MAOs will be required to adhere to the Medicare Part B benefits schedule, and will not be allowed to offer annual screening Pap smears/pelvic exams as supplemental benefits. As we have explained previously, our interests are in ensuring that beneficiaries receive high quality, effective health care services from their MA plans, and we are concerned that not adhering to the Medicare Part B schedule for screening services and instead offering screening services that may not be clinically appropriate or medically necessary is inconsistent with that goal. Moreover, accepted clinical standards not only limit annual screening Pap smear/pelvic exams to every 24-36 months for much of the population, but also call for discontinuing those screenings after a woman reaches a certain age. CDC reported that, starting in 2003 and becoming consistent across organizations in 2012, guidelines state that women with a history of adequate screening no longer should be screened after age 65 years[5]. Additionally, CDC has

[5] U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report: *Cervical Cancer Screening Among Women by Hysterectomy Status and Among Women Aged ≥65 Years — United States, 2000–2010.* Washington: U.S. Government Printing Office. January 4, 2013

reported that routine screening for cervical cancer by Pap testing is no longer recommended for women who have undergone a total hysterectomy (the removal of the uterus, including the cervix) or for adequately screened women after age 65 years. Before 2003, the American College of Obstetricians and Gynecologists (ACOG) recommended regular screening be continued posthysterectomy, the American Cancer Society (ACS) did not address screening posthysterectomy, and the U.S. Preventive Services Task Force (USPSTF) stated that most women did not benefit from posthysterectomy screening. In late 2002 and 2003, when the three organizations updated their guidelines, they all recommended that most women having had total hysterectomies for benign reasons should no longer be screened regularly, and USPSTF recommended that women aged >65 years with a history of normal screening results should no longer be routinely screened . Updates in 2009 and 2012 did not significantly change recommendations not to screen women post-hysterectomy. Thus, for most of the aged Medicare population, accepted clinical practice guidelines do not recommend annual screening Pap smear/pelvic exams. Note that our policy in no way restricts plans from providing medically necessary Pap smear/pelvic exams.

Rewards and Incentives Programs for Medicare Advantage Organizations

Over the past year, CMS has received several proposals from MAOs interested in implementing new enhanced MA rewards and incentives programs. In response, we expanded the rewards and incentives policy in the Marketing Guidelines (Chapter 3 of the Medicare Managed Care Manual) by eliminating the annual limit on the dollar amount plans may offer to beneficiaries.

CMS is interested in exploring how the existing rewards and incentive policy and guidelines may be expanded further to promote innovative programs to improve health outcomes and lower healthcare costs. In order to fully consider whether, and how, we could expand current Part C rewards and incentives policy, we are seeking information regarding the experience and impact of rewards and incentives programs currently offered in the commercial market. This could include rewards and incentives geared to participation in programs to promote wellness or positive lifestyle changes focused, for example, on diet/nutrition, exercise, stress management, etc. Specifically, we would like information and data related to such programs, particularly about those that have proven to be effective in improving health outcomes while reducing or maintaining costs and that may be appropriate for Medicare beneficiaries enrolled in MA plans.

Provider / Beneficiary "Shared Decision Making"

Sec. 3506 of the Affordable Care Act includes a provision to facilitate shared decision making in an effort to enable collaborative processes between patients, caregivers, and clinical staff. Additionally, there have been a number of recent studies that have demonstrated the value of high quality shared decision-making in reducing costs and potentially unnecessary care. Shared decision-making programs are geared to enhancing the patient's understanding of their medical condition, services and procedures, and the options available for treatment. Research suggests

shared decision-making is especially helpful when there is no clear "best" treatment option for an individual.

In addition to discussion with the provider, the provider may also offer decision aid information that will help the patient reach an informed decision about the care he or she would like to receive. In a shared decision-making environment, the patient:

- Understands the likely outcomes of various treatment options;
- Considers what is important about the risks and benefits of each option, based on personal values and preferences; and
- Fully participates in decisions about his or her medical care.

CMS is interested in facilitating shared decision-making as a feature of MA plans through the identification of current programs or unique approaches that have demonstrated effectiveness. Therefore, we are asking MAOs to share proposals or descriptions of their current shared decision-making programs that may help CMS establish standards for such approaches.

Elements of the programs or approaches should include:

- Identification of specific medical conditions for which shared decision making would be appropriate;
- Examples of decision aids used to effectively communicate appropriate care options;
- Use of patient and provider incentives to encourage participation. This should include information regarding the level of incentive that has proven effective in eliciting desired results.

Inappropriate shifting of drug coverage from Medicare Part B to Part D

Some drugs that are covered under Medicare Part B when provided incident to a physician service may be covered under Medicare Part D when dispensed upon a prescription from a pharmacy. Enrollees in an MA plan offering Part D coverage may elect to have a drug dispensed from a pharmacy and bring it to their MA plan physician for administration in the physician's office. This practice is not prohibited under Part C or Part D when the beneficiary elects, as a matter of personal preference, to obtain a drug from a pharmacy under Part D that is otherwise a Part B-covered drug when furnished at a physician's office out of the physician's own stock.

Nevertheless, an MA organization may not require enrollees to engage in this practice in order to force the enrollee to obtain drug coverage under Medicare Part D when coverage would otherwise be available under Medicare Part B. In other words, the decision to forgo Part B coverage for Part D coverage of a drug that would ordinarily be covered under Part B when furnished at a physician's office out of the physician's own stock rests entirely with the enrollee (and their physician) and such decision may not be mandated or influenced by the MA organization. This does not affect the MA organization's ability to contractually require its network physicians to obtain Part B drugs from specified suppliers that bill the MA organization

directly as long as such arrangements do not result in coverage being shifted from Part B to Part D (see Chapter 6, Appendix C of the Medicare Prescription Drug Benefit Manual "Part B Covered Drugs in the Context of a Professional Service").

Plans with Low Enrollment

Before the end of March 2013, CMS will send each MAO a list of plans that have been in existence for three or more years as of February 2013 (three annual election periods), and have fewer than 500 enrollees for non-SNP plans or fewer than 100 enrollees for SNP plans. The lists will not include plans with low enrollment that CMS determines are located in service areas that do not have a sufficient number of competing options of the same plan type.

Under our authority at 42 CFR §422.506(b)(1)(iv), MAOs must confirm through return email, that each of the low enrollment plans identified by CMS will be eliminated, consolidated with another of the organization's plans for CY 2014, or provide a justification for the renewal. If CMS does not find that there is a unique or compelling reason for maintaining a plan with low enrollment, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting business cases and what information is required in those submissions will be included with the list of low enrollment plans sent to the MAO.

CMS recognizes there may be reasonable factors, such as specific populations served and geographic location, that lead to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because of their focus on a subset of enrollees with certain medical conditions. CMS will consider all such information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs are to follow the CY 2014 renewal/non-renewal guidance in the final Call Letter to determine whether a low enrollment plan may be consolidated with another plan(s).

Overview of CY 2014 Benefits Bid Review

Portions of this guidance apply to section 1876 cost plans, MA plans, including employer group plans, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs) and Institutional Special Needs Plans (I-SNPs). Employer group plans, D-SNPs, and section 1876 cost plans are excluded from our evaluation to identify duplicative plans, also referred to as the "meaningful difference" evaluation. Similarly, employer group plans and section 1876 cost plans also are not evaluated for low enrollment. Medicare/Medicaid Plan guidance will be provided separately. Note: CMS reserve the right to review employer group plans for low enrollment and/or meaningful difference in future years.

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

Table 1. Plan Types and Applicable Bid Review Criteria

Bid Review Criteria	Applies to Non-Employer Plans (Excluding Dual Eligible SNPs)	Applies to Non-Employer Dual Eligible SNPs	Applies to 1876 Cost Plans	Applies to Employer Plans
Low Enrollment	Yes	Yes	No	No
Meaningful Difference	Yes	No	No	No
Total Beneficiary Cost	Yes	No	No	No
Maximum Out-of –Pocket (MOOP) Limits	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing	Yes	Yes	Yes	Yes
Service Category Cost Sharing	Yes	Yes	Yes[1]	Yes

[1] Section 3202 of the ACA established that MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration, skilled nursing care and renal dialysis services (42 CFR §§417.454(e) and 422.100(j)).

We have made changes to service category cost sharing amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) limits for CY 2014 and have provided explanations of these changes in each applicable section. While we understand that MAOs are being required to address new requirements that are being implemented under the Affordable Care Act, such as the medical loss ratio and health insurance providers fee, it is our expectation that MAOs address these issues independently of our requirements for benefits bid review. Therefore, we are not making specific adjustments or allowances for these changes in our requirements for benefits bid review. We are interested in receiving feedback regarding potential future changes to MA bid review process and welcome your comments.

Meaningful Difference (Duplicative Plan Offerings)

MAOs offering more than one plan in a given service area must ensure 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 2014, CMS will use plan-specific per member per month (PMPM) out-of-pocket cost (OOPC) estimates to identify meaningful differences among the same plan types.

OOPC estimates are based on a nationally representative cohort of more than 12,000 Medicare beneficiaries represented in the 2008 and 2009 Medicare Current Beneficiary Survey data and are used to provide estimated plan cost information to beneficiaries on Medicare Plan Finder. Estimated out-of-pocket costs for each plan benefit package are calculated on the basis of utilization patterns for the MCBS cohort. The calculation includes Parts A, B, and D services

and certain mandatory supplemental benefits, but not optional supplemental benefits. The plan's current enrollment and risk scores will not affect the OOPC calculation. The CY 2014 OOPC model incorporates updated PBP and formulary data, as well as more precise brand and generic drug cost sharing estimates for gap coverage, which utilize Food and Drug Administration data. All documentation and instructions associated with running the OOPC model are posted on the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html

We currently consider HMO and HMO-POS plans as separate plan types for our meaningful difference evaluation and are considering HMOs and HMO-POS to be one plan type going forward. Our analysis indicates that not all HMO-POS plans offer all Parts A and B benefits on an out-of-network basis without limitations. A reasonable business case can be made that HMO-POS plans are very similar to HMO plans. Therefore, we will be looking more closely at these plans in 2014.

CMS will evaluate meaningful differences among CY 2014 non-employer and non-cost contractor plans offered by the same MAO, in the same county, as follows:

1. The MAO's non-SNP plan offerings will be separated into four plan type groups on a county basis: (1) HMO/HMO POS; (2) Local PPO; (3) Regional PPO; and (4) PFFS.

2. SNP plan offerings will be further separated into groups representing the specific target populations served by the SNP. Chronic Care SNPs will be separated by the chronic disease served and Institutional SNPs will be separated into the following three categories: Institutional (Facility); Institutional Equivalent (Living in the Community); and a combination of Institutional (Facility) and Institutional Equivalent (Living in the Community). D-SNPs are excluded from the meaningful difference evaluation.

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 combined Part C and Part D OOPC PMPM estimate will be calculated for each plan. There must be a difference of at least $20.00 PMPM between the combined OOPC for each plan offered by the same MAO in the same county to be considered meaningfully different. Plan premium is not included in the meaningful difference evaluation.

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

CMS expects MAOs to submit CY 2014 plan bids that meet the meaningful difference requirements, but will not prescribe how the MAOs should redesign benefit packages to achieve the differences. Furthermore, CMS may choose not to allow MAOs to revise their bid

submissions if a plan's initial bid does not comply with meaningful difference requirements because MAOs 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 requirements. MAOs must follow the CY 2014 renewal/non-renewal guidance in the final Call Letter to determine if their plans may be consolidated with other plans.

Total Beneficiary Cost (TBC)

CMS will again exercise its authority under section 1854(a)(5)(C)(ii) of the Affordable Care Act to deny MAO bids, on a case-by-case basis, if it determines that the bid proposes too significant an increase in cost sharing or decrease in benefits from one plan year to the next through the use of the TBC requirement. A plan's TBC is the sum of plan-specific Part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost-sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. By limiting excessive increases in the TBC from one year to the next, CMS is able to ensure that beneficiaries who continue enrollment in the same plan are not exposed to significant cost increases.

We are proposing to reduce the allowed TBC change amount from $36.00 per member per month (PMPM) to $30.00 PMPM for CY 2014 bids. Based on an analysis of past bids, we believe plans should have the ability to adjust bids to meet this requirement, but we are interested in plans' comments about this threshold. As in past years, CMS is evaluating TBC for non-employer plans (excluding D-SNPs) and will calculate and provide to each plan factors that adjust for payment rate, quality bonus changes and other technical adjustments for changes in the PBP software. Thus, plans experiencing a net increase in benchmarks/bonus payments will have an effective TBC change amount below the $30.00 per member per month (PMPM) requirement. Conversely, plans experiencing a net decrease in benchmark and/or bonus payments will have an effective TBC change amount above the $30.00 PMPM requirement. CMS will provide detailed operational guidance and adjustment factors via an HPMS memo and HPMS posting following the final Call Letter.

CMS reserves the right to further examine and request additional changes to a plan bid even if a plan's TBC is within the required amount, if we find it is in the best interest of the MA program. We believe this approach not only protects beneficiaries from significant increases in cost sharing or decreases in benefits, but also ensures beneficiaries have access to viable and sustainable MA plan offerings. For plans that consolidate multiple CY 2013 plans into a single CY 2014 plan, CMS will use the enrollment-weighted average of the CY 2013 plan values to calculate the TBC. Otherwise, these plans will be treated as any other plan for the purpose of enforcing the TBC requirement.

Maximum Out of Pocket (MOOP) Limits

Table 1 below displays the CY 2014 mandatory and voluntary MOOP amount and the combined (catastrophic) MOOP amount limits applicable to LPPOs and RPPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing.

As codified at 42 CFR 422.100(f)(4), (5) and (6), 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. MA plans may establish as a MOOP any amount within the ranges shown in the table. We chose to display the ranges of cost sharing within which plans may establish their MOOPs in order to illustrate that MOOP limits may be lower than the CMS-established maximum amounts and what MOOP amounts qualify as mandatory and voluntary MOOP limits.

Table 1. CY 2014 Voluntary and Mandatory MOOP Range Amounts By Plan Type

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

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

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis. CMS will also apply this requirement separately to the following service categories for CY 2014: Inpatient Facility, Skilled Nursing Facility (SNF), Home Health, Durable Medical Equipment (DME), and Part B drugs. Please note that factors for Inpatient and SNF in Column 4 of the table below (Part B Adjustment. Factor to Incorporate Part B Cost Sharing) have been updated for CY 2014.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the Bid Pricing Tool (BPT). Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA,

column l) is compared to Original Medicare actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For inpatient facility and SNF services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

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

Table 2. Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	PMPM Plan Cost Sharing (Parts A&B) *(BPT Col. l)*	Original Medicare Allowed *(BPT Col. m)*	Original Medicare AE Cost sharing (Part A only) *(BPT Col. n)*	Part B Adjustment. Factor to Incorporate Part B Cost Sharing (Based on FFS data)	Comparison Amount *(#3 × #4)*	Excess Cost Sharing (#1 − #5, min of $0)	Pass /Fail
Inpatient	$33.49	$331.06	$25.30	1.398	$35.37	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.071	$10.59	$0.24	Fail
Home Health[1]	$0.01	$0.30	$0.00	0.150	$0.05	$0.00	Pass
DME	$3.00	$11.37	$2.65	1.000	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1.000	$0.33	$0.00	Pass

[1] Home health has no cost sharing under Original Medicare, so the comparison amount (#5) is calculated by multiplying the Medicare allowed amount (#2) by the Part B Adjustment Factor (#4).

Transferability of an MA enrollee's annual contribution toward their maximum out-of-pocket cost sharing limit (MOOP)

MA plans have asked whether the member dollar contribution toward their MA plan's annual MOOP is transferable when the enrollee makes a mid-year election to enroll in another MA plan of the same type offered by the MAO. We have determined that when an enrollee makes a mid-year election that changes their enrollment from one MA plan of the same type (i.e., HMO, PPO, PFFS) to another MA plan *of the same* type offered *by the same* MAO their accrued contribution

toward their annual MOOP limit should follow them and therefore count toward the annual MOOP in their new MA plan.

Service Category Cost-Sharing Requirements

We are continuing our current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower voluntary MOOP limit than is available to plans that adopt a higher, mandatory MOOP limit. Table 1 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans. CY 2014 bids must reflect enrollee cost sharing for in-network services that is not greater than the amounts displayed below. For LPPOs and RPPOs, these standards will be applied only to in-network services. All standards are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles.

The following list provides an overview of changes for CY 2014:

- Inpatient and home health requirements have been updated to reflect estimated changes in Original Medicare costs for 2014.
- The Skilled Nursing Facility (SNF) cost sharing requirement for the first 20 days has been reduced from $100 to $50 per day for voluntary MOOP plans and from $50 to $25 per day for mandatory MOOP plans to provide greater protection for beneficiaries. The allowable cost sharing requirement for SNF days 21 to 100 has been updated to reflect estimated changes in Original Medicare costs for 2014. Since cost sharing for the overall SNF benefit (i.e., both benefit periods) must be actuarially equivalent with Original Medicare, the cost sharing requirement change for the first benefit period should not impact the overall plan costs associated with the SNF benefit.
- Partial Hospitalization cost sharing has been added as a requirement for 2014.

Table 1. CY 2014 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	$3,973
Inpatient - 10 days	1a	$2,310	$1,848
Inpatient - 6 days	1a	$2,098	$1,678
Mental Health Inpatient - 60 days	1b	$2,475	$1,980
Mental Health Inpatient - 15 days	1b	$1,854	$1,483
Skilled Nursing Facility – First 20 Days[1]	2a	$50/day	$25/day

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Skilled Nursing Facility – Days 21 through 100[2]	2a	$152/day	$152/day
Emergency Care/Post Stabilization Care	4a	$65	$65
Urgently Needed Services	4b	$65	$65
Partial Hospitalization	5	$55	$55
Home Health	6a	20% or $35	$0
Primary Care Physician	7a	$35	$35
Chiropractic Care	7b	$20	$20
Physician Specialist	7d	$50	$50
Psychiatric and Mental Health Specialty Services	7e and 7h	$40	$40
Therapeutic Radiological Services	8b	20% or $60	20% or $60
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10
Renal Dialysis	12	20% or $30	20% or $30
Part B Drugs-Chemotherapy[3]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

[1]Section 3202 of the ACA established that 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, consistent with cost sharing guidance. 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 actuarially equivalent with Original Medicare.

[3] Part B Drugs - Chemotherapy cost sharing displayed is for services provided on an outpatient basis and includes administration services.

Part C Optional Supplemental Benefits

CMS will review non-employer bid submissions to ensure that beneficiaries electing optional supplemental benefits are receiving reasonable value. MAOs must ensure that the total value of all optional supplemental benefits offered to non-employer plans under each contract comply

with the following requirements: (a) margin is no greater than 15% and (b) retention, defined as margin plus administrative expenses, is no greater than 30%.

Part C Crosswalks: Segmentation

CMS has determined that organizations are permitted to change from a non-segmented plan to a segmented plan and crosswalk beneficiaries from the non-segmented plan to the segmented plan. This crosswalk must be completed through a crosswalk exception request. CMS will provide technical instructions for completing a crosswalk exception request in guidance to be released later this year. We will update Chapter 4 of the Medicare Managed Care Manual in the next release.

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

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

We have identified the following category of DME that may not be subject to full limitation based on brand/manufacturer for CY 2014:

Speech-Generating Devices: People who require speech-generating devices frequently have other disabilities; the speech-generating device is tailored to meet the individual's needs. For example, a child with cerebral palsy (CP) could accidentally change a setting on some devices and therefore, should be furnished with a device that is sensitive to the movements of a child with CP. Consequently, MA plans must furnish any medically-necessary speech-generating device purchased by an enrollee.

The following four categories of DME may be subject to partial limitation based on brand or manufacturer:

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

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

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

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

Cost Plan Competition Requirements

In accordance with the American Taxpayer Relief Act of 2012, beginning Contract Year (CY) 2014, CMS will non-renew cost plans in service areas or portions of service areas in which at least two competing MA local or two MA regional coordinated care plans that meet specified enrollment thresholds are available. Affected cost contractors will not be able to operate in affected service areas in 2015.

We will non-renew any portion of a cost plan's service area if there are at least two competing MA local or two MA regional coordinated care plans with a minimum of 5,000 enrollees (urban areas) or 1,500 enrollees (non-urban areas) for the entire year prior to the non-renewal. We will use 2013 enrollment data to determine the cost plans subject to non-renewal and contact affected plans in at the end of 2013 to permit cost contractors wishing to convert to Medicare Advantage plans for CY 2015 time to make the necessary arrangements, including filing a notice of intent to apply with CMS.

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

Cost plans may offer a mid-year service area expansion consistent with 42 CFR §417.402 and as noted above. Cost plans that offer Part D as Cost-PD plans are also subject to the same restriction on mid-year service area expansions as MA-PD plans in that they cannot expand into an area served by an MA-PD or PDP plan.

Expanding use of the Blue Button Initiative

CMS is interested in expanding use of the Blue Button ® Initiative among Medicare Advantage Organizations, which allows Medicare beneficiaries to download personal health information to a printer, computer, memory, or mobile device in the Blue Button format(s) and share that

information with their health care team and care providers. We recommend that MAOs add the Blue Button icon and functionality to existing or new plan portals or websites, thereby providing beneficiaries with one-click secure access to download and/or print their health information. HIPAA specifies that an individual's right of access to personal health information, as it applies to health plans, includes the health plan's enrollment, payment, claims adjudication, and case or medical management record systems, as well as any records used in whole or in part by or for the health plan to make decisions about the individual (45 C.F.R. 164.501). Blue Button provides an easy way for beneficiaries to download their personal health information to a file, which can then be saved on a personal computer and potentially used with other electronic personal health management tools.

Blue Button data is readily available; the name "Blue Button, "the Blue Button logo", and the slogan "Download My Data" have been registered by the Department of Veterans Affairs (VA) with the U.S. Patent and Trademark Office. The license to use these Blue Button Service Marks is available at no cost from the VA at: www.va.gov/bluebutton/apps/License.

We believe this added functionality has the potential to further advance CMS's overall quality strategy and supports efforts to empower beneficiaries to understand their health information and make informed decisions. Moreover, Blue Button has the potential to improve care coordination by allowing beneficiaries to readily and easily share up-to-date health information with their health care providers, health care team, as well as family members. We are soliciting comments from MAOs on how best to expand the use of the Blue Button Initiative.

Medicare Advantage Part C EOB

As noted in our October 18, 2012 HPMS memo entitled, "Final Part C EOB Models and Implementation of the Part C EOB, we expect to require use of the model EOB by October 2, 2013. (Note that Section 1876 cost plans are not required to issue a Part C EOB, and, as explained in the above-mentioned HPMS memo, we have decided, for the time being, to not require plans (including D-SNPs) to provide an EOB to dual eligible enrollees. Currently, we are reviewing comments that were submitted in response to our memorandum and the Paperwork Reduction Act notice published in the Federal Register on November 26, 2012, and will issue further guidance regarding the Part C EOB (including the final EOB templates) in the future.

Summary of Benefits (SB) Update

During the past year CMS evaluated the purpose, function, and effectiveness of the current Summary of Benefits (SB) document. Per the Medicare Marketing Guidelines, the SB is a standardized document that plans must distribute with an enrollment form, and provides consumers an overview of plan benefits in a consistent and uniform manner, so that individuals can compare plans.

CMS has sought feedback from both beneficiaries and the industry about the use of the SB in a variety of ways. In 2011, CMS issued a Federal Register Notice for Comment regarding challenges faced by Medicare-Medicaid enrollees, including difficulties with cost-sharing information in the SB. In 2012, CMS consumer tested the SB through one-on-one participant interviews to determine whether beneficiaries could identify the purpose of the SB and identify opportunities for increasing beneficiary comprehension.

CMS found that overall, beneficiaries had difficulty using the SB to understand plan benefits or compare plan benefits against Original Medicare (OM). The existing format (which compares benefits of the plan against those in OM) and some of the terminology used throughout the SB appears to create significant challenges with comprehension.

Overall, the MA organizations and PDP sponsors that provided feedback indicated they use the SB as a pre-enrollment document but implied the document is distributed only because it is required. In addition, the SB is often used to train staff on plan benefits. Therefore, organizations and sponsors would prefer to see a condensed version of the document that focuses on the benefits of the plan.

Based on this feedback, CMS is considering significant revisions to the structure and format of the SB with a focus on two areas: (1) limiting the description of benefits to those covered under the plan, addressing the scope, and removing the comparison of benefits against coverage under Original Medicare; and (2) describing plan benefits and cost-sharing using beneficiary friendly language. We are soliciting comments from the MA organizations and PDP sponsors that will assist us in creating an SB that is a more beneficiary friendly and useful document.

PBP Notes Update for CY 2014

CMS has generally allowed MAOs to include additional information about the benefit being offered in the notes sections in the PBP. The information in the notes sections is not to contain any cost sharing for the benefit/service that is not reflected in the PBP data entry field for the benefit/service. In addition, any information in a note must be consistent with the benefit/service as it is reflected in the PBP data entry fields. MAOs may not use the notes fields to specify conditions for coverage or cost sharing charges, because information entered in the notes fields is not captured to generate summary of benefits (SB) sentences. All cost sharing must be transparent and readily accessible to beneficiaries as they make plan comparisons.

An appropriate note contains only information applicable to the service category in which the note section is located and provides relevant information that reviewers need for bid evaluation; it does not repeat the cost sharing information entered in the data entry field. We have taken several steps to help plans present benefits without the need for extensive notes. We will include additional, minor clarifications regarding a number of acceptable supplemental benefits in a future HPMS memo. We realize that in the past, notes have often been used to support marketing material; therefore, we will continue to coordinate our efforts with our marketing review staff to

limit plans' use of notes to providing additional information and not as duplication, verbatim of the benefit descriptions.

Section 6055 of the Internal Revenue Code.

Section 1502(a) of the Affordable Care Act added new section 6055 (Reporting of Health Insurance Coverage) to the Internal Revenue Code to require every health insurance issuer to provide notice of minimum essential coverage to the Internal Revenue Service (IRS) and impacted individuals on an annual basis beginning in 2015. CMS is working to implement this provision as it relates to Medicare coverage and will provide additional information regarding what role, if any, MA organizations will play in this process.

Section III – Part D

Payment for Hospice and ESRD Beneficiaries under Part D

Introduction

Drugs and biologics covered under the Medicare Part A per-diem payment to a hospice program or included in the Part B bundled payment to an end-stage renal disease (ESRD) dialysis facility are not covered under Part D. To assist Part D sponsors in appropriately excluding these drugs from Part D payment, CMS previously issued guidance directing sponsors to place prior authorization (PA) requirements the categories of ESRD drugs that are always considered ESRD-related. For other drugs that may be ESRD-related and included in the bundled payment to ESRD facilities, and for drugs that may be covered under the hospice per-diem payment, our guidance has previously been to pay for the drug and retrospectively determine payment responsibility. If the drug was later determined to be the responsibility of the hospice or dialysis facility, the sponsor had to recover the Part D payment from the pharmacy and reverse the PDE. This approach, which is similar to the approach employed in certain Medicare secondary payer situations, has proven problematic for sponsors, pharmacies, and beneficiaries.

When we initially proposed the "pay-and-chase" approach, we thought that in the vast majority of situations, the respective parties would reliably follow Medicare rules and bill appropriately. For ESRD, the Medicare bundled payment to the dialysis facility includes all drugs and biologics used in the treatment of ESRD except "oral-only" drugs. For hospice, the Medicare per-diem payments cover drugs and biologics used primarily for the relief of pain and symptom control related to the terminal condition as well as related conditions. We now better understand that a hospice or ESRD dialysis facility may be uncertain about these definitions. A Part D sponsor will therefore be similarly uncertain about whether payment is the responsibility of either the hospice or dialysis facility or Part D. Therefore, we have learned this approach is often placing a significant financial burden on the pharmacy and beneficiary when payment for a drug is later determined to be the responsibility of the hospice or dialysis facility. In those instances, the Part D sponsor would have recovered the erroneous payment from the pharmacy, leaving the pharmacy to attempt recovery from the hospice or dialysis facility. The beneficiary who had

paid the Part D cost sharing to the pharmacy would have instead been liable for the coinsurance payment to the hospice (which may not exceed $5) or the ESRD cost sharing (which is 20% of the total bundled payment for ESRD-related services, which includes ESRD-related drugs). The pay-and-chase approach also continues to provide the erroneous impression to hospice providers or ESRD facilities and their patients that the drugs are coverable under Part D.

Proposed 2014 Hospice Drug Policy

In lieu of making conditional payment for drugs and biologics that may be covered under the Medicare Part A per-diem payment to a hospice program (as specified in section 1861(dd) of the Social Security Act and in Federal regulations at Part 418), we are proposing that, beginning January 2014, when a sponsor receives a transaction reply report (TRR) showing a beneficiary has elected hospice, the sponsor place beneficiary-level PA requirements on four categories of prescription drugs. The four categories include the following: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs. These four categories are drugs identified by the DHHS Office of Inspector General (OIG) as typically used to treat the symptoms generally experienced by hospice beneficiaries during the end of life. The OIG documented this finding in their review of Medicare payments for prescription drugs for beneficiaries in hospice in their final report (A-06-10-00059) dated June 28, 2012.

In their review, the OIG also identified 8 drug classes that included 54 drugs prescribed for chronic obstructive pulmonary disease (COPD) and 1 drug class for the 1 drug prescribed for amyotrophic lateral sclerosis (ALS). Therefore, we are soliciting comment on whether to extend the PA requirement to include these COPD and ALS drugs as well. We note that CMS may add to these categories or add specific drugs in the future.

The imposition of PA requirements means that payment for drugs in the hospice categories would stop and the pharmacy would receive a reject code on the response to the pharmacy's billing transaction indicating that prior authorization is required for adjudication of the claim. The pharmacy would need to initiate dialogue between the parties to resolve payment responsibility. This approach will prevent the payment of drugs by Part D that should have been covered by the hospice program facility. Drugs not paid by Part D would be furnished by the hospice facility or dispensed by the pharmacy and billed to the hospice facility. Hospices remain responsible for all drugs needed for palliation and management of the terminal illness and related conditions.

Proposed 2014 ESRD Drug Policy

CMS is proposing a similar approach for drugs and biologics that may, or may not, be included in the Medicare Part B bundled payment to an ESRD dialysis facility (as specified in section 1881(b)(14) of the Social Security Act and in Federal regulations at Part 413). That is, we are proposing that, when a sponsor receives a TRR showing an ESRD beneficiary is receiving renal dialysis services, beginning January 2014, the sponsor place beneficiary-level PA requirements on seven categories of prescription drugs that may be ESRD-related. The seven categories of

drugs listed in Table 5 in the preamble to the prospective payment final rule (CMS-1418-F, which appeared in the Federal Register on August 12, 2010), are determined to be ESRD-related when furnished to an ESRD patient and used as specified in the table. These include:

Table 1: Seven categories of prescription drugs that may be ESRD-related

Antiemetic	Drugs used to prevent or treat nausea and vomiting secondary to dialysis, excluding antiemetics used in conjunction with chemotherapy as these are covered under a a separate benefit category.
Anti-infectives	Drugs used to treat infections. These may include antibacterial and antifungal drugs.
Antipruritic	Drugs in this category have multiple clinical indications, but are included for their action to treat itching secondary to dialysis.
Anxiolytic	Drugs in this category have multiple actions, but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess fluid management	Drugs/fluids used to treat fluid excess/overload.
Fluid and electrolyte management including volume expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain management	Drugs used to treat graft site pain and to treat pain medication overdose.

We note that although the payment of "oral-only" ESRD drugs and biologics (for example, Sensipar®, Phoslo®, and Sevelamer) was to be included under the ESRD prospective payment beginning January 1, 2014, the American Taxpayer Relief Act of 2012 delayed implementation of this change until January 1, 2016. As a result, these drugs will continue to be eligible for reimbursement under Part D.

Beneficiary-level prior authorization will require that pharmacies facilitate a dialogue with prescribers at point-of-sale for drugs that may be ESRD-related for ESRD beneficiaries receiving renal dialysis services. This will limit the financial risk for pharmacies and beneficiaries in comparison to the pay-and-chase approach. Given the extensive reports of payment errors that have resulted from conditional payment, we believe this is a better and more efficient approach.

We expect that the prior authorization process will prompt discussion between the prescriber and the plan sponsor in order to establish whether the drug is, in fact, Part D or Part A or B. Thus, once the sponsor, pharmacy and prescriber have established payment responsibility, there will be no further delay in the beneficiary appropriately accessing the drug on this and future occasions. However, we are soliciting comment on the proposed approach and on whether, once

a claim has been rejected by the plan under a beneficiary-level prior authorization, there would be a benefit to sending a notice to the beneficiary explaining why.

Daily Cost-Sharing Requirements

Beginning January 1, 2014, Part D sponsors are reminded that they must establish and apply a daily cost-sharing rate to certain prescriptions that are dispensed by a network pharmacy for less than a 30 days' supply in accordance with 42 C.F.R. § 423.153(b)(4)(i). This requirement provides Part D enrollees, in consultation with their prescribers, the option of shorter days' supplies of initial fills of new prescriptions without the disincentive of the enrollees having to pay a full month's copayment or coinsurance. Enrollees are expected to be most likely to inquire of their prescribers whether a fill of less than a month's supply would be appropriate when first prescribed a chronic medication, particularly when faced with high cost-sharing, such as when purchasing the drug in the deductible phase of the benefit or in the coverage gap. Prescribers are expected to be particularly supportive of this prescribing option when the prescription is for a drug that has significant side effects, is frequently poorly tolerated, and when less than a month's supply of the prescription is clinically appropriate. This option also allows beneficiaries the ability to synchronize their prescriptions in consultation with their pharmacists without having to pay a full month's cost-sharing when less than a month's supply of medication(s) is dispensed during the synchronization process until all medications are on the same thirty or more days refill schedule. We intend to include language in future Medicare & You and Part D Evidence of Coverage (EOC) documents on the availability of daily cost-sharing rates, and on when and how beneficiaries should consider taking advantage of them.

In preparing bids for CY 2014, sponsors should take note that, in the case of a copayment, there will be a mandatory daily copayment field in the PBP for any tier where the plan has a copayment included in the cost-sharing. The maximum amount that can be entered for the Daily Copayment field will be based on the one-month copayment amount divided by the actual number of days entered for that one month supply for that specific tier. For example: If a plan enters a 31 day supply as a one-month supply and a one-month copayment of $35 for Tier 1, then the Daily Copayment entered for that tier cannot be higher than $1.12. ($35/31=$1.129). This data entry validation is to assist plans in complying with the requirement that the daily copayment cannot be an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case. Where a plan must round to a dollar and cents figure, the highest amount the plan could round to would be the nearest lower dollar and cents amount, as shown in the example.

Hospital Outpatient Drug Supplies During Observation Services

Medicare patients utilizing hospital observation services will generally continue their maintenance medications that are not necessarily related to the observation services themselves. Generally, only medications related to observation services are covered under Part B. Moreover, hospital billing systems, Part D reimbursement rates, and drug utilization review requirements

make it difficult for hospitals to participate as a Part D provider for drugs dispensed in these non-pharmacy outpatient settings. Maintenance medications not related to the observation services, when obtained from the hospital's inpatient pharmacy, often come at much greater cost, and must be paid directly by the patient. Complicating matters, consistent with 42 CFR 423.124(b), Part D sponsors are only required to reimburse out-of-network claims at the amount they would have been paid in-network. Thus, many beneficiaries cannot recover a significant portion of their out-of-pocket expenses for these drugs.

In May 2012, CMS issued a final rule (77 FR 29075) to amend 42 C.F.R. §482.23, the hospital Conditions of Participation (CoP) for nursing services to allow a patient (or his or her caregiver / support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures. As discussed in the preamble to the proposed rule, this new provision might provide hospitals with a means to make care more patient-centered and adaptable to patient and caregiver/support person needs. Additionally, effective self-administration of medications policies afford hospitals an opportunity to teach patient adherence to the proper medication regimen that could have a positive impact on reducing hospital lengths of stay and readmission. Although hospitals are still at liberty to disallow patients' own supplies for liability reasons, Part D sponsors need to be aware of this important change to the Medicare hospital CoPs in order to be prepared to accurately address enrollee questions.

Part D pharmacy access standards do not require Part D plans to contract with hospitals for dispensing drugs in these situations, and most hospitals have not been interested in contracting with Part D sponsors. If the beneficiary is unable to take his or her own supply of maintenance medications and has to obtain the medications from the hospital's inpatient pharmacy, the beneficiary may submit a request for reimbursement to the Part D plan for out-of-network reimbursement. We would expect that Part D plans will reimburse the beneficiary if the situation warranted out-of-network access (i.e. beneficiary could not reasonably have received drug from a network pharmacy and access is not routine), and if the dispensed drug is on the Part D plan's formulary or is otherwise covered under the plan pursuant to a formulary exception. Consistent with §423.124(b), the Part D plan is only required to reimburse the beneficiary the amount that it would have paid had the beneficiary obtained the drugs at a network pharmacy. The beneficiary remains responsible for any differential between what the hospital charged and the Part D plan reimbursement, although the entire amount paid by the beneficiary would count toward the true-out-of-pocket (TrOOP) expenses.

We expect plan sponsors to ensure that customer service representatives are aware of this policy change so they may assist beneficiaries in understanding their options. When beneficiaries contact the plan with questions about coverage of Part D drugs during hospital observation services, customer service representatives should be prepared to advise the callers to discuss with the hospital to determine if they have the option to avoid paying out-of-network differential

charges by self-administering their own supply of Part D medications (not related to observation services) as a result of this important change in Medicare CoPs.

Withdrawal of Part D Bids after CMS Approval

CMS is concerned about recent instances where new applicants for stand-alone Part D plans withdrew their approved bids and applications following the announcement of the Low Income Subsidy (LIS) benchmark. CMS strongly disapproves of this practice because it is disruptive to the operation of the Part D program and because it indicates that the withdrawing applicant was not prepared to administer the benefit.

CMS uses the information submitted during the bid process to calculate the national average bid amount and LIS benchmarks, which are announced in early August of each year. Plans whose premiums are at or below the LIS benchmark in a region are eligible for auto-enrollment and reassignment of LIS beneficiaries. It is important the bid data used to calculate the benchmark accurately reflects the premiums all PDPs will charge during the contract year. Although new applicants have no enrollment in their proposed plans and thus cannot affect the calculation of the benchmarks, we must apply this policy consistently across the program.

Throughout the application and bid process, new applicants attest that the information they submit for the bid and application is accurate and reflects the anticipated cost of administering the benefit for the full range of Medicare beneficiaries in the regions in which they intend to operate. Applicants also attest that they are prepared to administer the benefit in accordance with all applicable requirements, including accepting auto-enrollments and reassignments of LIS beneficiaries as applicable. The bid submissions and attestations are not supposed to be based on any assumptions about whether the applicant will be eligible for auto-enrollments and reassignments in the following contract year. When an applicant withdraws after the LIS benchmark is announced, this act calls into question whether the applicant attested truthfully and whether the assumptions and data underlying its bid accurately represented the cost of administering the benefit.

For these reasons, we strongly discourage new applicants from withdrawing their applications after the announcement of the LIS benchmark. We expect that all applicants whose applications and bids have been approved at that time will enter into a contract with CMS and operate their plans throughout the contract year for which they applied, regardless of whether or not they are eligible for auto-enrollments and reassignments of LIS-eligible beneficiaries. Furthermore, because late withdrawals call into question the accuracy and truthfulness of applicants' bids and attestations, CMS will apply additional scrutiny to future applications from new applicants who have withdrawn bids and applications after the announcement of the LIS benchmark.

Inappropriate Use of Prior Authorization (PA) Forms

Consistent with 42 CFR 423.153, Part D sponsors are directed to establish utilization management controls, such as prior authorizations, in order to reduce costs when medically appropriate and to prevent over- and under-utilization of prescribed medications. To obtain the information necessary to process prior authorizations, CMS is aware that some sponsors have designed prior authorization forms that require more information or more criteria than CMS has approved. Some of these more comprehensive forms contain the elements under applicable state laws to technically constitute a valid prescription.

CMS is aware that such prior authorization forms have subsequently been used as prescriptions to be filled by the sponsor's and/or PBM's own mail-order pharmacy, instead of the pharmacy at which the beneficiary presented the original prescription. According to Part D rules, this practice is not permitted and bypasses protections required by 42 C.F.R. §423.120(a)(10), which afford the beneficiaries the ability to use the pharmacy of their choice.

As a result of the inappropriate use of prior authorization forms as prescriptions, and despite guidance issued in the HPMS memo on May 4, 2012 entitled *Reminder or Prescription Transfer Requirements*, CMS continues to receive complaints that beneficiaries have not been able to obtain medications which required prior authorization at the pharmacy of their choice, but were ultimately dispensed by the sponsor's and/or PBM's own mail-order pharmacy. We remind sponsors that this practice violates CMS requirements and should be discontinued immediately. The choice of which network pharmacy to use is at the sole discretion and convenience of the beneficiary.

In response to the complaints referenced above, CMS has reviewed a number of drug specific prior authorization forms. Through this review, CMS has identified several non-allowable practices that cannot be included on prior authorization forms, examples of which are provided below:

- Requirements that are more restrictive than CMS-approved prior authorization criteria.
- Limited Access or Step Therapy restrictions not consistent with the CMS-approved formulary.
- Quantity Limits that are inconsistent with FDA max dosing or not consistent with the CMS-approved formulary.
- Prior Authorization criteria not submitted for HPMS approved formulary medications.
- Steering of physicians or beneficiaries to a sponsor's and/or PBM's own mail order pharmacy.
- Steering of physicians or beneficiaries to a sponsor's and/or PBM's own specialty pharmacy for drugs which are not Limited Access eligible.

Auto-Ship Refill Programs in Part D

To improve adherence, pharmacies often employ refill reminders to notify patients that a medication is soon due to be filled, or that a medication has already been filled and is ready for pickup. Consistent with fraud, waste, and abuse requirements in retail settings, medications that are not picked up by the patient must be returned to stock, and the claim must be reversed. However, some retail and mail-service pharmacies also employ "automatic refill" services that automatically trigger delivery of medications to the patient. While these pharmacies obtain an initial beneficiary consent to provide the automatic refill service, the pharmacies do not invariably verify that the beneficiary still needs the medication before each refill is delivered. In a related issue, CMS has received complaints indicating that some mail-service pharmacies automatically deliver new prescriptions that were phoned in or e-prescribed from the physician's office without confirming that the patient wants the prescription filled and delivered.

As a result of the automatic delivery practices described above, CMS has received complaints that beneficiaries have had medications delivered that had been previously discontinued or were otherwise unwanted and unnecessary at the time of delivery. Once the prescription is delivered, pharmacies are unable to return the medication to stock and generally do not reverse the claim if the patient does not want the prescription. Consequently, automatic delivery practices are potentially generating significant waste and unnecessary additional costs for beneficiaries and the Part D program overall. While proponents of these programs tout improved adherence, it remains unclear to us that permitting such programs would be cost-effective.

Therefore, to help control fraud, waste and abuse as required by 42 CFR 423.504, and ensure that Medicare beneficiaries only receive new prescriptions and refills that are requested, we believe Part D sponsors should require their network retail and mail pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. We believe unintended waste and costs could be avoided if pharmacies confirmed with the patient that a refill, or new prescription received directly from the physician, should be delivered. Such confirmation would be unnecessary if the beneficiary personally initiates the refill or new prescription request. This recommendation would not affect retail refill reminder programs that require the patient to pick-up the prescription.

While we are proposing this policy for coverage for 2014, we strongly encourage sponsors to make this a requirement of their network pharmacies that offer such automatic refill programs for 2013. Shipment of unwanted medications is not only wasteful, but also a source of significant beneficiary aggravation and a financial imposition that can negatively affect enrollee satisfaction with the plan. We also invite commenters to propose alternative interventions that would be effective in addressing this problem.

Incremental Fills of Schedule II Controlled Substances Prescriptions

As part of their compliance plans to detect, prevent, and correct fraud, waste, and abuse, sponsors must have internal controls in place that prevent Part D payment for illegal refills of Schedule II controlled substances prescriptions. In addition, these internal controls must ensure that any PDEs that are submitted for actual illegal refills of Schedule II drugs are promptly adjusted or deleted. The Drug Enforcement Agency (DEA) regulates Schedule II drugs, and the Controlled Substance Act prohibits the refilling of prescriptions for them. (See 21 U.S.C. § 829(a)). Schedule II controlled substances have the highest potential for abuse of any prescription drugs legally available in the United States.

We encourage the industry to promptly address the known limitation of the current HIPAA prescription drug billing standard with respect to distinguishing partial or incremental fills of an original prescription from refills. CMS understands that this limitation may currently result in partial fills of Schedule II controlled substances being billed in a manner that cannot be distinguished from refills, particularly in the LTC setting. Partial fills of Schedule II controlled substances are permissible under Federal law under certain circumstances and occur when a pharmacist does not dispense all doses of the prescribed medication at one time. Partial fills are not considered refills. A September 2012 OIG report found that three-quarters of Part D sponsors inappropriately paid $25 million for Schedule II controlled substances that were billed as refills in 2009. The OIG acknowledged that some of these drugs may have been inaccurately billed, and CMS believes these claims more likely represent legally dispensed partial fills as opposed to illegal refills. (See https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp).

Nevertheless, the limitation in the billing standard does not obviate the requirement for sponsors to have internal controls in place that prevent Part D payment for illegal refills of Schedule II controlled substances prescriptions and to ensure that any PDEs that are submitted for refills of Schedule II drugs are promptly adjusted or deleted.

We note that beginning January 1, 2013, 42 C.F.R. § 423.154 requires dispensing in no greater than 14-day increments at a time of certain brand drugs dispensed to Part D enrollees in LTC facilities. In light of the limitation of the current HIPAA billing standard with respect to partial fills versus illegal refills, and the expectation that this limitation will become more apparent after implementation of the LTC short-cycle dispensing requirement, we solicit comments from the industry on improving current billing practices to assist sponsors' internal controls to ensure they are not paying for illegal refills of Schedule II controlled substances.

Real-time, Direct Access to Systems that Adjudicate Claims and Process Appeals and Grievances

CMS is concerned that certain Part D sponsors have been unable to monitor effectively or respond promptly to problems created by the performance of the first tier, downstream, and related entities (i.e., "delegated entities") to which the sponsors have delegated the performance

of claims adjudication or appeals and grievances processing. CMS has seen that problems often arise in these areas because sponsors do not have real-time access to the systems delegated entities use to perform these functions on the sponsor's behalf. CMS is therefore clarifying that it expects sponsors to have real-time access to these and other critical systems in order to effectively monitor the performance of their delegated entities.

Pursuant to 42 CFR § 423.505(i)(1), a Part D sponsor is responsible for all activities under its contract with CMS, regardless of whether those activities are performed by a delegated entity under contract with the sponsor. Furthermore, pursuant to 42 CFR §423.505(i)(4)(iii), the contract between a sponsor and a delegated entity must specify that the sponsor will monitor the delegated entity's performance on an ongoing basis.

CMS does not believe that it is possible for a sponsor to fulfill its monitoring and performance obligations without real-time, direct access to systems that adjudicate claims, process appeals and grievances, and perform other critical functions. Lack of access can and has prevented sponsors from identifying, and has delayed their responses to, problems with, for example, ensuring beneficiaries' claims are appropriately processed in accordance with the CMS-approved formulary. Therefore, CMS expects that all sponsors make arrangement with their delegated entities to have direct, real-time access to these critical systems in order to perform their responsibilities under their Part D contract with CMS.

In 2013 and 2014, CMS will not take compliance action against sponsors solely for failing to have real-time access to critical systems. However, effective immediately, if CMS determines that a lack of real-time access causes a delay in a sponsor's identification of, or response to, a problem, CMS may issue a more serious compliance action against the sponsor than it otherwise would have.

Applicability of Rewards and Incentives in Part D

The most recent version of the Medicare Marketing Guidelines (MMG) includes new information at Section 70.3 on rewards and incentives that Medicare Advantage (MA) plans may offer enrollees who participate in certain programs. The rewards and incentives may be offered to current enrollees for Medicare-covered preventive services with zero-dollar cost share and may not be communicated in pre-enrollment marketing materials to encourage enrollment into a plan. Moreover, any reward or incentive should be related to health care, but may not be an item that could be considered a benefit, or a monetary rebate. While the guidance does not specifically reference Medicare Part D sponsors, the MMG are based in part on 42 CFR 423.2268 and apply to Part D sponsors as well.

In this draft Call Letter, we solicit comments from Part D sponsors to help us better understand whether corollary guidance on rewards and incentives for the Part D program would be beneficial. Since the current guidance specifying preventive services with zero-dollar cost share

does not apply to Part D, we wish to consider other potential applications of this general policy that could lead to improved outcomes and other program efficiencies.

For instance, rewards or incentives might be used to improve adherence by motivating enrollees to comply with their medication regimens. Incidentally, such incentives could also align with efforts to encourage enrollees to submit all of their claims, including low cost generic claims, under the Part D plan so that the plan can appropriately track that adherence. When an enrollee takes his medication regularly, but does not submit his claims under the Part D plan, the plan is generally unaware of such adherence.

We are interested in knowing the kinds of rewards or incentives Part D sponsors would propose to offer enrollees and the level of incentives Part D sponsors believe would be necessary to achieve positive outcomes. We are particularly interested in hearing from Part D sponsors that have established reward and incentive programs in their commercial business that have been effective in helping members reach specific goals. It would be helpful to know the nature of objective milestones a sponsor would define in order to determine that a reward or incentive is warranted, and how often the reward would be given to an enrollee (e.g., monthly, quarterly, etc.). By comparison, under the existing guidance for MA plans, rewards or incentives may exceed the $50 annual maximum associated with promotional activities, but must not exceed $15 in value per item. We welcome any other specific comments or suggestions on how we could successfully design and utilize rewards or incentives to improve care under the Part D program, including any concerns about discriminatory impacts or other unintended consequences and how these could be mitigated.

Payment of Extemporaneous Compounds from Compounding Pharmacies

In accordance with 42 CFR 423.120(d), Part D sponsors may cover extemporaneously compounded multi-ingredient compounds, including sterile compounds, which include at least one ingredient that independently meets the definition of a Part D drug. The Part D sponsors determine which, if any, of these compounds are on formulary, off-formulary, and/or are subject to prior authorization requirements. If a Part D sponsor covers a compound, in addition to the dispensing fee, it may only pay for the ingredient costs for those ingredients that independently meet the definition of a Part D drug.

In 2012, less than 0.1% of Part D claims were reported to CMS on prescription drug events (PDEs) as multi-ingredient compounds (Part D compounds). Our initial analyses of these compound PDEs show that more than 50% of the Part D compounds were from either a long term care (LTC) or home infusion pharmacy, which can be attributed in part to the increased use of sterile compounds dispensed in these settings. While only 33% of all Part D compounds likely were sterile compounds based on the drug reported on the PDE, more than 80% of these sterile compounds were from LTC and home infusion pharmacies. Of those Part D compounds that were filled at pharmacies other than LTC or home infusion, it appears that almost 90% are

non-sterile Part D compounds, the majority of which have a Part D drug that is typically used to make mouthwashes for mucositis or oral ulcer pain, oral liquid preparations, and topical preparations that are not otherwise available as FDA-approved combinations. Overall, these analyses appear to indicate that the small number of claims for compounds being covered by the Part D program are limited to the type of compounds one would expect are necessary to address legitimate medical needs that cannot be met with commercially-available FDA-approved combination products.

Part D sponsors cannot cover compounds made entirely from non-Part D drug ingredients, such as bulk powders or active pharmaceutical ingredients. However, some compounds include Part D drugs and get covered under Medicare Part D (e.g. intravenous antibiotic solutions provided in the home). While states regulate the pharmacies that extemporaneously compound patient-specific sterile products and establish the requirements that pharmacies must meet (e.g. USP 797 compliance), recent events involving non-Part D sterile compounds call into question whether or not we need additional safeguards to help ensure the safety and quality of sterile compounds covered under the Medicare Part D program.

For instance, in order to ensure that Part D only covers medically necessary Part D compounds, we could require Part D plans to consistently obtain justification via prior authorization from the prescriber as to why no FDA approved product is clinically suitable for the patient, for example, during drug shortages, or because the individual prescription requires a medication tailored to meet a patient's special medical needs. We solicit comments on:

- The feasibility of Part D sponsors implementing such utilization management modalities for extemporaneous compounds to help improve beneficiaries' safety,
- The possibility that any such prior authorization requirements could be waived in periods of any applicable Part D drug shortages, and
- Any other ideas to increase controls over the quality and safety of extemporaneously compounded products covered under Part D.

Million Hearts™ Initiatives

Million Hearts™, a U.S. Department of Health and Human Services initiative co-led by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) and executed by a host of federal, state, and private sector partners, aims to prevent one million heart attacks and strokes by 2017. More information about the Million Hearts™ initiative can be found at http://millionhearts.hhs.gov/index.html.

A recent study by Roger and colleagues (*Circulation*. 2012; 125:e2-e220) found that each year, Americans suffer 2 million heart attacks and strokes and 800,000 citizens die from heart attacks, stroke, and other cardiovascular diseases. The trauma of these largely preventable events affects families, workplaces, and communities and costs the nation over $444 billion in lost productivity and treatment as found by Heidenriech and colleagues (*Circulation*. 2011; 123:933-4).

Along with community-focused efforts to reduce tobacco use and sodium and trans fat consumption, the primary clinical aim in Million HeartsTM is to achieve excellence in the ABCS: aspirin for those at risk, blood pressure control, cholesterol management, and smoking cessation. Getting to excellence means making the ABCS a priority for professionals, health systems, insurers, employers, and people with or at risk for cardiovascular disease and by deploying effective teams, health information technology, and incentives for high performance.

The first target of the Million HeartsTM initiative is to control high blood pressure. Nearly one in three American adults (67 million) has high blood pressure, and more than half (36 million) are not under control. According to the Medicare Current Beneficiary Survey (MCBS), overall, more than 66 percent of Medicare beneficiaries have high blood pressure. High blood pressure contributes to nearly 1,000 deaths per day and accounts for nearly $131 billion in direct healthcare costs a year. Reducing the average systolic blood pressure by 12-13 mmHg could reduce stroke by 37%, coronary heart disease by 21%, cardiovascular disease mortality by 25%, and all-cause mortality by 13%.

The 36 million people with uncontrolled hypertension fall into the following three categories:

- 16 million are aware of their diagnosis and on treatment, but their hypertension is still uncontrolled;
- 14.1 million are not even aware that they have high blood pressure; and
- 5.7 million are aware but untreated.

Viewed through the insurance lens, of those with uncontrolled hypertension, where the percentages reflect the percent uncontrolled within their respective groups:

- 14. 1 million are Medicare beneficiaries (52%);
- 14.06 million have private insurance (51%);
- 2.3 million have other public insurance (49%); and
- 5.26 million have no insurance (72%).

Medicare Advantage Organizations (MAOs) and Part D Plan (PDP) Sponsors are well-positioned to contribute to rapid improvement in detection and control of hypertension. Drawing attention to the scope of the problem and prioritizing control is a first step. Improving access to blood pressure medication by removing financial barriers such as co-pays could improve blood pressure control. Furthermore, MAOs and PDP sponsors can contribute to better detection and control by facilitating home blood pressure monitoring, the sharing of those data with the treating provider, and the timely return of treatment advice to the patient.

CMS is suggesting several actions that MAOs and PDP Sponsors could take to improve access and adherence to anti-hypertensive medications.

First, for those plans that offer a $0 or a very low cost-share tier, we encourage sponsors to place blood pressure medications on this tier.

Second, we encourage sponsors to offer Medication Therapy Management (MTM) to beneficiaries who fill one or more prescriptions for anti-hypertensive medications. The CMS requirements for targeting beneficiaries for the MTM program are considered to be a minimum; sponsors are encouraged to offer MTM services to an expanded population of beneficiaries who may not meet the eligibility criteria per CMS' specifications, but who could benefit from MTM services. Offering MTM, including a comprehensive medication review, to this population could help improve their blood pressure control, increase their adherence to these vital medications, and empower these beneficiaries to self-manage their medications and their health condition. However, this would not result in additional payment under Medicare Part D.

Expansion of Part D Policy on Improving Utilization Review Controls

The section entitled, "Improving Drug Utilization Review Controls in Part D," of the Final CY 2013 Call Letter, set forth how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of prescribed covered Part D drugs. We have consolidated various documents related to this policy at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

In both the Final CY 2013 Call Letter and the HPMS memo of September 6, 2012, we indicated that our guidance applied only to overutilization of opioids. In the HPMS memo we also provided a possible targeting methodology that sponsors could use to identify potential instances of overutilization of opioids for case management.

In the September 2011 GAO report that identified instances of questionable access to prescription drugs, hydrocodone and oxycodone were noted as the most prevalent of the 14 classes of frequently abused drugs analyzed. While these drugs represented over 80 percent of the instances of potential doctor shopping that were identified, there were still 20 percent of instances that did not involve hydrocodone and oxycodone.

We are interested in comments about expanding the Part D Policy on Improving Utilization Review Controls to other drugs or classes of drugs, such as anti-psychotic drugs, amphetamine derivatives, benzodiazepines and non-benzodiazepine sleep aids. In addition to comments on which drugs or classes or drugs would be appropriate or inappropriate to target and why, we would be interested in thoughts on targeting methodology(ies) to identify potential cases of overutilization of any drugs or classes of drugs identified.

Drug Class Quantity Limits

In the supplemental guidance to the "Improving Drug Utilization Review Controls in Part D" section of the CY 2013 Call Letter, we stated that we would develop a submission mechanism for quantity limits (QLs) based upon cumulative daily morphine equivalent dose (MED) across the opioid class. For CY 2014, the Health Plan Management System (HPMS) formulary

submission file record layout will remain consistent with that for CY 2013, but QLs based on cumulative MED will be accepted for review. As a result, QLs based on MED will need to be submitted for review utilizing the existing QL fields: QL amount and QL days. Part D sponsors will be required to submit, as part of the HPMS formulary file, the lesser of either the MED-based QL for individual formulary products or the approved drug utilization management QL. This will provide for transparency in that both types of quantity limit restrictions would be displayed in Medicare Plan Finder, as well as other plan information. We recognize that claims for quantities below the MED-based QL could reject at point-of-sale (POS) depending upon previously dispensed quantities of other opioids. However, it is not feasible to collect additional quantity limit information based on all of the various possible combinations of opioids.

We are seeking industry comment regarding the cumulative MED level that could be implemented at POS that would not only be an effective safety measure, but also one that would not inappropriately restrict access to medically necessary drugs. While we have previously recognized an MED of greater than 120 mg as one component of a targeting approach for retrospective drug utilization review (DUR) and case management, we are interested in what MED level would be clinically appropriate to implement at POS to reject claims prospectively. Based on comments we receive to this draft, we will provide additional information in the final Call Letter.

Change in Part D Barbiturate Coverage

Under the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, as codified in 42 CFR §423.100, Medicare Part D began covering barbiturates (used for epilepsy, cancer, or chronic mental health disorder) and benzodiazepines as of January 1, 2013. Effective January 1, 2014, section 2502 of the Affordable Care Act (ACA) of 2010 revised §1927(d)(2) of the Social Security Act (the Act) by removing smoking cessation agents, barbiturates and benzodiazepines from the list of drugs that states may exclude from coverage under the Medicaid Program. By removing barbiturates and benzodiazepines from §1927(d)(2), these drug categories are no longer included in the list of drugs excluded from Medicare Part D under 1860D-2(e)(2).

Consequently, the practical effect of the ACA revision to §1927(d)(2) is that, beginning on January 1, 2014, the restriction on barbiturate coverage under Part D (i.e., the limitation that permits coverage only for epilepsy, cancer, and chronic mental health disorder indications), is removed. Thus, beginning January 1, 2014, barbiturates that otherwise meet the definition of a Part D drug under §1860D-2(e) may be covered under Part D for any medically accepted indication (as defined in 1927(k)(6)). However, despite the removal of the restrictions on barbiturates coverage, we do not believe that there are many more barbiturates that currently would meet the definition of a Part D drug. A preliminary review has identified only a few potential additional products likely to qualify as Part D drugs in 2014, the most notable being FDA-approved butalbital-containing products used for the treatment of headaches.

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 (other than defined standard) plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered; and, pursuant to 42 CFR 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. Since no changes have occurred in how we establish these parameters for CY 2014, nor in the applicable regulations, the benefit parameters for CY 2014 are set forth in Table 1 below.

CMS 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%, CMS will compare the average expected cost-sharing amounts submitted by sponsors in the PBP to the established copay thresholds to determine whether the coinsurance values are discriminatory. (Please note that for the Select Care/Diabetic Drug Tiers, although the maximum allowable coinsurance value is less than 25%, CMS will conduct the same cost-sharing analysis for these tiers).

As for CY 2013, the CY 2014 out-of-pocket costs (OOPC) model incorporates updated PBP and formulary data used for CY 2014 bid submissions, as well as more precise brand and generic drug determinations for gap coverage cost-sharing estimates, which utilize Food and Drug Administration (FDA) data and are more in line with the way the Part D benefit is administered. Using this model, the minimum monthly cost-sharing OOPC difference between basic and enhanced plan offerings will be $21. The minimum monthly cost-sharing OOPC difference between enhanced plan offerings will be $18. In addition, CMS still expects PDP sponsors that are offering two enhanced alternative plans within a service area, to include additional gap coverage of at least “some” (>10% to <65% of formulary drugs) brand drugs on the second enhanced plan. (Please see a request for industry comments on OOPCs for CY 2015 at the end of this section.)

We note that tier labeling and hierarchy requirements remain unchanged and are included in the Plan Benefit Package (PBP) tool, and that the review of specific tier cost sharing is in addition to the review for actuarial equivalence to the standard benefit across all tiers. To make the Specialty Tier methodology transparent, we will post it at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html.

Regulation (42 C.F.R. §423.578(a)(7)) allows Part D sponsors to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. This tier is

referred to as the "specialty tier". Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit or to an equivalent total amount for sponsors with decreased or no deductible under alternative prescription drug coverage designs. (Example: a $325 deductible and 25% cost-sharing of an initial coverage limit of $2790 is essentially the equivalent of $986.25 in out-of-pocket expenses, whereas no deductible and 33% cost-sharing of the same initial coverage limit is essentially the equivalent of $980.10 in out-of-pocket expenses.)

Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty tier. These are referred to as specialty tier-eligible drugs. By placing these drugs on a specialty tier, plan sponsors are restricted to charging cost sharing no greater than that permitted under the defined standard benefit. In return Part D sponsors are shielded from tier exceptions for the most expensive drugs, and need not increase their bids and all Part D premiums to maintain actuarial equivalence for an estimate of increased plan liabilities arising from approved tier exceptions.

This year the minimum specialty tier eligibility threshold remains $600. Refer to Table 1.

Table 1: Benefit Parameters

	CY2014 Threshold Values
Minimum Meaningful Differences (OOPC)[1]	
1st Enhanced Alternative Plan vs Basic Plan	$21
1st Enhanced Alternative Plan vs 2nd Enhanced Alternative Plan	$18
Maximum Pre-ICL and Additional Gap Coverage[2] Copay (R & NP) - 3 or more tiers	R/NP[3, 4]
Preferred Generic/Generic Tier	$10
Non-Preferred Generic Tier	$33
Preferred Brand/Brand Tier	$45
Non-Preferred Brand Tier	$95
Injectable Tier	$95
Select Care/Diabetic Tiers[5]	$10
Maximum Pre-ICL Coinsurance (R &NP) 3 or more tiers	R/NP[3, 4]
Preferred Generic/Generic Tier	25%
Non-Preferred Generic Tier	25%

	CY2014 Threshold Values
Preferred Brand/Brand Tier	25%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Select Care/Diabetic Tiers[5]	15%
Maximum Additional Gap Coverage[2] Coinsurance R &NP) - 3 or more tiers	R/NP[3, 4]
Preferred Generic/Generic Tier	50%
Non-Preferred Generic Tier	50%
Preferred Brand/Brand Tier	69%
Non-Preferred Brand Tier	69%
Injectable tier	69%
Select Care/Diabetic Tiers	69%
Minimum Specialty Tier Eligibility	
1 month supply at in-network retail pharmacy	$600

[1]These thresholds are based on the 95th percentile of the CY2013 December Bid Data run through the CY2014 OOPC model which incorporates CY2014 PBP and Formulary Data, 2008/9 MCBS Data, and FDA Data for brand/generic determinations related to coverage gap cost-sharing estimates.

[2] We have provided background information in Appendix 1 regarding our analysis to determine how much additional coverage in the gap over the basic benefit would be considered to be substantially different. If additional gap coverage of a brand tier includes generic drugs, then the coinsurance maximum for generic drugs of 50% applies to all drugs on that tier. Injectable, Select Care and Select Diabetic Drug tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to coinsurance maximums.

[3] These thresholds are based on the 95th percentile. They are subject to change based on an analysis of plans using the 95th percentile after CY 2014 bids are received. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary and for meaningful benefit offering tiers that have low or $0 cost-sharing (i.e., special needs plans targeting one or more specific conditions).

[4]"R" in the above chart refers to "in-network retail pharmacy" and "NP" refers to "in-network non-preferred retail pharmacy." An in-network retail (R) can only be designated as an in-network preferred retail pharmacy (P) if it offers a lower level of cost-sharing than an in-network non-preferred pharmacy (NP) in accordance with Section 50.9 of Chapter 5 of the Medicare Prescription Drug Benefit Manual.

[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.

CMS is specifically soliciting industry comment on the coinsurance threshold maximum proposed for the Select Care and Select Diabetic Drug tiers. Although no plans have submitted

cost-sharing using coinsurance amounts for these tiers in previous years, we wish to establish a threshold in advance for any plan who wishes to do so in the future.

CMS is also seeking industry comment regarding a possible change to the OOPC calculation methodology for CY 2015 specifically related to how non-formulary drug costs are estimated in the model. Currently, drugs used by the Medicare Current Beneficiary Survey (MCBS) cohort are included in the OOPC model and when on plan formularies have the applicable cost-sharing applied based on each plan's bid, whereas drugs that are included in the MCBS cohort but are not on plan formularies are calculated using the average PDE cost across all Part D plans. (Please refer to the CY 2013 OOPC methodology which can be found at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html)

We are considering a change to the CY 2015 OOPC model to have the MCBS cohort drugs which are non-formulary priced at the cost-sharing of the Part D sponsor's exceptions tier. This change would be based on an assumption that in most cases plan sponsors will provide a formulary exception for non-formulary drugs and therefore provide a more accurate reflection of the estimated OOPC. We would apply this methodology consistently for all plans.

Employer Group Waiver Plan (EGWP) Supplemental Prescription Drug Benefits

Beginning January 1, 2014, Part D sponsors are reminded that CMS will implement the change to the definition of Part D supplemental benefits in 42 CFR 423.100 (issued in CMS-4157-FC on April 12, 2012) that specifically excludes all supplemental benefits offered through EGWPs. This means that all supplemental prescription drug benefits offered through EGWPs will be non-Medicare benefits and considered other health insurance (OHI). Accordingly, if the non-Medicare supplemental benefits provide supplemental gap coverage for applicable drugs, these benefits are OHI that apply **after** the Coverage Gap Discount is calculated.

The change of the regulatory status of EGWP Part D supplemental coverage from a Medicare benefit to a non-Medicare benefit potentially subjects all such coverage to state or ERISA requirements. The Center for Consumer Information and Insurance Oversight (CCIIO) issued guidance that addresses regulatory status questions concerning non-Medicare supplemental prescription drug benefits that may be offered by EGWP sponsors (see http://cciio.cms.gov/resources/files/part-d-bulletin-1-25-2013.pdf). Although these will be non-Medicare supplemental prescription drug benefits, as a practical matter, such benefits will remain subject to Part D requirements because nearly all of the Part D supplemental coverage provided by EGWPs reduces cost-sharing on claims that already are covered under the basic Part D benefit.

PDE Guidance on Post-Point-Of-Sale Claim Adjustments

Purposes of the PDE Record

CMS requires the PDE to be an accurate record of how the benefit was administered in order to be able to validate plan sponsor compliance with approved benefit designs, as well as the delivery of appropriate Part D benefits such as low-income cost sharing subsidies and coverage gap discount payments. For instance, we must be able to confirm that the prescription drugs provided to beneficiaries and the cost sharing charged are both consistent with the formulary and benefit package approved by CMS. In addition, we must be able to calculate the federal risk sharing, reinsurance and low-income cost-sharing subsidies due to Part D sponsors in annual reconciliations, and be able to recalculate those subsidies at any later time if coverage year reconciliations are reopened. We must also maintain a record of the coverage gap discount amount on applicable drugs advanced by the sponsor at point-of-sale that must be reimbursed by the manufacturer of the applicable drug. PDE records must represent actual transactions and remain available for inspection and reconciliation, not only by CMS, but also by other parties, such as manufacturers and oversight agencies. These records are critical not only for accurate payment, but also for a wide range of sponsor compliance assessment activities, and other Part D program integrity audits.

Existing PDE Rules

Current PDE guidance states that the PDE is both an accurate record of how the benefit was administered through the point-of-sale transaction (plus any subsequent financial adjustments) and the final adjudication status of each Part D claim. For instance, from the 2011 PDE Participant Guide:

> PDE data also reflect how a plan has administered its Part D benefit package… The PDE is a summary record that documents the final adjudication of a dispensing event. Since the PDE record summarizes multiple transactions, the plan must maintain audit trails to PDE source data. CMS expects that the plan will be able to directly link any PDE to the individual claim transactions from which the PDE was extracted and replicate the summarization.

This policy exists to ensure the validity and accountability of the data necessary for Part D payment, as well as for program oversight and evaluation, as discussed above. Current guidance also states that any adjustments to amounts paid on claims must be reflected in adjusted or deleted PDEs. [For instance, see the 2011 PDE Participant Guide, Sections 3.6, 4.5.2, and 8.3.3. Also see the October 6, 2011 HPMS Memo "Revision to Previous Guidance Titled, "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs".] Therefore, in order to provide for accurate payment reconciliation, any adjustments to financial fields on Part D claims must be addressed through deletion of the original PDEs and the resubmission of corrected PDEs that reflect the corrected amounts actually paid to the provider.

Discussions between CMS and both pharmacies and sponsors reveal that retrospective audits of previous years' claims are resulting, in some cases, in complete recoupment of the amount originally paid to the pharmacy when non-financial data on the claim transaction, such as prescription origin codes or prescriber identifiers, are determined to be erroneous. The increasing incidence of these adjustments for "routine clerical errors" rather than incorrect payment amounts (financial errors) may be related to the incentives in contingency reimbursement arrangements with claim audit vendors. We are concerned that the growing practice of post-audit total claim recoupments from pharmacies is distorting Part D payment, as well as compromising Part D data integrity and impairing our ability to oversee the program.

With respect to claim adjustments attributable to administrative errors on claims, we see no way that both foundational PDE requirements—(1) accurate record of benefit administration and (2) final status of claim—can be satisfied if a legitimate Part D claim is accurately adjudicated at point of sale, but then 100% of the claim amount paid to the pharmacy is later recouped as a penalty for administrative data error. From our perspective, if a claim payment is fully recouped, the final adjudication status of the claim is appropriately $0.00 regardless of whether the recoupment was transacted via the reversal of a claim or a deduction from amounts payable on a remittance. In other words, if a PDE's final adjudication status is appropriately $0.00, then it would need to be because the claim never should have been paid, and the other elements of the PDE that reflect the beneficiary's cost sharing, low-income cost sharing (LICS) subsidy, or coverage gap discount would necessarily also be $0.00. The alternative would be that the claim has been treated as payable for purposes of beneficiary cost sharing, LICS and coverage gap discount, but treated as non-payable for purposes of the plan paid amount. In our view, such a result is inappropriate. The submission of a PDE record claiming to represent amounts ***actually paid*** greater than zero for a claim with a final status equal to zero is arguably the misrepresentation of the status of the claim and the submission of erroneous information. For these reasons, the correction of errors in any non-financial field required on the PDE that alters the financial transaction as it actually occurred at the point-of-sale (as reflected on file with CMS) distorts Part D payment and is inconsistent with the purpose of the PDE. This is not to say that contractual arrangements between Part D sponsors or their intermediaries and network pharmacies cannot specify financial penalties for administrative errors—only that a penalty consisting of full recoupment of the claim is incompatible with our requirements to submit a PDE record that simultaneously represents (1) how the benefit was administered and (2) costs actually paid that are eligible for reconciliation.

Therefore, we believe full claim recoupment (followed by PDE deletion) should only take place if the plan learns that a claim should not have been paid under Part D at all; for example, because it is fraudulent. In such cases, it would be correct to remove the record of the transaction from CMS databases because coverage and payment are prohibited under federal law.

We are therefore clarifying our requirements for the submission of PDE data with respect to corrections of three types of claim errors: financial, administrative, and coverage errors.

Financial errors are errors in payment calculation on claims that were otherwise appropriate for coverage; administrative errors are errors in non-financial fields required on a claim; coverage errors are errors in paid adjudication of claims that should not have been covered under Part D because, for instance, they are fraudulent. Specifically, we are clarifying that:

- the practice of recoupment of claims costs for administrative errors is not compatible with existing PDE guidance and the data submission requirements under 42 CFR 423.505(b)(8) and (9);
- any adjustment to claim payments for financial errors must be reported to CMS via corrected PDEs; and
- only PDEs that represent transactions that should not have been paid under Part D at all should be completely deleted from CMS databases.

Issues with Earlier Guidance

We acknowledge that previous CMS guidance and practice has permitted reporting of "pharmacy adjustments" as a component of DIR. However, for the reasons discussed above, we now better understand that such reported "pharmacy adjustments" are, in fact, claim adjustments that should be reflected solely in PDE adjustments to ensure appropriate payment. Therefore, we are eliminating the previous ambiguity that permitted claim adjustments to be reported in two different ways, and are clarifying that the PDE adjustment or deletion is the only reporting methodology consistent with payment accuracy.

Since the beginning of the program, the DIR instructions have provided the opportunity to report DIR in the category of "pharmacy payment adjustments". When we originally designated this category, we anticipated these would be rare events, such as the results of risk sharing adjustments, not claims corrections – although adjustments for claims corrections have been permitted to date. We have observed that these amounts have been growing, and understand that many of these adjustments are occurring as the result of retrospective audits of previous years' claims. Numerous pharmacy complaints, discussions with several sponsors and analysis of data submitted to CMS reveal that some sponsors have been retracting or "recouping" 100% of prior payment on claims from pharmacies because of "payment inaccuracies" due to "routine clerical errors", rather than incorrect payment amounts and including these amounts as "pharmacy adjustments" when reporting their DIR.

If such adjustments are reported to CMS in DIR, as opposed to corrected PDE submissions, both the accuracy of Part D payment, as well as the reliability and utility of PDE data, are compromised. While DIR amounts directly offset drug costs in risk-sharing reconciliation (when reported in the same year), DIR amounts do not fully offset reinsurance subsidies and do not at all offset LICS subsidies. Thus, reporting of claims adjustments via DIR reporting as opposed to corrected PDE submissions may result in overpayment of subsidies to the plan sponsor. Therefore, as discussed above, any adjustments to amounts paid on claims must be reflected in adjusted or deleted PDEs. In order to provide for accurate payment reconciliation, any

adjustments to financial fields on Part D claims that continue to result in a positive non-zero payment amount after adjustment must be addressed through deletion of the original PDEs and the resubmission of corrected PDEs that reflect the corrected amounts actually paid to the provider. While we acknowledge that our guidance has been ambiguous for DIR reporting for coverage years 2006 through 2011, we believe this guidance clarifies our requirements for reporting of claim adjustments to financial amounts on paid claims going forward. We will further clarify the purpose of the "pharmacy payment adjustments" field in the 2012 DIR reporting instructions later this Spring.

Post Point-of-Sale Per Claim Administrative Fees

We have received a number of questions regarding the imposition of per-claim administrative fees, levied by Part D sponsors or their intermediaries on pharmacies. Some examples we have heard of include charging a pharmacy $1.00 per claim to participate in the sponsor's preferred pharmacy network or chargeback of the dispensing fee. Upon consideration, we believe that any such post-point-of-sale claim adjustments violate our current guidance on negotiated prices. We have clearly stated that negotiated prices – the amounts on which beneficiary cost sharing and TrOOP calculations, as well as government subsidies are based – must be the amounts ultimately paid to the pharmacy.

42 C.F.R. §423.100—*Negotiated Prices*—are prices that… the network entity [pharmacy] will receive, in total, for a particular drug.

We believe that the practical effect, if not the intention, of per-claim fees deducted post point-of-sale is overstatement of negotiated prices at point-of-sale. If negotiated prices are overstated, then beneficiary cost sharing, beneficiary advancement through the Part D benefit phases, and government payment subsidies are overstated in contravention of our rules on negotiated prices. Therefore, we do not believe that per-claim administrative fees that alter the price ultimately paid to the pharmacy are consistent with Part D rules. We solicit comments on this conclusion. In addition, we are not generally aware of whether the questions we have received reflect current practices in the Part D market or are simply exploratory in nature. Therefore, we would also like to receive comments on whether and to what extent these types of adjustments have been or are currently in effect in the Part D market.

Medication Therapy Management

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 Sec. 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 2013 MTM program

annual cost threshold is $3,144. The 2014 MTM program annual cost threshold will be adjusted based on the annual percentage and finalized in the 2014 Call Letter.

The CMS eligibility targeting requirements are established as the minimum threshold; however, CMS encourages sponsors to optimize their programs, including their targeting criteria, to offer MTM to beneficiaries who will benefit the most from these services. Sponsors may also offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria per CMS' specifications. As discussed in the Million Hearts™ Initiatives section of this draft Call Letter, we encourage sponsors to offer MTM services to beneficiaries who fill at least one prescription anti-hypertensive medication to support this initiative to control high blood pressure and improve access and adherence to these medications. We have heard that some high performing plans have used MTM to improve their Part D Star Ratings in certain areas. Growing evidence of the value of MTM to improve beneficiaries' therapeutic outcomes indicates that more beneficiaries may benefit from these services.

In June 2011, CMS initiated a two-year project to examine the impact of Part D MTM programs on the Medicare Part D beneficiary population, with a particular focus on specific high-risk populations with strong clinical incentive to maintain drug therapy. A retrospective study cohort design was used to identify the impact of 2010 Part D MTM programs on high cost, high risk beneficiaries with congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). For the initial quantitative analysis, the study outcomes were divided into two categories (1) drug therapy (e.g., use of and adherence to evidence-based medications) and (2) resource utilization (e.g., all-cause and disease-specific hospitalizations and emergency room visits). The interim report is available at: http://innovation.cms.gov/Data-and-Reports.

Based on this study, we found that MTM programs effectively targeted high-risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment as well as those that experienced a recent visit to the hospital or emergency room. There was evidence that Medicare beneficiaries with CHF and COPD who were enrolled in MTM programs in 2010 – particularly those who received annual comprehensive medication reviews (CMRs) – experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services. This supports the hypothesis that the annual CMR may be one of the more crucial elements of MTM. Improvements in drug therapy outcomes included increased adherence to evidence-based medications for individuals' chronic conditions, and discontinuation of high-risk medications. At the overall PDP and MA-PD levels, there were significant cost savings associated with all-cause hospitalizations but not with disease-specific (e.g., CHF-specific or COPD-specific) hospitalizations. This may be explained because MTM is a comprehensive approach to improve medication use, adherence, and reduce the risk of adverse events and is not disease-specific disease management. Also, these findings support statements made in a recent Congressional Budget Office report that programs and services that manage the benefit well or improve prescription drug use might result in medical savings (Congressional Budget Office, *Offsetting*

Effects of Prescription Drug Use on Medicare's Spending for Medical Services, November 2012).

The next stage of this project will involve additional quantitative analysis to evaluate the effect of MTM on individuals with diabetes, investigate outcomes for beneficiaries with high costs or a high-prevalence of medication issues, and drill down on one or two case studies to evaluate the impact of narrowly defined drug therapy interventions. Qualitative analyses will also be performed, including in-depth case studies of how Part D MTM program services are implemented and their effectiveness, especially around what procedures may support the successful delivery of CMRs. At the conclusion of this study, a final report will be made available to the public. Best practices will also be examined which could result in more standardization of MTM service definitions and requirements in the future.

Coordination of Care

MTM can be used to promote the coordination of care. Beneficiaries should be encouraged to complete their annual CMR prior to their annual wellness visit, and to take their standardized medication action plan and personal medication list from their CMR to their annual wellness visit or any medical encounter (primary care physician or specialist visit, hospital admission, etc.). This summary can serve as a valuable tool to share information across providers and help reduce duplicate therapy and drug-drug interactions. CMS plans to include this message to beneficiaries beginning with the 2014 *Medicare & You Handbook* or other beneficiary communications. Part D sponsors are encouraged to communicate this recommendation to beneficiaries when notifying beneficiaries of their enrollment in the MTM program and when offering or scheduling CMRs, and to explore other opportunities to use MTM to better coordinate care. For example, CMRs may be beneficial after a transition in care or after a hospitalization.

Plan sponsors are encouraged to adopt standardized health information technology (HIT) for documentation of MTM services. Structured, universal codes are available for clinical coding of MTM services delivered to beneficiaries, such as findings, recommendations, and outcomes. The use of standardized coding systems improves the efficiency of documentation by the MTM provider, supports consistent clinical record keeping, facilitates the transfer of information between health care providers and beneficiaries, and will allow better collection and analysis of the impact of MTM services on beneficiaries' care. CMS is considering the expansion of the MTM reporting requirements to collect the findings and recommendations that were discussed during CMRs and listed in the beneficiary's medication action plan. Combining standardized coding systems (e.g., SNOMED) and industry-supported templates (e.g., NCPDP/HL7 MTM Templated CDA, see http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=842) will also enable sponsors to update and print summaries of CMRs in a standardized format based on standard elements in databases and EHRs rather than manipulating free-form text documents.

Optimizing the Delivery of MTM in LTC Settings

Sponsors must offer a CMR to all beneficiaries enrolled in their MTM program at least annually, and beginning January 1, 2013, this includes enrollees who are in long term care (LTC) settings. This provides new opportunities to serve this vulnerable population and improve their medication use and quality of care. While there is some overlap between the monthly drug regimen reviews (DRR) required in LTC and Part D MTM reviews, a CMR must meet the CMS service-level definition. For each CMR, the pharmacist or other qualified provider must conduct an interactive, person-to-person, or telehealth medication review and consultation of the beneficiary's medications (including prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements). It must be performed in real-time with the beneficiary (or the beneficiary's caregiver or other authorized representative who may take part in the CMR if the beneficiary cannot participate). It must provide a written summary of the results of the review in the CMS standardized format to the individual. The summary includes a personalized medication action plan and medication list for the beneficiary and/or their caregiver or authorized representative.

There may be different issues and opportunities to improve medication use through MTM for beneficiaries in the LTC setting compared to ambulatory settings. In the ambulatory setting, goals include ensuring the beneficiary is on the right drug and dose and improving medication adherence. In LTC, adherence is not an issue; rather, MTM can be used to identify overuse, medications without a clear indication, suboptimal dosing, and polypharmacy. Also, MTM could be used as an opportunity to align medication use with the beneficiary's goals and wishes in addition to the care team's.

Sponsors should ensure that their policies and procedures for offering and delivering CMRs, per CMS requirements, are effective for beneficiaries taking into consideration how to reach the beneficiary according to their setting and needs. In the LTC setting, a greater risk of both physical and cognitive issues may impact the beneficiary's ability to conduct a phone interview. Sponsors should consider using qualified providers to perform the CMR who have experience engaging beneficiaries and prescribers in the LTC setting, such as involvement of an independent consultant pharmacist who has a relationship with the LTC facility. To avoid conflicting recommendations, the MTM provider should coordinate the recommendations for drug therapy changes as a result of a MTM encounter with the beneficiaries' healthcare team at the facility, their caregiver or authorized representative, when applicable, and consultant pharmacist. Additional consideration could be given to coordinate MTM activities with the care plan meeting to assess current treatment regimens. The beneficiary or authorized representative should be invited to these meetings, and often the facility has an understanding of which beneficiaries are interested in being involved in their care or defer to their authorized representatives.

In the event the beneficiary is cognitively impaired and is unable to accept the offer to participate, the pharmacist or qualified provider may perform the CMR with the beneficiary's

caregiver, other authorized individual, such as the beneficiary's health care proxy or legal guardian, or prescriber. To the extent possible, preference should be given to involving the beneficiary's caregiver to further engage them in the management of the beneficiaries' medications. Regardless of cognitive status, many LTC residents may prefer to involve their authorized representative or caregiver in the CMR, and this should be considered when serving this population. Furthermore, beneficiaries in LTC are less likely to self-administer their own medications and cognition can vary on any given day even if it was determined that the beneficiary was not severely cognitively impaired. The nursing staff, including but not limited to the Director of Nursing, may be a valuable asset to ascertain information about a beneficiary's function, cognitive status, and medications, as well as caregiver(s) or authorized representative(s). If asked, plan sponsors should be able to present documentation or a rationale for determining if a beneficiary was deemed cognitively impaired.

Previously, we recommended that when a targeted beneficiary moves to a LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary. This contact could be the authorized representative, caregiver, or prescriber. Sponsors, or the MTM providers, could contact the admissions coordinator, MDS coordinator, Director of Nursing, or other appropriate facility staff person to ascertain if an authorized representative has been designated in their medical record or chart. Sponsors are encouraged to develop processes and procedures to contact the facility in the least burdensome manner to request assistance from the facility to identify beneficiaries who are not cognitively impaired and may be receptive to receiving a CMR, and beneficiaries who have a health care proxy. In the event that the definition of authorized representative differs by State or in settings other than LTC, we defer to State law.

One tool that could be used in nursing homes to identify if a beneficiary is cognitively impaired or able to participate in the CMR is the Brief Interview of Mental Status (BIMS) in the Minimum Data Set 3.0. Currently, Surveyors determine whether a resident is "interviewable." Residents may be identified as "interviewable" if they have a BIMS score of 8-15; at a score of 0-7 or 99, the resident may be identified as a "Family Interview Candidate" or as needing some other authorized representative.[6] A similar process could be used by MTM providers to evaluate if a beneficiary is "interviewable" and can participate in the CMR. The following algorithm could be applied using MDS 3.0.

[6] Memo from the Director, Survey and Certification Group. September 27, 2012. *Advance Copy of Interim Guidance - Revisions to State Operations Manual (SOM), Appendix P-Traditional Survey Protocol for Long Term Care (LTC) Facilities and Chapter 9/Exhibits including Survey Forms 672, 802, 802S and 802P.*

IF

1. MDS item C0500 [Brief Interview for Mental Status (BIMS) Summary Score] = 8-15

BIMS Summary Scoring

13 - 15: Cognitively intact

8 - 12: Moderately impaired

0 -7: Severe impairment

AND

2. MDS Item 80700 ("Makes Self Understood") = 0 or l

"Makes Self Understood" Scoring

0 = Understood

1 = Usually understood

2 = Sometimes understood

3 = Rarely/never understood

AND

3. MDS Item 80800 ("Ability to Understand Others") = 0 or l

"Ability to Understand Others" Scoring

0 = Understands

1 = Usually understands

2 = Sometimes understands

3 = Rarely/never understands

THEN: The resident should be considered able to receive a CMR.

We seek comments regarding other tools that could be used in LTC settings and in the community and assisted living settings where greater variation in available tools exists.

We will also expand the distribution of the Long Term Institutionalized (LTI) Resident Report to plans from two times per year to quarterly to assist sponsors in the identification of enrollees in LTC.

Promoting Beneficiary Awareness

To promote beneficiaries' awareness of these valuable programs, we will continue to enhance the information about MTM in the *Medicare & You Handbook* and on Medicare.gov. On the Medicare Plan Finder (MPF), a new MTM tab will be developed on the "Your Plan Details" page which will allow beneficiaries to view the plan's MTM program eligibility information and a link to the plan's MTM program web page. Therefore, beginning with the 2014 Health Plan Management System (HPMS) MTM Program Submission Module, sponsors will be required to report their MTM program web page URL with their program description (as part of the annual submission process). Additional MTM definitions will be added into the general tabs on Medicare.gov (such as Manage Your Health and Help & Resources) and glossaries. Examples

include but are not limited to: “Medication Review” or “Manage your Medications.” Currently, Part D sponsors are encouraged to post a blank Personal Medication List from the CMR standardized format on their website or provide information to beneficiaries about how to obtain a blank copy and to reach customer service. The plan’s website should also provide at a minimum the plan’s MTM eligibility requirements, who to contact for more information, and a high level summary of services offered as part of the MTM program.

Beginning in 2014, sponsors will be required to have a dedicated “Medication Therapy Management Program” page linked from their Medicare drug plan website (such as the services or benefits page) with specific information about their MTM program written in plain language appropriate for beneficiaries including:

- The plan’s specific MTM eligibility requirements, with an interactive tool for beneficiaries to input their information and determine if they may be eligible for the plan’s MTM program,
- Who to contact for more information, with customer service personnel prepared to answer questions about the MTM program,
- A high level summary of services offered as part of the MTM program, explanation of the purpose and benefits of MTM, and that this is a free service, and
- A description of how the beneficiary will be notified that they are eligible and enrolled in the MTM program, how they will be contacted and offered services, including the comprehensive medication review and targeted medication reviews, and a description of how the reviews are conducted and delivered, including time commitments and materials beneficiaries will receive.
- How the beneficiary may obtain MTM service documents, including a blank copy of the Personal Medication List.

If possible, this page should be accessible by clicking through a maximum of two links. We solicit comments about what MTM information should be required for display on plans’ websites for beneficiaries to ensure that the information is readily and consistently available.

Antipsychotic Data

CMS continues to pursue strategies to increase awareness of antipsychotic use in long term care. To that end, we are calculating a new metric defined as the percent of Medicare Part D beneficiaries 65 years and older who are continuously enrolled in a nursing home and who received atypical antipsychotic (AA) medication fills during the period measured. Based on 2011 Prescription Drug Event (PDE) data, Enrollment data, and Minimum Data Set (MDS) Assessments, the new metric is now posted for all contracts with more than 10 beneficiaries who:

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

These data are included for informational purposes only on the 2013 Display Measures page now available on the CMS Web site at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ PerformanceData.html. The data show 2011 atypical antipsychotic drug rates by contract that range from 3.03% to 66.67%. The table below reports the average rate for each organization type. Currently, CMS does not plan to integrate the data into the Star Ratings. At this point, we do not know what a "good" or expected rate is, but we want to inform sponsors of their rates. If a sponsor sees its rate is high, we would encourage them to work with the care team at the LTC facility to investigate whether the beneficiaries truly need the atypical antipsychotic drugs.

Based on a review of Medicare payments for atypical antipsychotic drugs in nursing homes, the DHHS Office of Inspector General (OIG) found 22 percent of the atypical antipsychotic drugs associated with the sampled claims did not comply with CMS standards regarding unnecessary drugs in nursing homes. The reasons cited in the OIG final report (OEI-07-08000150, May 2011) for noncompliance with CMS standards included excessive dose, excessive duration, inadequate indication for use, inadequate monitoring and/or the presence of adverse consequences that indicated that the dose should be reduced or discontinued. Given this finding, our expectation is that we will see these rates generally decline in the future as a result of MTM services and other increased efforts to curtail atypical antipsychotic drug use in LTC.

Table 1: Rates of Atypical Antipsychotic Drugs by Organization Type

Organization Type	Atypical Antipsychotic Drug Rate
MA Only	25.0
MA-PD	21.3
PDP	24.3
Low Income Newly Eligible Transition (LINET) Contractor	24.5

Two related nursing home quality measures which became available on the Medicare Nursing Home Finder Web site in 2012 will continue to be posted. Based on resident assessment information reported in the MDS, these quality measures reflect antipsychotic drug use by short-term stay and long term stay facility residents.

Improvements to the Prescription Drug Plan Information Files

We remain committed to improving Medicare Plan Finder (MPF) data that are available to the public. Currently, the Quarterly - Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information public use file includes a 30 day cost (average monthly cost at in-area retail pharmacies) by NDC. CMS is proposing to expand the pricing data to include extended day supply pricing for retail and mail order, when offered under a plan benefit package. Extended day supply pricing is already reported by sponsors as part of the Medicare Plan Finder pricing data requirements, so this change imposes no additional burden on sponsors. We expect this enhancement to be implemented in the first CY 2014 Quarterly - Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information public use file.

Coordination of Benefits (COB) User Fee

CMS is authorized to impose user fees on Part D sponsors for the transmittal of certain 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. Funding estimates for 2013 included some projects and contingent contract recompete transition costs for a number of COB-related systems that ultimately were not needed, resulting in a significant surplus. Upon this review of anticipated costs for COB activities for the upcoming contract year, we have determined that we will not be imposing COB user fees for contract year 2014. Please note that for contract year 2015, we anticipate imposing user fees again.

In contract year 2014, we will use the surplus 2013 COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- Coordination of Benefits Contractor (COBC) operation and maintenance;
- Drug data processing system management, which is used to collect prescription drug event (PDE) data for Part D payment purposes, including coordination of benefits with other payers, and to produce invoices for the coverage gap discount program;
- Medicare Advantage and Prescription Drug (MARx) system management of COB data;
- Creation and maintenance of a web-based portal that allows Part C plans and Part D sponsors to retroactively process enrollments, which helps ensure that COB information is accurate;
- Implementation of an automatic notification process that will advise other health insurers whenever a beneficiary's Part D COB information changes; and
- Review of Workers' Compensation settlement set-aside funds, which ensure that medical services are paid for by the appropriate party.

Part D Low Enrollment

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are

viable plan options. While we are particularly concerned with plans that have fewer than 500 enrollees, we urge sponsors to voluntarily withdraw or consolidate any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html to determine if any of their plans meet this criterion. In April 2013, we will notify plans with less than 1,000 enrollees of available consolidation/withdrawal options. We reserve the right to require low enrollment plans to consolidate/withdraw in the future based on the marketplace at that time to ensure that all Part D plans offered in the marketplace are attractive to beneficiaries and not adding to their confusion in selecting a plan best suited to their prescription drug coverage needs.

Preferred / Non-Preferred Pharmacy Networks

We remind Part D sponsors that the regulations that permit lower cost sharing at some network pharmacies also require that such cost sharing reductions must not increase CMS payments to the plans:

> **42 CFR 423.120(a)(9)— Differential cost-sharing for preferred pharmacies.** A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

We have begun to scrutinize Part D drug costs in PDPs with preferred networks, and comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks. We are concerned because our initial results suggest that aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks in some plans. Combined with lower cost sharing, we believe these higher unit costs may violate the requirement not to increase payments to such plans. We will be contacting the plan sponsors identified in our analysis to validate our findings in the near future.

We also remind all sponsors that beneficiary communications concerning preferred networks must be clear and unambiguous. Under no circumstances may sponsors inform LIS-entitled beneficiaries that they must fill prescriptions at preferred network pharmacies in order to get LIS copays. This means that both written and verbal communications between plan representatives and Medicare beneficiaries must be differentiated by LIS status, whether through mailings or Customer Service Representative (CSR) scripts.

Appendix 1 – Additional Gap Coverage

Consistent with our bid submission requirements provided at 42 CFR 423.265, a Part D sponsor's bid submission must reflect differences in benefit packages or plan costs that we determine to represent substantial differences relative to a sponsor's other bid submissions. In 2014, the standard drug benefit will provide 28% of generic drug and 2.5% of brand drug coverage in the gap. We expect that the additional gap coverage of drugs offered by plans will reflect meaningful enhancements over the standard prescription drug benefit.

To determine how much additional cost-sharing coverage in the coverage gap over the basic benefit would be recognized as substantially different, we considered the amount of additional coverage provided by the Part D sponsors in their plan benefit packages for CY 2013. Based on this analysis, we are setting the maximum copay cost-sharing thresholds at the pre-ICL thresholds values set for CY 2014 (see also Part D Benefit Parameters, Table 1 above). Similar to the pre-ICL cost-sharing analysis, we completed an analysis of the additional gap coverage copay cost-sharing associated with the 95th percentile across all initially submitted bids consisting of three or more tiers. Table 1 below shows the results of the threshold analysis of the CY 2013 bid submissions, as well as the 2014 copay thresholds. Note the 95th percentile was at or below the established pre-ICL thresholds, except for the Select Diabetic Tier which included coverage of only applicable drugs in the gap therefore the effective beneficiary cost-sharing was at the threshold level.

With respect to coinsurance cost-sharing, we found that the 95th percentile of plans offering coverage in the gap had cost-sharing levels for generics (including tiers with a mix of brands and generic drugs) of 50% coinsurance. This was the maximum coinsurance level allowed in CY2013 for tiers with additional gap coverage that included generic drugs. Because the standard gap coverage benefit for generic drugs is increasing to 28% for CY2014, we are setting the maximum coinsurance threshold for generics drugs at a beneficiary cost-sharing of 50%, which provides a benefit that is approximately 2 times the standard benefit of 28% for CY 2014. This is consistent with our approach last year. With respect to brand drugs, for which the standard benefit is 2.5% for CY 2014, we will maintain last year's threshold and require that the plan's benefit has beneficiary cost-sharing during the coverage gap that is equal to or less than 69% coinsurance. Table 2 below shows the results of the threshold analysis of the CY 2013 bid submissions, as well as the 2014 coinsurance thresholds.

Table 1. CY 2014 Maximum Copay cost-sharing for additional gap coverage offered by EA plans (MA-PD & PDP)

Tier Label[1]	# of plans	25th	50th	75th	95th	2014 Threshold
Preferred Generic/Generic Drugs						
R	1121	$0	$4	$6	$8	$10
P	207	$0	$2	$3	$5	$10
NP	207	$3	$7	$10	$10	$10
Non-Preferred Generic Drugs						
R	667	$5	$10	$12	$20	
P	65	$5	$5	$10	$12	$33
NP	65	$7	$7	$10	$17	
Preferred Brand Drugs						
R	491	$40	$45	$45	$45	
P	32	$40	$40	$40	$40	$45
NP	32	$45	$45	$45	$45	
Non-Preferred Brand Drugs						
R	444	$80	$86	$95	$95	
P	32	$76	$76	$76	$76	$95
NP	32	$95	$95	$95	$95	
Select Care Drugs						
R	44	$0	$0	$0	$0	
P	NA	NA	NA	NA	NA	$10
NP	NA	NA	NA	NA	NA	
Select Diabetic Drugs						
R	2	$20	$20	$20	$20	
P	NA	NA	NA	NA	NA	$10
NP	NA	NA	NA	NA	NA	

[1] Please note that "R" refers to "In-network retail pharmacy"; "P" refers to "In-network preferred retail pharmacy"; and "NP" refers to "in-network non-preferred retail pharmacy."

Table 2. CY 2013 Maximum Coinsurance cost-sharing for additional gap coverage offered by EA plans (MA-PD & PDP)

Tier Label[1]	# of plans	25th	50th	75th	95th	2014 Threshold
Preferred Generic/Generic Drugs						
R	6	50%	50%	50%	50%	50%
P	39	1%	1%	1%	50%	
NP	39	59%	59%	59%	59%	
Non-Preferred Generic Drugs						
R	NA	NA	NA	NA	NA	50%
P	5	50%	50%	50%	50%	
NP	5	50%	50%	50%	50%	
Preferred Brand Drugs						
R	47	25%	25%	50%	69%	69%
P	69	30%	30%	50%	50%	
NP	69	35%	35%	55%	55%	
Non-Preferred Brand Drugs						
R	67	41%	43%	44%	49%	69%
P	36	40%	50%	50%	50%	
NP	36	53%	55%	55%	55%	

[1] Please note that "R" refers to "In-network retail pharmacy", "P" refers to "In-network preferred retail pharmacy", and "NP" refers to "In-network non-preferred retail pharmacy." There was no additional gap coverage offered in 2013 for tiers labeled as Injectable, Select Care or Select Diabetic Drugs.

[2] The minimum additional gap coverage benefit of 50% for generic drugs and 69% for brand drugs is inclusive of the standard gap coverage drug benefit of 28% and 2.5% respectively in CY 2014.

Appendix 2 – Contract Year 2014 Guidance for Prescription Drug Plan (PBP) Renewals and Non-Renewals

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

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

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June (June 3, 2013) pursuant to 42 CFR §423.507(a)(2)(i). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with regulatory requirements, CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance, Chapter 3 of the Prescription Drug Benefit Manual and annual summer CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2014 is summarized below and defined in Appendix 3. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

1. New Plan Added

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor offering the PBP must submit enrollment transactions to MARx. No beneficiary notice is

required in this case beyond receipt of the Evidence of Coverage (EOC), and other documents as required by current CMS guidance, following enrollment.

2. Renewal Plan

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

3. Consolidated Renewal Plan

PDP sponsors are permitted to combine two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk. A PDP sponsor may not split a current PBP among more than one PBP for the following contract year. A PDP sponsor consolidating one or more entire PBPs must designate which of the renewal PBP IDs will be retained following the consolidation; the organization's designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary's election by moving him or her into the designated renewal plan ID. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. When consolidating two existing PBPs into a single renewal PBP, it is permissible for the single renewal PBP to result in a change from:

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

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

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

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

Current enrollees will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current enrollees. New enrollees must

complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5. Terminated Plan (Non-Renewal)

A PDP sponsor may elect to terminate a current PBP for the following contract year and must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) by June 3, 2013. In this situation, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period, as well as information about alternative options.

6. Consolidated Plans under a Parent Organization

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

Current enrollees of a consolidated renewal plan must receive a special notice along with a standard ANOC. Plan sponsors should use the CMS model for this special notice provided in Appendix 4 of this Call Letter.

<u>Requests to Change a Basic Plan to an Enhanced Plan</u>

PDP sponsors should note that, as a general matter, CMS will not permit renewal or consolidation of a PBP when it involves moving enrollees from a basic benefit design to an enhanced alternative benefit design, unless very limited conditions are met.

Such renewals or consolidations must always be pre-approved by CMS. We have approved such requests in a very limited number of situations when a sponsor has determined how to provide a

significantly more efficient basic benefit in the next coverage year (including a meaningfully different OOPC). We would generally expect these to be one-time events for a sponsor. In these cases, the reclassification of the plan type and transfer of enrollees from a basic plan design to an enhanced plan has made sense because the enhanced plan provided a more comparable year-to-year benefit transition compared to the new level of benefits in the new proposed basic plan. The transfer of enrollees in these cases has kept the beneficiaries in a plan with comparable benefits, while allowing more efficient basic plans with lower premiums to be offered on the market.

We will not approve this sort of change if the existing basic plan under consideration has a premium below the LIS benchmark or de minimis premium in the current coverage year. This is to ensure that auto-enrollees are not moved to a plan with a supplemental premium and a reduced premium subsidy, as well as to ensure the requested change in classification of plan type is not aimed at reducing the number of enrollees who had been previously auto-enrolled. For existing basic plans that are above the benchmark and had not elected to waive de minimis premium, enrollees with LIS are not auto-enrollees, but are instead choosers. As such, they are assumed to have previously agreed to be enrolled in a plan where premium was not fully subsidized.

In general, the conditions that must be met in order for us to approve such a renewal or consolidation include (but may not be limited to) all of the following:

a) the existing basic benefit PBP must not be under the benchmark premium in the current year;
b) the premium of the enhanced alternative benefit PBP in the next coverage year must the same or less than the existing basic PBP;
c) the benefits of the enhanced alternative benefit PBP in the next coverage year must be better than or similar to the existing basic benefit PBP;
d) all of the sponsor's plans must continue to meet the minimum meaningful differences OOPC threshold values; and
e) the PDP sponsor must move all enrollees into the same enhanced benefit design PBP.

These policies would also apply if a sponsor had one PBP with a basic benefit design and wished to terminate this plan and offer a new basic plan. That is, the sponsor would have to redesignate the previous basic plan as an enhanced plan, and move all of the enrollees into that new enhanced plan, in order to offer a new basic plan.

Organizations must also request a crosswalk exception for requests to change a basic plan to an enhanced plan and receive permission from CMS prior to submitting such bids. However, this does not guarantee that the actual bid submission will be approved by CMS during the bid review process.

Appendix 3 – Contract Year 2014 Guidance for Prescription Drug Plan (PBP) 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 2014 that is not linked to a 2013 plan. HPMS Plan Crosswalk Designation: New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
2	Renewal Plan	A PDP sponsor continues to offer a CY 2013 PBP in CY 2014. The same PBP ID number must be retained in order for all current enrollees to remain in the same PBP in CY 2014.	HPMS Plan Crosswalk Definition: A 2014 plan that links to a 2013 plan and retains all of its plan service area from 2013. The 2014 plan must retain the same plan ID as the 2013 plan. HPMS Plan Crosswalk Designation: Renewal Plan	The renewal PBP ID must remain the same so that current enrollees will remain in the same PBP ID. The PBP sponsor does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2014. 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 2013 into a single renewal PBP for CY 2014. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2014 after consolidation.	HPMS Plan Crosswalk Definition: Two or more 2013 plans that consolidate into one 2014 plan. The 2014 plan ID must be the same as one of the consolidating 2013 plan IDs. HPMS Plan Crosswalk Designation: Consolidated Renewal Plan	The PDP sponsor's designated renewal PBP ID must remain the same so that CMS can consolidate current enrollees into the designated renewal PBP ID. The PDP sponsor does not submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2014.	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 2013 prescription drug PBP in CY 2014 and expands its EGWP service area to include additional regions. The PDP sponsor must retain the same PBP ID number in order for all current enrollees to remain in the same PBP in CY 2014.	HPMS Plan Crosswalk Definition: A 2014 800-series plan that links to a 2013 800-series plan and retains all of its plan service area from 2013, but also adds one or more new regions. The 2014 plan must retain the same plan ID as the 2013 plan. HPMS Plan Crosswalk Designation: Renewal Plan with an SAE	The renewal PBP ID must remain the same so that current enrollees in the current service area will remain in the same PBP ID. The PDP sponsor does not submit enrollment transaction for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2014. 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 2013 PBP.	HPMS Plan Crosswalk Definition: A 2013 plan that is no longer offered in 2014. HPMS Plan Crosswalk Designation: Terminated Plan	The PDP sponsor does not submit disenrollment transactions. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization must submit enrollment transactions to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
6	Consolidated Plans across Contracts under the Same Parent Organization	A parent organization combines two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk.	Exceptions Crosswalk Request: Sponsors must submit an exceptions request to CMS, which will complete the crosswalk on behalf of the sponsor HPMS Plan Crosswalk Designation: The plan being crosswalked must be marked as a terminated plan in the HPMS crosswalk. The remaining 2014 plan must be active and contain the applicable service area from the terminated plan being crosswalked.	PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. CMS will effectuate this renewal option and HPMS will record the consolidation of one or more whole PBPs. The PDP sponsor does not submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment election for current enrollees to remain enrolled in the renewal PBP in 2014. New enrollees must complete enrollment request.	Current enrollees are sent a special notice (based on the CMS model in Appendix 4) along with a standard ANOC.

Appendix 4 – Contract Year 2014 Guidance for PDP PBP Renewal Option 6 Special Disenrollment Model Notice

CMS Model Notice

Contract Year 2014 Guidance for PDP PBP Renewal Option 6 Special Disenrollment Notice
<Insert Date>

IMPORTANT NOTICE: Your Medicare Prescription Drug Coverage Is Changing

Dear <member name>,

<Organization name> will no longer offer <terminating plan name> after December 31, 2013. To make sure you continue to have the same level of Medicare Prescription Drug coverage, **you'll be enrolled in our <receiving plan name> starting January 1, 2014.**

Your new plan coverage starts January 1

<Organization name> has approval from Medicare to transfer your enrollment into our <receiving plan name> for 2014. Medicare approved this transfer because the prescription drug benefits in <receiving plan name> are similar to the prescription drug benefits you've been getting in <terminating plan name>. See the attached information about this new plan.

Here's what to do next

If you do nothing, you'll be a member of <receiving plan name> starting January 1, 2014. After reviewing your ANOC/EOC, if you have questions about your prescription drug benefits or how this new plan works, including what your costs will be or which pharmacies you can use call <receiving plan name> at <receiving plan phone number>. You should use this letter as proof of coverage under <receiving plan name> until you get your membership card.

You should look carefully at the prescription drug benefits of <receiving plan name> to see if they meet your needs. Although the prescription drug benefits are similar to the prescription drug benefits you have now, they may be different in ways that are important to you.

What if you don't want to be in this plan?

If you don't want to be in <receiving plan name> in 2014, you have the right to choose another Medicare Prescription Drug Plan **anytime between October 15 and December 7.** Your new coverage will start on January 1, 2014.

Here are your options for Medicare Prescription Drug coverage:

Option 1: If you do nothing, you'll get prescription drug coverage from <receiving plan> starting January 1, 2014.

Option 2: You can join another Medicare Prescription Drug Plan. Joining a new plan will automatically disenroll you from <receiving plan name>. You should compare the plans available in your area. You can call the plans to get more information about their rules and coverage and find a plan that meets your needs.

Option 3: You may be able to join a Medicare Advantage plan.
You can join a Medicare Advantage plan if you have both Part A and Part B. Medicare Advantage plans cover all your Part A and Part B services and usually include additional coverage, such as prescription drugs (Part D). Costs, extra coverage and rules vary by plan. Joining a new plan will automatically disenroll you from <receiving plan name>. You should compare the plans available in your area. You can call the plans to get more information about their rules and coverage and find a plan that meets your needs.

Other information you need to know:
If you qualify for Extra Help (the low-income subsidy) for 2014, you have the right to change plans at any time.

If you have an employer or union group health plan, VA benefits, or TRICARE for Life, call your insurer or benefits administrator to find out how to join a new plan.

If you get help from the Medicaid program, contact <State Medicaid Agency and phone number> to learn how joining a new plan affects your Medicaid coverage.

Get help and more information about your options
If you need more information about your changing coverage, please call us at <Phone Number> <Days & Hours>. TTY users should call <insert number >. Tell the customer service representative you got this notice.

To join another Medicare Prescription Drug Plan, you should compare available plans and join one that meets your needs. You should find out which plans cover the prescriptions you take. For help comparing plans and joining a plan that works for you, visit http://www.medicare.gov, or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You can also call your State Health Insurance Assistance Program for free personalized counseling at <SHIP phone number>.

To see if your state has a program for people with limited income and resources, call your State Medical Assistance Office at <State Medical Assistance Office Number>. You may be able to get help paying Medicare premiums, deductibles and coinsurance. TTY users should call <State Medical Assistance Office> at <TTY Number>.

Sincerely,

<CEO or other official of PDP organization>

[Insert Federal contracting statement.]
[Insert Material ID number] [insert **CMS Approved** *followed by mm/dd/yyyy]*
["Model Beneficiary Notice for CMS Approved Crosswalk Situations"- (material submission code # 2054).]

Appendix 5 - Summary of Comments to the Request for Comments on the 2014 Star Ratings and Beyond

On November 30, 2012 CMS sent out a Request for Comments to Part C and D sponsors, stakeholders and advocates that described a proposed methodology for the 2014 and 2015 Star Ratings for Medicare Advantage (MA) and Prescription Drug Plans. The purpose of this early alert was to provide plans and advocates with advance notice of the methodology and changes so CMS can identify modifications needed in advance of the issuance of this draft 2014 Call Letter. The comment period provided for in this request for comments closed on January 3, 2013. We received approximately 80 sets of comments from organizations representing plans, pharmaceutical companies, consumer groups, and measurement development organizations. Below is a summary of the proposed changes announced in the Request for Comments, a description of the comments received, and how CMS has addressed these comments in the draft Call Letter.

2014 Star Ratings

New Measures Proposed for the 2014 Ratings

Special Needs Plans (SNP) Care Management measure (Part C SNPs).

Proposed Change: CMS indicated on November 30, 2012 that we were considering adding this measure that captures the completion of initial and annual standardized health risk assessments among SNPs.

Summary of Comments:

- Several commenters supported the inclusion of this measure.
- Several commenters suggested delaying the implementation to allow plans to understand the specifications of the measure and to take actions.
- Several commenters requested more information and data (e.g., national average).
- Some commenters were confused by the difference between this measure and the existing Part C measure.
- Some commenters were concerned this measure did not take into consideration that members could refuse to complete an assessment, not complete an assessment, or not be reached despite the care team's best efforts.
- Several commenters made suggestions about changing the 90-day period over which the assessment would occur.
- Some commenters asked to clarify whether this measure would differentiate between new and existing members.
- Some commenters suggested that this measure should be treated as a process measure with a weight of 1.

- One commenter was concerned that plan sponsors would take different approaches in completing assessments, which would create inconsistency.
- One commenter suggested this measure should be posted at the plan benefit package level, instead of contract level.
- One commenter suggested establishing separate benchmarks for community-based SNPs versus institutional SNPs, as significant differences exist in reporting performance between SNP types.

CMS Response:
CMS has decided to delay implementation of this measure to the 2015 Star Ratings and continue it only as a display page measure for 2014. In the fall of 2012 CMS provided additional clarifications regarding how to treat assessments falling over multiple reporting years. Delaying the implementation an additional year will ensure that plans are collecting the data similarly. This measure does take into account new and existing members. As stated in the Medicare Health & Drug Plan 2013 Part C & Part D Display Measure Technical Notes, page 9, "The numerator for this measure is the sum of the number of initial assessments performed on new SNP enrollees during the reporting period and the number of annual reassessments performed on SNP enrollees eligible for a reassessment." When this measure is included in the Star Ratings, it will be assigned a weight of "1" as it is a process measure. If plans are interested in seeing scores on this measure, they should look at the information currently on the CMS Star Ratings display page.

Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).

Proposed Change: CMS indicated on November 30, 2012 that we were considering adding this measure that is based on the Pharmacy Quality Alliance (PQA) endorsed measure, Completion Rate for Comprehensive Medication Review (CMR), which measures the percentage of MTM-eligible beneficiaries who received a CMR. It is defined as the percent of Medication Therapy Management (MTM) program enrollees who received a Comprehensive Medication Review (CMR), based on validated 2012 beneficiary-level plan-reported MTM data (collected as part of the Part D reporting requirements).

Summary of Comments:

- Many commenters requested that CMS provide a standardized definition of Long Term Care (LTC) and a clear industry standard to identify LTC status; some commenters stated that they were using the patient location codes of 03,04,05 to identify LTC status.
- Several commenters requested more frequent Long Term Institutionalized (LTI) reports.
- Some commenters requested CMS evaluate whether Targeted Medication Reviews (TMRs) may be a more effective means of measuring the quality of a plan sponsor's MTM program.

- Some commenters requested an adjustment in the measure to account for differences in LTC population prevalence amongst plans and reduce potential incentive for plan sponsors to limit their targeted MTM population.
- Many commenters suggested keeping this as a display measure and publishing thresholds.
- Some commenters are concerned with differences in prevalence of the LTC population amongst plans and are requesting an adjustment to account for disease severity.
- A few commenters requested clarification on "nursing home stay".
- Some commenters do not support the CMS suggestion to use the Long Term Institutionalized (LTI) report to identify LTC membership due to the infrequency and timing of its release.
- Some commenters stated that CMS should exclude patients who opt out of the MTM program.
- Some commenters support this new measure.

CMS Response:
CMS has decided to delay implementation of this measure to the 2015 Star Ratings and continue it as a display page measure for 2014. During this period of transition from display measure to star rating measure, CMS will continue to work with the industry to clarify specifications of the measure. For 2014, the measure would continue to be defined as the percent of non-LTC MTM program enrollees who received a CMR. The denominator is the number of non-LTC beneficiaries who were at least 18 years or older as of the beginning of the reporting period and who were enrolled in the MTM program for at least 60 days during the reporting period. The numerator is the number of beneficiaries from the denominator who received a CMR during the reporting period. Beginning in 2013, LTC beneficiaries are no longer exempt from the CMR requirement, and sponsors are required to offer CMRs to all beneficiaries enrolled in the MTM program at least annually regardless of setting. CMS proposes adding this measure to the Star Ratings in 2015 using 2013 data with the inclusion of LTC beneficiaries in the measure calculation.

Some commenters requested that CMS publish thresholds in advance for the MTM display measure. CMS does not create thresholds for display measures. Thresholds will only be available when the measure is a star rating measure.

A lot of commenters said the lack of frequency of the LTI reports made it harder for plans to correctly identify LTC residents. To remedy this issue, CMS is also planning on releasing more frequent updates to the LTI report. These reports will be issued quarterly instead of semiannually.

Changes to the Methodology of Current Measures

CMS invited comment on the fact that we were considering modifying the methodology for the following measures:

Call Center – Foreign Language Interpreter and TTY Availability (Part C and D) – Affects Puerto Rico Plans only.

Proposed Change: Recognizing that Spanish is the predominant language in Puerto Rico, beginning in 2013 CMS is proposing to measure English as a foreign language for contracts for which Puerto Rico is the exclusive service area. We are proposing to replace "non-English language" with "foreign language" in the metric to reflect this change.

Summary of Comments:

- Several commenters supported this change.
- One commenter suggested moving this measure to the display page so that plans have time to understand and react.

CMS Response:
CMS plans to proceed to make this change for the 2014 Star Ratings.

Quality Improvement (Part C and D).

Proposed Change: CMS' methodology currently includes a hold harmless provision for contracts with overall ratings of 4 or more stars that would have their overall rating decreased with the addition of the improvement measure(s). CMS stated on November 30, 2012 that we were considering proposing to modify this provision to apply also for the individual measures being evaluated for improvement. That is, if a contract receives 5 stars in an individual measure for 2 years, we may consider they maintained/improved performance for purposes of the improvement measure(s), regardless if their measure data have declined in the 2nd year.

Summary of Comments:

- Several commenters supported this proposal.
- Some commenters requested clarification on the definition of "maintained" as opposed to "improved."
- One commenter recommended that measures that received 5-star ratings in both years be considered as having "improved" performance.
- Some commenters recommended considering holding plans harmless if their individual measure stars were 4-stars in the two years being evaluated for improvement.
- One commenter recommended that measures should be considered non-applicable (N/A) for those plans with an overall star rating of 4.0 or greater.
- Some commenters advocated for consistency in the application of the "hold harmless" provisions across the Overall Rating and the Part C and D Summary Ratings.

- One commenter suggested instead of using a single measure, the improvement metric should be used for every star measure.
- One commenter suggested only evaluating those measures whose methodology remains constant.

CMS Response:
We have added additional language to the Call Letter to clarify the change. If a contract receives 5 stars in an individual measure for the two years being measured and demonstrates a statistically significant decline (at the 0.5 significance level) on the eligible measure, this measure will not be included in the contract's improvement measure calculation. Improvement scores of 0 (equivalent to no net change on the eligible measures included in the improvement calculation) will also receive 3 stars when assigning the star ratings for the improvement measure. Only measures with no significant technical specification changes over the two years being evaluated are included in the improvement measure.

High-Risk Medication Use (Part D).

Proposed Change: CMS invited comment on a proposal that the updated PQA HRM list be applied to calculate the HRM measure for the 2014 Star Ratings using 2012 Prescription Drug Event (PDE) data. Also, based on requests for clarification, CMS proposed that the following clarification be made to the measure's technical notes: This measure calculates the percentage of Medicare Part D beneficiaries 65 years or older who received two or more prescription fills for the same HRM drug with a high risk of serious side effects in the elderly.

Summary of Comments:

- Most commenters opposed CMS' application of the updated PQA HRM list for the 2014 Star Ratings (using 2012 Prescription Drug Event (PDE) due to the timing of the announcement citing that 2012 formulary, benefits, and quality initiatives could not be aligned to reflect these changes. Commenters requested that CMS delay the implementation of the updated list, and suggestions ranged from applying the new list to 2013, 2014, or 2015 PDE (2015, 2016 and 2017 Star Ratings, respectively).
- Many requested clarification about how Part D coverage of benzodiazepines and barbiturates effective January 1, 2013 will impact this measure.
- A few expressed concerns that the AGS states that the Beers list should not be applied in a punitive manner, is not a substitute for professional judgment, or should not be used in a manner to dictate prescribing for individual patients.
- Several technical requests or questions were received, including:
    - Stratify age-groups for varying risks,
    - Adjust for SNPs and LIS beneficiaries,
    - Exclude hospice, LTC and palliative care patients,
    - Compliance to CMS' transition policy and potential conflicts with this measure,

- Calculate cumulative day supply for nitrofurantoin and non-benzodiazepine hypnotics, and
- Evaluate the maximum dose of digoxin for indications other than atrial fibrillation.

CMS Response:

- CMS has decided to delay implementation of the updated HRM list to the 2013 PDE for the 2015 Star Ratings.
- In the 2013 Call Letter, CMS had alerted plans of potential changes to the HRM list effective for either the 2014 or 2015 Star Ratings (using 2012 or 2013 PDE data). In preparation for this change, CMS began to release 2012 HRM reports using the updated PQA HRM list via the Patient Safety website last summer. While we agree that plans should have adequate time to develop and implement initiatives, we disagree that these changes should be delayed beyond the 2015 Ratings (based on 2013 PDE data).
- The original PQA HRM list (i.e., the one used for the 2013 Star Ratings) will continue to be applied to calculate the HRM measure for the 2014 Star Ratings using 2012 PDE data.
- Since CMS began using the updated PQA HRM medication list to calculate the 2012 HRM rates provided to contracts via the Patient Safety Analysis Website in August 2012, CMS will redesign the reports to also include 2012 HRM rates using the original PQA HRM list. The timing for when the revised reports will be launched is still being determined. We also anticipate releasing 2013 reports in April or May of 2013.
- Part D coverage of barbiturates (used in the treatment of epilepsy, cancer, or a chronic mental health disorder) and benzodiazepines began in January 2013. The updated PQA HRM list only includes barbiturates. It does not contain benzodiazepines. Therefore, the calculation for the 2015 Star Ratings using the 2013 PDE data measure calculation will reflect Part D coverage changes, and Part D covered barbiturates will be included.
- CMS applies PQA-endorsed measure specifications, also endorsed by the National Quality Forum (NQF). Subsequently, requests for changes to specifications, including age-group stratification, evaluation of other medical chart data, and expansion of the measure to patients under 65 years old, should be directed to the PQA and NQF.
    - Refer to CMS' Technical Notes document for a description of the measure's methodology. CMS has adopted the PQA's specifications which include calculation of cumulative days' supply and average dose of specific medications such as nitrofurantoin, or medication classes like non-benzodiazepine hypnotics.
    - The PQA Quality Metrics Expert Panel and the National Committee for Quality Assurance Geriatric Measure Advisory Panel considered the recommendation of an average daily digoxin dose of 0.125mg and lower appropriate guidance for elderly persons. If a higher dose is required, it is assumed that this would be a rare event and not affect the measure rate.

- CMS does not modify the quality measures for specific plan-types, such as SNPs, or lowering quality standards for certain patient populations, such as LIS beneficiaries.
- We disagree that CMS' transition policy contradicts this measure. The transition policy allows for a one-time fill of a medication during the 90-day transition period, while plans coordinate with the beneficiaries' prescribers to consider safer alternatives. The HRM measure methodology was updated, beginning with the 2013 Star Ratings, and beneficiaries are only included in the numerator if they received two or more fills of the same HRM.
- Significant specification changes such as adoption of PQA's updated list would result in suspension of a pre-determined 4-star threshold (if applicable). Weighting of measures is only affected when new measures are introduced. We expect that a pre-determined 4-star threshold will not be set for this measure for several years, and that this measure will continue to be excluded from the Improvement measure, given the additional specification changes. CMS will continue to base star thresholds on statistical analyses and the relative ranking of contracts' scores.

Diabetes Treatment Measure (Part D).

Proposed Change: None.

Summary of Comments:

- Several technical requests or questions were received, including:
    - Consider age thresholds.
    - Consider exclusion of co-morbidities such as ESRD. Reasons varied for why someone was not on an ACE/ARB and include history of worsening of renal function while on drug therapy, late stages of renal disease including patients on dialysis, hyperkalemia, hypersensitivity to medication, angioedema, hospice, expired, or intolerance to drug therapy.
    - Use of supplemental data (for medication discontinuation, contraindications, etc).

CMS Response:
CMS is not proposing any changes to this measure. CMS applies PQA-endorsed measure specifications, also endorsed by the National Quality Forum (NQF). Subsequently, requests for changes to specifications, including age-group stratification, evaluation of other medical chart data, and expansion of the measure to patients under 65 years old, should be directed to the PQA and NQF.

Medication Adherence for Oral Diabetes Medications (Part D).

Proposed Change: CMS asked for comments on a proposal to adopt PQA's changes to this measure's specifications for the 2015 Star Rating (using 2013 PDE data), specifically the

addition of two additional drug classes, meglitinides and incretin mimetic agents; both are indicated for monotherapy.

Summary of Comments:

- A majority of commenters misunderstood the intent of adding these 2 drug classes, or the manner in which claims for these drugs would be treated. As a result, many requested that the change be delayed an additional year to 2016 Star Ratings. It was not clear to some commenters that CMS proposed this as a change for the 2015 Star Ratings, not 2014, and expressed concern about implementation for 2014 Star Ratings.
- There were some requests to incorporate insulin therapy into this measure. (Currently, beneficiaries who have one or more prescriptions for insulin in the measurement period are excluded).
- Several commenters pointed out that the measure name should be revised as incretin mimetic agents are injectables.
- One asked if this measure can parallel the HEDIS comprehensive diabetes care measure.
- Commenters continued to request the ability to submit supplemental databases to CMS to account for apparent non-adherence – e.g., claims filled via discount programs outside of Part D; clinical changes; secondary payers.
- A few requested more information about how CMS will evaluate if a pre-set 4-star threshold should be suspended, due to this change.
- Several technical requests or questions were received, including:
    - Adjust for SNPs and LIS beneficiaries, or create separate ratings.

CMS Response:

- We will clarify that the proposal is for the 2015 Star Ratings (using 2013 PDE data), to adopt PQA's changes from evaluating adherence across four classes of oral diabetes medications (biguanides, sulfonylureas, thiazolidinediones, and DiPeptidyl Peptidase (DPP)-IV Inhibitors) to evaluating a total of six classes of diabetes medications (previous four classes with the addition of meglitinides and incretin mimetic agents). The new proportion of days covered (PDC) calculation would determine if the beneficiary is covered by at least one drug from any of the six classes of diabetes drugs.
- PQA's Quality Metric Expert Panel recommended a change to the measure, to capture the use of incretin mimetic agents and meglitinide medications. These medications are indicated for mono-therapy in the treatment of diabetes. Including these two medication classes ensures that members will be counted as adherent if they switch from a medication in another class to an incretin mimetic or meglitinide.
- The purpose of this change is to allow a more comprehensive evaluation of beneficiaries' prescribed diabetes therapy by including all classes approved for monotherapy; CMS believes this will help improve the accuracy of this measure.

- Per PQA-endorsed specifications, beneficiaries who have one or more prescriptions for insulin in the measurement period are excluded.
- We also propose renaming the measure to: Medication Adherence for Diabetes Medications.
- We feel this measure complements other Star Rating Measures related to diabetes; ensuring medication adherence is just one facet of helping manage this chronic disease.
- CMS will determine if these changes are significant, and if so, this would necessitate the suspension of a pre-established 4-star threshold (if established for 2014 Star Ratings). CMS will provide advance notice of this.
- CMS does not modify the quality measures for specific plan-types, such as SNPs, or changing quality standards for certain patient populations, such as LIS beneficiaries.
- For the Medication Adherence measures for Diabetes, Hypertension and Cholesterol, CMS will continue to use a slightly modified PDC calculation to adjust for overlapping prescriptions for the same drug using generic name (ingredient name). PQA specifies using GCN (which includes strength). Because medication adherence is measured using claim fill dates and days' supply as a proxy for utilization, there are some clinical scenarios where using GCN may be too restrictive. In cases where a beneficiary's prescriber changes the dose of the medication, the beneficiary may be instructed to begin the new dose immediately or to begin the new dose after finishing the supply of the former dose. For this reason, CMS uses a broader interpretation of the PDC calculation using generic name. We recently revisited this decision and tested the impact of using the generic name versus GCN method on the Adherence measure rates. We reviewed the Adherence measure rates using claims data between January 1, 2012 and October 31, 2012 as of October 31, 2012. The differences were negligible. On average, the Adherence measure rates across all Part D plans were 0.3-0.5 percentage points lower when using GCN compared to generic name. But, considering these are highly weighted measures, and there may be clinical scenarios were using the GCN may not be appropriate, we will continue to use the generic name method.

MPF Price Accuracy (Part D).

Proposed Change: When comparing the Prescription Drug Event (PDE) total cost to the Plan Finder total cost, CMS has not penalized contracts when the point of sale (POS) costs are lower than the advertised costs. Contracts are penalized if the POS costs are higher than the advertised costs. CMS indicated on November 30, 2012 that we were considering changing the methodology to account for any cases where the POS cases are different from the advertised costs, in order to discourage the display of falsely high prices for select drugs or drug classes in attempt to reduce enrollment by some beneficiaries.

Summary of Comments:

- Multiple commenters requested that this new methodology for measuring price accuracy be made a display measure for 2014 (using 2012 Plan Finder and PDE data) while the impacts of this change are studied. Some noted that CMS' guidance changed between 2012 and 2013; for 2012, CMS instructed sponsors with different pricing structures for certain pharmacy services to submit the highest pricing structure. In 2013, CMS instructed pricing to reflect the applicable retail cost for retail pricing or the mail order price for mail order pricing. Commenters requested therefore this new methodology is applied beginning with analysis of 2013 data for a 2015 Display or Star Rating.
- Multiple commenters asked CMS to define the phrase "substantially different", in terms of how much of a difference between MPF display prices and PDE prices would cause negative impacts to the plan's rating of this measure.
- Multiple commenters were concerned with CMS' comparisons of PDE prices to MPF displayed pricing due to factors that may cause point of sale pricing to fluctuate, in some cases on a daily basis, as opposed to MPF's data refresh ever two weeks. Specific factors cited as causes for fluctuations at the point of sale include MAC pricing, new generics and new generic manufacturers, and frequent negotiations between plans and pharmacies. Some commenters requested that MPF files be submitted (and thus MPF be refreshed) more often than every two weeks.
- Multiple commenters were concerned with the display of copays, coupons, floor pricing, and ceiling pricing displayed on the MPF and charges at the point of sale not being accurately reflected in the scoring methodology.
- Multiple commenters requested clarification about which drugs and drug classes will be selected when applying this proposed methodology to the current Accuracy Measure.

CMS Response:
For the Price Accuracy measure, CMS has decided to continue the methodology used for the 2013 Star Ratings for 2014 Star Ratings. As clarification, CMS' current methodology compares MPF display to PDE pricing by evaluating a drug's PDE unit cost to the corresponding unit cost displayed on MPF at the time, since beneficiaries may be in varying phases of their benefit throughout the year. Any differences can impact the scoring. While factors such as pharmacies' discounted generics programs may affect what the beneficiary pays at the point of sale, they do not affect the calculation of this measure.

As a separate evaluation, CMS remains interested in evaluating cases where PDE unit costs are less than MPF unit costs. It will be important to examine the impact of CMS' guidance changes between 2012 and 2013, as well as determine if CMS should focus on certain drugs or drug classes where there is higher concern that higher prices could be displayed to discourage enrollment by some beneficiaries, versus the current measure's evaluation of all drugs. CMS will share additional information as the measure is developed, and determine based on testing results if these separate results can be shared via a 2014 Display Measure.

Rounding of measure data.

Proposed Change: CMS proposed on November 30, 2012 to round all measure data and cut-points used for CMS' Star Ratings, including Part D Patient Safety measures, to whole numbers in order to avoid small differences in decimal values that result in differences in performance ratings.

Summary of Comments:

- Several commenters supported this change.
- Several commenters requested clarification and examples.
- Several commenters suggested that rounding to whole numbers should not be universal but based upon the individual measure (e.g., CTM, appeals).
- Some commenters were concerned about measures where a very small absolute change actually could represent a relatively large change.
- One commenter suggested that the number of decimal places should be based upon statistical properties that dictate how many decimal places are valid.

CMS Response:
CMS has provided additional clarification and examples in the draft Call Letter: For the measures rounded to whole numbers, we will use standard rounding rules where raw measure scores that end in less than 0.50 are rounded down and raw measure scores that end in 0.50 or more are rounded up. The Complaint measures are rounded to two decimal points, the Improvement measures are rounded to three decimal points, and the Part D Appeals Auto-forward is rounded to one decimal point. The rounding discussed here does not apply to the overall and summary ratings.

Four-Star Thresholds

Proposed Change: Similar to 2013, CMS invited comments on November 30, 2012 on whether to continue to apply previously established 4-star thresholds, unless changes have been made to a measure's technical specifications. CMS proposes to set 4-star thresholds for all measures that have been part of the Star Ratings for at least two years based on the historical data.

Table 1: Proposed 2014 Part C and D New 4-star Thresholds

Measure	MA-only	MA-PDs	PDPs
Adult BMI assessment	≥ 61%	≥ 61%	-
COA – medication review	≥ 81%	≥ 81%	-
COA – functional status assessment	≥ 75%	≥ 75%	-
COA – pain screening	≥ 56%	≥ 56%	-
Plan all-cause readmissions	≤ 11%	≤ 11%	-
Complaints	≤ 0.19	≤ 0.19	≤ 0.19
Audit	> 60	> 60	> 60
Voluntary disenrollment	≤ 10%	≤ 10%	≤ 10%
Medication Adherence for Oral Diabetes Medications	-	≥ 76%	≥ 77%
Medication Adherence for Hypertension (RAS antagonists)	-	≥ 77%	≥ 79%
Medication Adherence for Cholesterol (Statins)	-	≥ 72%	≥ 74%

CMS has emphasized the importance of supporting the Million Hearts™ initiative. A number of measures in the Star Ratings are consistent with this aim, as they monitor cardiovascular care, blood pressure, and medication adherence. For 2015 Star Ratings, we are proposing to raise the 4-star thresholds for the following measures.

Table 2: Proposed 2015 Revised 4-star Thresholds

Measure	Revised 4-star Threshold
Cardiovascular Care- Cholesterol Screening	≥ 87%
Controlling Blood Pressure	≥ 65%
Diabetes Treatment	MA-PDs ≥ 87%; PDPs ≥ 84%
Medication Adherence for Oral Diabetes Medications	MA-PDs ≥ 78%; PDPs ≥ 79%
Medication Adherence for Hypertension (RAS antagonists)	MA-PDs ≥ 79%; PDPs ≥ 81%
Medication Adherence for Cholesterol (Statins)	MA-PDs ≥ 74%; PDPs ≥ 76%

Summary of Comments:

- Many commenters said that the 4-star thresholds for the diabetes treatment and adherence measures were set too high. There should be an incremental increase from year to year.
- Some commenters stated that it was not appropriate to use same thresholds for different populations (SNPs vs. MA-PDS, LIS/Non LIS).
- Some commenters requested that CMS share the data/methods used to determine the extent of the increase in the 4-star thresholds.

- Some commenters supported the increase to the 4-star thresholds.
- A few commenters recommended that CMS keep the 4-star cut point stable.
- Some commenters suggested delaying the implementation of the Million Hearts™ benchmarks to allow time for intervention.
- A few commenters said that, per the 2013 Call letter, the 4-star thresholds would continue unless specifications changed. No specifications changes have been made, yet CMS proposes to increase the thresholds.
- Some commenters requested more advance notice of these threshold changes.
- One commenter suggested a 1% increase in the diabetes treatment and adherence measures.

CMS Response:
Given the improvement in performance from year to year, CMS does not think it is unreasonable to increase the 4-star thresholds for the diabetes treatment and adherence measures for the 2015 Star Ratings by 2 percentage points. These measures have been fairly stable for the past few years and plans have had ample opportunity to get their processes in place to ensure a higher standard of care for all their members. Review of the threshold trend data shows that plans are improving their performance in these measures from year to year as they promote better health outcomes for their beneficiaries and CMS would expect that trend to continue.

At this time, CMS does not plan to implement different thresholds for different populations. Plan sponsors should be working to ensure that their members are all receiving the same high quality care.

Some commenters suggested keeping the 4-star thresholds stable. The purpose of the fixed 4-star threshold is to set a higher level of quality attainment. This would not be achieved by keeping the 4-star threshold the same forever.

To clarify, based on some comments we have received, CMS will not apply 4-star thresholds to any measure where there has been significant change in the methodology from year to year. This does not apply here. There has been no significant change in methodology for these measures from year to year.

No changes are being made in the draft Call Letter from what was proposed in the Request for Comments.

Changes in the Calculation of the Part C and D Ratings and the Overall Rating

Proposed Change: In constructing Star Ratings for public reporting and the Quality Bonus Payment program, a key concern is the possibility of generating Star Ratings that do not reflect a contract's "true" performance. After evaluating multiple strategies, CMS indicated on November 30, 2012 we were considering changing the way MA, MA-PD, and PDP ratings are

calculated. Instead of basing the overall star calculation on an average of star ratings for each individual measure (e.g., 1-5 stars), CMS proposes beginning with the 2014 Star Ratings to calculate the overall and summary star ratings by using the individual measure scores themselves (e.g., percent, rate, or score), which are more precise reflections of the performance data than the measures' star ratings, and result in lower misclassification rates of overall contract performance.

Summary of Comments:

- Several commenters supported this change.
- Many commenters requested clarification on the specifics of the proposed methodology.
- Some commenters stressed the methodology needs to be transparent and easy to interpret.
- Commenters made the following suggestions with regard to calculations:
    - Adding half-star thresholds at the measure level, rather than bringing in the actual rate.
    - Including fractional stars instead of the rates at the measure level.
    - Moving to a more continuous 1-10 rating system at the metric level.
    - Eliminating the rounding of rates and star ratings in order to differentiate plans between the cut points.
    - Using measure-level stars as continuous variables (e.g., 3.6).
- One commenter asked to ensure no plan would be harmed by this change in methodology.
- One commenter asked to ensure changes would still fairly reward contracts performing above the 5-star threshold without a performance ceiling.
- Some commenters suggested delaying implementation to allow plans adequate time to react.

CMS Response:
There is a detailed explanation of the calculation and examples included in the Call Letter. In order to calculate the overall and/or summary star ratings that are on the scale of the stars (which ranges from 1 to 5 possible stars), each individual measure raw score must be rescaled prior to calculating a weighted average using the existing weights. For each individual measure, this rescaling produces a continuous score between 0 and 5.

Low Performer Icon

Proposed Change: CMS currently assigns the Low Performer Icon (LPI) to contracts receiving less than 3 stars for their Part C or Part D summary ratings for the last 3 consecutive years. CMS proposed on November 30, 2012 assigning the LPI to any MA-PD contract receiving 2.5 stars or lower for any combination of their Part C or their Part D summary ratings for three consecutive years. This change would encourage consistent improvement in the quality of care across all of the C and D measures.

Summary of Comments:

- Several commenters supported this change.
- Several commenters recommended using the overall rating rather than combining the summary ratings.
- Some commenters recommended delaying the implementation to allow plans to understand and take corrective action.
- Some commenters requested clarification on timing for implementation.
- One commenter requested clarification of whether the assignment of the LPI would result in corrective action.
- One commenter was concerned that when LPIs were for dual SNPs and there might not be alternative plans in the area.

CMS Response:
Contracts are responsible for providing adequate care and services across both Part C and Part D. We are adopting our proposed changes because we believe doing so will encourage consistent improvement in the quality of care across all of the Part C and D measures for MA-PD contracts. CMS is planning to implement this change for the 2014 Star Ratings to be displayed on Medicare Plan Finder.

Weighting Categories of Measures

Proposed Change: We indicated that we were considering keeping the same weighting categories used for the 2013 Star Ratings, in which outcome and intermediate outcome measures were given 3 times the weight of process measures, while patient experience and access measures were given 1.5 times the weight of process measures. We invited comment on our plan to assign new Star Ratings measures a weight of "1" in the first year, and then the weight in the second year would depend on the weighting category.

Summary of Comments:

- Several commenters suggested that the Quality Improvement measure should be assigned a weight of "1".
- Plan all-cause readmissions should be assigned a weight of 1 as it has been reported instable by NCQA.
- A couple of commenters said that Improving or Maintaining Physical Health and Improving or Maintaining Mental Health are more appropriate as Patient Experience measures, and therefore should be weighted at 1.5.
- Patient experience measures should be increased from 1.5 to 2 or higher.
- A few comments said to assign a weight of "1" to all measures based on survey-reported data, the revised HRM measure, and medication adherence measures.
- Outcome and intermediate outcomes should be in place for at least 1-2 years before they are weighted at a 3; they should be weighted a 1 until they are tested for 1-2 years for stability.

- If changes are made to an existing measure, weight of “1” should be used.

CMS Response:
We are planning to continue our current weighting strategy. Some commenters believe that measures based on survey data should receive a low weight. CMS believes that beneficiaries can accurately report information about their experiences receiving care, their health status, and about the services they have received. Beneficiaries are the best source of information about their experiences receiving care.

The HEDIS values used in the Plan All-cause Readmission measure have been stable for the past two HEDIS submissions (HEDIS 2011 & HEDIS 2012). The variables reported instable by NCQA were added to HEDIS 2012 submissions and are not used in the Plan All-cause Readmission measure used in the Star Ratings.

Integrity of Star Ratings

Proposed Change: CMS has taken several steps in the past years to protect the integrity of the data; however we continue to guard against new vulnerabilities when inaccurate or biased data are included. CMS invited comment on a policy to reduce a contract’s measure rating to 1 star if we determine that biased or erroneous data have been submitted by the plan. This would include cases where CMS finds plans’ mishandling of data, or inappropriate processing or implementation of practices have resulted in biased or erroneous data.

Summary of Comments:

- A few commenters asked for clarification and examples for this change. One commenter asked whether this change would apply if plans understate, rather than overstate, their performance.
- Several plans supported this change.
- Plans commented that CMS should not give plans a 1 star if it was under appeal.
- Plans requested clarification as to whether this change would be retrospective for past years.
- A few commenters asked for more detail in the draft call letter, for example how this policy interacts with corrective action plans, CMS’ approach to evaluating HEDIS, CAHPS or HOS, and whether failure of data validation is referring to the annual Reporting Requirement data validation process.
- CMS already accounts for negative audit performance in the "Beneficiary Access and Performance Problems" measure. It is redundant to count that again.

CMS Response:
CMS has previously applied this policy in the Star Ratings. In the Request for Comments, we laid out a list of examples that have been used up to this point to review the accuracy of data used for Star Ratings. This list is not exhaustive, and it is intended to provide some indication of

the current methods CMS uses to determine if data are not complete or are inaccurate. CMS will continue to reduce this measure's rating to 1 star for a contract identified with this issue.

CMS uses data validation results when evaluating the accuracy of plan-reported data, specifically beginning with the 2013 Grievance and MTM CMR display measures. As stated in CMS' Technical Notes, contracts with low data validation scores for data reported and used for these measures are excluded. The data validation process directly assesses if plans accurately reported data; therefore, failing to meet CMS' standards should prohibit a contract from being measured using invalid data. In 2014, CMS will not have any Star Ratings measures that use plan-reported data. However, this same policy would be applied in the future, should those measures be added to the Star Ratings.

We disagree that this policy is redundant. Common areas of concern may be measured in both Star Ratings and in Audit protocols. Failure of an audit finding may impact Star Ratings' quality assurance processes, but not result in a contract's audit score to be diminished. We would assert that egregious instances where contracts have failed to meet CMS' requirements are appropriately identified in audit findings, compliance actions, and as well could result in CMS considering the current data for a related measure as invalid. This policy protects against contracts receiving higher ratings than their actual performance would indicate.

Disaster Planning

Proposed Change: We invited comment on a proposal that plans contact CMS through the Part C and D Plan Ratings mailboxes if they believe their operations and/or clinical care have had major issues as a result of the Hurricane Sandy that would impact the Star Ratings measures. As each plan's situation is unique, we indicated we would ask for a description and justification for why each plan believes their Star Ratings may have been adversely affected and for which measures they are claiming an impact and for how long.

Summary of Comments:

- A couple of commenters noted that it is important to take into account provider-driven measures, measures focused on plan operations, and any survey-based measures that may reflect Medicare beneficiary frustration unrelated to their plan's performance.
- A couple of commenters asked for clarifications and details of calculation of those measures that are requested.
- A couple of commenters asked for formal guidance that can be applied consistently for disasters.
- CMS should work with impacted plans to identify short and long term impacts on their participation in the MA-PD programs.

CMS Response:
CMS is asking any contracts impacted by Hurricane Sandy that have not notified CMS yet of any anticipated issues to do so by February 28, 2013. CMS will work with each contract to determine the most appropriate strategy given their individual circumstances.

Measures Being Removed from Star Ratings and New Measures for the Display Page

Proposed Change: CMS indicated on November 30, 2012 that we were considering transitioning the Enrollment Timeliness, Getting Information from Drug Plan, and Call Center—Pharmacy Hold Time measures to the 2014 display page.

- Many commenters supported this change.
- Two opposing this change commented that:
    - These measures are understood by Medicare beneficiaries; they are important measures, and they demonstrate plans' investment of resources.
    - High and consistent plan performance should not be the reason for removal; also, it leaves the system more pronounced with outcome measures.

CMS Response:
CMS is planning to transition these measures to the display page.

New Measures Added to the Display Page

Proposed Change: We invited comment on a proposal to release the following measures on the 2014 display page in preparation for them being potentially included as 2015 Star Rating measures: Use of Highly Rated Hospitals; Pharmacotherapy Management of COPD Exacerbation (PCE); and Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET).

Summary of Comments:

- For Highly Rated Hospitals:
    - Several commenters were concerned that this measure would be examining regional/geographic differences in the delivery system rather than plan performance.
    - One commenter suggested that an adjustment to account for the performance level for hospitals available in each service area was needed.
    - Commenters were concerned that some plans may serve areas that do not have hospitals that meet the threshold VBP scores.
    - Concern about the validity of this measure as a measure of health plan quality.
    - Plans should not have an incentive to only recruit members in areas with highly rated hospitals.

- Hospitals may use this measure as leverage during contract negotiations with plans resulting in increased fee demands from highly rated hospitals.
- Plans don't have power to affect where ER patients are taken care of.
- Conflicts with other CMS regulations (MA are required to contract with at least one hospital per county in their service area and meet certain CMS geographic access standards; CMS policies on not enrollees to hospitals).
- Not all hospitals even participate in the hospital VBP.
- Cost plans are not responsible for Medicare part A.
- Hospital ratings are based on FFS beneficences.

CMS Response:
CMS plans to continue doing analysis of the data for this measure. Depending on the results of these analyses, this measure may be added to the display page for informational purposes only.

Summary of Comments:

- For Pharmacotherapy Management of COPD Exacerbation (PCE) (Part C):

    - Several commenters supported inclusion of this measure.
    - Some commenters were concerned about small denominators and the reliability and variability of the data.
    - Stand-alone PDPs do not have access to inpatient discharge data, and cannot identify individuals that should receive medications.
    - HEDIS specifications may not account for any fills prior to hospitalization that may generate a refill-too-soon error post discharge.
    - This measure only makes sense for those newly diagnosed with COPD; the ability for a plan to impact this measure is limited.
    - One commenter asked whether the length of the member's stay in the facility would be taken into consideration for the 14 day measure.
    - One commenter said to exclude patients with fill of steroid or bronchodilator within 90 days of hospital admission, or include and expand timelines so fill occurs within 90 days of hospital discharge.

CMS Response:
CMS is planning to add this measure to the 2014 display page. This measure is for MA contracts and not PDPs. Analysis of submitted data suggests that there is little missing data for this measure and there is variation in scores.

Summary of Comments:

- For Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET):

    - Some commenters requested following clarifications:

        - How will cut points be established for both measures?
        - Will there be a star for each measure for the initiation and engagement, or one composite?
        - HEDIS AOD penalizes Plan Sponsors that actively screen for AOD since this detects more abuse and raises the denominator significantly.
        - Stand-alone PDPs do not have access to hospital inpatient and outpatient data of enrollees, and therefore would not be able to determine individuals who fall under this measure.
    - Some commenters were concerned about the underlying quality and validity of the claims data.
    - One commenter was concerned about a plan's ability to impact this measure.
    - One commenter said that there is increased risk for plans under heightened privacy laws regarding disclosure of patient's sensitive information.
    - This measure only impacts a small number of members.
    - This measure should be limited to 18 and above.
    - One commenter noted that the incidence of alcohol and substance abuse varies by SES factors.
    - CMS should ensure MA plans serving population with a higher proportion of individuals with AOD will not be disadvantaged.

CMS Response:
CMS is planning to and add this to the 2014 display page. This measure is for MA contracts and not PDPs. Analysis of submitted data suggests that there is little missing data for this measure and there is variation in scores. The measure is just for beneficiaries 18 and older.

HEDIS Scores for Low Enrollment Contracts

Proposed Change: As a precursor to potentially including low enrollment contracts in the 2015 Star Ratings, CMS indicated that we proposed to publish HEDIS scores for low enrollment contracts as part of the 2014 display page. Contracts with less than 1,000 enrollees are first submitting HEDIS data to CMS in the summer of 2013. These data will be analyzed and presented on the display page prior to these data becoming part of the Star Ratings in 2015.

Summary of Comments:

- A few commenters expressed support for this proposal.
- A few commenters recommended that CMS continue to require that plans report at least half of the measures to receive a star rating, and that plans reporting fewer measures than this (including because of small denominators) be awarded a "N/A" as is currently done.
- A couple commenters suggested that low enrollment contracts should be rated separately, or that there should be different cut-points for different size plans.

- A few expressed concern that the sample size is too small to achieve appropriate statistical significance.
- A few expressed concern that data from low-enrollment contracts will unfairly measure these plans.
- One plan requested that CMS define what constitutes a "low-enrollment contract" for purposes of Star Ratings.
- A few suggested that CMS test the performance of some low-enrollment contracts to study any effects on larger plans, or incorporate the remaining low-enrollment contracts into Star Ratings on an incremental basis.

CMS Response:
We will be analyzing the HEDIS data once submitted to see what is feasible given the small sample sizes.

CAHPS measures about contact from a doctor's office, health plan, pharmacy, or prescription drug plan

Proposed Change: CMS invited comment on a plan to add questions to the CAHPS Survey focusing on contact from a doctor's office, health plan, pharmacy, or prescription drug plan. For example, the questions would focus on asking about reminders for appointments, tests or treatment, to get a flu shot or other immunization, or screening tests such as breast cancer or colorectal cancer screening; following up after a hospital stay; and reminders to fill or refill a prescription, and to ensure medications are taken as directed.

Summary of Comments:

- Several commenters supported the inclusion of this measure, and a few requested more information about the proposed measures.
- One commenter requested that questions be worded to reduce ambiguity. For example, the questions should be revised to specify which entity (doctor, pharmacy, or plan) initiated the contact with the member in order to accurately apply a rating to the plan.
- There was a comment that this measure adds minimal value to existing measures like whether members received a flu shot.
- Some expressed concerns about member's recall, and urged that CMS consider using objective data rather than surveys.
- One contract suggested that CMS evaluate the validity and reliability of responses using at least two years of data, and consider case-mix adjustment for people with mental/cognitive problems and surrogate reporting.

CMS Response:
CMS is planning to proceed with adding these questions to the CAHPS Survey and then they will be posted on the display page for informational purposes.

Forecasting to 2015 and Beyond

Potential New Measures

Disenrollment Reasons.

Proposed Change: CMS invited comment on the possibility of implementing a PDP and MA Plan Disenrollment Reasons survey in 2013. A random sample of voluntary disenrollees at each contract would be surveyed as close as possible to the actual disenrollment. The primary reasons for disenrollment may be considered for new measure(s) to be included in Star Ratings in the future.

Summary of Comments:

- Several commenters supported this measure.
- There were requests for more information about the survey, method, language, and pilot results. For example, it was asked who is responsible for administering the survey, how CMS will handle plan terminations, how the results will be used for Star Ratings, how cut points will be established, and how we will handle small samples.
- A few commenters suggested moving from plan to plan within a contract, or one contract to another contract with a parent organization, should not be held against the contract.
- One commenter stated that CMS should not penalize plans for disenrollment due to provider organization/network disruptions.
- One commenter stated that beneficiaries can disenroll for reasons that are not related to plan quality; disenrollment reasons needs to be based on those that plans have control over.
- One commenter was concerned that this would disadvantage plans with a large LIS population since LIS members are allowed to change plans every month. They requested that auto-enrolled beneficiaries should be excluded from the disenrollment survey. Similarly, SNP plans would be disadvantaged since disenrollment can occur monthly as opposed to MAs that only allow disenrollment once a year.
- It was requested that disenrollment reasons be released to plans soon after the information is gathered so plans can perform root cause analysis.
- One commenter suggested that there is another existing measure for voluntary disenrollment.
- One commenter suggested that this is an additional burden to members who are already subject to many surveys.

CMS Response:
CMS is planning to proceed to implement the PDP and MA Plan Disenrollment Reasons survey in 2013. This is similar to the voluntary disenrollment reasons information that CMS used to make publicly available for health plans prior to 2006 when the reasons for disenrollment were linked to the disenrollment rates information. CMS will be providing reports back to contracts

with results for their enrollees with comparisons to state, region and national estimates. The primary purpose of the plan reports is to assist MA and PDP contracts with quality improvement efforts, and to that end, we will provide both summary measures and drill-down item information. If a beneficiary moves from one plan to another within the same contract, they are not included in this measure.

CAHPS – Health Information Technology – EHR measures.

Proposed Change: CMS invited comment on adding a small set of questions to the CAHPS survey to obtain information on the use of electronic health records from the patient perspective. CMS is currently exploring modifying for the health plan setting a subset of questions that have previously been developed for the Clinician & Group CAHPS Survey. If CMS goes forward with these items, they would be implemented in the 2014 CAHPS survey.

Summary of Comments:

- Several commenters supported the inclusion of this measure.
- It was stated that the CAHPS survey was already too long. If this is to be included, other less important questions should be eliminated.
- One commenter suggested that members may be confused as to whether the questions pertain to their personal physician or the health plan itself.
- Another commenter was concerned that the Medicare population might have confusion and negative feedback simply because the member is not familiar with the use of electronic health records. It was suggested that the use of modern technology in this population may not be seen as a positive change but an invasion of privacy and cause for distrust.
- There was some concern that these measures do not capture whether members derived value from improved IT services, and they do not adequately include online IT services.
- One commenter recommended considering a measure that evaluates from a patient's perspective whether or not education was delivered relative to disease state or medication through HIT; whether patient care plans are shared through HIT between providers and health systems.
- One commenter said that whether the member thinks his physician is using technology effectively will have little effect on plan performance.
- CAHPS may not be the right vehicle for collecting information on this issue. May be better to address this through Medicaid/Medicare Electronic Health Record Incentive program.
- This measure would be a disadvantage for plans serving members in rural areas or small provider practice slow to adapt to EHRs; early adopters could be disadvantaged.
- One commenter said that health plans have no control or say in practice on the use of EHR.

CMS Response:
CMS will take this feedback into consideration as it decided whether to go forward with these items for the 2014 CAHPS survey. CMS recognizes that this is an evolving area so initially these measures would be collected and fed back to plans as part of their annual CAHPS Plan Reports for informational purposes to support quality improvement.

CAHPS – Complaint Resolution

Proposed Change: CMS invited comment on using beneficiaries' responses regarding their satisfaction with the resolution of their complaints as a new display measure.

Summary of Comments:

- Several commenters supported this measure.
- Some commenters were concerned about likely small denominators, low reliability, and recall bias.
- One commenter asked for clarification on the definition.
- Some commenters thought it was duplicative of current complaints rate measure.
- Other commenters thought we should consider use of objective data to determine whether a plan adequately initiated and followed through with complaint resolution procedures.
- A commenter was concerned about CAHPS' self-report survey methods for special need beneficiaries.
- Data must reflect only complaint situations caused by plans and solved by plans, but members will not understand difference between a health plan complaint and a Medicare complaint.
- One commenter asked to clarify whether there was any correlation or disconnection between a member's perception and what was being categorized as a complaint.
- Should limit to complaints within plan's control.

CMS Response:
CMS plans to continue to explore whether to add this measure to the display page to complement the information collected through CTM. However, this measure would be added to the display page for informational purposes only.

<u>Changes to Measure Specifications or Calculations</u>

Breast Cancer Screening for HEDIS 2014.

Proposed Change: CMS invited comment on the fact that the National Committee for Quality Assurance is considering making the following modifications to this measure:

- Raising the denominator upper age to 74 years;
- Stratifying the measure into two age-group-based rates: 40-49 years and 50-74 years; and
- Changing the numerator time frame from 24 months to 30 months.

Summary of Comments:

- Several commenters supported the proposal.
- Some commenters noted to include only the upper age band due to controversy over the appropriateness of screening for ages 40-49; concern about the statistical validity of the age 40-49 cohort due to small sample
- Some commenters supported the extension of the upper age cut point to 74 and reporting by two age bands.
- One commenter did not support changing the numerator from 24 to 30 months, as it is inconsistent with USPSTF.
- There was support for changing the numerator time frame from 24 to 30 months.
- Some commenters wanted to exclude members with significant disability and mental illness making it technically unfeasible to obtain mammography, members residing in nursing homes, palliative care or hospice.
- NCQA is not changing the measure. If CMS proceeds, plans would have to keep two datasets, which leads to a risk of error.

CMS Response:
CMS will share these comments with NCQA for their consideration. CMS plans on continuing to use the NCQA specification for this measure so if NCQA makes a modification, CMS plans on adopting it for the Star Ratings program.

HOS Calculations.

Proposed Change: The Star Ratings incorporate health outcome measures from the Health Outcomes Survey (HOS). CMS invited comment on the fact that we were exploring alternative scoring approaches such as a model that combines multiple health dimensions into a score from 0 to 1 where 0 represents death and 1 represents optimum functioning.

Summary of Comments:

- More information was requested about this proposal.
- It was suggested that CMS pursue this effort to ensure plans serving populations with high morbidity and mortality will not be disadvantaged.
- There were some concerns about lack of case mix adjustment and low response rates by family members of deceased members.
- One commenter expressed concern that the 0-1 score implies an enrollee has a greater risk of death based on his response to survey, which could present significant problems. They recommend that CMS continue with its current scoring methodology instead.

CMS Response:
CMS is still exploring whether it would be useful to make a change in the current HOS scoring methodology. CMS will keep plans informed on the outcome of the analyses. If the additional

work proves successful, CMS would consider adding the measure derived from this model to the 2015 display page and potentially to Star Ratings in subsequent years.