February 17, 2012

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

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 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 2013. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2013 are also discussed. For 2013, CMS will announce the MA capitation rates on the first Monday in April 2012, in accordance with the timetable established in section 1853 (b)(1)(B) of the Act.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage, which is a key factor in determining the MA capitation rates.

Attachment II sets forth the changes in payment methodology for CY 2013 governing payment for original Medicare benefits and rebate obligations. Attachment III sets forth the changes in payment methodology for CY 2013 for Part D benefits. Attachment IV presents the annual adjustments for CY 2013 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 2013 Call Letter for Medicare Advantage (MA) organizations (MAOs); 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: AdvanceNotice2013@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 2, 2012, release of the Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 p.m. Eastern time on Friday, March 2, 2012.

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2013 ADVANCE NOTICE
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Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2013

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 (pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a specified amount (new Affordable Care Act rate set under section 1853(n)(2) of the Act).

The applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1). For 2013, this rate is the greater of: 1) the county's 2013 FFS rate or 2) the 2012 applicable amount increased by the CY 2013 national per capita MA growth percentage. For 2013, the specified amount will be based on a percentage of the 2013 FFS rate.

The changes being implemented in the MA payment methodology for CY 2013 are described below.

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 2013 is 2.3 percent. This estimate reflects an underlying trend change for CY 2013 in per capita costs of 1.1 percent and, as required under section 1853(c)(6)(C) of the Act, adjustments to the estimates for prior years as indicated in the table below.

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

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

	Aged+Disabled
2013 Trend Change	1.1%
Revision to CY 2012 Estimate	1.1%
Revision to CY 2011 Estimate	0.9%
Revision to CY 2010 Estimate	-0.6%
Revision to CY 2009 Estimate	-0.3%
Revision to CY 2008 Estimate	-0.1%
Revision to CY 2007 Estimate	0.2%
Revision to CY 2006 Estimate	-0.2%
Revision to CY 2005 Estimate	0.1%
Revision 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.

FFS Growth Percentage

The Affordable Care Act of 2010 requires 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 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 2013 divided by projected FFS USPCC for 2012.

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 2013 FFS USPCC	$763.21	$5,095.33
Prior projected 2012 FFS USPCC	$743.54	$5,015.16
Percent increase	2.6%	1.6%

These estimates are preliminary and could change when the final rates are announced on April 2, 2012, in the final Announcement of Calendar Year (CY) 2013 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 2, 2012, Announcement.

Attachment II. Changes in the Payment Methodology for CY 2013

PART C

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 (pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a specified amount (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 is proposing to rebase the FFS rates for 2013.

The current FFS rates are based on each county's per capita cost relative to the national average FFS per capita cost for the period 2005-2009. The 2013 rates will be based on each county's costs relative to the national average FFS cost for the period 2006-2010. Rebasing the FFS rates will have a differential effect across geographic areas depending on how each county's costs changed in the base period. For example, in 2010, CMS implemented a cap on outlier payments for Home Health Prospective Payment System reimbursements. This particular change in reimbursements, along with strengthening fraud and abuse protections, resulted in a reduction in the 2010 FFS claims data in certain areas compared to the national average. Rebasing the 2013 rates provides CMS the opportunity to adjust Medicare Advantage rates to reflect cost savings realized in the FFS program as a result of the administration's commitment to combating fraud and abuse in Medicare Programs. CMS seeks comments on the decision to rebase.

Applicable Amount

The applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1), which will be phased-out under the Affordable Care Act. For 2013, this rate is the greater of: 1) the county's 2013 FFS rate or 2) the 2012 applicable amount increased by the CY 2013 National Per Capita Medicare Advantage Growth Percentage.

Specified Amount

For 2013, the specified amount is based on the following formula:

(2013 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 2013 applicable percentages for counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2012 FFS costs, because 2012 is the most recent FFS rate rebasing year prior to 2013. 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.

We have published each county's preliminary Applicable Percentage on the CMS website at: http://www.cms.gov/MedicareAdvtgSpecRateStats/.

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 2012 Rate Announcement, CMS is conducting a nationwide three-year demonstration that will be in effect from 2012 to 2014 to test an alternative method for

determining QBPs. The demonstration will test whether providing scaled bonuses to MA organizations with three or more stars will lead 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%

CMS will apply the QBP percentage to the applicable amount and the specified amount when calculating the blended benchmark and will not cap the blended rate at the level of the pre-Affordable Care Act rate for plans with 3 to 5 stars.

A new MA contract offered by a parent organization that has not had any MA contract(s) with CMS in the previous three years is treated as a qualifying contract, per statute, and is assigned three stars for QBP purposes for 2013. These contracts are treated as new MA contracts during the demonstration until the contract has enough data to calculate a star rating. For a parent organization that has had MA contract(s) with CMS in the previous three years, any new MA contract under that parent organization will receive a weighted average of the star ratings earned by the parent organization's existing MA contracts.

A low enrollment contract is a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan. Low enrollment plans were qualifying plans for 2012. In subsequent years, the Secretary is directed to develop a methodology to assign star ratings to low enrollment organizations. For 2013, low enrollment contracts receive 3 stars for QBP purposes.

Qualifying County Bonus Payment

Beginning with payment year 2012, the Affordable Care Act extended a double quality percentage point increase to a qualifying plan located in a "qualifying county." (An MA plan's star rating is the rating assigned to its contract.) Under the demonstration, a qualifying plan is a plan that has a quality rating of three stars or higher. For 2013, 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 2013 that is less than the national average FFS spending for 2013. The 2013 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 2013 Rate Announcement.

CMS will publish a complete list of qualifying counties in the 2013 Rate 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/MedicareAdvtgSpecRateStats/.

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/MedicareAdvtgSpecRateStats/.

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.

For 2013, 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. While the Pre-ACA rebate was equal to 75 percent of the difference between the plan benchmark and the plan bid, the Affordable Care Act stipulates that by 2014, new rebate percentages will apply, based on a plan's star rating, and these new percentages will be phased-in during 2012 and 2013, as shown in Table II-3.

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

Star Rating	2012	2013	2014
4.5+ Stars	73.33%	71.67%	70%
3.5 to <4.5 stars	71.67%	68.33%	65%
< 3.5 stars	66.67%	58.33%	50%

The law mandates one exception for determining the level of rebate for 2013: a new plan 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 2013, and they will be treated as having a star rating of 3 stars.

The amount of rebate that plans must offer enrollees is phased-in over 3 years. In 2012, the rebate amount was the sum of 2/3 of the pre-ACA rebate amount and 1/3 ACA rebate amount; in 2013, the rebate amount is the sum of 1/3 of the pre-ACA rebate amount and 2/3 of the ACA rebate amount; and in 2014, the rebate amount equals the ACA rebate amount.

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 2013, we will first calculate the 2013 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 2013 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 2013 is 2.4% of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2013 ratebook. We will also publish the rates with and without the IME reduction for the year.

Section C. ESRD State Rates

For 2013, CMS has revised the underlying dialysis rates based on FFS costs. To calculate dialysis State rates, CMS used Medicare FFS claims data for beneficiaries in dialysis status between the years 2006 and 2010 to determine the average geographic adjustment (AGA) for each State and to determine the 2010 national average per capita FFS dialysis cost. The State AGAs were standardized to the proposed 2013 ESRD risk adjustment model. CMS then adjusted the 2010 national average by each State AGA to determine revised 2010 State rates and trended these rates to 2013 using the ESRD dialysis growth trend. The final rate for 2013 will be the estimated 2013 fee-for-service amount. The final 2013 State rates will be developed by taking into account the MIPPA 2008 carve-out of indirect medical education (IME) and the $5.25 ESRD user fee.

Section D. Clinical Trials

In 2013, 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 2014

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 The list of network areas for plan year 2014 will appear in the *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies* and will also be available on the CMS website at http://www.cms.hhs.gov/PrivateFeeforServicePlans/. We will use January 1, 2012 enrollment data to identify the location of network areas for plan year 2014.

RISK ADJUSTMENT

Section F. CMS-HCC Risk Adjustment Model

In 2013, CMS will implement an updated version of the aged/disabled CMS-HCC risk adjustment model used to pay for aged/disabled beneficiaries enrolled in MA plans. Disease groupings are the same as in past models; however, the factors are different.

When CMS recalibrates the CMS-HCC risk adjustment model with more recent data, an updated coefficient is calculated for each diagnosis group and demographic characteristic in the model (e.g., age, sex), which represents the marginal (additional) cost of that diagnosis group or demographic characteristic in predicting FFS per capita costs. These coefficients are then converted to relative cost factors by dividing each by the per capita cost predicted for a specific year. For the CY 2013 recalibration, CMS used predicted per capita costs for 2011. The relative factors are used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year.

The updated model was calibrated using 100 percent fee-for-service (FFS) claims for the years 2008 and 2009. The current CMS-HCC model is calibrated on a 5 percent sample of 2004 and 2005 data. Recalibrating the model on more current and complete data results in more appropriate relative weights for each HCC as they reflect more recent coding and expenditure patterns in FFS Medicare. The updated model also reflects revised constraints. Constraints are implemented on HCCs for a myriad of reasons, including retaining the appropriate statistical relationship between the level of severity of HCCs, limiting variation where coding is new or otherwise does not well represent clinical experience, and where the sample size for specific HCCs does not result in a stable estimate. For example, in the current model, End-Stage Liver Disease and Cirrhosis of Liver were constrained to the same coefficient, and Cystic Fibrosis and Chronic Obstructive Pulmonary Disease were constrained to the same coefficient; however, neither of these constraints are present in the updated model. Drug/Alcohol Psychosis and Drug/Alcohol Dependence continue to remain constrained to each other in both the current and new model, while Diabetes with Renal or Peripheral Circulatory Manifestation, Diabetes with

Neurological or Other Specified Manifestation, Diabetes with Acute Complications, and Diabetes with Ophthalmologic or Unspecified Manifestation have been newly constrained to each other in the updated model.

In addition, recalibrating with more recent and complete data adjusts the model for increases in predicted FFS expenditures between calibration years. Recalibration of the CMS-HCC model can result in changes in relative risk scores for individual beneficiaries and for average plan risk scores, depending on individual beneficiaries' combinations of diagnoses. CMS takes into account the quality and completeness of coding when fine tuning the CMS-HCC risk adjustment model. As part of our ongoing process to identify and analyze ways to improve the model, we are exploring the incorporation of additional aspects of coding quality and completeness. As part of this effort, the results of our analyses would inform our careful weighing of the best future model design to both predict Medicare costs and to capture conditions that beneficiaries present in clinical situations and that MA plans are treating. CMS may consider incorporating into our assessment of coding quality such characteristics as the relationship between diagnostic reporting and quality measures, and the extent to which plans are providing screening opportunities to a variety of enrollee subpopulations, or only to a narrow subset.

The risk adjustment models for ESRD and PACE will not change from those announced in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.

In Attachment V of this Notice, we provide the relative cost factors for each HCC for each segment of the aged-disabled model.

Section G. Adjustment for MA Coding Pattern Differences

CMS is proposing an MA coding pattern difference adjustment of 3.41% for payment year 2013, the same adjustment it applied in payment year 2012.

Section H. New Enrollee Risk Scores for Chronic SNPs

For 2013, CMS will update the model used to create new enrollee risk scores for new enrollees in chronic SNPs. 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 have specific conditions as a condition of enrollment, the average new enrollee risk score is likely to understate these beneficiaries' risk.

The Chronic SNP (C-SNP) new enrollee model is built upon the CMS-HCC model, detailed within Section F. The C-SNP new enrollee risk score factors for 2013 for C-SNP enrollees are included in Attachment V, Table 4. 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 original entitlement. The C-SNP new enrollee factors comprise the standard new enrollee factors, plus an incremental amount.

Section I. 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 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. The final normalization factors will be published in the 2013 Rate Announcement, to be released April 2, 2012.

I1. Normalization Factor for the CMS-HCC Model

The preliminary 2013 normalization factor for the aged-disabled model is 1.028.

To calculate the normalization factor for the CMS-HCC risk adjustment model, CMS used the risk adjustment model to be implemented in 2013 to calculate five years of risk scores for the FFS population. For the 2013 normalization factor, CMS used risk scores from 2007 to 2011 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 2011 to the payment year of 2013.

I2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2013 normalization factor for the ESRD dialysis model is 1.023.

To calculate the normalization factor for the CMS-HCC ESRD dialysis model, CMS uses the ESRD risk adjustment model to be implemented in 2013 and calculates five years of dialysis risk scores for the FFS population. For the 2013 normalization factor, CMS used risk scores from 2007 to 2011 to calculate an annual trend. The 2013 factor will adjust for four years of risk score growth, i.e., from the denominator year of 2009 to the payment year of 2013.

I3. Normalization Factor for Functioning Graft and PACE Models

The preliminary 2013 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model, and the PACE risk adjustment model is 1.070, which will adjust for risk score growth over the four years from the denominator year of 2009 to the payment year of 2013.

I4. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The preliminary 2013 normalization factor for the RxHCC model is 1.034.

To calculate the normalization factor for the RxHCC risk adjustment model, CMS used the risk adjustment model to be implemented in 2013 and calculated 5 years of risk scores for the population of Medicare beneficiaries enrolled in Part D plans. For the 2013 normalization factor, CMS used risk scores from 2006-2010 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 2010 to the payment year of 2013.

Section J. Frailty Adjustment

Frailty Adjustment for Programs of All Inclusive Care for the Elderly (PACE) organizations.

CMS is required by law to ensure that payments to PACE organizations reflect the frailty of the PACE population. CMS has updated the current frailty adjustment factors for 2013. CAHPS data, which we use to calibrate the frailty factors, and HOS data, which we use to calculate frailty scores for payment, both collect Activities of Daily Living (ADL) information via mail surveys with telephone follow-up. The current frailty model is based on CAHPS data collected between March 2003 and February 2004. In 2013, the frailty model will be recalibrated using CAHPS data collected between February 2008 and August 2008.

CMS is not proposing to change the way we calculate the contract-level frailty score; we will use the results from each PACE organization's 2012 Health Outcome Survey-Modified (HOS-M) survey to calculate each contract-level frailty score for CY2013. CMS will not apply negative contract-level frailty scores (in other words, the frailty score for any PACE contract with a negative frailty score will be set to zero). PACE frailty scores for payment year 2013 will be calculated at 100 percent of the most recently calibrated frailty factors associated with the CMS-HCC model used to pay PACE plans. Table II-1 below presents the preliminary recalibrated PACE frailty factors for CY 2013.

Frailty Adjustment for Fully Integrated Dual Eligible (FIDE) SNPs

Under Section 3205(b) of the Affordable Care Act (ACA), CMS may pay a frailty adjustment to fully integrated dual eligible (FIDE) SNPs if the SNP has similar average levels of frailty to the PACE program. FIDE SNPs are also required by the ACA to have capitated contracts with States for Medicaid benefits, including long-term care.

For 2013, MA organizations will need to have contracted with a vendor to field the 2012 Health Outcome 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).

In order to compare FIDE SNP frailty scores to PACE frailty scores for 2013, we will first establish a PACE organization range of frailty based upon those PACE organizations with at least 100 respondents to the 2012 HOS survey. Once the PACE range is established, those FIDE SNPs that have a frailty score above the minimum PACE score in the range will receive a frailty add-on to the risk scores of beneficiaries enrolled in their FIDE SNP. For comparison purposes, both the PACE range of frailty and the FIDE SNP frailty scores will be based upon the frailty factors used to calculate the frailty scores for payment to the FIDE SNP plans as published in this Notice.

For 2013, low enrollment (30 or fewer respondents to the HOS/HOS-M) or new FIDE SNPs (those who were not eligible to participate in the 2012 HOS due to the length of time the plan was in operation) will not be eligible to receive a frailty score, and therefore will not receive a frailty add-on to their beneficiaries risk scores. Table II-1 below presents the preliminary recalibrated FIDE SNP frailty factors for CY 2013.

For 2013, CMS has recalibrated the FIDE SNP frailty factors to reflect both the new model in effect for 2013 and to update the CAHPS data upon which these factors are based. CAHPS data, which we use to calibrate the frailty factors, and HOS data, which we use to calculate frailty scores for payment, both collect ADL information via mail surveys with telephone follow-up. The current frailty model is based on CAHPS data collected between March 2003 and February 2004. In 2013, the frailty model will be recalibrated using CAHPS data collected between February 2008 and August 2008.

Table II-1. Preliminary Recalibrated Frailty Factors for CY 2013

ADL	FIDE SNP Factors (Non-Medicaid)	PACE Factors (Non-Medicaid)	FIDE SNP Factors (Medicaid)	PACE Factors (Medicaid)
0	−0.062	−0.062	−0.198	−0.189
1-2	0.151	0.152	0.000	0.000
3-4	0.276	0.272	0.154	0.147
5-6	0.276	0.272	0.387	0.380

Section K. MSP Factor

MA capitation payments are initially calculated as if Medicare were always the primary payer; adjustments to the rates for situations in which Medicare is secondary are made as part of actual payment. The MSP adjustment factor is applied as a reduction to payment for working aged and working disabled beneficiaries. The MSP factor is calculated as the ratio of the actual Medicare

spending for all MSP beneficiary months to the predicted amount of Medicare spending that the model predicts for these MSP beneficiary months. Actual spending was calculated using the 2009 claims from the same analytic files used to recalibrate the CMS-HCC model. The predicted amount was calculated using the newly recalibrated CMS-HCC model, which is calibrated using only months in which Medicare is the primary payer. MSP status was determined using the working aged/working disabled status indicator from the Medicare Enrollment DataBase (EDB) for 2009.

CMS has recalculated the MSP adjuster for working aged and working disabled beneficiaries. The preliminary 2013 MSP factor is 0.173. CMS will continue to apply the MSP adjustment to individual-level payments.

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2013

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

The Affordable Care Act, as enacted in section 3301 and amended by section 1101of HCERA , phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit by reducing beneficiary coinsurance for drugs in the gap for applicable beneficiaries. This reduction in cost sharing began in CY 2011 and continues through CY 2020, ultimately resulting in 75% cost sharing for applicable drugs, prior to the application of any manufacturer discounts, and 25% cost sharing for other covered Part D drugs (non-applicable drugs). Applicable drugs are defined at section 1860D-14A(g)(2) of the statute and are generally brand covered Part D drugs that are either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (BLA). Non-applicable drugs are covered Part D drugs that do not meet the definition of an applicable drug (i.e. generic drugs). The reductions in cost sharing, in conjunction with the coverage gap discount program, will serve to effectively close the Medicare Part D benefit coverage gap for non-LIS beneficiaries by CY 2020.

In 2013, the coinsurance under basic prescription drug coverage for certain beneficiaries is further reduced from 2012 for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. The coinsurance charged to eligible beneficiaries will be equal to 79% or actuarially equivalent to an average expected payment of 79%. Also in 2013, the coinsurance under basic prescription drug coverage for certain beneficiaries is reduced for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. The coinsurance charged to eligible beneficiaries will be equal to 47.5% of the negotiated price or actuarially equivalent to an average expected payment of 47.5%.

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

The 79% coinsurance for non-applicable drugs and 47.5% coinsurance for applicable drugs in the coverage gap represent an increase in plan liability and a reduction in beneficiary cost sharing. Therefore we further specify that these increased plan liability amounts do not count towards TrOOP. Part D sponsors must account for the reductions in cost sharing and increased plan liability when developing their Part D bids for payment year 2013.

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

Section 3301 of the ACA, as amended by section 1101 of HCERA, phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit. By 2020, beneficiary costsharing for all covered brand and generic drugs and biological products will equal 25% until the beneficiary reaches catastrophic coverage. The cost sharing reductions, in conjunction with the coverage gap discount program, will serve to effectively close the coverage gap for applicable (i.e. non-low-income) beneficiaries by CY 2020. The coinsurance for applicable (brand) drugs in the coverage gap uses a definition of negotiated price that excludes the dispensing fee. This issue affects both the amount beneficiaries pay at the point-of-sale and Part D sponsor liability for dispensing fees (and vaccine administration fees, if any) for applicable drugs in the coverage gap. Clarification is necessary regarding this issue as it affects how plan sponsors will bid.

We clarify the following four step approach for determining manufacturer, beneficiary, and plan sponsor liabilities for coverage gap claims:

1) The manufacturer liability is calculated by multiplying the 50% discount percentage and the negotiated price (as defined in §1860D-14A(g)(6));

2) The beneficiary coinsurance is calculated by subtracting the 50% discount percentage (as defined in 42 CFR 423.104(d)(4)(iv)) from the applicable gap percentage and multiplying the difference by the negotiated price (as defined in section 1860D-14A(g)(6));

3) Beneficiary liability is calculated by adding the beneficiary coinsurance in step 2 to a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance; and

4) Sponsor liability is calculated as the balance, by subtracting the beneficiary liability and the manufacturer discount amount from the total cost of the applicable drug claim. Part D sponsors must account for their liability for the dispensing fees (and vaccine administration fees, if any) in their Part D bids.

For example, in 2013, the manufacturer liability for a brand drug with the negotiated price of $98, a $2 dispensing fee, and $0 vaccine administration fee will be $49 (50% of $98). The beneficiary coinsurance will be $46.55 (97.5% minus 50%, with the difference multiplied by $98). The beneficiary liability will be $47.50 ($46.55 plus 47.5% of the $2 dispensing and vaccine administration fee. The 47.5% is calculated by subtracting the 50% discount percentage from the 97.5% applicable gap percentage). The sponsor liability will be $3.50 ($98 plus $2 minus $49 and minus $47.50).

This approach is consistent with the way cost sharing is handled for non-applicable drugs in the gap. The cost sharing reductions, in conjunction with the coverage gap discount program, will

serve to effectively close the Medicare Part D benefit coverage gap for applicable beneficiaries by CY 2020.

We further specify that sponsor liability for the dispensing fee (and vaccine administration fee, if any) does not count toward TrOOP.

Section C. Clarification of Plan and Beneficiary Liabilities Related to the Negotiated Price

We also propose to apply the logic explained in "Section B. Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap" to all the cost components of the negotiated price across all phases of the benefit. Cost components of the negotiated price include ingredient cost, sales tax, dispensing fee, vaccine administration fee, and any other cost component. This will ensure 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.

We propose 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. For example, if a beneficiary had a 25% coinsurance and the negotiated price consistes of ingredient cost, dispensing fee, vaccine administration fee and sales tax, then the beneficiary liability would be understood as 25% of the ingredient cost, 25% of the dispensing fee, 25% of the vaccine administration fee, and 25% of the sales tax. While this may appear obvious, actual practice today permits sponsors to allocate liability for cost components 100% to plans, 100% to beneficiaries, or proportionally between plan and beneficiary based on the cost-sharing percentage on a claim. Our proposed approach would resolve any ambiguity if, for example, it is necessary to determine what portion of the sales tax was paid by the beneficiary and plan if the sales tax needs to be refunded. Similarly, if the beneficiary has a $30 copay on a $100 negotiated price that includes all the same cost components, then the beneficiary liability for each cost component would be 30%.

We solicit comments on this proposal and are interested in understanding if there are any foreseeable complications or if any exceptions are needed. We are especially interested in comments concerning the application to straddle claims, enhanced benefits, and any further clarifications that may be necessary.

Section D. Update of the Rx-HCC Model

For 2013, CMS has recalibrated the RxHCC risk adjustment model using diagnosis data from 2008 FFS claims and 2009 expenditure data from Prescription Drug Event (PDE) data. 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 (2008), and (2) entitled to Part D and enrolled in a PDP for at least one month in the prediction year (2009). To recalibrate the model, data for the entire eligible population of FFS beneficiaries, as described above, were used.

In addition to the data update, CMS also made adjustments to the 2009 PDE data to approximate the 2013 benefit structure by incorporating 21% plan liability for non-applicable (generic) drugs and 2.5% plan liability for applicable (brand) drugs in the coverage gap. CMS made adjustments to CPP (Covered Plan Pay), and calculated TrOOP (True-Out-Of-Pocket), GDCB (Gross Drug Cost Below the Threshold), and GDCA (Gross Drug Cost Above the Threshold) amounts that would have occurred with the plan liability implicit in the 2013 benefit structure. The adjustments to plan liability and TrOOP amounts are applied to non-low income beneficiaries' costs only, since the gap adjustment is not applicable to low income beneficiaries. 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 (e.g., age/sex group, low income status, disability status).

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

We create 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 is 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 2010 to create the relative factors for the model. The denominator, which is used to create relative factcors for all segments of the model, is $1,152.85.

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 E. Payment Reconciliation

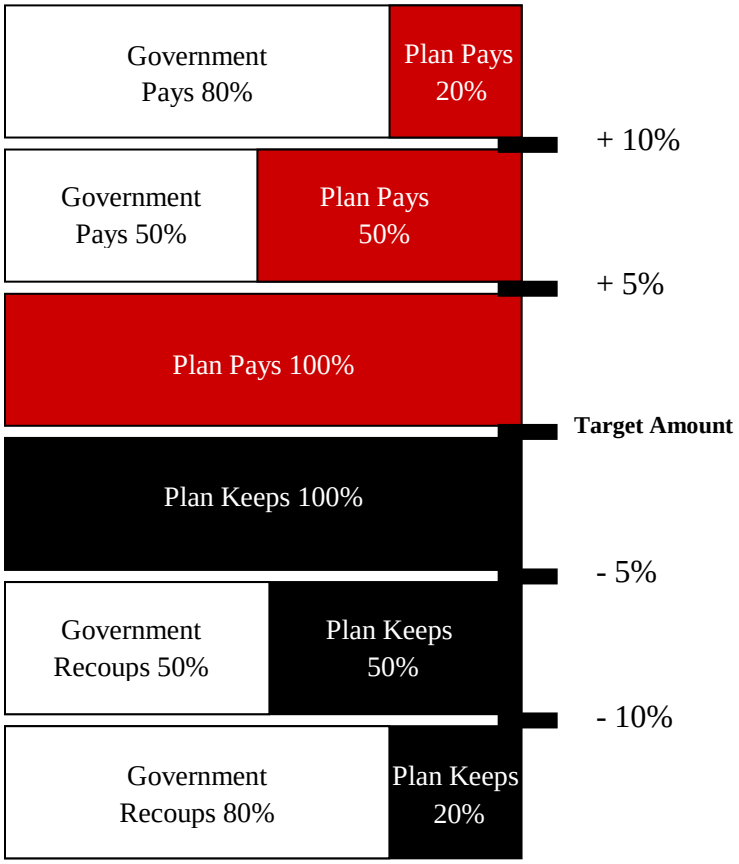
Pursuant to section 1860D-15(e) (3)(C) of the Act and the regulations at 42 CFR 423.336 (a)(2)(ii), CMS may establish higher risk percentages for Part D risk sharing beginning in payment year 2012. The risk sharing payments provided by CMS limit Part D sponsors' exposure to unexpected drug expenses.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

increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS.

CMS has evaluated the risk sharing amounts for 2006 – 2010 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, as in payment year 2012, CMS will apply no changes to the current risk percentages for payment year 2013. 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 payment year 2012. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2013. 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 2013.

Figure 1. Part D Risk Corridors for 2013



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 F. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2013

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 increases along with any increase 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.

Updates to Part D Benefit Parameters

The benefit parameters listed above will be increased by 1.40% for 2013 as summarized by Table III-1 below. This increase reflects the 2012 annual percentage trend of 3.31% as well as a multiplicative update of −1.85% for prior year revisions. Please see Attachment IV for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 1.40% from their 2012 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 4.29% for 2013 as summarized in Table III-1 below.

This increase reflects the 2012 annual percentage trend in CPI of 1.83%, as well as, a multiplicative update of 2.41% 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 (i.e. non-LIS) beneficiaries per section 1860D-2, the total covered Part D spending may be different for applicable and non-applicable (i.e. LIS) beneficiaries. Therefore, CMS is releasing the two values described below:

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

- Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries – this is an *estimate* of the average amount of total drug spending for an applicable (i.e. non-LIS) beneficiary to 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, 79% 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 2012	Prior year revisions	Annual percentage increase for 2012
Applied to all parameters but (1)	3.31%	−1.85%	1.40%
CPI (all items, U.S. city average): Applied to (1)	1.83%	2.41%	4.29%

Part D Benefit Parameters

	2012	2013
Standard Benefit		
Deductible	$320	$325
Initial Coverage Limit	$2,930	$2,970
Out-of-Pocket Threshold	$4,700	$4,750
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,657.50	$6,733.75
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,730.39	$6,938.69
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) [category code 3]	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold (1)	$1.10	$1.15
Generic/Preferred Multi-Source Drug (5)	$3.30	$3.50
Other (5)	$0.00	$0.00
Above Out-of-Pocket Threshold		
Over 100% FPL [category code 1]		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,940 (individuals) or ≤ $10,410 (couples) (6) [category code 1]		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $11,570 (individual) or $23,120 (couple) [category code 4]		
Deductible	$65.00	$66.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Retiree Drug Subsidy Amounts		
Cost Threshold	$320	$325
Cost Limit	$6,500	$6,600

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

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

(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are eligible for the coverage gap discount program, this is the estimated average amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.

(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (couple) was not receiving home and community-based services qualify for zero cost-sharing as of January 1, 2012, as specified by the Secretary.

(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2012 values of $65.23, $1.11, and $3.34, respectively.

(6) These amounts do not include a $1,500 per person burial allowance. The actual amount of resources allowable will be updated for payment year 2013.

Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2013

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (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 2013, 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).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

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

Deductible: From $320 in 2012 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $2,930 in 2012 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,700 in 2012 and rounded to the nearest multiple of $50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.60 per generic or preferred drug that is a multi-source drug, and $6.50 for all other drugs in 2012, 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 $2.60 per generic or preferred drug that is a multi-source drug, and $6.50 for all other drugs in 2012, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $65[1] in 2012 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.60 per generic or preferred drug that is a multi-source drug, and $6.50 for all other drugs in 2012, and rounded to the nearest multiple of $0.05.

II. 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 $1.10 per generic or preferred drug that is a multi-source drug, and $3.30 for all other drugs in 2012[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

<u>Annual Percentage Increase</u>

For the 2007 and 2008 payment 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 payment year, the annual percentage increases are based on Part D program data. For the 2013 payment year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\text{August 2011 – July 2012}}{\text{August 2010 – July 2011}} = \frac{\$2{,}923.80}{\$2{,}830.13} = 1.0331$$

[1] 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 2012 value of $65.23.

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2012 values of $1.11 per generic or preferred drug that is a multi-source drug, and $3.34 for all other drugs.

In the formula, the average per capita cost for August 2010 – July 2011 ($2,830.13) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2011 – July 2012 ($2,923.80) is calculated based on actual Part D PDE data incurred from August – December, 2011 and projected through July, 2012.

The 2013 benefit parameters reflect the 2012 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 III-1.

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

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	6.74%	7.31%
2008	5.36%	5.97%
2009	4.44%	4.25%
2010	3.07%	3.08%
2011	2.96%	2.44%
2012	4.67%	2.27%

Accordingly, the 2013 benefit parameters reflect a multiplicative update of -1.85% for prior year revisions. In summary, the 2012 parameters outlined in section I are updated by 1.40% for 2013 as summarized by Table III-2.

Table III-2. Annual Percentage Increase

Annual percentage trend for July 2012	3.31%
Prior year revisions	−1.85%
Annual percentage increase for 2013	1.40%

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

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

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 payment year 2013, the September 2012 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 2012 CPI based on the projected amount included in the President's FY2013 Budget.

The September 2011 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for payment year 2013 is calculated as follows:

$$\frac{\text{Projected September 2012 CPI}}{\text{Actual September 2011 CPI}} \; or \; \frac{231.048}{226.889} = 1.0183$$

(Source: President's FY2013 Budget and Bureau of Labor Statistics, Department of Labor)

The 2013 benefit parameters reflect the 2012 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2011 annual percentage increase. The 2012 parameter update reflected an annual percentage trend in CPI of 1.42%. Based on the actual reported CPI for September 2011, the September 2011 CPI increase is now estimated to be 3.87%. Thus, the 2013 update reflects a multiplicative 2.41% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 4.29% for 2013 as summarized by Table III-3.

Table III-3. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2012	1.83%
Prior year revisions	2.41%
Annual percentage increase for 2012	4.29%

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

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

For 2013, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $6,938.69. It is calculated as the ICL plus 100% beneficiary cost sharing divided by the weighted gap coinsurance factor. The factor is calculated assuming 100% beneficiary cost sharing in the deductible phase, 25% in the initial coverage phase and in the coverage gap, 79% for non-applicable (generic) drugs and 97.5% for applicable (brand) drugs.

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

$$\text{ICL} + \frac{\text{100\% beneficiary Cost Sharing in the gap}}{\text{weighted gap coinsurance factor}} \text{ or } \$2{,}970 + \frac{\$3{,}763.75}{94.836\%} = \$6{,}938.69$$

- 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* $4,750 − $986.25 = $3,763.75

Weighted gap coinsurance factor is calculated as follows:

(Brand GDCB % for non-LIS × 97.5% coinsurance for applicable drugs) + (Generic GDCB % for non-LIS × 79% cost sharing for non-applicable drugs)

or

(85.6 × 97.5%) + (14.4% × 79%) = 94.836%

- 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 2011 PDEs.
- Gap cost sharing for applicable drugs is the cost sharing incurred by applicable beneficiaries for applicable (brand) drugs in the coverage gap.
- 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 2011 PDEs.
- Gap cost sharing for non-applicable drugs is the coinsurance incurred by applicable beneficiaries for non-applicable (generic) drugs in the coverage gap.

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $310 and $6,300, respectively, for plans that end in 2011, and, as $320 and $6,500, respectively, for plans that end in 2012. For 2013, the cost threshold is $325 and the cost limit is $6,600.

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

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

Variable	Disease Group	Community Factors	Institutional Factors
Female			
0-34 Years		0.210	0.950
35-44 Years		0.217	0.950
45-54 Years		0.276	0.950
55-59 Years		0.343	1.031
60-64 Years		0.415	1.031
65-69 Years		0.279	1.131
70-74 Years		0.337	1.025
75-79 Years		0.426	0.900
80-84 Years		0.525	0.772
85-89 Years		0.651	0.700
90-94 Years		0.786	0.576
95 Years or Over		0.822	0.447
Male			
0-34 Years		0.117	1.089
35-44 Years		0.133	0.960
45-54 Years		0.193	0.960
55-59 Years		0.272	1.020
60-64 Years		0.337	1.082
65-69 Years		0.283	1.281
70-74 Years		0.346	1.178
75-79 Years		0.436	1.178
80-84 Years		0.534	1.104
85-89 Years		0.656	1.041
90-94 Years		0.824	0.883
95 Years or Over		0.993	0.796
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.202	0.096
Medicaid_Female_Disabled		0.103	0.096
Medicaid_Male_Aged		0.232	0.096
Medicaid_Male_Disabled		0.099	0.096
Originally Disabled_Female		0.228	-
Originally Disabled_Male		0.160	-

Disease Coefficients	Description Label	Community Factors	Institutional Factors
HCC1	HIV/AIDS	0.458	1.732
HCC2	Septicemia/Shock	0.766	0.796
HCC5	Opportunistic Infections	0.465	0.471
HCC7	Metastatic Cancer and Acute Leukemia	2.175	0.910
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	0.919	0.576
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.706	0.413
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.187	0.240
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation[1,4]	0.371	0.413
HCC16	Diabetes with Neurologic or Other Specified Manifestation[1,4]	0.371	0.413
HCC17	Diabetes with Acute Complications[1,4]	0.371	0.413
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation[1,4]	0.371	0.413
HCC19	Diabetes without Complication[1]	0.127	0.173
HCC21	Protein-Calorie Malnutrition	0.745	0.358
HCC25	End-Stage Liver Disease	1.006	0.937
HCC26	Cirrhosis of Liver	0.413	0.350
HCC27	Chronic Hepatitis	0.262	0.350
HCC31	Intestinal Obstruction/Perforation	0.310	0.352
HCC32	Pancreatic Disease	0.362	0.374
HCC33	Inflammatory Bowel Disease	0.302	0.283
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.585	0.670
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.361	0.304
HCC44	Severe Hematological Disorders	1.129	0.600
HCC45	Disorders of Immunity	0.945	0.533
HCC51	Drug/Alcohol Psychosis[3]	0.373	-
HCC52	Drug/Alcohol Dependence[3]	0.373	-
HCC54	Schizophrenia	0.517	0.407
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.360	0.301
HCC67	Quadriplegia, Other Extensive Paralysis	1.147	0.518
HCC68	Paraplegia	1.061	0.480
HCC69	Spinal Cord Disorders/Injuries	0.491	0.238
HCC70	Muscular Dystrophy[3]	0.464	-
HCC71	Polyneuropathy	0.321	0.277
HCC72	Multiple Sclerosis	0.516	0.157
HCC73	Parkinson's and Huntington's Diseases	0.643	0.138
HCC74	Seizure Disorders and Convulsions	0.278	0.192
HCC75	Coma, Brain Compression/Anoxic Damage	0.580	0.060
HCC77	Respirator Dependence/Tracheostomy Status	1.767	2.129
HCC78	Respiratory Arrest	1.117	1.121
HCC79	Cardio-Respiratory Failure and Shock	0.531	0.485
HCC80	Congestive Heart Failure	0.346	0.228
HCC81	Acute Myocardial Infarction	0.294	0.439
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.274	0.439
HCC83	Angina Pectoris/Old Myocardial Infarction	0.170	0.331
HCC92	Specified Heart Arrhythmias	0.289	0.245

Disease Coefficients	Description Label	Community Factors	Institutional Factors
HCC95	Cerebral Hemorrhage	0.359	0.151
HCC96	Ischemic or Unspecified Stroke	0.265	0.151
HCC100	Hemiplegia/Hemiparesis	0.534	0.069
HCC101	Cerebral Palsy and Other Paralytic Syndromes[3]	0.131	-
HCC104	Vascular Disease with Complications	0.594	0.470
HCC105	Vascular Disease	0.302	0.138
HCC107	Cystic Fibrosis	0.385	0.378
HCC108	Chronic Obstructive Pulmonary Disease	0.340	0.378
HCC111	Aspiration and Specified Bacterial Pneumonias	0.734	0.605
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.206	0.197
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.236	0.440
HCC130	Dialysis Status	1.348	2.228
HCC131	Renal Failure	0.297	0.353
HCC132	Nephritis	0.116	0.353
HCC148	Decubitus Ulcer of Skin	1.165	0.517
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.476	0.291
HCC150	Extensive Third-Degree Burns[3]	1.246	-
HCC154	Severe Head Injury	0.580	0.060
HCC155	Major Head Injury[3]	0.171	-
HCC157	Vertebral Fractures without Spinal Cord Injury	0.467	0.154
HCC158	Hip Fracture/Dislocation[3]	0.435	-
HCC161	Traumatic Amputation	0.793	0.266
HCC164	Major Complications of Medical Care and Trauma	0.311	0.325
HCC174	Major Organ Transplant Status	1.084	0.925
HCC176	Artificial Openings for Feeding or Elimination	0.659	0.861
HCC177	Amputation Status, Lower Limb / Amputation Complications	0.793	0.266
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections[3]	0.597	-
D_HCC44	Disabled_Severe Hematological Disorders	1.340	0.633
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.383	0.284
D_HCC52	Disabled_Drug/Alcohol Dependence	0.105	0.284
D_HCC107	Disabled_Cystic Fibrosis[3]	2.556	-
Disease Interactions			
INT1	DM_CHF[2]	0.150	0.111
INT2	DM_CVD	0.150	0.051
INT3	CHF_COPD	0.278	0.248
INT4	COPD_CVD_CAD	0.233	0.118
INT5	RF_CHF[2,3]	0.262	-
INT6	RF_CHF_DM[2]	0.600	0.373

NOTES:

[1] Includes Type I or Type II Diabetes Mellitus.

[2] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

[3] HCC or disease interaction excluded from institutional model because estimated coefficient less than 0 or t-statistic less than 1.0.

[4] HCC15, HCC16, HCC17 and HCC18 are constrained to be equal.

The 2011 denominator of $9,004.65 used to calculate both the community and institutional factors is the national predicted average annual cost under the model.
DM is diabetes mellitus (HCCs 15-19).
CHF is congestive heart failure (HCC 80).
COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).
SOURCE: RTI International analysis of 2008/2009 Medicare 100%FFS claims.
SOURCE: RTI International analysis of 2008/2009 Medicare 100% institutionalFFS claims.

Table 2. Preliminary Disease Hierarchies for the CMS-HCC Model

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in This Column…	…Then Drop the Associated Disease Group(s) Listed in This Column
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8, 9, 10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16, 17, 18, 19
16	Diabetes with Neurologic or Other Specified Manifestation	17, 18, 19
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26, 27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68, 69, 100, 101, 157
68	Paraplegia	69, 100, 101, 157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78, 79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82, 83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105, 149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131, 132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75, 155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 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 MA organization's payment will be based on HCC 148 rather than HCC 149.

Table 3. 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	0.545	0.919	-	-
35-44 Years	0.723	1.097	-	-
45-54 Years	0.881	1.255	-	-
55-59 Years	0.957	1.331	-	-
60-64 Years	1.094	1.468	-	-
65 Years	0.504	1.085	1.108	1.689
66 Years	0.506	0.920	1.043	1.457
67 Years	0.506	0.920	1.043	1.457
68 Years	0.543	0.957	1.080	1.494
69 Years	0.569	0.983	1.106	1.520
70-74 Years	0.660	0.991	1.274	1.605
75-79 Years	0.864	1.165	1.478	1.779
80-84 Years	1.057	1.358	1.671	1.972
85-89 Years	1.264	1.565	1.878	2.179
90-94 Years	1.264	1.565	1.878	2.179
95 Years or Over	1.264	1.565	1.878	2.179
Male				
0-34 Years	0.233	0.788	-	-
35-44 Years	0.510	1.065	-	-
45-54 Years	0.754	1.309	-	-
55-59 Years	0.885	1.440	-	-
60-64 Years	0.951	1.506	-	-
65 Years	0.517	1.248	0.931	1.662
66 Years	0.532	1.135	1.083	1.686
67 Years	0.579	1.182	1.130	1.733
68 Years	0.617	1.220	1.168	1.771
69 Years	0.657	1.260	1.208	1.811
70-74 Years	0.784	1.249	1.481	1.946
75-79 Years	1.046	1.445	1.743	2.142
80-84 Years	1.249	1.648	1.946	2.345
85-89 Years	1.424	1.823	2.121	2.520
90-94 Years	1.424	1.823	2.121	2.520
95 Years or Over	1.424	1.823	2.121	2.520

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 2011 denominator of $9,004.65 used to calculate the new enrollee factors is the national predicted average annual cost under the model.

SOURCE: RTI International analysis of 2008/2009 Medicare 100% FFS claims for Medicare beneficiaies with less than 12 months of Part B in the base year (2008).

Table 4. 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	0.676	1.337	-	-
35-44 Years	0.903	1.564	-	-
45-54 Years	1.094	1.755	-	-
55-59 Years	1.210	1.871	-	-
60-64 Years	1.328	1.989	-	-
65 Years	0.721	1.760	1.951	2.990
66 Years	0.711	1.590	1.875	2.754
67 Years	0.781	1.660	1.945	2.824
68 Years	0.794	1.673	1.958	2.837
69 Years	0.818	1.697	1.982	2.861
70-74 Years	0.937	1.743	2.097	2.903
75-79 Years	1.136	1.897	2.258	3.019
80-84 Years	1.313	2.074	2.435	3.196
85-89 Years	1.460	2.221	2.582	3.343
90-94 Years	1.616	2.377	2.738	3.499
95 Years or Over	1.590	2.351	2.712	3.473
Male				
0-34 Years	0.632	1.446	-	-
35-44 Years	0.978	1.792	-	-
45-54 Years	1.109	1.923	-	-
55-59 Years	1.241	2.055	-	-
60-64 Years	1.307	2.121	-	-
65 Years	0.806	1.818	1.786	2.798
66 Years	0.784	1.867	1.901	2.984
67 Years	0.835	1.918	1.952	3.035
68 Years	0.858	1.941	1.975	3.058
69 Years	0.880	1.963	1.997	3.080
70-74 Years	1.026	1.995	2.233	3.202
75-79 Years	1.259	2.112	2.368	3.221
80-84 Years	1.453	2.306	2.562	3.415
85-89 Years	1.635	2.488	2.744	3.597
90-94 Years	1.772	2.625	2.881	3.734
95 Years or Over	1.982	2.835	3.091	3.944

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 International analysis of 2008/2009 C-SNP continuing enrollees.

Table 5. 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		-	0.211	-	0.385	1.512
35-44 Years		-	0.415	-	0.575	1.486
45-54 Years		-	0.543	-	0.662	1.425
55-59 Years		-	0.549	-	0.642	1.340
60-64 Years		-	0.563	-	0.613	1.296
65 Years		0.401	-	0.438	-	1.391
66 Years		0.401	-	0.438	-	1.391
67 Years		0.401	-	0.438	-	1.391
68 Years		0.401	-	0.438	-	1.391
69 Years		0.401	-	0.438	-	1.391
70-74 Years		0.390	-	0.435	-	1.313
75-79 Years		0.394	-	0.432	-	1.266
80-84 Years		0.404	-	0.425	-	1.218
85-89 Years		0.413	-	0.411	-	1.164
90-94 Years		0.406	-	0.383	-	1.081
95 Years or Over		0.371	-	0.307	-	0.929
Male						
0-34 Years		-	0.214	-	0.416	1.500
35-44 Years		-	0.362	-	0.544	1.512
45-54 Years		-	0.492	-	0.598	1.419
55-59 Years		-	0.503	-	0.576	1.327
60-64 Years		-	0.522	-	0.544	1.279
65 Years		0.427	-	0.369	-	1.337
66 Years		0.427	-	0.369	-	1.337
67 Years		0.427	-	0.369	-	1.337
68 Years		0.427	-	0.369	-	1.337
69 Years		0.427	-	0.369	-	1.337
70-74 Years		0.418	-	0.374	-	1.295
75-79 Years		0.406	-	0.369	-	1.263
80-84 Years		0.402	-	0.367	-	1.240
85-89 Years		0.396	-	0.360	-	1.216
90-94 Years		0.419	-	0.373	-	1.166
95 Years or Over		0.423	-	0.365	-	1.073
Originally Disabled Interactions with Sex						
Originally Disabled		-	-	-	-	0.023
Originally Disabled_Female		0.070	-	0.106	-	-
Originally Disabled_Female_Age 65		-	-	-	-	-
Originally Disabled_Female_Age 66-69		-	-	-	-	-
Originally Disabled_Female_Age 70-74		-	-	-	-	-
Originally Disabled_Female_Age 75+		-	-	-	-	-
Originally Disabled_Male		0.010	-	0.095	-	-
Originally Disabled_Male_Age 65		-	-	-	-	-
Originally Disabled_Male_Age 66-69		-	-	-	-	-
Originally Disabled_Male_Age 70-74		-	-	-	-	-
Originally Disabled_Male_Age 75+		-	-	-	-	-

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC1	HIV/AIDS	1.769	2.351	2.135	2.546	0.929
RXHCC5	Opportunistic Infections	0.110	0.128	0.087	0.178	0.085
RXHCC8	Chronic Myeloid Leukemia	1.965	2.118	2.383	2.842	1.168
RXHCC9	Multiple Myeloma and Other Neoplastic Disorders	1.259	1.522	1.134	1.357	0.619
RXHCC10	Breast, Lung, and Other Cancers and Tumors	0.216	0.212	0.249	0.258	0.105
RXHCC11	Prostate and Other Cancers and Tumors	0.031	0.057	0.106	0.056	0.080
RXHCC14	Diabetes with Complications	0.266	0.191	0.293	0.289	0.175
RXHCC15	Diabetes without Complication	0.187	0.153	0.225	0.236	0.125
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.297	0.764	0.246	0.661	0.110
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.048	0.061	0.018	0.054	0.058
RXHCC20	Thyroid Disorders	0.038	0.097	0.048	0.101	0.036
RXHCC21	Morbid Obesity	0.044	-	0.032	0.042	0.056
RXHCC23	Disorders of Lipoid Metabolism	0.104	0.119	0.128	0.165	0.060
RXHCC25	Chronic Viral Hepatitis	0.075	-	0.224	0.106	-
RXHCC30	Chronic Pancreatitis	0.105	0.137	0.041	0.075	0.035
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.039	0.050	0.032	0.075	0.035
RXHCC32	Inflammatory Bowel Disease	0.290	0.237	0.200	0.343	0.066
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.134	0.113	0.158	0.166	0.064
RXHCC38	Aseptic Necrosis of Bone	0.059	0.187	0.053	0.200	0.096
RXHCC40	Psoriatic Arthropathy	0.329	0.429	0.600	1.057	0.423
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.172	0.248	0.209	0.396	0.083
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.137	0.248	0.176	0.273	0.083
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.059	0.145	0.113	0.159	0.022
RXHCC47	Sickle Cell Anemia	0.040	0.142	0.048	0.501	0.142
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.243	0.430	0.278	0.292	0.386
RXHCC49	Immune Disorders	0.172	0.158	0.203	0.219	0.141
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.040	0.042	0.048	0.107	0.044
RXHCC54	Alzheimer`s Disease	0.499	0.310	0.312	0.188	0.025
RXHCC55	Dementia, Except Alzheimer`s Disease	0.274	0.103	0.140	0.036	-
RXHCC58	Schizophrenia	0.385	0.521	0.590	0.875	0.314
RXHCC59	Bipolar Disorders	0.333	0.401	0.399	0.610	0.279
RXHCC60	Major Depression	0.261	0.323	0.311	0.408	0.193
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.159	0.213	0.206	0.407	0.153
RXHCC62	Depression	0.132	0.164	0.135	0.218	0.109
RXHCC63	Anxiety Disorders	0.053	0.123	0.070	0.168	0.093
RXHCC65	Autism	0.159	0.281	0.444	0.556	0.153
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.025	0.281	0.444	0.324	-
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.018	0.162	0.317	0.241	-
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	-	0.013	0.168	0.103	-
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.177	0.308	0.189	0.358	0.048
RXHCC72	Spinal Cord Disorders	0.078	0.141	0.044	0.071	-
RXHCC74	Polyneuropathy	0.084	0.189	0.081	0.186	0.059

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC75	Multiple Sclerosis	0.568	0.932	0.627	1.526	0.176
RXHCC76	Parkinson`s Disease	0.417	0.483	0.277	0.246	0.149
RXHCC78	Intractable Epilepsy	0.317	0.590	0.261	0.733	0.102
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.186	0.226	0.118	0.268	0.050
RXHCC80	Convulsions	0.093	0.101	0.069	0.180	0.022
RXHCC81	Migraine Headaches	0.127	0.228	0.121	0.186	0.112
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.082	0.144	0.107	0.158	0.090
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.251	0.429	0.271	0.392	0.112
RXHCC87	Congestive Heart Failure	0.163	0.074	0.224	0.097	0.095
RXHCC88	Hypertension	0.155	0.072	0.202	0.091	0.060
RXHCC89	Coronary Artery Disease	0.155	0.082	0.142	0.055	0.017
RXHCC93	Atrial Arrhythmias	0.055	0.045	0.015	-	-
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.069	0.009	0.054	-	-
RXHCC98	Spastic Hemiplegia	0.135	0.239	0.049	0.151	0.016
RXHCC100	Venous Thromboembolism	-	0.044	-	0.080	-
RXHCC101	Peripheral Vascular Disease	0.058	0.048	0.098	0.062	-
RXHCC103	Cystic Fibrosis	0.215	0.758	0.236	1.401	0.153
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.215	0.134	0.236	0.210	0.115
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.132	0.134	0.110	0.210	0.041
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	-	0.072	-	0.038	0.037
RXHCC111	Diabetic Retinopathy	0.106	0.077	0.085	0.044	0.040
RXHCC113	Open-Angle Glaucoma	0.164	0.124	0.177	0.142	0.117
RXHCC120	Kidney Transplant Status	0.268	0.246	0.346	0.506	0.346
RXHCC121	Dialysis Status	0.220	0.246	0.301	0.506	0.240
RXHCC122	Chronic Kidney Disease Stage 5	0.123	0.157	0.137	0.173	0.122
RXHCC123	Chronic Kidney Disease Stage 4	0.123	0.157	0.137	0.173	0.122
RXHCC124	Chronic Kidney Disease Stage 3	0.099	0.157	0.107	0.173	0.072
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.034	0.047	0.031	0.062	0.039
RXHCC126	Nephritis	0.034	0.020	0.031	0.062	0.018
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.040	0.066	0.025	0.053	-
RXHCC145	Pemphigus	0.108	0.172	0.181	0.263	-
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.158	0.198	0.292	0.131
RXHCC156	Narcolepsy and Cataplexy	0.269	0.419	0.356	0.516	0.091
RXHCC166	Lung Transplant Status	0.984	0.735	0.900	1.175	0.336
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.482	0.269	0.436	0.399	0.149
RXHCC168	Pancreas Transplant Status	0.268	0.246	0.346	0.298	0.149
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.222
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.341
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.199
NonAged_RXHCC60	Major Depression	-	-	-	-	0.126
NonAged_RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.084
NonAged_RXHCC62	Depression	-	-	-	-	0.055
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.037
NonAged_RXHCC65	Autism	-	-	-	-	0.084
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.578
NonAged_RXHCC78	Intractable Epilepsy	-	-	-	-	0.032
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	-
NonAged_RXHCC80	Convulsions	-	-	-	-	-

Note:

The 2010 denominator of $1,152.85 used to calculate the 2013 RxHCC model facors is the national predicted average annual cost under the model.

Source: RTI Analysis of 100% 2009 PDE SAF, 2008-2009 HPMS, 2009 CME, and 2008-2009 Denominator.

Table 6. Preliminary 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	0.465	0.907	-	-
35-44 Years	0.738	1.180	-	-
45-54 Years	1.012	1.454	-	-
55-59 Years	1.115	1.557	-	-
60-64 Years	1.166	1.608	-	-
65 Years	0.727	1.169	1.118	1.560
66 Years	0.738	1.180	0.889	1.331
67 Years	0.738	1.180	0.889	1.331
68 Years	0.738	1.180	0.889	1.331
69 Years	0.738	1.180	0.889	1.331
70-74 Years	0.715	1.157	0.715	1.157
75-79 Years	0.676	1.118	0.676	1.118
80-84 Years	0.668	1.110	0.668	1.110
85-89 Years	0.590	1.032	0.590	1.032
90-94 Years	0.590	1.032	0.590	1.032
95 Years or Over	0.590	1.032	0.590	1.032
Male				
0-34 Years	0.318	0.760	-	-
35-44 Years	0.565	1.007	-	-
45-54 Years	0.810	1.252	-	-
55-59 Years	0.916	1.358	-	-
60-64 Years	0.997	1.439	-	-
65 Years	0.769	1.211	1.002	1.444
66 Years	0.765	1.207	0.765	1.207
67 Years	0.765	1.207	0.765	1.207
68 Years	0.765	1.207	0.765	1.207
69 Years	0.765	1.207	0.765	1.207
70-74 Years	0.737	1.179	0.737	1.179
75-79 Years	0.666	1.108	0.666	1.108
80-84 Years	0.563	1.005	0.563	1.005
85-89 Years	0.505	0.947	0.505	0.947
90-94 Years	0.505	0.947	0.505	0.947
95 Years or Over	0.505	0.947	0.505	0.947

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,152.85. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. Concurrently ESRD is defined as at least one month in the prediction year (2009) of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y).

Source: RTI Analysis of 100% 2009 PDE SAF, 2008-2009 HPMS, 2009 CME, and 2008-2009 Denominator.

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

Variable	Baseline – Not Concurrently ESRD and Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.855	1.421	-	-
35-44 Years	1.192	1.758	-	-
45-54 Years	1.237	1.803	-	-
55-59 Years	1.139	1.705	-	-
60-64 Years	1.104	1.670	-	-
65 Years	0.841	1.407	1.087	1.653
66 Years	0.564	1.130	0.817	1.383
67 Years	0.564	1.130	0.817	1.383
68 Years	0.564	1.130	0.817	1.383
69 Years	0.564	1.130	0.817	1.383
70-74 Years	0.604	1.170	0.857	1.423
75-79 Years	0.653	1.219	0.906	1.472
80-84 Years	0.692	1.258	0.945	1.511
85-89 Years	0.715	1.281	0.968	1.534
90-94 Years	0.715	1.281	0.968	1.534
95 Years or Over	0.715	1.281	0.968	1.534
Male				
0-34 Years	0.790	1.356	-	-
35-44 Years	1.059	1.625	-	-
45-54 Years	1.038	1.604	-	-
55-59 Years	0.921	1.487	-	-
60-64 Years	0.855	1.421	-	-
65 Years	0.681	1.247	0.744	1.310
66 Years	0.434	1.000	0.584	1.150
67 Years	0.434	1.000	0.584	1.150
68 Years	0.434	1.000	0.584	1.150
69 Years	0.434	1.000	0.584	1.150
70-74 Years	0.492	1.058	0.492	1.058
75-79 Years	0.497	1.063	0.497	1.063
80-84 Years	0.526	1.092	0.526	1.092
85-89 Years	0.555	1.121	0.555	1.121
90-94 Years	0.555	1.121	0.555	1.121
95 Years or Over	0.555	1.121	0.555	1.121

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,152.85. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. Concurrently ESRD is defined as at least one month in 2009 of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y).

Source: RTI Analysis of 100% 2009 PDE SAF, 2008-2009 HPMS, 2009 CME, and 2008-2009 Denominator.

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

Variable	Baseline – Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.029	2.297
35-44 Years	2.029	2.297
45-54 Years	1.985	2.253
55-59 Years	1.985	2.253
60-64 Years	1.944	2.212
65 Years	1.974	2.242
66 Years	1.831	2.099
67 Years	1.831	2.099
68 Years	1.831	2.099
69 Years	1.831	2.099
70-74 Years	1.586	1.854
75-79 Years	1.510	1.778
80-84 Years	1.409	1.677
85-89 Years	1.213	1.481
90-94 Years	1.213	1.481
95 Years or Over	1.213	1.481
Male		
0-34 Years	2.020	2.288
35-44 Years	2.020	2.288
45-54 Years	1.936	2.204
55-59 Years	1.855	2.123
60-64 Years	1.760	2.028
65 Years	1.761	2.029
66 Years	1.633	1.901
67 Years	1.633	1.901
68 Years	1.633	1.901
69 Years	1.633	1.901
70-74 Years	1.573	1.841
75-79 Years	1.519	1.787
80-84 Years	1.485	1.753
85-89 Years	1.354	1.622
90-94 Years	1.354	1.622
95 Years or Over	1.354	1.622

NOTES:

1. The Part D Denominator used to calculate relative factors is $1,152.85. This Part D Denominator is based on the combined PDP and MA-PD populations. MA-PD risk scores were adjusted to account for new model diagnoses not yet submitted for the MA-PD population.
2. Concurrently ESRD is defined as at least one month in in the prediction year (2009) of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y).

Source: RTI Analysis of 100% 2009 PDE SAF, 2008-2009 HPMS, 2009 CME, and 2008-2009 Denominator.

Table 9. Preliminary list of Disease Hierarchies for the Revised RxHCC Model

DISEASE HIERARCHIES

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: 2013 Call Letter

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How to Use This Call Letter

The 2013 Call Letter contains information on the Part C and Part D programs. Also, we indicate when certain sections apply to section 1876 cost plans, Programs of All-Inclusive Care for the Elderly (PACE), and employer and union-sponsored group waiver health plans (EGWPs).

Over the past year, CMS has committed its resources to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage (MA) and prescription drug plans (PDP). As part of this effort, CMS published a proposed regulation (4157-P) on October 11, 2011, which would make revisions to the Parts C and D regulations. CMS is currently reviewing comments submitted by the public and is in the process of developing the policies for the final rule.

The content of this draft Call Letter is limited to clarification of current policy and operational guidance. However, certain requirements contained in the final rule (4157-F) may be reflected in this year's final Call Letter, even if they have not been included in this draft Call Letter, as an opportunity will have already been provided to comment on such requirements as part of the rulemaking process. We remind sponsoring organizations to continue to familiarize themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Advantage and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, Health Plan Management System (HPMS) data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you 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: Heather Rudo at Heather.Rudo@cms.hhs.gov (Part C issues) and Lisa Thorpe at Lisa.Thorpe@cms.hhs.gov (Part D issues).

Section 1 – Program updates

Below is a combined calendar listing of side-by-side key dates and timelines for operational activities that pertain to MA, MA-PD, PDP 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.

2013*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, 2012	Release of the 2013 MAO/MA-PD/PDP/Service Area Expansion Applications.	✓	✓	✓
January 11 & 18, 2012	Industry training on 2013 Applications.	✓	✓	✓
February 21, 2012	2013 Applications are due to CMS.	✓	✓	✓
Late February 2012	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓		
March 1, 2012	CMS releases guidance concerning updates to Parent Organization designations in HPMS.	✓	✓	✓
March 2, 2012	Initial Submission deadline for risk adjustment data with dates of service January 1, 2011 through December 31, 2011.	✓		✓
March 15, 2012	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2012).	✓	✓	
March 26, 2012	Release of the Health Plan Management System (HPMS) formulary submissions module.	✓	✓	
Late March/Early April 2012	CY 2013 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.	✓	✓	
TBD	Conference call with industry to discuss the 2013 Call Letter.	✓	✓	✓

2013*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**
Early April 2012	Information about renewal options for contract year 2013 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
April 2012	Medicare Advantage and Part D Spring Conference.	✓	✓	✓
April 2, 2012	2013 Final Call Letter released. Announce CY 2013 MA Capitation Rates and MA and Part D Payment Policies. *(Applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 6, 2012	Release of the 2013 Plan Benefit Package (PBP) online training module	✓	✓	✓
April 6, 2012	Release of the 2013 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	
April 16, 2012	2013 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT). Transition Attestations due to CMS *(Part D sponsors only)*	✓	✓	
April 23, 2012	Release of the 2013 Medication Therapy Management (MTM) Program Submission Module in HPMS.		✓	
April/May 2012	CMS contacts Medicare Advantage Organizations (MAO) and PDPs with low enrollment plans.	✓	✓	✓
May 2012	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2013 will be available for all organizations.	✓	✓	
May 2012	Release of Medicare Marketing Guidelines for CY 2013.	✓	✓	✓

2013*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 2, 2012	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, 2012. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓
May 7, 2012	2013 MTM Program submission deadline.		✓	
May 11, 2012	Release of the 2013 Bid Upload Functionality in HPMS	✓	✓	✓
Late-May/June 2012	CMS sends qualification determinations to applicants based on review of the 2013 applications for new contracts or service area expansions.	✓	✓	✓
June to Early September, 2012	CMS completes review and approval of 2013 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	
June 1, 2012	Release of the 2011 DIR Submission Module in HPMS.		✓	
June 4, 2012	Release of the 2013 Actuarial Certification Module in HPMS	✓	✓	✓

2013*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
June 4, 2012	Deadline for submission of CY 2013 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2013 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 2013. 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 2013.	✓	✓	✓
June 6, 2012	Sponsors may begin to upload agent/broker compensation information in HPMS.	✓	✓	✓
June 6, 2012	Release of the 2013 Marketing Module in HPMS.	✓	✓	
June 8, 2012	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.	✓	✓	
Mid/Late June 2012	Release of the CY 2013 Summary of Benefits (SB) hard copy change request module in HPMS.	✓		✓
Late June 2012	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.	✓	✓	✓
July1, 2012	All Dual Eligible SNPs are required to have a contract with the State Medicaid Agency.	✓		
July 5, 2012	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.		✓	
July 30, 2012	2013 MTM Program Annual Review completed.		✓	
Late July 2012	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓

2013*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 2012	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 2012	CMS releases the 2013 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the Medicare Advantage regional PPO benchmarks	✓	✓	✓
Early August 2012	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓
August 1, 2012	Plans are expected to submit model Low Income Subsidy (LIS) riders in HPMS.		✓	
August 1, 2012	CMS informs currently contracted organizations of its decision to not renew of a contract for 2013.	✓	✓	
August 23-27, 2012	First CY 2013 preview of the 2013 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	
August 29 – August 31, 2012	First CY 2013 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
Late August 2012	Contracting Materials submitted to CMS.	✓	✓	✓
End of August/Early September 2012	Plan preview period of star ratings in HPMS.	✓	✓	
September 2012	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓
September 7, 2012	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2011 through June 30, 2012.	✓		✓

2013*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**
Mid-September 2012	All 2013 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓
September 11 – September14, 2012	Second CY 2013 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
September 30, 2012	CY 2013 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 30th. 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 30th. Note: With the exception of the ANOC/EOC, LIS Rider, and abridged or comprehensive formularies, no additional materials may be sent prior October 1.	✓	✓	✓
October 1, 2012	Organizations may begin marketing their CY 2013 plan benefits. Note: Once an organization begins marketing CY 2013 plans, the organization must cease marketing CY 2012 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2012 materials upon request, conduct one-on-one sales appointments and process enrollment applications.	✓	✓	✓

2013*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**
October 1, 2012	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, 2012	Tentative date for 2013 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
October 2, 2012	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, 2012.	✓	✓	✓
October 6-31, 2012	CMS mails the 2013 *Medicare & You* handbook to Medicare beneficiaries.	✓	✓	✓
October 11, 2012	Plan ratings go live on medicare.gov.	✓	✓	
October 15, 2012	Part D sponsors must post PA and ST criteria on their websites for the 2013 contract year.		✓	
October 15, 2012	2013 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓	✓
November 9, 2012	Notices of Intent to Apply (NOIA) for CY 2014 due for MA, MA-PD, PDPs, and “800 series” EGWPs and Direct Contract EGWPs.	✓	✓	✓
Late November 2012	Display measures data are posted in HPMS for plan review.	✓	✓	
Late November 2012	2013 Readiness Assessment due to CMS	✓	✓	

2013*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 – December, 2012	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, 2012	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.			✓
December 1, 2012	Cost-based plans must publish notice of non-renewal.			✓
December 7, 2012	End of the Annual Coordinated Election Period.	✓	✓	
Mid December 2012	Display measures data on CMS.GOV updated.	✓	✓	
2013				
January 1, 2013	Plan Benefit Period Begins.	✓	✓	✓
January 1 – February 14, 2013	MA Annual 45-Day Disenrollment Period (ADP).	✓		
Early January 2013	Release of CY 2014 MAO/MAPD/PDP/SAE/EGWP applications.	✓	✓	✓
Mid January, 2013	Industry training on CY 2014 applications.	✓	✓	✓
January 31, 2013	Final Submission deadline for risk adjustment data with dates of service January 1, 2011 through December 31, 2011.	✓		✓
Late February 2013	Applications due for CY 2014.	✓	✓	✓
March 1, 2013	Initial Submission deadline for risk adjustment data with dates of service January 1, 2012 through December 31, 2012	✓		✓
September 6, 2013	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2012 through June 30, 2013	✓		✓

Coordination of Benefits (COB) User Fees

We review and update this user fee annually to reflect the costs associated with such COB activities for the specific year. Since this user fee reflects the annual funding for COB-related activities, user fees may vary (increasing or decreasing) yearly to reflect those needs. Our projection of the incremental on-going costs of Part D COB activities in 2013 indicates the user fee must be decreased to $1.17 per enrollee per year for contract year 2013. The 2013 COB user fee will be collected at a monthly rate of $0.13 for the first 9 months of the coverage year (for an annual rate of $0.0975 per enrollee per month) for a total user fee of $1.17 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2013 bids.

In 2012, we will implement a new process for the creation of the table of supplemental payer routing information used by the switch community to identify claims that are supplemental to Part D. Initially, the table will be a combination of the table currently created by the CMS COB contractor and a new table to be created by the Part D Transaction Facilitator based on the information in the Part D COB file. During 2012, we plan to refine this process, enabling us to move to exclusive use of the Transaction Facilitator table. We are also working to assist ADAPs and SPAPs by implementing a new procedure to address problems caused by the delays associated with monthly processing of their eligibility data by the COB contractor. Under the new procedure, the Transaction Facilitator will reprocess ADAP and SPAP claims transactions once a week for four weeks then once monthly for 2 months when a Part D plan is not initially identified for an ADAP or SPAP member. These changes will improve the identification of claims supplemental to Part D and increase the volume of reporting (N) transactions to Part D sponsors to support accurate TrOOP calculation and the handling of refunds/recoveries resulting from retrospective claims adjustments.

We welcome comments from Part D sponsors and other entities providing prescription drug coverage on ways we might improve the quality, reliability and timeliness of beneficiary coverage-related data required to correctly coordinate benefits and track TrOOP.

Enhancements to the Plan Ratings

We are committed to continuing to improve the Part C and Part D quality performance measurement system to increase the focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. To that end, we have been working on developing a more robust system to measure quality and performance of Part C and Part D contracts. As new measures are developed and adopted, they will be incorporated into the Plan Ratings published each year on the Medicare Plan Finder website and used to determine star ratings for quality bonus payments. We view the MA quality bonuses (also referred to as value-based payments) as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

In December 2011, CMS sent out a Request for Comments to Part C and D sponsors, stakeholders and advocates that described CMS' proposed methodology for the 2013 Plan 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 so that CMS could identify any needed changes in advance of the Call Letter. We received 88 comment letters. As a result of these comments, we are now proposing that two measures be included as a display measure, rather than a measure included in the Star Ratings (measures from the Hospital Inpatient Quality Reporting program and the Medication Therapy Management Comprehensive Medication Review measure). In addition, we added a number of technical comments to further clarify our proposals.

The current Plan Ratings strategy, laid out in the 2012 Call Letter, is consistent with CMS' Three-Part Aim (better care, healthier people/healthier communities, and lower costs through improvements) with measures spanning the following five broad categories:

- **Outcomes**
  Outcome measures focus on improvements to a beneficiary's health as a result of the care that is provided.
- **Intermediate outcomes**
  Intermediate outcome measures help move closer to true outcome measures. Controlling Blood Pressure is an example of an intermediate outcome measure where the related outcome of interest would be better health status for beneficiaries with hypertension.
- **Patient experience**
  Patient experience measures represent beneficiaries' perspectives about the care they have received.
- **Access**
  Access measures reflect issues that may create barriers to receiving needed care. Plan Makes Timely Decisions about Appeals is an example of an access measure.
- **Process**
  Process measures capture the method by which health care is provided.

2013 Plan Ratings

For the 2013 Plan Ratings, we are continuing to make enhancements to the current methodology to further align it with the Three-Part Aim. Below we describe the enhancements being considered for the 2013 Plan Ratings. Unless noted below, we do not anticipate changing the methodology from the 2012 Plan Ratings. The 2012 methodology can be found at https://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp under the 2012 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.

As announced in previous years, we will review on an annual basis the quality of the data across all measures, variation among plans, and the measures' accuracy and validity before making a final determination about inclusion of measures in the Plan Ratings. This review will occur once data are received in Summer 2012.

New Measures

We are considering adding the following measures to the 2013 Plan Ratings.

- Survey measures of care coordination from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey that will be administered in 2012 (Part C). This includes questions related to the following areas:

  - Whether doctor had medical records and other information about the enrollee's care;
  - Whether there was follow up with the patient to provide test results;
  - How quickly the enrollee received test results;
  - Whether the doctor spoke to the enrollee about prescription medicines;
  - Whether the enrollee received help managing care; and
  - Whether the personal doctor is informed and up-to-date about specialist care.

  Some of these are new questions for the Medicare Advantage CAHPS survey in 2012 and all of the questions were drawn from existing CAHPS surveys. Once the data are available after survey administration, we will construct a care coordination composite using factor analysis and determine its reliability prior to making a final decision about inclusion. We will ensure through the reliability analyses that we are capturing true differences in performance across contracts.

- A measure of quality improvement (Part C and D). The proposed methodology for the improvement measure is to calculate improvement at the individual measure level and use statistical tests to determine whether there has been significant improvement or decline at the measure level prior to creating a measure of net improvement at the contract level. The steps are:

  1) For each measure that has been collected for two years using the same specifications, calculate a contract-level improvement score. This will be a simple change from year one to year two.
  2) Perform a t-test for the year-to-year change at the measure level. Score the change into significant decline, no change, or significant improvement.
  3) Net the improvements (e.g., number of significant improvements minus number of significant declines at the contract level).
  4) Score the net improvement/decline count into a 5-star classification by examining the distribution and setting cut points.

This proposed methodology would provide all contracts with at least two years' worth of data with an improvement score. We are considering how to account for contracts already achieving high scores across most measures. Our methodology will not penalize high-performing plans and will not reward improvement over attainment.

Since all of the measures in this section would be first year measures, the weight assigned to any of them we adopt in our final measures would be "1".

Changes to the Methodology of Current Measures

We are considering modifying the methodology for the following current measures:

- Medicare Plan Finder (MPF) composite (Part D). We will limit the comparison between Prescription Drug Event (PDE) and Plan Finder prices to only the first, second, and third quarter PDEs, as Plan Finder prices are locked on Medicare.gov at the end of September. Based on industry feedback that the price stability component of this measure was driven mainly by drug manufacturer changes and not affected by individual Part D sponsors, we will consider revising this measure to evaluate only the accuracy of PDE prices to posted Plan Finder prices. The price stability portion of this measure will be moved to the CMS display page. Prior to 2011 Plan Ratings, CMS had produced the price accuracy and price stability as two separate measures.

- High-Risk Medication (HRM) measure (Part D). CMS will continue to explore changes to this measure for the 2013 Plan Ratings such as accounting for single fills or fills made under the Part D transition benefit. These modifications may result from specification changes made by the Pharmacy Quality Alliance (PQA) or National Committee for Quality Assurance (NCQA) about the types of fills that may be excluded. The PQA and NCQA are also considering modifying the specifications and medication list based on the American Geriatrics Society's (AGS) update to the Beers List. We will consider applying these updates to future Plan Ratings and changes to the measure medication list will not be retroactively applied for the 2013 Plan Ratings. Rather, CMS will apply changes to the medication list when evaluating sponsors' CY2012 or CY2013 PDE (depending on the timing of the PQA/NCQA specification changes) for the 2014 or 2015 Plan Ratings, respectively. We will also evaluate the inclusion or exclusion of benzodiazepines and specified barbiturates in the measure calculation at that time. Due to specification changes, the previously established 4-star threshold will not be applied for the 2013 Plan Ratings. Instead, all of the star thresholds for this measure will be based on statistical analyses and relative ranking of plans' scores. This measure will continue to be included in the calculation of the overall Plan Rating.

- Adherence (ADH) measures (Part D). Medication adherence continues to be a high priority, and CMS' publication of these three disease/drug class specific measures complement many CMS and HHS initiatives, including cardiovascular disease

prevention. While this measure will continue to be based on PDE, we will continue work to improve beneficiary and pharmacist education and help maximize the claims submitted to sponsors and therefore included in PDE. We will continue to use Proportion of Days Covered (PDC) as a proxy for beneficiaries' adherence to their prescribed medications. We will continue to work with our quality measure development partners to examine appropriate methods of adjusting the PDC measure calculation for the 2013 Plan Ratings, to account for beneficiaries' inpatient stays (such as inpatient hospitals or skilled nursing facilities) in which their medication fills would not be included in PDE data. Any other changes are expected to be minor.

- Plan Makes Timely Decisions about Appeals (Part C). The calendar year 2011 data will include dismissed appeals. The metric will be defined as percent of appeals timely processed by the contract (numerator) out of all the contract's appeals decided by the IRE (includes upheld, overturned, partially overturned and dismissed appeals) (denominator). This is calculated as: ([Number of Timely Appeals] / ([Appeals Upheld] + [Appeals Overturned] + [Appeals Partially Overturned] + [Appeals Dismissed]) * 100. The measure will include *all* Standard Coverage, Standard Claim, and Expedited appeals (including Dismissals) received by the IRE, regardless of the appellant. This includes appeals requested by a beneficiary, appeals requested by a party on behalf of a beneficiary, and appeals requested by non-contract providers. This is not a significant change from prior years.

- Call Center – Foreign Language Interpreter and TTY/TDD Availability (Part C and D). In 2011, this measure was not collected from contracts that only had Special Needs Plans (SNPs). In 2012, we will resume collecting this measure from all SNPs. There will also be a modification in 2012 regarding how successful contacts are defined for this measure. The calculation of this measure is the number of successful contacts with the interpreter or TTY/TDD divided by the number of attempted contacts. Successful contact with an interpreter will be defined as **establishing contact with a translator and either starting or completing survey questions. Successful contact with a TTY/TDD service will be defined as establishing contact with a TTY/TDD operator who can answer questions about the plan's Medicare Part C or Part D benefit.** The prospective enrollee phone number will be used for this measure. Due to these specification changes in how successful contacts are defined and the inclusion of SNP plans, the previously established 4-star threshold will not be applied for the 2013 Plan Ratings.

- Enrollment Timeliness (Part C and D). We are considering expanding this measure from PDPs and MA-PDs to include MA-only contracts. The data timeframe for this measure will be January 1, 2012 through May or June 2012, depending on availability of June data in time for the 2013 Plan Ratings, and the measure includes only enrollment transactions that happened during this timeframe.

- Beneficiary Access and Performance Problems (Part C and D). The methodology is being modified so the effectiveness score for contracts that received a full performance audit will be replaced with the percentage of elements passed out of all elements audited. We are exploring setting a minimum threshold of 5 audited elements in order to include audit results in the final calculation, and we will adjust the CAP reporting period from the current 14 months to the 12 months from 1/1 to 12/31 of a year. There are no other changes to methodology.

Four Star Thresholds

Similar to 2012, we will continue to apply previously established thresholds for a 4-star rating, unless changes have been made to a measure's technical specifications. As stated earlier, because of planned technical specification changes, the previous 4-star thresholds for the HRM and Call Center – Foreign Language Interpreter and TTY/TDD Availability measures will not be applied. We are also reviewing the methodology to determine cut points and thresholds for Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. The current thresholds for all other measures can be found in the Technical Notes available at https://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp under the 2012 Plan Ratings link.

Weighting Categories of Measures

We propose to keep the same weighting categories used for the 2012 Plan 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 will assign new Plan Ratings measures a weight of "1" the first year, and then the weight in the second year would depend on the weighting category. We will continue to weight the HRM and Diabetes Treatment measures as intermediate outcome measures, as they had been in 2012 Plan Ratings. CMS had considered changing their weighting category to process measures. These measures, however, examine plans' influences on promoting safe and appropriate medications for beneficiaries over 65 years of age, and evidence-based prescribing for patients with diabetes and hypertension, which are outside the scope of simply measuring the delivery of health care. Recategorizing these two important patient safety measures as process measures would actually contradict CMS' continuing efforts to recognize quality initiatives by prescription plans. The following table lists the proposed 2013 Plan Ratings measures and their weighting categories.

Table VI-1 2013 Plan Ratings

Measure Name	2013 Proposed Weighting Category	2013 Proposed Weight
Breast Cancer Screening	Process Measure	1
Colorectal Cancer Screening	Process Measure	1
Cardiovascular Care – Cholesterol Screening	Process Measure	1
Diabetes Care – Cholesterol Screening	Process Measure	1
Glaucoma Testing	Process Measure	1
Annual Flu Vaccine	Process Measure	1
Improving or Maintaining Physical Health	Outcome Measure	3
Improving or Maintaining Mental Health	Outcome Measure	3
Monitoring Physical Activity	Process Measure	1
Adult BMI Assessment	Process Measure	1
Care for Older Adults – Medication Review	Process Measure	1
Care for Older Adults – Functional Status Assessment	Process Measure	1
Care for Older Adults – Pain Screening	Process Measure	1
Osteoporosis Management in Women who had a Fracture	Process Measure	1
Diabetes Care – Eye Exam	Process Measure	1
Diabetes Care – Kidney Disease Monitoring	Process Measure	1
Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3
Diabetes Care – Cholesterol Controlled	Intermediate Outcome Measure	3
Controlling Blood Pressure	Intermediate Outcome Measure	3
Rheumatoid Arthritis Management	Process Measure	1
Improving Bladder Control	Process Measure	1
Reducing the Risk of Falling	Process Measure	1
Plan All-Cause Readmissions	Outcome Measure	3
Getting Needed Care	Patients' Experience and Complaints Measure	1.5
Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5
Customer Service	Patients' Experience and Complaints Measure	1.5
Overall Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5
Overall Rating of Plan	Patients' Experience and Complaints Measure	1.5
Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5
Beneficiary Access and Performance Problems	Measures Capturing Access	1.5
Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5
Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5
Reviewing Appeals Decisions	Measures Capturing Access	1.5
Call Center – Foreign Language Interpreter and TTY/TDD Availability	Measures Capturing Access	1.5
Call Center – Pharmacy Hold Time	Measures Capturing Access	1.5
Appeals Auto–Forward	Measures Capturing Access	1.5
Appeals Upheld	Measures Capturing Access	1.5
Enrollment Timeliness	Process Measure	1
Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1.5
Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5

Measure Name	2013 Proposed Weighting Category	2013 Proposed Weight
Getting Information From Drug Plan	Patients' Experience and Complaints Measure	1.5
Rating of Drug Plan	Patients' Experience and Complaints Measure	1.5
Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1.5
MPF Composite	Process Measure	1
High Risk Medication	Intermediate Outcome Measure	3
Diabetes Treatment	Intermediate Outcome Measure	3
Part D Medication Adherence for Oral Diabetes Medications	Intermediate Outcome Measure	3
Part D Medication Adherence for Hypertension (ACEI or ARB)	Intermediate Outcome Measure	3
Part D Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3
Survey measures of care coordination from the Consumer Assessment of Healthcare Providers and Systems (CAHPS)*	Patients' Experience and Complaints Measure	1
Improvement*	Outcome Measure	1

*If included in the 2013 Plan Ratings, this would be weighted as "1" because it would be a first year measure. After that, it would be weighted according to its weighting category.

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

Display measures on cms.gov are not part of the Plan Ratings calculation. Instead, they may be measures that have been transitioned from the Plan Ratings, or they could be new measures that are being tested before inclusion into the Plan Ratings. Similar to the 2012 display page, plans will have the opportunity to preview their data in the display measures prior to release on our 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.

We are considering transitioning the Pneumonia Vaccine (Part C) and Access to Primary Care Doctor Visits (Part C) measures to the 2013 display page, and removing them from calculation of 2013 Plan Ratings. The Pneumonia Vaccine measure is being moved to the display page due to the long recall period for this measure. Access to Primary Care Doctor Visits is being moved to the display page since there is little variation in the scores across contracts with the scores being skewed very high. Both pneumonia vaccinations and access to primary care doctor visits are very critical to providing high quality care. Although we are moving these to the display page, we expect contracts to continue to pay attention to these areas. CMS will continue to monitor rates for these two measures and will follow-up with contracts if we see an unexpected decline in performance. Also, if the focus on these two areas changes, CMS may consider adding them back into the Plan Ratings.

We are also considering including the following measures that are currently under development on the 2013 display page:

- Measures from the Hospital Inpatient Quality Reporting program (formerly known as Reporting Hospital Quality Data for Annual Payment Update) (Part C). (See

http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473 for a list of measures.) We are exploring whether the individual-level hospital data can be associated with individual MA contracts. We are examining the quality of Health Insurance Claim Numbers (HICNs) available on the hospital-level data to determine the feasibility of linking the hospital data to contract numbers. We will then analyze the data to determine if we can create an MA contract-level measure of the hospital care that enrollees in each contract receive. As we develop the measure, we will consider rural and urban differences in access to hospitals.

- Grievance rate per 1,000 enrollees (Part C and D) (minimum enrollment will be required to calculate a rate; similar exclusion criteria as the complaint rate measures). We will use both Part C and D validated plan-reported CY2011 grievance data to create grievance rates for MA-PDs, PDPs, and MA-only plans.

- Appropriate implementation of Part D transition processes (Part D). The data for this measure will be obtained through CMS' monitoring of Part D sponsors' transition programs. The recent HPMS memo released on 12/30/11 re: CY2012 Part D transition monitoring program analysis provides additional information. We will evaluate the program's activities before making a decision about inclusion on the 2013 display page.

- Serious reportable adverse events (includes SRAEs and Hospital Acquired Conditions (HACs)) (Part C). See https://www.cms.gov/HealthPlansGenInfo/Downloads/PartCTechSpecs_Oct11.pdf for more information about data specifications. Adding this measure to the display page will depend on validation results.

- Special Needs Plans (SNP) Care Management measure (Part C SNPs). See https://www.cms.gov/HealthPlansGenInfo/Downloads/PartCTechSpecs_Oct11.pdf for more information about data specifications. Adding this measure to the display page will depend on validation results.

- Calls Disconnected when Customer Calls Health Plan (Part C). This information has been collected for Part C contracts and will now be displayed similar to data for Part D contracts.

- Medication Therapy Management (MTM) program measure (Part D), based on the Pharmacy Quality Alliance (PQA) approved measure, Completion Rate for Comprehensive Medication Review (CMR). This measures the percentage of MTM-eligible beneficiaries who received a CMR (annual interactive person-to-person or telehealth consultation with written summaries). It serves to promote the delivery of this required and valuable MTM service to Medicare Part D beneficiaries. We will calculate the 2013 display measure using 2011 beneficiary level plan-reported MTM data (collected as part of the Part D reporting requirements). The denominator will include Part D beneficiaries who were at least 18 years of age and were enrolled in the MTM

program for at least 60 days (requiring the beneficiary to be enrolled in the MTM program as of October 31 is redundant and will not be used). A minimum number of MTM-eligible beneficiaries will be required in order to calculate a contract's percentage for this measure. Since sponsors were not required to offer CMRs for long-term care (LTC) residents in 2011, MTM beneficiaries that are LTC residents will be excluded. The following beneficiaries will be included: Special Needs Plan (SNP), skilled nursing facility (SNF), and low-income subsidy (LIS) beneficiaries. Also, beneficiaries who opt-out of the CMR or do not respond to offers for the CMR will not be excluded because doing so could mask barriers to access, patient dissatisfaction with the sponsors' MTM program, or ineffective methods of outreach. CMS will provide additional information about the rates and minimum number to calculate a contract's percentage during the plan preview period of the 2013 display measures. We recommend implementation of this measure for the 2014 Plan Ratings. CMS will consider other MTM quality or outcomes measures when developed and endorsed through a public consensus process.

- Price Stability (Part D). As described in the *Changes in the Methodology of Current Measures*, CMS will evaluate separating this measure from the MPF composite measure and moving it to the display page.

- Appeals Upheld - Expand to include plans' redeterminations (Part C and D). In response to requests to expand the current Plan Rating based on IRE data, we will investigate creating a new 2013 Part C and D display measure to include plan-reported validated appeals data. This display measure may combine the current IRE data used in the Plan Ratings, or be a separate measure of plans' performance.

It is expected that all other 2012 display measures will continue to be shown on cms.gov.

Summary of Changes to the Methodology for 2013 Plan Ratings

As described above, we are considering the addition of a small set of new measures to the 2013 Plan Ratings, including a measure of quality improvement. There are some potential modifications to the MPF composite, HRM, Adherence, Plan Makes Timely Decisions about Appeals, Call Center – Foreign Language Interpreter and TTY/TDD Availability, Enrollment Timeliness, and Beneficiary Access and Performance Problems measures. Two Part C measures (Pneumonia Vaccination and Access to Primary Care Doctor Visits) will be moved to the display page. We are considering maintaining the weights (3 for outcomes and intermediate outcomes, 1.5 for patient experience and access measures and 1 for process measures) assigned to each of the categories of measures that were used in the 2012 Plan Ratings.

2014 Plan Ratings

New Measures

Stakeholders will have the opportunity to comment on proposed enhancements to 2014 Plan Ratings in late 2012. As in past years, we will review the quality of the data across all measures, variation among plans, and the measures' accuracy and validity before making a final determination about inclusion of measures in the Plan Ratings.

We are considering adding the following measures to the 2014 Plan Ratings:

- Measures from the Hospital Inpatient Quality Reporting program (formerly known as Reporting Hospital Quality Data for Annual Payment Update) (Part C). (See http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473 for a list of measures.)

- Use of highly rated hospitals by plan members (Part C). This would combine information about the use of hospitals by plan members with the total performance score that will be calculated for each hospital as part of Hospital Value-based Purchasing. The total performance score is proposed as part of the Notice of Proposed Rulemaking, "Medicare Program; Hospital Inpatient Value-Based Purchasing Program," published on January 7, 2011.

- Evaluation of a contract's Chronic Care Improvement Program (CCIP) and Quality Improvement Project (QIP) (Part C).

- Medication Therapy Management (MTM) Completion Rate for Comprehensive Medication Review (CMR) program measure (Part D). Release as a Plan Rating would follow production as a 2013 display measure.

- Grievance rate per 1,000 enrollees (Part C and D). Release as a Plan Rating would follow production as a 2013 display measure.

- Appropriate implementation of Part D transition processes by plans to ensure continuity of care for beneficiaries (Part D). Release as a Plan Rating would follow production as a 2013 display measure.

- Serious reportable adverse events (includes SRAEs and Hospital Acquired Conditions (HACs)) (Part C). See https://www.cms.gov/HealthPlansGenInfo/Downloads/PartCTechSpecs_Oct11.pdf for more information about data specifications. Adding this measure will depend on validation results.

- Special Needs Plans (SNP) Care Management measure (Part C SNPs). See https://www.cms.gov/HealthPlansGenInfo/Downloads/PartCTechSpecs_Oct11.pdf for

more information about data specifications. Adding this measure will depend on validation results.

All new measures will receive a weight of "1".

Additional Methodological Enhancements for 2014

We will continue to explore the feasibility of controlling for the concentration of providers in a geographic area, such as through Health Professional Shortage Areas (HPSAs). We are analyzing the feasibility and impact of adjusting for HPSAs using the recently revised methodology and data. As we know more about the feasibility of adjusting for provider shortage areas as part of the Plan Ratings, we will inform plan sponsors.

HEDIS 2013 Requirements

We are proposing to eliminate the 1,000 member enrollment threshold for reporting the Healthcare Effectiveness Data and Information Set (HEDIS). All contracts would be required to collect and submit audited HEDIS summary data to us beginning with measurement year 2012, that is due to be submitted to us on June 15, 2013. The following contract types are required to submit HEDIS data for measurement year 2012: §1876 Cost, Employer/Union Only Direct Contract Private Fee-For-Service (PFFS), Local Coordinated Care Plans (CCPs), Medical Savings Account (MSA), PFFS, Regional CCP, Employer/Union Only Direct Contract Local CCP, Religious Fraternal Benefits (RFB) PFFS, and RFB Local CCP types. Closed cost contracts are required to report HEDIS regardless of enrollment closure status. During the measurement year, if a plan's Health Plan Management System (HPMS) contract status is listed as a consolidation, a merger, or a novation, the surviving contract must report HEDIS data for all members of the contract. If a contract status is listed as a conversion in the measurement year, the contract must report if the new organization type is required to report. Any organization that reports HEDIS summary data must also report patient-level data to the designated CMS contractor. Information on HEDIS summary data collection and data submission and patient-level data collection and data submission are covered in separate HPMS memoranda.

For HEDIS 2013 requirements, we will continue collecting audited HEDIS data from all benefit packages designated as Special Needs Plans (SNPs) that had 30 or more members enrolled as reported in the February 2012 SNP Comprehensive Report.

Low Enrollment Contracts

We will begin to collect HEDIS data for low-enrollment contracts that have enrollment under 1,000 members for measurement year 2012. Currently, there is very little information available on the quality of care provided by low-enrollment contracts. We are currently working on a strategy to create Plan Ratings scores for contracts with low enrollment.

Timeline

We will provide as much advance notice of the final decisions on changes to the Plan Ratings as possible, but sponsors are encouraged to take proactive steps to put in place quality assurance efforts in the areas noted above in order to have a head start in effecting improved outcomes.

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years

In last year's call letter, CMS stated that we consider contracting organizations (i.e., MA organizations and PDP sponsors) with less than an "average" or three-star summary plan rating to be out of compliance with the requirements of the Part C or D programs. Consistent with last year, CMS does not believe it is in the beneficiaries' best interest for CMS to continue to contract with organizations whose performance is consistently out of compliance with Medicare requirements. Contracting organizations should interpret a less than "average" (or three-star) summary rating on either their Part C or D performance to be a notice from CMS that they are to take corrective action to come into compliance with program requirements. CMS will continue a policy of issuing formal compliance notices each year to all sponsors that earned low ratings for that year. In 2013, CMS will further the goals of facilitating beneficiary enrollment into higher quality plans by issuing notices to individuals enrolled in plans with less than three stars in three consecutive years, alerting them to the organization's low rating and offering an opportunity to contact CMS to request a special enrollment period (SEP) to move into a higher quality plan.

CMS considers organizations that fail for three straight years to achieve at least a three-star summary rating on Part C or D to have ignored their obligation to meet program requirements and to be substantially out of compliance with their Medicare contracts over a significant period of time. In our view, such plans have demonstrated a serious lack of commitment to the programs and their enrollees. These organizations should expect CMS to apply closer scrutiny to their operations and to issue notices to their plan members alerting them to the organization's low rating. They should also expect CMS to initiate action to terminate their contracts following: 1) our publication of the set of annual plan ratings that assigns the organization its third consecutive summary rating of less than three stars and 2) our confirmation that the data used to calculate the star ratings reflect the sponsor's substantial non-compliance with Part C or Part D requirements. CMS would pursue such actions in a manner consistent with our existing statutory and regulatory Part C and D contract termination authority.

Section II. Part C

CY 2013 Bid Review

This guidance applies to section 1876 cost contractors (cost plans), non-employer MA plans, including Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-

SNPs) and Institutional Special Needs Plans (I-SNPs). D-SNPs and cost contractors are excluded from our evaluation to identify duplicative plans, also referred to as the "meaningful difference" evaluation. Table VI-2 on page 74 of this draft Call Letter shows criteria used in bid review and the plan types to which they apply. Note: We reserve the right to review employer plans for low enrollment and/or meaningful difference in future years.

A. Cost Sharing, Actuarial Equivalence, Maximum Out-of-Pocket (MOOP) Limits, Total Beneficiary Cost (TBC) and Meaningful Difference

With few exceptions, the process, standards and requirements for review and approval of submitted CY 2013 bids will be the same as that for CY 2012 bids. Plan bids will be evaluated for actuarial equivalence in addition to service category level cost sharing, TBC, and meaningful difference.

The only changes proposed to the cost sharing standards are:

- An update to the per day limit on cost sharing standards for days 21 through 100 of skilled nursing facility care (to $150.00).
- The addition of a cost sharing standard for urgent care ($65.00).

The minimum total OOPC difference used to evaluate meaningful difference between plans in a service area, currently set at $20.00 per member per month, will remain unchanged. The MOOP limits and the TBC change amount (approximately 10% or $36.00 per member per month) will remain the same as CY 2012 and plans will be expected to satisfy the criteria in their initial bid submissions. To the extent that CMS increases the amount of the maximum Part B premium buy-down in the Bid Pricing Tool (BPT), we will provide a Part B premium adjustment for the difference between the maximum Part B premium buy-down for CY 2012 ($96.40) and the new amount for CY 2013. In addition, similar to last year, we will provide factors **that adjust for payment rate, quality bonus changes and other technical adjustments for changes in the PBP software.** 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. All cost sharing standards are shown in Tables VI-3 and VI-4 on pages 75 and 76 of this draft Call Letter.

B. Plans With Low Enrollment

During April or May 2012, CMS will send each MAO a list of plans that have been in existence for three or more years but, as of April 2012, have fewer than 500 enrollees for non-SNP plans and 100 enrollees for SNP plans. The lists may 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.

Currently, we allow plans that have enrollment below our low enrollment thresholds for three years or more the flexibility to submit justifications for renewal. We are now considering eliminating that flexibility for plans with sustained very low enrollment, e.g., fewer than 25

enrollees. We have become concerned about the plans' operational viability and the quality of care they can provide. In implementing this policy, we may take into consideration the plan's geographic location, as well as whether the plan has a pattern of growth and if there is reason to expect that enrollment will increase to 100 or 500, depending on plan type, to qualify for renewal.

The following chart displays several of the MA benefit reviews conducted by CMS and identifies which reviews do not apply to certain plan types.

Table VI-2. Plan Types and Applicable Bid Review Criteria

Bid Review Criteria	Applies to Non-Employer Plans	Applies to Dual Eligible SNPs	Applies to Cost Contractors	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	Yes	Yes
PMPM Actuarial Equivalent Cost Sharing	Yes	Yes	Yes	Yes
Service Category Cost Sharing	Yes	Yes	As directed in section 3202 of the ACA*	Yes

* Section 3202 of the ACA established that MA plans and cost contracting plans may not charge enrollees higher cost sharing for chemotherapy administration, skilled nursing care and renal dialysis services than is charged under original Medicare.

Table VI-3 provides the CY 2012 mandatory MOOP amount that MA plans may not exceed; the maximum voluntary MOOP amount that, if adopted, would result in greater flexibility for individual service category cost sharing; and the combined (catastrophic) MOOP amounts applicable to LPPOs and RPPOs.

Table VI-3. CY 2013 Voluntary and Mandatory MOOP 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

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 for plans that adopt the higher mandatory MOOP limit. Table VI-4 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans. CY 2012 plan 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.

Table VI-4. CY 2013 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	$3,935
Inpatient - 10 days	1a	$2,231	$1,785
Inpatient - 6 days	1a	$2,016	$1,613
Mental Health Inpatient - 60 days	1b	$2,471	$1,977
Mental Health Inpatient - 15 days	1b	$1,796	$1,437
Skilled Nursing Facility – First 20 Days[1]	2a	$100/day	$50/day
Skilled Nursing Facility – Days 21 through 100[1]	2a	$150/day	$150/day
Emergency Care/Post Stabilization Care	4a	$65	$65
Urgently Needed Services	4b	$65	$65
Home Health	6a	20% or $30 copay	$0
Primary Care Physician	7a	$35 co-pay	$35 co-pay
Chiropractic Care	7b	$20 co-pay	$20 co-pay
Physician Specialist	7d	$50 co-pay	$50 co-pay
Psychiatric Services	7h	$40 co-pay	$40 co-pay
Therapeutic Radiological Services	8b	20% or $60 co-pay	20% or $60 co-pay
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 co-pay
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10 co-pay
Renal Dialysis	12	20% or $30 co-pay	20% or $30 co-pay
Part B Drugs-Chemotherapy[2]	15	20% or $75 co-pay	20% or $75 co-pay
Part B Drugs-Other	15	20% or $50 co-pay	20% or $50 co-pay

1. 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.

2. Chemotherapy includes administration services. Chemotherapy drugs and administration services in an inpatient setting are covered under the MA plan's inpatient benefit coverage.

PBP Notes Update for CY 2013

We have generally allowed MAOs to include additional information about the benefit being offered in the notes sections in the PBP. The information in the notes section cannot 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 supplemental information that reviewers need for bid evaluation; it does not repeat the cost sharing information entered in the data entry field. For CY 2013, we have taken several steps to help plans present benefits without the need for extensive notes. Below, we propose to clarify certain supplemental benefits in order to improve plans' understanding about services that are appropriately offered as supplemental benefits. We will include additional, minor clarifications regarding a number of acceptable supplemental benefits in a future HPMS memo. We realize that notes are often used to support marketing material; therefore, we will coordinate our efforts with our marketing review staff to limit plans' use of notes to providing additional information and not as a duplication, verbatim of the benefit descriptions.

Limits on Coverage of DME Based on Brand/Manufacturer

In our October 11, 2011, proposed rule (76 FR 63050-63052), we proposed that network-based MA plans may, within a specified category of DME, limit coverage to specific manufacturers' DME products or brands. We believe that implementation of our proposal would help ensure that MAOs maximize program efficiencies by driving enrollee utilization to specific DME products for which MAOs may have negotiated bulk discounts. We also believe it important to clarify our policies for ensuring appropriate and adequate enrollee access to DME.

The proposed rule describes beneficiary protections with respect to access, appeals, and medical necessity, and would require plans to establish transition periods, address mid-year changes to preferred DME items and supplies, and disclose DME coverage limitations to enrollees.

Should the proposed rule be finalized, we will publish separate guidance on the new requirements.

Supplemental Benefits

During the CY 2012 bid review process, we discovered that some MAOs and cost contractors were claiming "services" as supplemental benefits under a coordinated care plan that should already be inherent in the coordinated care plan model. In other words, they were attempting to claim credit and costs for the kind of care coordination that is expected under a coordinated care plan. In this draft Call Letter, we are clarifying our interpretation of what services are considered

to be inherent in the "coordinated care" plan model, and thus cannot be offered as "supplemental" benefits.

For purposes of this clarification, we will use "care coordination" as the term to describe the broad group of activities that we believe are integral to the care provided to enrollees of MA "coordinated care" plans and section 1876 cost contracts. We note at the outset that the statute defines a "coordinated care plan" in section 1851(a)(2)(A)(i) in terms of specific network-based care delivery models: "HMO" plans and "PPO" plans. Section 1876 cost plans, by definition, must either be a Federally-qualified HMO or meet similar standards as a Medicare-certified "Competitive Medical Plan." Inherent in this delivery model is having a network in place under which care is actively coordinated by the health plan.

In the case of an MA coordinated care plan, the regulations at 42 C.F.R. 422.4(a)(1) specify the existence of a "network of providers" that are "under contract or arrangement" with the MAO to "deliver" benefits covered under the plan, subject to approval by CMS of the "availability" and "quality" of the services provided by that network and expressly references coordination of care and "incentives" to "furnish high quality and cost-effective care." Regulations at 42 C.F.R. 422.112(b) expressly require MAOs offering coordinated care plans to conduct specific activities in order to ensure continuity of care and integration of services through contracted providers, including: establishing policies addressing how services are coordinated, offering an ongoing primary care source to each enrollee, programs for coordination of plan services with community and social services, conducting assessments of health care needs, procedures to ensure that the MAO and network providers have information required for effective and continuous patient care and quality review, procedures for appropriate and confidential sharing of information among network components, and procedures to ensure that enrollees are informed of specific health care needs that require follow-up, and training in self care and other measures to promote health. In the case of cost contracts under section 1876, if the health plan is a Federally-qualified HMO, it is similarly expressly required under 42 C.F.R. 417.106(c) to take specific steps to ensure continuity of care.

The terminology used across plans to refer to benefits and services varies greatly so that one plan's "case management" may be referred to by other plans as "disease management," "care coordination" or various other terms. We expect that <u>all</u> beneficiaries enrolled in an MA coordinated care plan or cost plan receive care coordination services that enhance the efficiency and effectiveness of the health care delivered under the plan. Furthermore, as is discussed at length elsewhere in this draft Call Letter, coordinated care plans that are SNPs are expected to provide a higher level of care coordination and disease management as integral to the "special" care provided to their enrolled beneficiaries.

We found that a number of MAOs submitted PBPs in CY 2012 claiming what we found to be essentially care coordination, as a mandatory "supplemental benefit." This finding suggests that

absent this “supplemental” benefit, the plans would not be providing care coordination as an integral component of their delivery of MA plan benefits, as required.

Similarly, we are concerned about the number of MAOs that included “disease management” as a “supplemental” benefit in submitted bids for CY 2012. Again, we view management of coordinated care plan enrollees’ diseases as inherent in the care coordination that gives coordinated care plans their name. In addition, all MA plans are expressly required under the regulations to provide disease management to a target population under their Chronic Care Improvement Programs (CCIPs) (42 CFR 422.152(c)). Because we believe there are some services that could be included as “supplemental” benefits that support required disease management activities and programs and in an effort to increase the transparency of benefit design, we set forth below examples of services that plans could reasonably offer as “supplemental” benefits under an “enhanced disease management” program for CY 2013.

In the following sections, we present examples of “enhanced” benefits that we would consider appropriate for inclusion as “supplemental” benefits for CY 2013. Our intent in providing the following benefit descriptions is to help MAOs that offer coordinated care plans and cost contracts, to differentiate between: (a) plan activities that are presumed to be included in any coordinated care plan’s delivery of benefits; (b) benefits covered under Medicare Parts A and B; and (c) enhancements to disease management-related activities that may be offered as supplemental benefits. The other general criteria for a benefit to qualify as a supplemental benefit stated in Chapter 4 of the Medicare Managed Care Manual (MMCM) remain unchanged.

We are presenting these benefits as examples of acceptable supplemental benefits because the services included: 1) are directly health related; 2) have value to the enrollee; 3) have costs beyond the administrative costs that a coordinated care plan would be expected to incur in coordinating the provision of MA plan and cost plan benefits; and 4) are not covered under original Medicare Part A or B. The “Enhanced Disease Management” (EDM) benefit we define is an example of a benefit that is comprised of three integral parts, any one of which may be offered as a supplemental benefit, but that, when combined, comprise the more comprehensive EDM benefit. That is, an approvable EDM benefit would include all three parts as integral to the benefit but, if a plan chooses to offer one or more of the defined parts as separate supplemental benefits in addition to offering an EDM benefit or without also offering an EDM benefit, that would be acceptable.

MAOs and cost contractors may continue to develop their own unique benefit packages as they determine what is most appropriate for their enrollees while keeping in mind our expectations related to care coordination and disease management. The examples of acceptable supplemental benefits we provide below are for guidance only; non-SNPs and cost contractors are not required to adopt these example supplemental benefits in their CY 2013 plan benefit packages.

With respect to SNPs, we believe that a plan that must by law have the capability to address the needs of enrollees with "special needs" necessarily must include the Enhanced Disease Management defined below, as well as other services and activities that are in addition to those provided by non-SNP MA plans. Integral to the SNP Model of Care (MOC) are annual assessments to identify the specialized needs of each enrolled beneficiary and establishment of an interdisciplinary care team that is responsible for ongoing coordination and oversight of the specialized care provided to the enrolled beneficiaries. Although non-SNP plans may not be providing any assessments that are in addition to the Medicare required Annual Wellness Visit (AWV), we believe that the higher level of assessment required for each SNP-enrolled beneficiary as well as the higher level of disease management specified below in the definition of the EDM benefit, are services and activities that are integral to a SNP's MOC.

For CY 2013, we expect that SNPs will provide in the PBP a description of the services and activities they provide as integral to the annual assessment required in the MOC, that are in addition to those covered under the AWV. The description of those additional activities and services must be entered in the PBP notes field labeled 'Annual Physical Exam,' at PBP item B-14b as a mandatory supplemental benefit.

Enhanced Disease Management (EDM)

By definition, a disease management benefit will focus on enrollees who have an identified disease or condition. Thus, for purposes of bid approval, we expect that an EDM offered as a "supplemental" benefit by a coordinated care plan should focus on enrollees with identified diseases/conditions and be comprised of the three services described below. An EDM supplemental benefit that we propose to approve for CY 2013 would be provided by qualified, professional staff, and include sufficient non-Medicare Part A or B covered services so that it is clear to us and beneficiaries that the benefit provides added value for enrolled beneficiaries. The benefit would be expected to result in targeted enrollees' increased awareness about treatments, reportable signs and symptoms and available medications related to the diseases/conditions. Based on current plan offerings, plan enrollees with specific chronic diseases such as diabetes, heart failure, and COPD are the groups most commonly targeted for disease management. However, MAOs and cost contractors may offer additional enhanced disease management services to any group(s) of enrollees they choose.

Services that we would expect to be included in a supplemental "EDM" benefit for coordinated care plans, and which we would expect to approve as supplemental benefits, would include the following three activities:

- **Enrollees in the target group being assigned to qualified case managers with specialized knowledge about the disease(s) who contact the enrollee to provide additional case management and monitoring services.** We believe that this should be an essential aspect of an effective EDM program and it is important for MAOs and cost

contractors to understand the difference between the assignment of case managers for all enrollees and the assignment of a case manager with specialized knowledge about a specific individual enrollee's disease(s). The case manager assigned to the enrollee should work to ensure that the enrollee makes and keeps appointments necessary to receive appropriate care from physicians and other health care providers including obtaining preventive services. The case manager should facilitate the enrollee's participation in both standard disease management activities and supplemental EDM programs offered by the plan. The assigned case manager or other qualified plan staff should ensure that all scheduled monitoring of the enrollee takes place and that information is analyzed and communicated to all enrollees of the care team so that early signs of deterioration in the enrollee's condition are detected and action is taken to prevent further deterioration.

- **Educational activities being provided by certified or licensed professionals that are focused on the specific disease/condition.** Educational programs are designed to help enrollees develop knowledge and self-care skills and to foster the motivation and confidence necessary to use those skills to improve health. Examples of educational services that we believe would qualify as a supplemental benefit include provision of information about the specific disease process(es), treatments and drug therapies, signs and symptoms to watch for, self-care strategies and techniques, dietary restrictions, and nutritional counseling.

- **Routine monitoring is conducted of measures, signs and symptoms, applicable to the specific disease(s)/condition(s) of the enrollee.** We expect the MAO or cost contractor to collect and act upon this information in order to coordinate care in an appropriate and timely manner. Clinical staff with specialized knowledge of the enrollee's specific disease/condition should conduct this review.

Although plans may refer to an EDM benefit by titles of their choosing in marketing material and SNPs also will describe included services in their Model of Care (MOC), for PBP data entry purposes, the benefit would be entered with the title "Enhanced Disease Management" in an "Other" supplemental benefit field. Using a uniform title for the benefit will streamline CMS bid review and enhance beneficiaries' ability to make comparisons across plan benefit packages. MAOs and cost contractors that submit PBPs may enter notes that describe services not included in the definition of the EDM benefit provided in this Call Letter, but if the benefit is being offered as defined, no note should be entered in the PBP notes field for EDM because it would be unnecessary and duplicative. During CY 2013 bid review, CMS expects its contractor to require removal of any extraneous or duplicative notes from the PBP. The MAOs and cost contractors that submit PBPs will be required to attest that all required aspects of the EDM supplemental benefit, as described in the final Call Letter, are included in the plan's EDM supplemental benefit.

$0 Cost Sharing Preventive Services

The selection of the Medicare covered $0 cost share preventive services and the frequency they are provided to beneficiaries is based on efficacy and clinical research. As such, we believe that we should adhere to the established schedule for providing those preventive services. However, we realize that MA plans prefer to offer services in addition to those covered under original Medicare and have therefore identified two Medicare covered $0 cost share preventive services for which we believe it would be appropriate, subject to the plan provider's determinations, to allow additional sessions to be provided as supplemental benefits. Please note that this means plans may no longer provide additional sessions of any of the other Medicare covered $0 cost share preventive services as supplemental benefits. For instance, plans may not offer annual screening Pap tests and pelvic exams as supplemental benefits. As Medicare Part B benefits, screening Pap tests and pelvic exams must be offered every two years as $0 cost share preventive services; otherwise, plans must cover only medically necessary Pap tests and pelvic exams. We propose to allow plans to offer as supplemental benefits otherwise non-Medicare covered sessions of the following two Medicare covered $0 cost sharing preventive services in CY 2013.

1. Additional sessions of smoking and tobacco cessation counseling –

   - Required Medicare benefit: Two cessation attempts per year. Each attempt includes a maximum of 4 face-to-face counseling sessions comprised of intermediate (3-10 minutes) counseling sessions or intensive (>10 minutes) counseling sessions with a physician or other Medicare-recognized practitioner; up to 8 sessions in a 12 month period (42 CFR 410.64 and Medicare Claims Processing Manual, Pub 100-04, Chapter 18).

   - Eligible supplemental benefit: Plans may offer additional sessions of face-to-face intermediate counseling and/or additional sessions of face-to-face intensive counseling per contract year and/or the plans may offer as a supplemental benefit interactive, on-line or telephone-based coaching and support programs to enhance enrolled beneficiaries' successful smoking and tobacco cessation.

2. Medical Nutrition Therapy (MNT) –

   - Required Medicare benefit: Three hours of one-on-one counseling in the first year and 2 hours per year in subsequent years only when provided by a registered dietician or nutrition professional to beneficiaries diagnosed with diabetes, renal disease or who have received a kidney transplant within the last three years (42 CFR 410.130-134 and Medicare Claims Processing Manual, Pub 100-04, Chapter 18).

   - Eligible supplemental benefit: Plans may offer additional hours of one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to all or a disease-defined group of its enrollees. Plans may offer additional hours of one-on-one

MNT counseling provided by a registered dietician or other nutrition professional, to enrollees with diabetes and renal disease or who have received a kidney transplant in the last three years in addition to the MNT services those enrollees are entitled to as a required Medicare Part A and B plan benefit.

Web and Telecommunication Technologies

MAOs have historically proposed supplemental benefits that are based on web and telecommunication technologies to increase access to care, enhance care coordination, and reduce unnecessary health care visits. The terminology used across plans to refer to benefits and services varies greatly so that one plan's "medical monitoring" may be referred to by other plans as "telemonitoring," or by the brand names of software products. For purposes of defining and clarifying supplemental benefits, we have identified four categories of telecommunications services that we define and label below. We believe that use of some common terminology for these services will greatly reduce confusion for CMS, beneficiaries and plans, about what services a plan covers. We use the labels: "Telehealth;" "Telemonitoring services;" "Web- and Telephone-Based Technologies;" and "Personal Emergency Response Systems (PERS)" as the labels for the groups of services and activities we define immediately below.

We have approved many web-based and telecommunication benefits, but continue to be concerned that these benefits preserve an effective doctor-patient relationship and ensure quality health care. The following descriptions are intended to provide MAOs and cost contractors with information to support the development of acceptable supplemental benefits that use web and telecommunication technologies. We are interested in comments regarding these and other technologies that may be used in providing quality health care to MA enrollees.

Covered Telehealth: The Medicare Part B telehealth program was implemented to provide limited medical services, such as office visits and consultations, in either a non-Metropolitan Statistical Area county or rural health professional shortage area. By definition, telehealth services that would already be covered under Part B are not suitable for approval as a supplemental benefit (42 CFR 410.78).

Telemonitoring services: MAOs and cost contractors may propose a supplemental benefit that provides in-home equipment and telecommunication technology to monitor enrollees with specific health conditions (e.g., hypertension or chronic heart failure). The benefit should be referred to as "Telemonitoring services" in the PBP and may not duplicate items or services provided under original Medicare (e.g., glucometers for diabetic beneficiaries). In addition, the supplemental benefit description should address the following issues: (a) telemonitoring services must supplement, rather than replace, face-to-face physician visits; (b) the enrollee must have had an initial physician visit to diagnose or confirm the diagnosis of the specific condition; (c) except in rare circumstances, the data must be collected/transmitted at least weekly, but may be required daily or more frequently, as appropriate for the particular disease; (d) the equipment

provided to the enrollee must be disease-appropriate; (e) the enrollee must be trained on how to transmit the data properly; (f) health care professionals must monitor and take action, as needed, based on the collected/transmitted data; (g) the enrollee's physician must be included in the communication process; and (h) all devices must comply with applicable state and federal requirements. MAOs and cost contractors should include in notes a description of the monitoring services they propose to provide as supplemental benefits.

Web- and Telephone-Based Technologies: MAOs and cost contractors may propose a supplemental benefit in which the process of diagnosing and treating some conditions includes the enrollee answering a series of questions online and/or via telephone. We want to ensure that this type of service will not be used as a substitute for an effective, ongoing doctor-patient relationship, but rather, will be supportive of that relationship and of efficient delivery of needed care. Plans offering such a benefit should ensure that: (a) medical protocols are established and regularly updated based on relevant clinical guidelines and that prescribing and/or treatment recommendations are consistent with the State laws in the jurisdiction where the MAO operates and are within the provider's scope of practice; (b) when contacting the system, the enrollee is made aware that he or she is not required to use the system and can contact his/her plan provider directly, although perhaps at a later time; (c) the information provided by the enrolled beneficiary during the web- or phone-based process is directed to his/her PCP and will become part of the medical record; and (d) a method and protocol for monitoring the use of the system by enrolled beneficiaries that will identify potential misuse and supplantation of appropriate PCP visits has been developed and is implemented for the contract year the benefit is offered. The MAO must provide CMS with this information upon request.

We expect to approve Web- and Telephone-Based Technologies proposed in plan bids for CY 2013 that satisfy the criteria listed above.

For purposes of PBP data entry, plans proposing this type of supplemental benefit must enter it in an "Other" supplemental benefit field and title it in the PBP as Web- and Telephone-Based Technologies to support CMS bid review and the ability for beneficiaries to make comparisons across plan benefit packages. Furthermore, because we have not provided a clear definition of the services that would be included in a Web- and Telephone-Based Technologies benefit, in order for us to approve such a proposed supplemental benefit, MAOs and cost contractors must include in the PBP notes field a description of the web- and/or telephone-based services they propose to provide as supplemental benefits.

Personal Emergency Response System (PERS): MAOs and cost contractors may propose a supplemental benefit that provides an enrollee with an in-home device to notify appropriate personnel of an emergency (e.g., a fall). A PERS may not be a cell or portable telephone because those devices do not meet our criteria that a supplemental benefit must be primarily health related and as presented in Chapter 4 of the MMCM, the PERS devices are currently acceptable supplemental benefits.

Health Education

In the bids submitted for CY 2012, a number of plans included in their benefit packages "health education" as a mandatory supplemental benefit. In many cases, the benefit was not described in the PBP, while in other cases the benefit was described as providing written material, such as brochures regarding resources available in the community, newsletters, and web sites. Coordinated care plans are required to provide this type of information as part of the basic plan benefit package (42 C.F.R. 422.112(b)). In this draft Call Letter, we are clarifying our expectation that a health education supplemental benefit would also include the services of a certified health educator or other qualified health professional and that the education provided would include opportunities for interaction between the enrollee and the educator.

For CY 2013, we expect to approve a health education program as a supplemental benefit if it is offered to all enrolled beneficiaries or targeted to groups of enrollees based on specific disease conditions. The benefit will provide more than written material and go beyond content alone to include interaction with a certified health educator or other qualified health professional. The interactive sessions are expected to: primarily provide health information; encourage enrollees' adoption of healthy behaviors; build skills to enhance enrollees' self care capabilities; align with the overall goal to improve participants' health. The benefit may be provided in a number of modalities including, but not limited to, group sessions in which the educator provides information or skills instruction, one-on-one instruction sessions, and interactive web- and/or telephone-based coaching to reinforce what an enrollee learned in a group or individual session.

For CY 2013, plans that choose to offer health education as a supplemental benefit will be required to use the PBP notes section to describe the services, specifically who will be providing the services and how the services will be provided.

Special Needs Plans (SNPs)

A. New Benefit Flexibility for Certain Special Needs Plans

In our proposed rule published October 11, 2011 (76 FR 63108), we proposed to amend our regulations at 422.102(e) to allow certain fully-integrated dual eligible SNPs (FIDE SNPs) to offer supplemental benefits beyond those that we currently permit for MA plans. In the preamble to that rule, we indicated that we would further describe the criteria that we would use to implement this proposed benefits flexibility in the draft and final CY 2013 Call Letters. Below, we describe qualifying criteria—including qualifying standards and SNP contract design requirements—that we would consider applying to SNPs seeking this benefit flexibility in the event that the proposal in the October 11, 2011 proposed rule is adopted in a final rule. We also outline types and categories of benefits that we would consider allowing SNPs to offer under this proposed flexibility. Finally, we outline the mechanism through which SNPs would be permitted to request to be considered for the new proposed benefit flexibility.

a) Contract Design Requirements for Plans Participating in the Benefits Flexibility Initiative

In our proposed rule, we proposed to limit this benefit flexibility to FIDE SNPs, as defined at 42 CFR 422.2, because we believed that limiting the proposed benefit flexibility to FIDE SNPs is appropriate because FIDE SNPs are best positioned to achieve the objective of keeping Medicare-Medicaid ("dual eligible") beneficiaries who are at risk of institutionalization in the community. We also requested comment on whether extending supplemental benefit flexibilities under our proposed §422.102(e) to SNP types other than FIDE SNPs could measurably reduce unnecessary utilization and improve beneficiary outcomes in an equivalent manner. Below are contract design requirements that we would consider applying in order to qualify for the proposed benefits flexibility.

Under the requirements we would consider applying, in order to meet the minimum contract requirements, for the purposes of qualifying for our proposed benefits flexibility in CY 2013, SNPs would be required to:

- Be a specialized MA plan for special needs individuals described in section 1859(b)(6)(B)(ii) of the Act;
- Be operational in CY 2013, and have operated in CY 2012;
- Provide 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, where 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 CFR §422.107.

We would apply these contract design requirements at the individual SNP plan (i.e., SNP plan benefit package) level as well as at the stand-alone SNP (i.e., SNP-only) contract level.

b) Qualifying Criteria for SNPs Participating in the Benefits Flexibility Initiative

In the preamble to our October 11, 2011 proposed rule, we proposed that SNPs be required to meet quality criteria (as defined in this Draft Call Letter and our Final Call Letter) in order to be considered for the proposed new benefit flexibility.

If our proposal were adopted, we would consider applying the following qualifying criteria in order to be considered to meet the proposed quality threshold, for the purposes of qualifying for our proposed benefits flexibility.

1) a 3-year approval of its model of care for CYs 2012-2014 by the National Committee for Quality Assurance (NCQA)[3]; and

2) Either:

    1. Be in a contract with a 3 star[4] (or higher) overall (i.e., Parts C and D) rating for CY 2012 on the Medicare Plan Finder website; or

    2. Where the SNP is in a contract that does not have sufficient enrollment to generate a star rating, high ratings on selected CY 2011 SNP plan-level HEDIS measures.[5]

3) In addition, the SNP must not be a consistent 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 2013 application cycle past performance review methodology.[6]

c) Types and Categories of Benefits CMS may Approve under the Benefits Flexibility Initiative

In the preamble to the proposed rule, we included examples of the kinds of benefits that could be offered under the proposed new benefit flexibility provision. These examples were included partly based on comments received from external stakeholders regarding this initiative in the CY 2012 draft Call Letter, as well as in response to our October 11, 2011 proposed rule.

We do not intend for these additional Medicare supplemental benefits to replace Medicaid benefits for enrollees that are eligible to receive identical Medicaid services. Rather, we seek to give SNPs flexibility to design their benefits in a way that adds value to the beneficiary by augmenting and/or bridging the gap between Medicare and Medicaid covered services. We believe that the additional supplemental benefits that could potentially be available under this

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[3] In order to receive a 3-year approval from NCQA, plans must receive a score of eighty-five (85) percent or higher on NCQA's evaluation of their Models of Care (MOC). The scoring criteria established by CMS are based on 11 clinical and non-clinical elements of the MOC.

[4] The star ratings summarize the quality and performance of Part C and Part D contracts and cover up to 50 measures for a Medicare Advantage contract.

[5] The plan must receive 75% or greater on at least five of the following measures: Controlling Blood Pressure, Appropriate Monitoring of Patients Taking Long-Term Medications, Board Certified Physicians (Geriatricians), Care for Older Adults—Medication Review, Care for Older Adults—Functional Status Assessment, Care for Older Adults—Pain Screening, and Medicaid Reconciliation Post-Discharge.

[6] The 2013 past performance methodology is described in our "2013 Application Cycle Past Performance Review Methodology Update" memo issued via the Health Plan Management System (HPMS) on December 2, 2011. 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 2013 application cycle analysis looks at performance from January 1, 2011 through February 28, 2012. 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.

proposed provision are most appropriate for individuals who need assistance with activities of daily living (ADLs). This may include, for example, eating, drinking, dressing, bathing, grooming, toileting, transferring, and mobility) or instrumental activities of daily living, (IADLs), e.g., transportation, grocery shopping, preparing food, financial management, and taking medication correctly. Furthermore, if our proposal is adopted in a final rule, we would consider requiring SNPs to offer any new supplemental benefits they provide under this provision to the beneficiary at zero cost.

If our proposal were adopted in a final rule, we also would consider requiring that, as a condition of offering these additional supplemental benefits, qualified SNPs specifically describe the benefits 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 for CY 2014. We would consider requiring SNPs to resubmit portions of their MOCs annually in order to reflect any new supplemental benefits they would be offering under this benefit flexibility initiative. Additionally, if our proposal were adopted in a final rule, we would consider including these specific SNPs in MOC implementation reviews/audits.

CMS is also considering requiring SNPs that would participate in this proposed benefit flexibility to submit a mandatory quality improvement project (QIP) on a topic that CMS would determine in consultation with stakeholders. Plans would be able to choose this QIP topic based on a list of topics designed to assess the effect of this new benefit flexibility (e.g., reduction of LTC utilization, preventing partial dual eligibles from declining to full-dual status). CMS would provide SNPs with additional operational details in future guidance. We request comments on this approach.

For any new supplemental benefit that a SNP participating in this proposed initiative chooses to include in its bid, we would afford the SNP considerable latitude to define appropriate coverage limitations in its plan benefit package. We request comment on possible restrictions that we should establish to govern the scope of these supplemental benefits if our benefits flexibility proposal is adopted in a final rule. Below, we set forth guidance on specific supplemental benefits that we would consider permitting SNPs to offer as part of the new benefits flexibility initiative if it is adopted in a final rule.

Table VI-5. Supplemental Benefits for Consideration

Proposed Benefit Category	Benefit Description	Acceptable Means of Delivery	PBP description
Non-Skilled In-home Support Services	Non-skilled services and support services performed by a personal care attendant to assist individuals with disabilities and/or chronic conditions with performing ADLs and IADLs as necessary to support recovery, to prevent decline following an acute illness, prevent exacerbation of a chronic condition, or to aid with functional limitations. This benefit category would also include non-medical transportation that assists in the performance of IADLs.	Services would be performed by individuals licensed by the State to provide personal care services, if applicable.	Describe the criteria the plan intends to use (e.g., level of care need, ADL limitations, etc.) to determine which enrollees are eligible for personal care services.
In-Home Food Delivery	Meal delivery service (beyond the limited coverage described in Chapter 4, Section 30.5, of the Medicare Managed Care Manual (MMCM) for individuals who cannot prepare their own food (IADL limitation) due to functional limitations with ADLs or short-term functional disability, or for individuals who, based on a physician's recommendation, require nutritional supplementation following an acute illness or as a result of a chronic condition.	Meals would be provided consistent with plan policies for ensuring nutritional content (e.g., minimum recommended daily nutritional requirements)	Describe the Medicare meal benefit comprehensively, and clearly distinguish meal benefits for individuals who would already qualify under current meal benefit guidance from meal benefits under an expanded definition. Describe any limits imposed on meal benefits (e.g., duration, criteria for eligibility, number of meals/day).

Proposed Benefit Category	Benefit Description	Acceptable Means of Delivery	PBP description
Supports for Caregivers	Provision of respite care – either through a personal care attendant or provision of short-term institutional-based care – for beneficiary caregivers. Coverage may include benefits such as counseling and training courses (related to the provision of plan-covered benefits) for caregivers.	Specific caregiver support benefits must directly relate to the provision of plan-covered benefits.	Describe how benefits relate to plan-covered benefits, as well as any limitations (e.g., number of counseling/support sessions covered per year, number of hours/days of respite care covered per year and/or episode).
Home Assessments, Modifications, and Assistive Devices for Home Safety	Coverage of home safety/assistive devices, and home assessments and modifications beyond those permitted in Chapter 4, Section 30.3, of the MMCM. Coverage may include items/services such as rails in settings beyond the beneficiary's bathroom.	Home assessments would be performed by trained personnel (e.g., occupational therapists), or by persons with qualifications required by the State, if applicable.	Describe benefit comprehensively, and clearly distinguish safety assessments and devices already covered under Chapter 4 of the MMCM from additional benefits qualified SNPs could provide. Describe enrollee criteria for receiving these additional benefits (e.g., beneficiary at risk of falls, etc.)
Adult Day Care Services	Services such as recreational/ social activities, meals, assistance with ADLs/IADLs, education to support performance of ADLs/IADLs, physical maintenance/rehabilitation activities, and social work service.	Provided by staff whose qualifications and/or supervision meet State licensing requirements.	Describe the criteria imposed for receipt of adult day care services (e.g., prior authorization by a medical practitioner, institutional level of care requirement, etc.)

d) Requests to Participate in the Proposed New Benefit Flexibility Initiative

SNPs that believe that they meet the draft qualifying criteria set forth in (a) – (c) above, and that wish to participate in the proposed benefit flexibility, if the benefit flexibility proposal is finalized and the final rule is adopted, would be required to notify us of their intent to participate by March 2, 2012. We will review these participation requests and, if the benefits proposal is finalized in our CY 2013 rule and a final rule is adopted as proposed, we would notify those plans that qualify according to our final evaluation criteria in April whether requests to participate have been approved. We would also provide qualified SNPs with additional operational guidance on bid submission and benefits requirements at that time. SNPs should not discuss the specifics of their proposed benefits in their participation requests. Rather, qualified SNPs would include their specific proposed benefits as a part of their PBPs during bid submission, and we would approve SNPs' specific new supplemental benefits, as appropriate and provided these proposed benefits conform to our policy.

Plans that would wish to be considered for participation in this proposed initiative if the proposal is finalized and the final rule is adopted, must send their participation requests to us via email at snp_mail@cms.hhs.gov.

B. Marketing Flexibilities for Special Needs Plans

Through CMS' Medicare-Medicaid Coordination Alignment Initiative (see http://www.cms.gov/medicare-medicaid-coordination/Downloads/FederalRegisterNoticeforComment052011.pdf for more information), we have identified SNP marketing as an area in which different requirements in the Medicare and Medicaid programs may have created barriers to high quality, seamless, and cost-effective care for dual eligible beneficiaries. We are considering allowing integrated SNPs (those that provide 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, where such coverage is consistent with State policy; coordinate delivery of covered Medicare and Medicaid primary, acute, and long-term care services throughout their entire service area; and possess a valid contract arrangement with the State, in accordance with CMS policy and the requirements at 42 CFR §422.107) to take advantage of certain marketing flexibilities starting in CY 2013. These flexibilities could include streamlining joint review processes and different requirements for standardized and other marketing materials for integrated SNPs than apply to other plan types. We solicit comments on how we could streamline marketing requirements and review processes for integrated SNPs to provide more useful and integrated information to dual eligible beneficiaries as part of our broader effort to better align the Medicare and Medicaid programs.

C. State Role in Marketing Plan Sponsors' Products

CMS Medicare Marketing Guidelines do not apply to marketing done by State governments and marketing materials created by the State do not need to be reviewed or submitted in HPMS. The only exception to this is when a State is acting on behalf of a plan sponsor, as this could be considered plan sponsor marketing (as though the State is a contractor). Therefore, we clarify that States may market or provide information to current or prospective Medicare beneficiaries on plan sponsors' products, including a subset of all plan sponsors' products available in their State. Guidance related to joint CMS/State review of marketing materials for plans participating in CMS' Medicare-Medicaid Coordination Capitated Financial Alignment Demonstration will be provided separately through demonstration-specific guidance.

D. Revision to the cure process for NCQA approval of SNP MOCs

The model of care (MOC) is required for the SNPs as part of their quality improvement program. The MOC is comprised of eleven elements that are clinical as well as non-clinical in nature, and designed to help the SNPs provide high quality of care for their specific target populations.

For the SNP model of care (MOC) approval process, we have implemented a multi-year approval process that grants SNP plans with higher MOC scores a longer approval period before they are required to resubmit their MOC for subsequent approval. The specific timeframes for approvals are as follows:

- 3-year approval: SNP that scores 85 percent or higher on NCQA's evaluation of its MOC.
- 2-year approval: SNP that scores between 75- 84 percent on NCQA's evaluation of its MOC.
- 1-year approval: SNP that scores between 70-74 percent on NCQA's evaluation of its MOC.
- No approval: SNP with a MOC score below 70 percent based on NCQA's evaluation.

For Contract Year (CYs) 2012 and 2013, SNPs with MOC scores below 85 percent on their initial submission have two additional opportunities (i.e., cures) to resubmit their MOCs and improve their MOC scores up to an 85 percent score, enabling them to achieve a 3-year MOC approval.

Under current law, SNPs are only authorized through calendar year 2014. Should SNP authorization be extended into 2014, we would continue to raise the bar to ensure that high quality MOCs are submitted by the SNPs. For MOCs submitted for NCQA approval during CY 2013 for CY 2014, we will limit the number of cures offered for MOCs during the SNP approval process. Only SNPs that have a failing score (less than 70 percent) for their initial MOC submission will have a cure opportunity to achieve a score within the passing range of 70-74 percent. **Regardless of the score following that cure, those SNPs will only receive a one-year approval**.

Our proposed MOC approval timeframes for CY 2014 and subsequent years are as follows:

- 3-year approval:
  - Afforded to SNPs that receive a score of 85 percent or higher on their initial MOC submission. **There are no cure opportunities for these SNPs.**
- 2-year approval:
  - SNPs that score between 75-84 percent on their initial MOC submission. **There are no cure opportunities for these SNPs.**
- 1-year approval:
  - SNPs that score between 70-74 percent on their initial MOC submission. **There are no cure opportunities for these SNPs**;
    or
  - SNPs that score less than 70 percent on their initial MOC submission and subsequently attain a score of 70 percent or higher after they have had one opportunity to cure.
- No approval: SNPs that with MOCs that score below 70 percent after one cure opportunity. **SNPs that score below 70 percent on their initial submission have one cure opportunity to achieve a passing score.**

The table below summarizes the proposed review and cure process for MOCs for 2014:

Table VI-6. MOC Proposed Review and Cure Process

Score for Initial MOC Submission (%)	MOC Score (points)	Cure Options	Post 1st Cure Score	Final Approval Status
85% to 100%	136-160	No cure options	N/A	3-year approval
75% to 84%	120-135	No cure options	N/A	2-year approval
70% to 74%	112-134	No cure option	N/A	1-year approval
69% or below	111 or Below	One cure option	70% or higher	1-year approval
69% or below	111 or Below	One cure option	69% or below	No approval

We are proposing this policy because we believe this change will provide added incentive for SNPs to develop and submit comprehensive and thoughtful MOCs for initial NCQA approval. This proposed policy also allows us to reward those SNPs that have demonstrated their ability to independently develop high-quality MOCs with a longer-term approval.

E. <u>All Dual Eligible SNPs Required to Contract with State Medicaid Agencies</u>

Beginning in Contract Year 2013, all Medicare Advantage Organizations that offer Dual Eligible Special Needs Plans (D-SNPs) (existing, new and expanding) will be required to have contracts with the State Medicaid Agencies in the States in which they operate.

As in prior years, when completing the SNPs Proposal in HPMS during the February application period, in the appropriate area, SNPs may either submit the completed and signed contract for CY 2013 or describe the status of its negotiations with the State. MAOs are to upload contracts

secured with the State Medicaid Agencies during the February 2012 application period only if they have been completed and ratified (i.e., signed indicating approval by both parties). In the absence of a ratified contract, SNPs should describe the status of their negotiations in the D-SNP State Medicaid Agency Contract Upload Document. The final submission date for the contracts for operation in CY 2013 is July 1, 2012. Please refer to our HPMS memorandum of January 30, 2012, entitled, "Guidance for Submitting State Medicaid Agency Contracts," for more information.

For renewal/non-renewal purposes, an MAO will not be permitted to create a new D-SNP PBP without a State contract. Additionally, any existing D-SNPs that have not obtained a State contract will not be permitted to continue operation and the beneficiaries will be disenrolled to original Medicare with the option to enroll in another MA plan. Therefore, an MAO that offers one or more current D-SNP PBP and is unable to obtain the respective State contract(s) for CY 2013 should terminate those D-SNP PBPs pursuant to the non-renewal instructions provided in section 140 of Chapter 4 of the Medicare Managed Care Manual. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming guidance, to be released this summer, providing non-renewal and service area reduction guidance and model notices. For more information regarding State contracting requirements for D-SNPs, please see section 40.5 of Chapter 16b of the Medicare Managed Care Manual.

With respect to those instances in which an existing D-SNP fails to secure a direct State Medicaid Agency contract or a subcontracting arrangement that meets the requirements described in our HPMS Memo of January 30, 2012, CMS is soliciting comments on possible approaches for transitioning beneficiaries in these D-SNPs to other MA plans offered by the same organization that are available in the same service area. CMS' current policy with respect to plan non-renewals, in general, is that beneficiaries affected by plan non-renewals be disenrolled to Original Medicare, with a special election period through the end of February of the new contract year, during which they could enroll in another MA plan. However, CMS is also concerned about unnecessary disruptions to beneficiary care, and is aware that beneficiaries enrolled in D-SNPs, even those without a state contract, may enjoy some level of integration of their Medicare and Medicaid benefits that would be lost were they to be disenrolled to Original Medicare. Thus, CMS is soliciting comments on whether and under what conditions these beneficiaries might be transitioned into other plans offered by the same organization.

F. Capitated Financial Alignment Demonstration

CMS recently issued guidance on key dates and plan selection processes, as well as other demonstration information, for organizations interested in offering demonstration plans in 2013 under the Capitated Financial Alignment Demonstration in a January 25, 2012 HPMS memorandum. The memorandum is also available at http://www.cms.gov/medicare-medicaid-coordination/downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf. We encourage organizations to carefully review this guidance and provide us with feedback on its

contents. We anticipate providing additional detail on demonstration requirements and plan selection processes, including in the CY 2013 Final Call Letter.

Private Fee-for-Service (PFFS) Plans

A. Private Fee-for-Service (PFFS) Balance Billing

Our policy regarding Private Fee-for-Service (PFFS) balance billing is delineated in 42 CFR 422.100(b)(2) and 42 CFR 422.216(b)(1)(ii) and in the Medicare Managed Care Manual (Chapter 16a, Section 80). However, the statute does not explicitly state whether and when the maximum out-of-pocket (MOOP) limit applies under the two balance billing scenarios that exist within PFFS. It is important to distinguish between the two different balance billing scenarios because only one of the two scenarios counts toward beneficiaries' MOOP limit. The two scenarios are as follows:

1. If the provider is deemed/non-contracting and non-participating under Original Medicare participation rules, up to 15% balance billing is permitted. However, the plan – not the beneficiary – must pay the 15%. In this case, the balance billed amount would not count toward the beneficiary's MOOP limit, but the base cost sharing for the visit or service continues to count towards the limit.
2. If the provider is deemed or contracted, and the balance billing is explicitly included in the plan's contract with the provider or in the terms and conditions of payment, the provider may balance bill up to 15% of the total plan payment amount for services. In this case, the beneficiary is responsible for the balanced billed amount, and this amount would count towards the MOOP limit.

We will be updating Chapter 16a to reflect this policy on PFFS balance billing.

Regional Preferred Provider Organizations and Local Preferred Provider Organizations

A. RPPO and LPPO Deductible

The MA regulations at 42 CFR section 422.101(d)(1) establish requirements for regional PPO plans (RPPO) plans that choose to have a deductible. In its recent proposed rule, we proposed clarifications of the requirements for both RPPOs and local PPOs that elect to charge a deductible. In addition, in order to make rules for all PPO plans consistent, we proposed to extend the same deductible requirements that currently apply to RPPOs to local PPO plans (FR 76 63057). If finalized as proposed, the rules that would apply to both local and RPPOs that choose to charge a deductible in CY 2013 are as follows:

1. All PPO plans (local and regional) that choose to apply a deductible must establish a single deductible that applies to all Part A and B services, both in- and out-of-network (OON) combined. PPOs may not apply separate deductible amounts for in-network and OON services.

2. PPO plans (local and regional) may elect to exclude any in-network Part A or B service(s) from the deductible.

    - Medicare covered in-network $0 cost share preventive services must be excluded from the deductible: and
    - PPO plans may choose to exclude OON Medicare covered $0 cost share preventive services from the deductible.

3. There are no restrictions on the deductible that may be applied for non-Medicare covered supplemental benefits. That is, the plan may include or exclude any supplemental service from the deductible, in-network or OON.

Section 1876 Cost Plans

A. Supplemental Benefits for Section 1876 Cost Plans

Although cost plans are prohibited from offering mandatory supplemental benefits, we have permitted cost contracts to include collections of optional supplemental benefits in addition to their basic Parts A and B benefits as separate plan benefit package (PBPs) in order to indicate to potential enrollees in Medicare Plan Finder and Medicare & You that optional supplemental benefits are available. We do not, however, consider such collections of optional supplemental benefits as separate plan benefit packages, and cost contracts cannot require that potential enrollees choose one of the collections of supplemental benefits in order to enroll. If a cost contract wishes to discontinue a package of optional supplemental benefits for a subsequent contract year, we do not consider this a termination of a PBP. Any cost plan optional supplemental package marked as "terminated" for Contract Year (CY) 2013 will be required to be crosswalked via the plan crosswalk to another supplemental package offered by the cost contract. Cost contractors in this situation must transition enrollees to the cost plan's basic Parts A and B package – with or without Part D depending on the enrollee's original election – via the HPMS Plan Crosswalk. Additional detail on this issue is provided in the renewal/non-renewal guidance in this Advanced Notice and Call Letter.

B. Cost Plan Renewals and Service Area Reductions or Expansions

In accordance with the Affordable Care Act, beginning Contract Year (CY) 2013, cost plans will be non-renewed 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 plans will be non-renewed for any portion of their service areas where there are at least two competing MA local or two MA regional coordinated care plans meeting specified enrollment thresholds for the entire previous year (i.e., CY 2012 for the initial cycle of non-renewals). The minimum enrollment thresholds are 5,000 enrollees for urban areas and 1,500 enrollees for non-urban areas. Cost contractors would not be able to operate in affected service areas in 2014. 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.

We will provide affected cost plans CY 2012 data on MA plans in the service area that will be used to determine if cost plans will receive non-renewal notices for specified cost contract plans or portions of service areas for CY 2013 based on the MA plan "competition" provisions described above. (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.

Section III. Part D

Preferred/Non-Preferred Network Pharmacies

With the increase in the number of Part D plans offering cost sharing differentials between "preferred" and non-preferred" network pharmacies, we have begun to receive reports of beneficiary and pharmacy confusion over whether preferred cost sharing is available at individual pharmacies. We believe a primary source of this confusion arises when beneficiaries do not select a specific pharmacy when they compare Part D plans using the Medicare Plan Finder. Therefore, we are changing the Plan Finder as soon as possible to require the beneficiary to select a pharmacy for purposes of providing cost estimates that reflect the selected pharmacy's status as preferred or non-preferred in the plan's network. We believe this change would eliminate the possibility that a beneficiary will obtain cost estimates and plan selections based on preferred pharmacy cost sharing when that beneficiary does not intend to use pharmacies in the preferred pharmacy network. We note that the selection of a particular pharmacy in Plan finder for this purpose has no bearing on the beneficiary's ability to fill prescriptions at any network pharmacy.

We are also proposing that sponsors of plans that offer both preferred and non-preferred cost sharing clearly designate their pharmacy contracts—including their standard terms and conditions available to any willing pharmacy—as either preferred or non-preferred Part D network contracts to improve transparency around these arrangements. We solicit comments on preferred Part D networks in general and other ideas on how to make these arrangements more transparent to Medicare beneficiaries.

Integration with ACOs and Other CMS Innovation Models

We are very interested in Part D sponsors of stand-alone prescription drug plans (PDPs) playing a greater role in managing the care of our beneficiaries in Original Medicare and contributing to overall health outcomes. One possible strategy under consideration to further this goal would be to enable business arrangements between the new Medicare Shared Savings Program Accountable Care Organizations (ACOs) or Pioneer ACOs and Part D sponsors for improved coordination of pharmacy care. Given the potential legal, policy, and program integrity complexities involved in the integration of Part D sponsors and CMS Medicare ACO programs or innovation models, we are still in the phase of evaluating the pros and cons of permitting such arrangements. To assist with our evaluation, we would like to solicit comments from Part D sponsors and other stakeholders on possible strategies for achieving better coordination between stand-alone Part D plans and ACOs. We would like to receive information on specific activities that such coordination could consist of and on the benefits that could accrue to beneficiaries and the Medicare program from such interventions. Finally, we are also interested in seeking feedback from Part D sponsors on innovative payment or service delivery models that promote improved medication adherence.

Notes: For more information about Accountable Care Organizations, please visit the CMS website: http://www.cms.gov/ACO/.

Low Enrollment Plans (Stand-alone PDPs only)

Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options continue to be a concern to us. While we are particularly concerned about the smallest plans, we urge sponsors to consider withdrawing or consolidating any stand-alone plan with less than 1,000 enrollees on a voluntary basis. Sponsors are strongly encouraged to view data on plan enrollment count at: www.cms.hhs.gov/MCRAdvPartDenrolData/ to determine if any of their plans meet this criterion. In April 2012, we will provide plans with less than 1,000 enrollees a reminder of available options.

Benefit Thresholds

Each year, in order to implement certain regulations, we set forth certain benefit parameters which are based on updated data analysis, and therefore, are subject to change from year to year. Specifically, pursuant to § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package 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 2013, nor in the applicable regulations, the benefit parameters for CY 2013 are set forth in Table VI-7 below. We note that the review of specific tier cost sharing is in addition to the review for actuarial equivalence to the standard benefit across all tiers.

We also note that for CY 2014, we may change our approach with respect to cost-sharing and premiums. More specifically, we are considering using an out-of-pocket costs (OOPC) or market basket approach to set thresholds for increases in cost-sharing and premiums whereby we would deny Part D plan bids with significant increases in either, pursuant to our authority in the Section 3209 of the Patient Protection and Affordable Care Act of 2010.

Table VI-7 Benefit Parameters

	Proposed CY2013 Threshold Values
Minimum Meaningful Differences(OOPC)[1]	
1st Enhanced Alternative Plan vs Basic Plan	$24
1st Enhanced Alternative Plan vs 2nd Enhanced Alternative Plan	$29
Maximum Pre-ICL and Additional Gap Coverage[2] Copay (INP & INNPP) - 3 or more tiers	INP/INNPP[3]
Preferred Generic/Generic Tier	$10
Non-Preferred Generic Tier	$33
Preferred Brand/Brand Tier	$45
Non-Preferred Brand Tier	$95
Injectable tier	$95
Maximum Pre-ICL Coinsurance (INP &INNPP) - 3 or more tiers	INP/INNPP[3]
Preferred Generic/Generic Tier	25%
Non-Preferred Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Maximum Additional Gap Coverage[2] Coinsurance (INP &INNPP) - 3 or more tiers	INP/INNPP[3]
Preferred Generic/Generic Tier	59%
Non-Preferred Generic Tier	59%
Preferred Brand/Brand Tier	69%
Non-Preferred Brand Tier	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 CY2012 November Bid/Formulary Data, 2006/7 MCBS Data to be consistent with the manner in which other thresholds for CY 2013 are based. Also, please note that there was a methodological change in the MCBS determination of drug utilization in 2006 such that PDE data are now being used instead of beneficiary self-reporting.

[2] We have provided background information in Appendix D 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 59% applies to all drugs on that tier. Injectable drug tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand tiers.

[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 2013 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). Also please note that INP means "In-network pharmacy"; INPP means "In-network preferred pharmacy"; and INNPP means in-network non-preferred pharmacy. **The INPP cost-sharing amount submitted must be less than the INNPP threshold in accordance with Section 50.9 of Chapter 5 of the Medicare Prescription Drug Benefit Manual.**

Plan Finder

We are committed to continuing to improve the Medicare Plan Finder (MPF) tool to give beneficiaries and caregivers the best possible drug cost estimate when comparing Part D plans. To that end, we are developing enhancements for implementation on the MPF. The enhancements are:

- Provide a mechanism to submit and display floor pricing. Floor pricing is used when a sponsor negotiates a minimum price that a given pharmacy can charge the beneficiary when filling a prescription. "Floor" pricing is often used to defray the cost of dispensing very low cost generics. This enhancement will allow the calculation of the co-pay amount, co-insurance, or calculated cost when a floor price applies to a given drug. We will launch this enhancement during the spring 2012 refresh.

- Provide a mechanism to submit and display ceiling pricing. Ceiling pricing reflects an agreement between a plan sponsor and a pharmacy to charge a specific amount for a defined list of medications at a defined fill quantity. The ceiling price is set below the standard plan copay for those medications in order to provide an additional cost savings for the beneficiary. In order to capture the required data for displaying ceiling pricing, additional fields will be added to the Pricing File to support the submission of the ceiling price and the ceiling quantity at a NDC/Pharmacy level. The ceiling price enhancement is expected to be implemented in September 2012 for the CY 2013 MPF display.

- Provide a mechanism to submit and display pricing for 30, 60, or 90-day fills at both retail and mail order. New fields and new indicators may be required on the Pricing File to allow submission of 30-day and 60-day unit cost pricing for mail order and 60-day and 90-day unit cost pricing at retail. We also expect this enhancement to be implemented in September 2012 for the CY 2013 MPF display.

We will provide as much advance notice of these changes as possible, but sponsors are encouraged to take proactive steps to put in place the logic for these changes.

Online Enrollment through the Medicare Plan Finder (MPF)

We want beneficiaries to be able to make informed decisions about selecting health and prescription drug plans. The Medicare Plan Ratings (a 5-star ratings system) provide information to beneficiaries on individual plans' quality and performance. Beginning with the 2011 Open Enrollment Period (OEP), we developed a low-performing plan icon that would provide a visual symbol to help beneficiaries more easily identify plans that have received ratings of fewer than 3 stars for three consecutive years. For the 2012 OEP, we added explicit messaging to warn beneficiaries about enrolling into low performing plan.

In an effort to assist in guiding beneficiaries towards selecting higher performing plans, we propose to disable the MPF online enrollment function for the 2013 OEP, for new enrollees in the Medicare health and prescription drug plans with the low-performing plan icon. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in geographical areas with limited plans) will be warned, via explanatory messaging of the plan's poorly rated performance, and directed to contact the plan directly to enroll.

Misuse of Five-Star Rating

The overall rating is defined as the highest rating assigned to a contract by CMS. Plans that receive a 5-star rating as their highest rating are referred to as "five-star contracts." It has come to our attention that certain sponsors are instead using their star rating in one category or measure to imply a higher overall plan rating for their marketing materials than is actually the case. For example, a plan which received a five-star rating in customer service promotes itself as a "five-star plan" when its overall plan rating is actually only two stars. We will scrutinize Parts C and D marketing materials to ensure they are not misleading in this manner. Sponsors must only use plans' overall ratings in marketing materials so as to not mislead Medicare beneficiaries into enrolling in plans based on inaccurate information.

Complaint Tracking Module (CTM) Monitoring

For CY2013, we are planning to update the Evidence of Coverage (EOC) notice that is sent annually to beneficiaries to include two additional links: the online complaint form and a beneficiary complaint resolution web survey.

Complaint Survey

As background, we contracted with IMPAQ International to conduct a survey of beneficiaries who filed a complaint against their plan, using information from the Complaints Tracking Module. The survey focused on the beneficiaries' satisfaction with the plan and the complaint process and the complaint resolution process. The survey population included beneficiaries with closed urgent or immediate need complaints that were filed during the period January – May 2011 for all complaint categories, except for "CMS issue" and other excluded categories.

Beneficiary satisfaction was assessed using three questions from the survey: overall satisfaction with the complaints process, satisfaction with the plan, and how likely beneficiaries were to stay with their current plan. Approximately 55% of the beneficiaries reported being satisfied with the complaint handling process, 55.4% reported being satisfied with their plan, and 63.8% reported that they were likely to stay with their plan. The majority of beneficiaries (79.4%) who said they were very unlikely to stay with their plan were also dissatisfied with how the complaint process was handled.

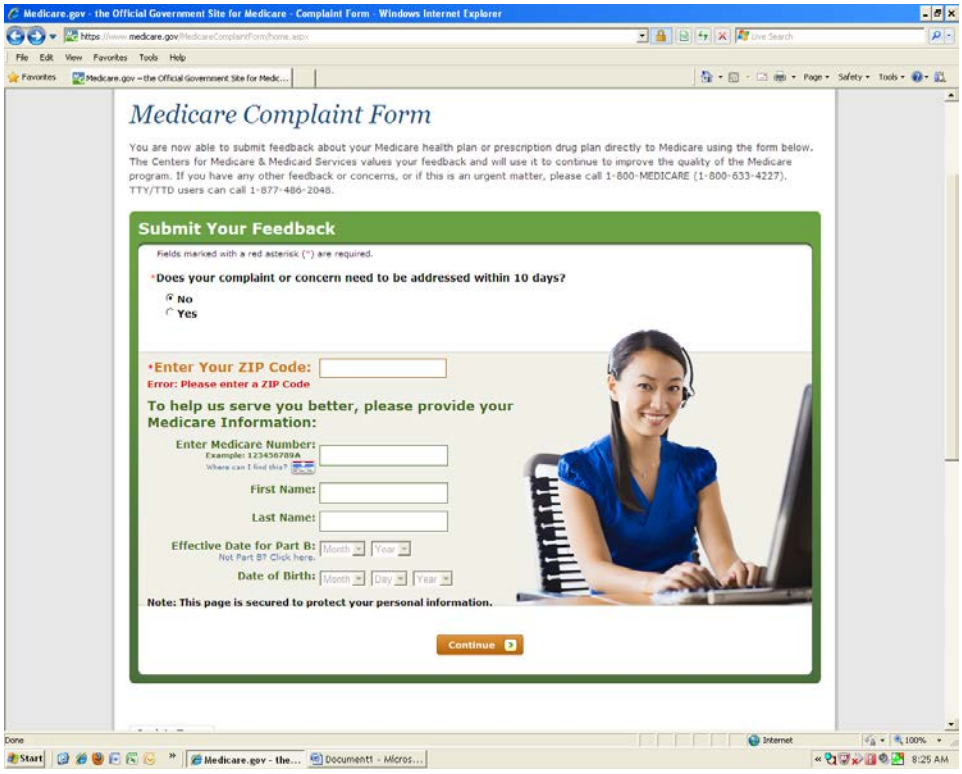
The effectiveness of the complaint resolution was also evaluated. Beneficiaries were asked if they thought their complaint was settled and to rate their satisfaction with the final outcome of the complaint. A total of 71.9% of beneficiaries understood that their complaint was considered settled from the plan's perspective, and 63.6% of beneficiaries were satisfied with the final outcome of their complaint, indicating that the resolutions reached by plans were effective from the beneficiaries' perspective.

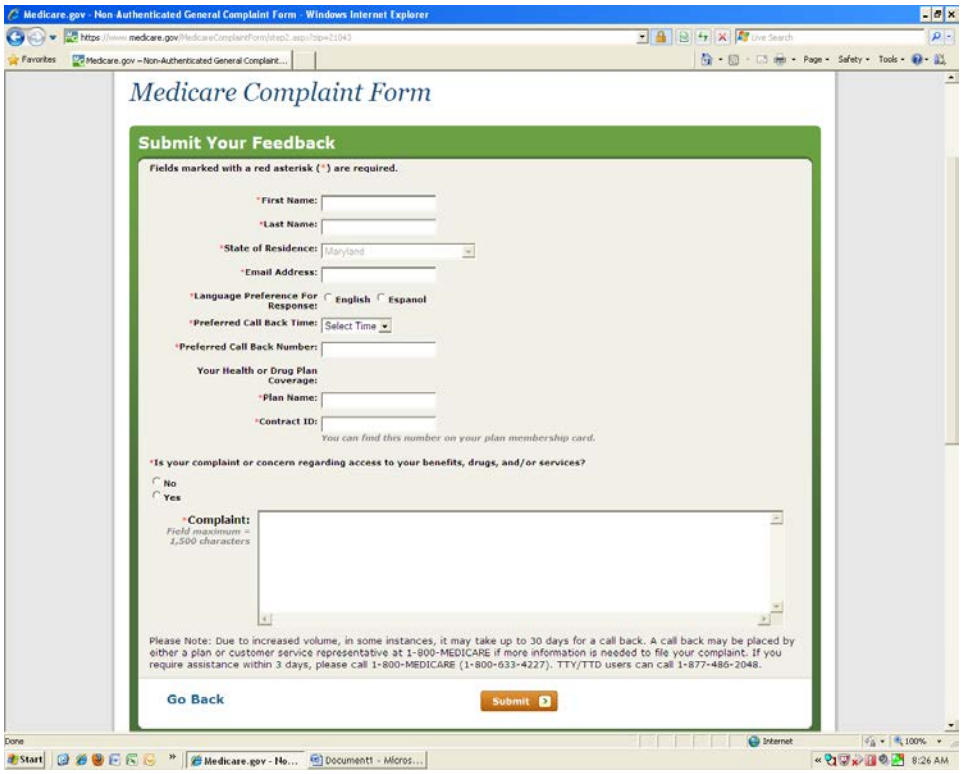
Based on these findings, we believe that obtaining beneficiaries' satisfaction with their plans complaint resolution process is an important patient protection. In 2012, a web-based version of this beneficiary survey will be made available via a link on the same page as the online complaint form. This will provide an easier way to capture information on the complaint resolution process.

Medicare Online Complaint Form

Pursuant to Section 3311(b) of The Affordable Care Act, we implemented an electronic Medicare online complaint form. The online complaint form went live December 2010 and has been placed in three locations: 1) on the www.medicare.gov homepage; 2) on the Medicare Plan Finder homepage; and 3) on the Medicare Ombudsman homepage. As provided in42 CFR 423.505(b)(22)(ii), MAOs and PDP sponsors are required to prominently display a link to this electronic complaint form on their websites.

Medicare Electronic Online Complaint Form:





Medication Therapy Management (MTM) Programs

In implementing Section 10328 of the Affordable Care Act, we consulted extensively with stakeholders to develop the standardized format for the action plan and summary that plan sponsors must provide to beneficiaries after their comprehensive medication review (CMR). A CMR is an interactive, person-to-person or telehealth medication review and consultation, including an individualized, written summary of the interactive consultation. The standardized format, instructions for implementation, and frequently asked questions will be posted on the CMS MTM web page (http://www.cms.gov/prescriptiondrugcovcontra/082_mtm.asp) no later than April 2012. The implementation instructions include document, page, and field specifications; delivery requirements; additional guidance; and a completed sample. Part D sponsors must begin using the standardized format no later than January 1, 2013.

We encourage the industry to develop clear and consistent service level expectations for the delivery of MTM and CMRs. Where currently possible, we are setting expectations around MTM implementation issues. We provide the following clarifications based on Part D sponsor and industry questions:

- Targeted beneficiaries are auto-enrolled, so sponsors should not wait for program or CMR acceptance from the beneficiary to provide the required minimum MTM services.
- The provision of the action plan and written summary in our standardized format requires certain minimum service levels for the CMR, such as discussion of the beneficiary's concerns with their drug therapy, collection of the purpose and instructions for using their medications, review of a beneficiary's medications including prescription, non-prescription drugs and supplements to aid in assessing medication therapy, and engaging beneficiaries in management of their drug therapy.
- Sponsors should offer to provide the targeted beneficiary a CMR as soon as possible after enrollment into the MTM program, but no later than 60 days after being enrolled in the MTM program.
- Sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries so they are able to receive MTM services and a CMR versus only reaching out via passive offers. Sponsors may increase beneficiary engagement by providing telephonic outreach after mailed outreach.

As noted in the Plan Ratings section, we are considering including the Pharmacy Quality Alliance (PQA) MTM measure on the 2013 display page. This MTM measure calculates the percentage of beneficiaries in the MTM program who received a CMR. Sponsors are also encouraged to leverage effective MTM to improve the Plan Ratings (e.g. increase adherence to medications, reduce the use of high risk medications, and optimize diabetes treatment) and to use the monthly reports on the Part D Patient Safety Analysis website to help identify for whom targeted MTM interventions may be beneficial and achieve better outcomes.

Beneficiary Awareness

We are committed to increasing beneficiaries' awareness about MTM programs, and sponsors are encouraged to promote the value of MTM services to beneficiaries. Information about MTM programs was included in the 2012 *Medicare & You Handbook*, and we will continue to enhance the information provided. Medicare beneficiaries are now able to view 2012 MTM program eligibility information through a link on the Medicare Plan Finder (MPF), and we are exploring other ways to integrate this information into the MPF. Sponsors should ensure that their customer service representatives and staff are familiar with the plans' MTM program. Starting in 2013, sponsors will be required to have a link on their website to MTM program information. Customer service and the website should 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. Part D sponsors are also 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.

MTM Program Submissions

Annually, sponsors must submit an MTM program description to us for review and approval through the Health Plan Management System (HPMS) MTM Program Submission Module. Some Part D sponsors have informed us that they offer MTM services to beneficiaries beyond those who meet the required CMS targeting requirements. This is permitted, but lack of information on these beneficiaries affects our analysis of MTM program outcomes and structuring of control groups for study. In the 2013 Part D reporting requirements and the MTM Program Submission Module for 2013, we will begin to capture information about programs and beneficiaries identified as being eligible for MTM, whether based on our specifications or other plan-specific targeting criteria. Additional details on the 2013 Part D reporting requirements, including the proposed data elements for capturing MTM enrollee level information, will be provided during the associated PRA public comment periods and OMB clearance process. We will provide 2013 submission guidance after finalization of the 2013 Call Letter.

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 $3000 increased by the annual percentage specified in §423.104(d)(5)(iv). Accordingly, the 2012 MTM program annual cost threshold is $3,100.20, not $3,000. The 2012 MTM program annual cost threshold will be updated for 2013 using the annual percentage increase specified in the Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and will be clarified in the final 2013 Call Letter.

We expected more Part D beneficiaries would be eligible for MTM following changes to the eligibility criteria requirements in 2010. However, the eligibility rate has remained at 10 to 13% since 2006. We are concerned that the Part D sponsors are restricting their MTM eligibility

criteria to limit the number and percent of beneficiaries who qualify for these programs and are required to be offered CMRs. We are conducting an analysis to examine the combinations of chronic diseases Part D plan sponsors require for targeted enrollment and prevalence in the Medicare population. We are also evaluating the extent to which MTM programs target populations with medication therapy issues and the programs' impact on clinical outcomes and costs. Changes to these eligibility requirements are being examined, and sponsors should optimize their targeting of beneficiaries who are most likely to benefit from access to MTM services.

For 2013, we are designating two additional core chronic diseases for targeting: Alzheimer's disease and End-Stage Renal Disease (ESRD) requiring dialysis. These chronic diseases were targeted by over 10% of MTM programs in 2011. We will also add Atrial Fibrillation to the list of non-core chronic diseases in the selection table in the HPMS MTM Program Submission Module. In addition, beginning in 2013, sponsors are expected to target at least five out of the nine core chronic conditions, which modifies the current criteria of at least four out of seven core chronic diseases.

Improving Drug Utilization Review Controls in Part D

It has become apparent to us that sponsors need to employ more effective concurrent and retrospective drug utilization review (DUR) programs to address overutilization of medications in order to protect beneficiaries and to comply with drug utilization management (DUM) requirements at 42 CFR §423.153 et seq. In fact, we believe that several improvements to formulary management processes are needed to be employed by Part D sponsors to curb overutilization, and are proposing specific features along with recommendations in this regard, which are described below. For CY 2013, we would expect to see such DUM and DUR safety improvements applied to opioids, at a minimum, for reasons we also explain below. We are also proposing that sponsors share beneficiary-level data about overutilization when a beneficiary changes plans, as detailed below. Finally, we remind sponsors that we will be monitoring the use of these tools to ensure that they are appropriately implemented and emphasize their ability to make referrals to the appropriate agencies when they suspect fraudulent activity in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefit Manual.

Background

A recent Government Accountability Office (GAO) report highlighted evidence that effective concurrent DUR has not been fully implemented across the Part D program (GAO-11-699 September 2011 http://www.gao.gov/new.items/d11699.pdf). This report summarized findings of egregious overutilization of medications from Part D beneficiaries who were obtaining medications from a minimum of five different prescribers and a maximum of fifty prescribers, with the vast majority of beneficiaries receiving medications from between five and ten providers. The medications most often identified as being potentially overprescribed were

hydrocodone containing products (e.g., Vicodin™ and Lortab™) followed distantly by oxycodone containing products (e.g., Percocet ™ and Oxycontin ™). Of the 14 classes of frequently abused drugs analyzed, hydrocodone and oxycodone were the most prevalent. These drugs represented over 80 percent of the instances of potential doctor shopping identified. Therefore, our proposal is applicable to opioids beginning CY 2013. In addition, we believe that if point of sale (POS) safety edits, such as "therapeutic duplication," "maximum dose exceeded," "refill too soon," or quantity limits (QLs) were appropriately implemented, such egregious overutilization can be averted.

On September 28, 2011, we issued a memorandum through HPMS ("September memo") relating to inappropriate overutilization of drugs and solicited comments from industry stakeholders regarding methods to improve DUR controls. Based on comments that were received, we learned that we needed to first clarify and reinforce current Part D policy relating to utilization management strategies available to Part D sponsors to combat inappropriate overutilization of prescription drugs. Therefore, as described in our December 13, 2011, memorandum entitled "Clarification of Medicare Part D Policies with Respect to Overutilization," and issued through HPMS, Part D sponsors must first ensure that they are fulfilling the current regulatory requirements with respect to DUR. Effective formulary DUM programs, when layered on concurrent DUR systems, should strongly diminish the likelihood of inappropriate overutilization. Thus, the processes described in the September memo were not meant to be a substitute for, but rather be a supplement to, effective DUR and DUM programs that should currently be implemented by sponsors.

As detailed in Chapter 7 of the Prescription Drug Benefit Manual, the regulations at 42 CFR 423.153(c)(2) require that each Part D sponsor have concurrent DUR systems, policies, and procedures designed to ensure that a review of prescribed drug therapy is performed before each prescription is dispensed to an enrollee, typically at the POS or point of distribution. The Part D sponsor's concurrent DUR program must include a number of checks each time a prescription is dispensed, including one for overutilization.

Plan sponsors are in a unique position to evaluate medication overutilization. They are a central data collection point for beneficiary medication dispensing events, which may be generated from multiple providers and pharmacies, which may be unaware that a beneficiary is receiving the same drug (or therapeutic equivalent) simultaneously from different providers and pharmacies.

As noted above, we believe that an adequate system to assist in preventing overutilization of prescribed medications would include several levels of formulary management to curb overutilization of medications, including opioids. The first level is what we are terming, "Improved Use of Concurrent Claim Safety Edits (Safety Controls at POS)." In addition to the current POS edits mentioned above, sponsors should apply safety edits that minimize the risk of overutilization of individual medications contained in combination products, such as opioid products containing acetaminophen, which does have maximum dosing limits when the

ingredient acetaminophen is considered across all unique combination products. The second level is "Improved Use of Formulary Utilization Management Designs (QLs at POS)," such as quantity limits (QLs), which can also be applied to medications that do not have a clear maximum dose, such as opioids that do not contain acetaminophen. The third level is "Improved Retrospective DUR Programming and Case Management," to identify patterns that suggest drug overutilization based on number of prescribers and doses, patterns of prescribing, and cumulative dosing, and then employ clinical case management intervention strategies. We discuss each level in detail below as they would pertain to opioids, since we are recommending that the improvements outlined here be applied to opioids, at a minimum, for CY 2013, while sponsors consider their implementation to address overutilization of other medications.

Level One: Improved Use of Concurrent Claim Edits (Safety Controls at POS)

All drugs (including the six protected classes and controlled substances) should be subject to DUR safety controls, such as early refill edits, maximum dose limitations (as described in the Food and Drug Administration (FDA) approved label for most drug products), and therapeutic duplication (i.e., patient receiving same drug or drug within the same class two days prior). As long as they are consistent with FDA labeling, these safety edits can be implemented without submission to or approval by us. We believe that Part D sponsors, through the appropriate use of concurrent DUR systems, have the ability to substantially improve patient safety by reducing the incidence of inappropriate overutilization. However, based on the comments submitted in response to our September memo, it is evident that not all sponsors are fully utilizing available concurrent DUR tools. For example, while opioid analgesics do not always have a clearly defined approved maximum daily dose, those products that contain acetaminophen (APAP) do. We would expect all sponsors to consider the APAP content of opioid analgesics and implement edits in their systems that prevent the dispensing of unsafe daily doses of APAP (greater than 4gm/day as recommended by the FDA). Comments on the September memo indicated that some sponsors believe our existing formulary guidance restricts their ability to implement such safety edits. Consequently, we are taking this opportunity to clarify that we consider safety edits to prevent dispensing of unsafe dosing of drugs to be part of the concurrent DUR requirements for all Part D drugs. While POS edits provide a broad first level of beneficiary safety, more sophisticated levels of formulary management need to be employed by Part D sponsors to prevent overutilization, as discussed in further detail below.

Level Two: Improved Use of Formulary Utilization Management Designs (QLs at POS)

<u>A) QLs/FDA Maximum Dose</u>

Part D sponsors are permitted to apply QLs at the FDA maximum approved dosing to covered Part D drugs, including drugs within a protected class, in order to promote safe use (by not allowing dosages beyond maximum dose). We note that 42 CFR §423.120(b)(2)(vi)(B) permits

exceptions to the protected classes requirement for "utilization management processes that limit the quantity of drugs due to safety."

B) QLs/No Maximum Dose

Part D sponsors may also apply QLs to drugs, as appropriate, for which there is no clearly defined maximum dose in the approved labeling, such as most opioid analgesics, to ensure safety, promote cost effectiveness, and to decrease fraud, waste and abuse. When developing QLs in such cases, sponsors' Pharmacy and Therapeutic (P&T) committees should consider existing best practices to control overutilization through formulary management. Sponsors are reminded that QLs below the FDA labeled maximum daily dose must be included as part of the HPMS formulary submission and are subject to our approval. We note that 42 CFR §423.120(b)(2)(vi)(B) permits exceptions to the protected classes requirement for "utilization management processes that limit the quantity of drugs due to safety.,

C) QLs/Below FDA Maximum Dose

Finally, Part D sponsors may apply QLs, as appropriate, below the FDA maximum approved dosing to encourage cost-effectiveness through dose optimization, if the optimal dose is included on the plan formulary. An example of dose optimization would be to promote use of one 80mg controlled release (CR) tablets rather than two 40mg CR tablets to achieve an 80mg CR tablet dose through QL restrictions on the 40mg CR tablets. This example would be permitted so long as the 80mg CR tablet is also on formulary; however, it would not be permitted as to protected class drugs since such QLs would not be due to safety.

Level Three: Improved Retrospective DUR Programming and Case Management

All Part D sponsors must have retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate use of specific drugs or groups of drugs, or of medically unnecessary care, among enrollees in a Part D plan (42 CFR §423.153(c)(3)). As noted above, in the September memo, we outlined additional retrospective DUR processes that Part D sponsors should adopt to address potential overutilization. The primary intent of this guidance was to provide sponsors with additional DUR level processes to detect and prevent inappropriate overutilization should an event go undetected by the claim level controls described above. This improved process is multifaceted, and the effectiveness will be highly dependent upon P&T committees and clinical case managers. While some sponsors felt that implementing such a process would be resource-intensive, the overall comments did not suggest that such an approach is unreasonable and did acknowledge that drug overutilization is a concern. The following paragraphs outline our proposal in more detail, again using opioids by way of example, and address the comments that we received regarding our proposal.

The opioid class of medication possesses many challenges for sponsors to ensure beneficiary safety. The application of current utilization management tools, such as maximum dose safety edits at POS, approved QLs through formulary review process, or therapeutic duplication logic, may not be as effective in identifying overutilization of opioids when compared to other classes of medications. Therapeutic duplication edits at the POS may not be programmed to the level of sophistication to prevent overutilization for opioids, and are often soft edits overridden at the pharmacy. These POS edits may not distinguish between drugs within a therapeutic class, or may be overly sensitive and identify regimens that are commonly used for pain management. Challenges such as concurrent use of long-acting with short-acting products, titration of dose, switching agents within the class, and new prescriptions written monthly for schedule II drugs (often by different doctors) highlight the need for sponsors to implement effective retrospective DUR programs to identify beneficiaries who are at risk for overutilization of these medications. While we recognize that some beneficiaries may require high doses for appropriate indications to maintain analgesia, these medications may pose significant safety hazards to beneficiaries when overprescribed and not appropriately monitored.

Sponsors should have DUR programming that identifies patterns which suggest that the identified patients may be at risk of overutilization, so that these cases may be further analyzed clinically for possible fraud, waste and abuse across all sponsors' formulary medications, including opioids. Beneficiaries receiving multiple opioid products, from multiple providers, dispensed from multiple pharmacies, may be at risk for harm and overutilization. Once identified, case management should be employed which would include outreach to prescribers and beneficiaries. Other examples are beneficiaries for whom a plan has approved QLs in excess of the normal limit set by the plan, or beneficiaries for whom soft edits are consistently overridden, could trigger a referral for retrospective review/case management. Sponsors can discuss and develop a management plan with a beneficiary's providers through a case management plan. Once a beneficiary is identified as at risk for safety and overutilization, sponsors can develop beneficiary centered utilization controls that can be implemented at POS to address safety issues that are not captured through level one and two controls.

CMS conducted an informal survey of five Part D plans that demonstrated the limits of current utilization edits for beneficiaries receiving controlled substances and the need for retrospective DUR programs to identify patients at risk that has case management and prescriber communication as included features. The following example illustrates what retrospective DUR could identify as possible overutilization that would not be identified through use of normal utilization management tools and POS safety edits, and although the case below is centered around the use of opioids, its lessons can be applied to all classes of drugs to trigger retrospective DUR:

> A beneficiary is receiving care from thirteen different physicians over the course of one year. Nine of these providers are writing for controlled substances. The patient is receiving methadone 30mg/day from one provider routinely each month, while receiving

oxycodone SR 80mg three tablets/day routinely each month from another provider. Neither provider prescribes the other prescriber's medication, so it is conceivable that they are each unaware the patient is on both of these Schedule II controlled substances, which must be rewritten each month. In addition, the patient is receiving #90 Hydrocodone 10mg/acetaminophen 650mg each month from a different provider with five refills while receiving #90 Hydrocodone 7.5mg/acetaminophen 750mg also with five refills within one week from a different provider. The patient appears to be taking 4.2 gm of acetaminophen per day which is over the FDA maximum recommended dose due to risk of hepatic toxicity.

We note several observations that can be made about this case:

- Use of multiple prescribers for multiple controlled substances places the beneficiary at risk for harm and suggests overutilization of medications;
- Normal safety edits at the POS or formulary management tools, such as quantity limits, would not be triggered since dosing for each product was within the FDA maximal dosing limits;
- Patterns of scheduled maintenance opioid therapy (both long and short duration medications) that repeat from month to month, from different providers, need to be investigated to ensure patient safety and prevent overutilization;
- Schedule III narcotics, unlike Schedule II narcotics, are not required to be rewritten each month allowing up to five refills and can more easily pose a threat of recurrent overprescribing--daily acetaminophen exposure can be dangerous, and the intent of each prescriber above was to provide a lower quantity of a hydrocodone/acetaminophen containing product, and to that end, a limited quantity of opioid exposure;
- The FDA daily maximum dose of 4gm of acetaminophen across all scheduled substances should be implemented by plans and is found at http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm;
- Sponsors should develop effective DUR programs which include case management, outreach to providers, and if necessary, beneficiary-level controls to prevent overutilization of opioid therapy and ensure beneficiary safety.

Using variables such as those outlined above, Part D sponsors should create and monitor beneficiary-level reports to identify patterns of apparent duplicative drug use over sustained periods of time and/or across multiple drug products. Clinical staff, such as case managers, should review the reports and the beneficiaries' medication histories, and when warranted, intervene with prescribers, pharmacies, and beneficiaries to ascertain medical necessity. We will develop monitoring protocols to ensure sponsors are implementing effective controls against overutilization.

Some sponsors have stated that this level of review and monitoring will be resource-intensive. However, as we have indicated above, the improved overutilization reviews are meant to

complement existing, sound DUM and DUR. As such, sponsors should implement programs in a manner that eliminates the need to review borderline cases of inappropriate overutilization. More effective implementation of concurrent DUM, as described above, should minimize the incidence of cases that will need to be reviewed at this more resource-intensive level, as comments on the September memo demonstrate that many sponsors are not currently applying tools, such as QLs and safety edits as effectively as they could be.

In response to the September memo, we received comments suggesting that prescribers are currently non-responsive to retrospective DUR requests, and that this non-responsiveness and the sponsors' lack of authority over providers would reduce the impact of overutilization review activities. Therefore, under our proposal, to the extent that a Part D sponsor has identified a bona fide safety concern through an established overutilization review program, and has made reasonable efforts to contact the prescriber and beneficiary, the sponsor may move forward with an overutilization protocol. More specifically and by way of example, in the event that a beneficiary's prescription drug claims for opioid analgesics cannot be established as medically necessary to the plan's satisfaction, the sponsor may implement beneficiary-level edits at POS at all pharmacies that result in the rejection of claims, or rejection of quantities in excess of plan established limits of opioid analgesics, for the beneficiary. As noted in the September memo, any such denials would of course be subject to routine exceptions and appeals processes. CMS reminds Part D sponsors that we will be monitoring the use of all these tools to ensure that they are appropriately implemented. Sponsors that establish inappropriate controls will be issued compliance notices.

Data Sharing Between Sponsors

Some organizations also expressed concerns that once they have implemented these edits for a beneficiary, the beneficiary could disenroll from their plan and enroll in another organization's plan and re-engage in overutilization of medications. They suggested that we should restrict the enrollment rights of dually-eligible beneficiaries who were identified through overutilization efforts. Section 1860D-1(b)(3)(D) of the Act permits LIS beneficiaries access to special election periods, and we will review our guidance in this area. In the meantime, however, we are proposing that for CY 2013, a sponsor could share the record and actions generated by overutilization review, e.g., the record from the retrospective DUR review/case management, as well as beneficiary-specific POS edits, with the successor sponsor. That is, if a Part D sponsor implemented POS edits for a beneficiary based on retrospective review, and that beneficiary then voluntarily disenrolled and enrolled in another plan, the initial sponsor may share this information with the new sponsor, who may immediately implement similar beneficiary-level edits if the new sponsor is satisfied that the documentation supports such edits. We expect Part D sponsors to promptly comply with requests for such documentation.

It is our view that HIPAA permits such data sharing between sponsors. 45 CFR §164.506(c)(3) permits a covered entity to disclose protected health information (PHI) to another covered entity

for the payment activities of the entity that receives the information. The definition of "payment" in §164.501 includes "review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care …" as long as they relate to the individual to whom health care is provided. Thus, a sponsor may share a beneficiary's PHI with a subsequent sponsor if it related to medical necessity or appropriateness of care.

Reporting Suspected Fraudulent Activity

Finally, sponsors are reminded that if a sponsor believes a beneficiary, prescriber, and/or pharmacy is involved in fraudulent activity, they should make referrals to the appropriate agencies in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefit Manual. Please note that MEDIC may be reached at the following number 1-877-7SAFERX (1-877-772-3379).

Summary

In order to more effectively address overutilization in CY 2013, we are delineating several improvements to formulary management processes that we believe should be employed by Part D sponsors to comply with the drug utilization management (DUM) requirements at 42 CFR §423.153 et seq., as described above. Specifically, we would consider implementation of these levels by a sponsor to be a minimum standard for compliance with 42 CFR §423.153 with respect to overutilization of opioids beginning CY 2013. Should these levels of DUR not prove effective at establishing medical necessity and result in plan implementation of beneficiary-level POS edits, which we believe would be a rare instance, we are also proposing that sponsors share beneficiary-level data about overutilization when a beneficiary changes plans, as also detailed above.

Section IV. Cost Contractor Enrollment Mechanisms

Allowing Cost contractors to use the Employer Group Enrollment Mechanism

Consistent with recent changes to 42 CFR 417.430, cost plans may use enrollment mechanisms, as approved by CMS, in addition to paper enrollment applications. On August 8, 2011, CMS released guidance regarding the use of telephonic and internet enrollment mechanisms by cost contractors. Beginning with the 2013 contract year, we are expanding the allowed alternative enrollment mechanisms to include the group enrollment mechanism similar to what is used by MA and prescription drug plans. Cost contractors may use this alternative enrollment request mechanism in place of individual paper enrollment request forms.

Cost contractors may accept voluntary enrollment requests directly from the employer or union that sponsors cost plan coverage for its members in any of the enrollment mechanisms described in the cost plan enrollment manual (except auto or facilitated enrollment). In addition, the cost

contractor may also accept enrollment requests using either the group enrollment process or the optional enrollment request mechanism described below.

CMS will provide further guidance on the group enrollment mechanism in an update to the cost plan enrollment manual to be released later this year.

Allowing Individuals to Leave Medicare Advantage Plans to Enroll in Cost Plans with 5 Stars

CMS previously established the 5-Star Special Election Period (SEP) allowing beneficiaries to enroll in an MA plan or prescription drug plan with a 5-star quality rating outside of the normal MA/PDP election periods. On November 16, 2011, CMS released guidance allowing individuals to use the 5-star SEP to disenroll from an MA plan in order to enroll in a 5-star cost plan. In addition, CMS established a coordinating Part D SEP for individuals who use the 5-star SEP to enroll in a 5-star cost plan to simultaneously enroll in either the cost plan's optional supplemental Part D benefit or a standalone PDP. These SEPs were effective on December 8, 2011.

MAO and PDP Sponsor Renewal/Non-Renewal Options for CY 2013

In this Call Letter, we provide detailed guidance regarding the plan renewal and non-renewal options available to MAOs and PDP sponsors for CY 2013.[7]

Each year, current MAOs and PDP sponsors that continue their contracts are required to complete the Health Plan Management System (HPMS) Plan Crosswalk in a way that reflects Plan Benefit Package (PBP) renewal and non-renewal decisions and delineates, for enrollment purposes, the relationships between PBPs offered under each of their contracts for the coming contract year. Plans should refer to section 140 of Chapter 4 of the Medicare Managed Care Manual for information about standard renewal options. This guidance outlines information and options specific to CY 2013.

MAOs and PDP sponsors must also adhere to certain notification requirements, as specified in this guidance. While most renewal options must be completed using the HPMS Plan Crosswalk, there are limited exceptions to this requirement. These exceptions are described in the Medicare Managed Care Manual for MAOs and in Appendices A-1 and A-2 for PDP sponsors. CMS will also provide precise technical instructions for completing the HPMS Plan Crosswalk for each MAO or PDP sponsor renewal or non-renewal option in the HPMS Bid Submission User Manual scheduled to be released May 11, 2012.

Overall, this renewal and non-renewal guidance is based on two underlying principles: (1) the maximization of beneficiary choice; and (2) the protection of beneficiaries' previous enrollment choices. We believe that beneficiaries should have the opportunity to make active enrollment elections into Original Medicare, a Medicare Advantage or Cost healthcare plan option, or a PDP option that best fits their particular needs.

As provided under 42 CFR 422.254, 422.256, 423.265, and 423.272, CMS reviews bids to ensure that an organization's or sponsor's plans in a service area are substantially different from those of other plans offered by the organization or sponsor in the area with respect to key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. In addition, under 42 CFR 422.506 and 423.507, we may non-renew plans that do not meet minimum enrollment thresholds after a specified length of time. This Call Letter contains information about how these requirements will be operationalized for CY 2013.

Although many of the renewal options outlined in this guidance are permissible despite year-to-year changes in benefits, premiums, and cost-sharing, we urge organizations and sponsors to maintain comparable benefits across contract years to the greatest extent possible in order to ensure that enrollees' enrollment elections remain valid. Section 3209 of the Affordable Care

[7] Note that this guidance is for *plan* level renewals and non-renewals only. The annual *contract*-level renewal and non-renewal guidance will be released the summer of 2012.

Act of 2010 provides CMS with authority to deny plan bids if an organization's or sponsor's proposed PBP includes significant increases in cost sharing or decreases in benefits offered.

Appendices A-1 and A-2 outline permissible renewal and non-renewal options specific to CY 2013 for PDP sponsors, including their method of effectuation, systems enrollment activities, enrollment procedures, and required beneficiary notifications. Appendix C is a CMS model notice that corresponds to PDP scenario 6. MAOs should refer to section 140 of Chapter 4 of the Medicare Managed Care Manual for information about standard renewal options. Renewal/Non-renewal options concerning non-network and partial network PFFS plans transitioning to partial or full network PFFS plans are provided in section 160 of Chapter 16a of the Medicare Managed Care Manual. This guidance outlines information and options specific to CY 2013.

MAOs offering special needs plans (SNPs) should note the options for SNP transitions potentially affected by State contracting efforts in the Special Needs Plan section above at page xx. Additionally, renewal/non-renewal options concerning D-SNPs are provided in section 60.3 of Chapter 16b of the Medicare Managed Care Manual. Please note that only renewal/non-renewal options that can be effectuated while adhering to CY 2013 State contracting requirements will be permitted.[8] For more information regarding State contracting requirements for D-SNPs, please see section 40.5 of Chapter 16b of the Medicare Managed Care Manual and refer to our HPMS memorandum of January 30, 2012, entitled, "Guidance for Submitting State Medicaid Agency Contracts."

Organizations and sponsors should also be aware that approval of a bid does not necessarily mean a submitted HPMS Plan Crosswalk or crosswalk exception meets CMS requirements and will be accepted by CMS. Therefore, organizations and sponsors should submit their crosswalks and crosswalk exception requests as early as possible and contact CMS staff for clarification if there is any uncertainty about whether CMS requirements will be met and the exception will be granted. Organizations and sponsors are also urged to use this guidance to determine whether their renewal or non-renewal arrangements adhere to CMS standards. If CMS requirements are met, bids as well as HPMS Plan Crosswalks and crosswalk exceptions will be approved accordingly. Organizations and sponsors that have questions about their exceptions requests should send an email to hpmscrosswalkexceptions@cms.hhs.gov well before the bid submission deadline.

Each renewal and non-renewal option outlined in the Medicare Managed Care Manual and Appendix B-2 includes, where applicable, instructions or deadlines for requesting particular renewal options that organizations and sponsors cannot themselves effectuate in the HPMS Plan Crosswalk. Organizations and sponsors will *not* be able to make changes to their HPMS Plan

[8] Options outlined in Chapter 16b of the Medicare Managed Care Manual that pertain to D-SNPs without a State contract will be removed through the annual chapter update to be completed shortly following the release of this Call Letter.

Crosswalks once bids are submitted to CMS on June 4, 2012. After that point, CMS will only make changes to organizations' and sponsors' HPMS Plan Crosswalks under exceptional circumstances.

Furthermore, any renewal options that require organizations and sponsors to submit crosswalk exception requests and manual enrollment transactions must be completed both correctly and completely pursuant to instructions that CMS will release later this year. A detailed timeline for HPMS Plan Crosswalks and crosswalk exception request submissions will be included in the forthcoming instructions. However, as stated above, organizations and sponsors should prepare their renewal and non-renewal options in advance so that they are able to submit any crosswalk and crosswalk exceptions as early as possible.

The June 4, 2012 deadline for bid submissions is incorporated in the *2013 MA, MA-PD, Part D and Cost-Based Calendar* at the beginning of this Call Letter. In addition, the calendar includes a June 4, 2012 deadline for MA plans, MA-PD plans, PDPs, and Medicare cost-based contractors and cost-based sponsors to submit a CY 2013 full contract or partial contract (PBP level) non-renewal or service area reduction notice to CMS. This notification must be made in writing and should be sent to nonrenewals@cms.hhs.gov. CMS will release guidance this summer which will include instructions for notifying the impacted beneficiaries and information about the associated requirements, including model termination notices, consistent with 42 CFR §422.506(a) and 41 CFR §423.507(a). Organizations and sponsors should refer to this forthcoming guidance for more information about full-contract non-renewal and plan termination processes.

Appendix A-1 – Contract Year 2013 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.hhs.gov/ PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage.

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[9] 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 2013 is outlined in Appendix B-2 and summarized below. 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

[9] CY 2013 bids are due no later than June 4, 2012.

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. As a general matter, CMS will not permit renewal of a PBP when it involves moving enrollees from a basic benefit design to an enhanced alternative benefit design. 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:

(1) A basic benefit design (meaning either defined standard, actuarially equivalent standard, or basic alternative benefit designs) to another basic benefit design;

(2) An enhanced alternative benefit design to a basic benefit design; or

(3) An enhanced alternative benefit design to another enhanced alternative benefit design.

We will not, however, permit consolidation of two existing PBPs into a single renewal PBP through the HPMS Plan Crosswalk when it involves a change from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

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 4, 2012.[10] 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. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming guidance, to be released this summer, providing non-renewal and service area reduction guidance and model notices.

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,

[10] CY 2013 bids are due no later than June 4, 2012 pursuant to 42 CFR §423.507(a)(2)(i).

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 C of this Call Letter.

Appendix A-2 – Contract Year 2013 Guidance for Prescription Drug Plan Renewals and Non-Renewals

	Activity	Guidelines	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 2013 that is not linked to a 2012 plan. **HPMS Plan Crosswalk Designation:** New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
2	Renewal Plan	A PDP sponsor continues to offer a CY 2012 PBP in CY 2013. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same PBP in CY 2013.	**HPMS Plan Crosswalk Definition:** A 2013 plan that links to a 2012 plan and retains all of its plan service area from 2012. The 2013 plan must retain the same plan ID as the 2012 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 2013. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	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 2012 into a single renewal PBP for CY 2013. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2013 after consolidation. When a PDP sponsor combines an enhanced PBP with a basic PBP, the HPMS crosswalk only allows a crosswalk to a consolidated PBP that offers a basic benefit design.	**HPMS Plan Crosswalk Definition:** Two or more 2012 plans that consolidate into one 2013 plan. The 2013 plan ID must be the same as one of the consolidating 2012 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 2013.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	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 2012 prescription drug PBP in CY 2013 and expands it s 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 2013.	**HPMS Plan Crosswalk Definition:** A 2013 800-series plan that links to a 2012 800-series plan and retains all of its plan service area from 2012, but also adds one or more new regions. The 2013 plan must retain the same plan ID as the 2012 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 2013. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.
5	Terminated Plan (Non-Renewal)	A PDP sponsor terminated the offering of a 2012 PBP.	**HPMS Plan Crosswalk Definition:** A 2012 plan that is no longer offered in 2013. **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	Guidelines	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 2013 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 2013. New enrollees must complete enrollment request.	Current enrollees are sent a special notice (based on the CMS model in Appendix C) along with a standard ANOC.

Appendix B – CMS Model Notice

Contract Year 2013 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, 2012. 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, 2013>.**

Your new plan coverage starts January 1

<Organization name> has approval from Medicare to transfer your enrollment into our <receiving plan name> for 2013. 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, 2013>. 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 2013, you have the right to choose another Medicare Prescription Drug Plan **anytime between <xxxxx date> and <xxxxx date>.** Your new coverage will start on January 1, 2013.

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, 2013>.

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 best meets your needs.

Option 3: You may be able to join a Medicare Advantage plan.

Other information you need to know:

If you qualify for Extra Help (the low-income subsidy) for 2013, 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 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 C

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 2013, the standard drug benefit will provide 21% 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 2012. Based on this analysis, we are setting the maximum copay cost-sharing thresholds at the pre-ICL thresholds values set for CY 2013 (see also Benefit Parameters Table VI-7 above). Similar to the pre-ICL cost-sharing analysis, we completed an analysis of the additional gap coverage copay cost-sharing associated with the 95 percentile across all initially submitted bids consisting of three or more tiers. Table VI-8 below shows the results of the threshold analysis of the CY 2012 bid submissions, as well as the 2013 copay thresholds. Note that in all cases, the 95th percentile was at or below the established pre-ICL thresholds.

Table VI-8. CY 2012 Maximum Copay cost-sharing for additional gap coverage offered by EA plans (MAPD & PDP)

Tier Label[1]	# of plans	25th	50th	75th	95th	2013 Threshold
Preferred Generic/Generic Drugs						
INP	1,065	$2	$5	$6	$8	$10
INPP	106	$0	$4	$5	$7	
INNPP	106	$2	$5.5	$10	$11	
Non-Preferred Generic Drugs						
INP	383	$5	$8	$10	$25	$33
INPP	17	$5	$5	$5	$10	
INNPP	17	$12	$12	$12	$20	
Preferred Brand Drugs						
INP	384	$39	$40	$42	$45	$45
INPP	1	$45	$45	$45	$45	
INNPP	1	$45	$45	$45	$45	
Non-Preferred Brand Drugs						
INP	374	$80	$80	$85	$87	$95
INPP	0	NA	NA	NA	NA	
INNPP	0	NA	NA	NA	NA	

[1] Please note that INP means "In-network pharmacy"; INPP means "In-network preferred pharmacy"; and INNPP means in-network non-preferred pharmacy.

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 and brands at a maximum level of 69% coinsurance. Therefore, we are setting the maximum coinsurance threshold for generics drugs at a beneficiary cost-sharing of 59%, which provides a benefit that is approximately two times the standard benefit of 21% for CY 2013. This is consistent with our approach last year. With respect to brand drugs, for which the standard benefit is 2.5% for CY 2013, 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 XZ below shows the results of the threshold analysis of the CY 2012 bid submissions, as well as the 2013 coinsurance thresholds.

Table VI-9. CY 2012 Maximum Coinsurance cost-sharing for additional gap coverage offered by EA plans (MAPD & PDP)

Tier Label[1]	# of plans	25th	50th	75th	95th	2013 Threshold
Preferred Generic/Generic Drugs						
INP	7	50%	50%	69%	69%	59%
INPP	5	50%	50%	50%	50%	
INNPP	5	50%	50%	50%	50%	
Non-Preferred Generic Drugs						
INP	0	NA	NA	NA	NA	59%
INPP	0	NA	NA	NA	NA	
INNPP	0	NA	NA	NA	NA	
Preferred Brand Drugs						
INP	48	25%	25%	55%	69%	59%
INPP	37	20%	50%	50%	50%	
INNPP	37	35%	55%	50%	55%	
Non-Preferred Brand Drugs						
INP	34	41%	43%	43%	50%	59%
INPP	37	30%	50%	50%	50%	
INNPP	37	40%	55%	55%	55%	

[1] Please note that INP means "In-network pharmacy"; INPP means "In-network preferred pharmacy"; and INNPP means in-network non-preferred pharmacy.

[2] The minimum additional gap coverage benefit of 41% for generic drugs and 31% for brand drugs, is inclusive of the standard gap coverage drug benefit of 21% and 2.5% respectively in CY 2013.