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

## SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 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 2012. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2012 are also discussed. For 2012, CMS will announce the MA capitation rates on the first Monday in April 2011, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

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

The Administration remains committed to a permanent, fiscally responsible, solution to the Medicare physician payment system. A permanent solution would improve payment rates for Medicare Advantage plans as well as physicians in the future. If such a solution – or even a temporary extension to prevent a payment cut in 2012 -- could be enacted early this year, it could affect MA rates for 2012.

Attachment II sets forth the changes in payment methodology for CY 2012 for original Medicare benefits and rebates. Attachment III set forth the changes in payment methodology for CY 2012 for Part D benefits. Attachment IV presents the annual adjustments for CY 2012 to the Medicare Part D benefit parameters for the defined standard benefit. Attachment V presents the preliminary ESRD and RxHCC risk adjustment factors.

Attachment VI provides the draft CY 2012 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: <u>AdvanceNotice2012@cms.hhs.gov</u>. Comments or questions also may be mailed to:

Deondra Moseley Centers for Medicare 7500 Security Boulevard C1-13-07 Baltimore, Maryland 21244

Comments may be made public, so submitters should not include any confidential or personal information. In order to receive consideration prior to the April 4, 2011 release of the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM Eastern time on Friday, March 4, 2011.

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

Attachments

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## Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year 2012

The Affordable Care Act establishes a new blended benchmark as the MA county rate, effective 2012. Beginning in 2012, county rates will be determined by blending two components: an <u>applicable amount</u> (pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a <u>specified amount</u> (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 2012, this rate is the greater of: 1) the county's 2012 FFS rate or 2) the 2011 applicable amount increased by the CY 2012 national per capita MA growth percentage. For 2012, the specified amount will be based on a percentage of the 2012 FFS rate.

#### 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 2012 is 0.7 percent. This estimate reflects an underlying trend change for CY 2012 in per capita costs of -3.32 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.

As required by Section 3201 of the Affordable Care Act of  $2010^1$ , the capitation rates for 2011 were the same as the capitation rates for 2010; therefore, the CY 2011 Rate Announcement did not publish final estimates of the MA growth percentages or the associated key assumptions tables. We will be calculating the 2012 rates as if there was an update in 2011 and that update was 0%. We then follow the typical process of comparing the updated projection to the update used in the prior year. The table below reflects the current trend for 2011 as well as for 2012. Our new estimates are higher than those actually used in calculating the CY 2010 capitation rate book for CYs 2006, 2007, and 2010 and lower than the estimates for CYs 2004, 2005, 2008, and 2009 that were published on April 6, 2009. Section 1853(c)(1)(D)(i) of the Act, as added by sections 4101(e) and 4102(d) of the Health Information Technology for Economic and Clinical Health Act (HITECH Act), requires that electronic health record (EHR) incentive payments be excluded from the calculation of the adjusted average per capita cost.

The following tables summarize the estimates for the change in the national per capita MA growth percentage for aged/disabled rates (Table I-1) and ESRD rates (Table I-2).

<sup>&</sup>lt;sup>1</sup> The original version of section 3201 was repealed and replaced with the current version in section 1102 of the Reconciliation Bill that amended the Senate-passed version of the Affordable Care Act.

	Aged+Disabled
2012 Trend Change	-3.32%
2011 Trend Change	2.75%
Revision to CY 2010 Estimate	3.56%
Revision to CY 2009 Estimate	-0.83%
Revision to CY 2008 Estimate	-0.75%
Revision to CY 2007 Estimate	0.18%
Revision to CY 2006 Estimate	0.02%
Revision to CY 2005 Estimate	-0.31%
Revision to CY 2004 Estimate	-0.44%
Total Change	0.70%

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

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

For 2012, CMS will retabulate the ESRD state rates with fee-for-service costs based on 2008 data. The table below shows the dialysis-only national growth percentage for each year from 2010 to 2012. The final rate for 2012 will be the estimated 2012 fee-for-service amount.

Table I-2. National Per Capita MA Growth Percentage – ESRD

	ESRD
2012 Trend Change	0.94%
2011 Trend Change	2.11%
2010 Trend Change	3.36%
Total Trend	6.54%

Notes: The total percentage change is multiplicative, not additive, and may not exactly match due to rounding.

These estimates are preliminary and could change when the final rates are announced on April 4, 2011 in the final Announcement of Calendar Year (CY) 2012 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 will also be presented in the April 4, 2011 Announcement.

## Attachment II. Changes in the Payment Methodology for Original Medicare Benefits for CY 2012

### PART C

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

There are a number of changes being implemented in the MA payment methodology for CY 2012 as a result of payment changes enacted in the Affordable Care Act.

#### New Methodology for 2012 County Rates

The Affordable Care Act establishes a new blended benchmark as the MA county rate, effective 2012. Beginning in 2012, county rates will be determined by blending two components: an <u>applicable amount</u> (pre-Affordable Care Act rate set under section 1853(k)(1) of the Act) and a <u>specified amount</u> (new Affordable Care Act rate set under section 1853(n)(2) of the Act). As required under section 1853(n)(4) of the Act, the blended benchmark is capped at the level of the 1853(k)(1) applicable amount. For additional information about the Affordable Care Act changes to the rate calculation, please see proposed rule CMS-4144-P, which is available at <u>http://edocket.access.gpo.gov/2010/pdf/2010-28774.pdf</u>.

#### 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 2012, this rate is the greater of: 1) the county's 2012 FFS rate or 2) the 2011 applicable amount increased by the CY 2012 National Per Capita Medicare Advantage Growth Percentage.

For regional plans, CMS will determine the 2012 applicable amount using the same rules as established prior to the Affordable Care Act by first establishing the component of each MA region's benchmark that is based on the CY 2012 MA county rates (weighted by the number of MA eligible beneficiaries, and then by determining the average of regional plan bids for a region). These two components will then be weighted together by the percentage of Medicare beneficiaries enrolled in Fee-for-Service (FFS) vs. Medicare Advantage (MA) plans nationwide to determine the 2012 rate.

#### Specified Amount

The specified amount is based upon the following formula:

(2012 FFS rate minus IME phase-out amount) \* (applicable percentage + applicable percentage quality increase)

We will rebase the 2012 county FFS rates in accordance with section 1853(c)(1)(D)(ii) of the Act, which requires CMS to rebase the FFS rates at least every three years. 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 2012 applicable percentages counties in the 50 States and the District of Columbia, CMS will rank counties from highest to lowest based upon their 2009 FFS costs, because 2009 is the most recent FFS rate rebasing year prior to 2012. 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:

Quartile	Applicable Percentage
4 <sup>th</sup> (highest)	95%
3rd	100%
2nd	107.5%
1 <sup>st</sup> (lowest)	115%

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

We have published each county's 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 achieve at least four stars in a five-star quality rating system. Under the Secretary's authority to conduct demonstration projects to test changes in methods of payment<sup>2</sup> 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 their quality scores, compared to what would occur under the current law bonus structure. 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. For additional information please see: <u>http://www.cms.gov/apps/docs/Fact-Sheet-2011-Landscape-for-MAe-and-Part-D-FINAL111010.pdf</u>.

The QBP percentage for each star rating will be as follows:

<sup>&</sup>lt;sup>2</sup> Section 402(a)(1)(A) of the 1967 Social Security Amendments, as amended.

Stars Rating	QBP Percentage
Less than 3 stars	0%
3 stars	3%
3.5 stars	3.5%
4 stars	4%
4.5 stars	4%
5 stars	5%

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

Under the demonstration for 5 star plans, CMS will apply the QBP percentage to the entire 2012 blended county rate, and will not cap the blended rate at the level of the pre-Affordable Care Act rate. For plans with 3 to 4.5 stars, the QBP percentage will be applied as an add-on to the Applicable Percentage before multiplying the Applicable Percentage by the 2012 FFS rate to determine the Specified Amount.

CMS is considering modifying the foregoing demonstration design to further incent more rapid and larger year-to-year quality improvement. Specifically, we are considering applying the QBP percentages noted in the table above to the entire blended county rate for 3, 3.5, 4 and 4.5 star plans, in addition to the blended county rate for 5 star plans. In addition, we are considering to what extent the benchmarks for 3, 3.5, 4, and 4.5 star plans need to be capped under this revised demonstration design. We are also considering ways to transition plans from the demonstration to current law requirements as outlined under the ACA, between 2012 and 2014. We are soliciting comments on the above demonstration features, including the potential modifications to the demonstration that we are considering.

We are also interested in comments on how best to incent plans to achieve a 5 star rating. Plan star ratings for 2011 will be used in determining 2012 QBP percentages. Contracts that did not have an overall plan rating for 2011 fall into two categories: new MA contracts or low enrollment contracts. 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 2012 and 2013, and 3.5 stars in 2014. 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 an average of the star ratings earned by the parent organization's existing MA contracts, weighted by the December 2010 enrollment. 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. For 2012, low enrollment contracts receive 3 stars for QBP purposes under the demonstration.

#### Qualifying County Bonus Payment

Beginning with payment year 2012, the Affordable Care Act extends a double quality percentage point increase to a qualifying plan located in a "qualifying county." (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. 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 2012 that is less than the national average FFS spending for 2012. For example, a plan with a rating of 3.5 stars will have 3.5 percentage points added to the applicable percentage for a total of 7 percentage points. If this qualifying county has an applicable percentage of 95 percent, this is increased to 102 percent.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) established a schedule for the phase-in of risk-adjusted rates and the phase-out of the demographic-only rates. Payments in 2004 were calculated using a 70/30 blend of demographic rates and risk rates. Due to the payment blend in 2004, counties that meet criterion 1 are defined as those counties in the March-December 2004 aged, disabled, or risk ratebooks that were assigned urban floor rates. The 2004 aged, disabled, and risk rate books can be obtained at: <a href="http://www.cms.gov/MedicareAdvtgSpecRateStats/RSD/list.asp">http://www.cms.gov/MedicareAdvtgSpecRateStats/RSD/list.asp</a>.

CMS will calculate the MA penetration rate of a county using data from our enrollment database systems. The numerator represents the total number of county residents enrolled in MA in a county in December 2009. The numerator will be calculated by using all MA plan types, including demonstration plans. The denominator represents the total number of MA eligible county residents in December 2009. Hospice and ESRD beneficiaries are included in both the numerator and denominator.

The 2012 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 2012 Rate Announcement.

CMS will publish a complete list of qualifying counties in the 2012 Rate Announcement. The listing will contain all counties that meet all three criteria as stated in Section 1853(o)(3)(B) of the Act. We have published 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 (%).

These elements can be found at the CMS website at <u>http://www.cms.gov/</u> <u>MedicareAdvtgSpecRateStats/</u>.

#### 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. Each county will be assigned to one of three transition periods - two, four, or six years. A county's specific transition period is determined by the difference between the county's Projected 2010 Benchmark Amount and 2010 Applicable Amount. The Projected 2010 Benchmark Amount is 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.

In order to calculate the Projected 2010 Benchmark Amount, CMS took the following steps:

- First, CMS modified each county's Applicable Percentage by adding 1.5 percentage points (3 percentage points in qualifying counties) to create each county's Modified Applicable Percentage. (The statute provides at section 1853(n)(3)(C)(ii)(II) that the 2012 applicable percentage increase of 1.5 percentage points (at section 1853(o)(1)(A)) should be applied to this 2010 calculation.)
- 2. Then CMS tabulated the 2010-only Modified Specified Amount by multiplying the 2010 county FFS rate by the 2010 Modified Applicable Percentage.
- 3. Next, CMS tabulated the Projected 2010 Benchmark Amount by adding 50 percent of the 2010 Applicable Amount to 50 percent of the 2010-only Modified Specified Amount.

Finally, each county's Projected 2010 Benchmark Amount was compared to each county's 2010 Applicable Amount to determine the applicable transition period. The county transition period will be based on the differentials in the table below.

Table II-3 County transition periods:

Two Year County BlendFour Year County Blend		Six Year County Blend
Difference between 2010	Difference between 2010	Difference between 2010
Applicable Amount and	Applicable Amount and	Applicable Amount and
Projected 2010 Benchmark is	Projected 2010 Benchmark is at	Projected 2010 Benchmark
< \$30	least \$30 and less than \$50	is at least \$50

The transition periods for each county (2, 4, or 6 years) 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.

	Two Year Co	unty Blend	Four Year Co	ounty Blend	Six Year Co	ounty 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.

Section 1854(b)(1)(C) of the Affordable Care Act changes the calculation of the amount of monthly rebate an MA plan must provide an enrollee, and mandates that 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 and these new percentages will be phased-in during 2012 and 2013, as shown in Table II-5.

Table II-5. 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 two exceptions for determining the level of rebate for 2012: a low enrollment plan will be treated as having a star rating of 4.5 stars and 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 and low enrollment plans is for purposes of determining the rebate level only, and not for other payment purposes.

The amount of rebate that plans must offer enrollees is phased-in over 3 years. In 2012 the rebate amount is 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.

Uses of Rebate Dollars

The unamended version of the Affordable Care Act (the Senate bill) would have imposed new restrictions beginning in 2012 on the use of the rebate dollars, which MA organizations are required under section 1854(b)(1)(C)(i) to provide to beneficiaries if their bid is below the benchmark. Under the Senate bill, the existing provisions in section 1854(b)(1)(C)(i) specifying how rebate dollars could be used were to continue to apply "for plan years before 2012," and thus applied for 2011.

The reconciliation act amending the Senate version of the Affordable Care Act, deleted the statutory language containing the new restrictions on the use of rebates for year 2012 and beyond, while leaving in place the language making the existing rules applicable only to years before 2012. The reconciliation act further amended the Senate version by adding a new section 1854(b)(1)(C)(iii) governing the amount of rebates. As a result, there are no specific statutory requirements in place after 2011 with respect to how rebates are to be applied, while leaving in place the obligation in section 1854(b)(1)(C)(i) to pay rebates, and provisions governing the amount of such rebates.

In our review of bids under section 1854(a)(6) CMS accordingly proposes to apply the same rules for use of rebate dollars for 2012 that applied for 2011, meaning that MA organizations could continue to use rebate dollars only for the purposes set forth in section 1854(b)(1)(C)(ii).

#### Section B. Changes to the Medicare Advantage Ratebook

County rates represent the upper limit that the government will pay Medicare Advantage Plans, on a standardized basis, per person per month for coverage of original Medicare benefits. Prior to 2011, county rates were based on average FFS costs or the prior year rate grown by the MA growth percentage. In 2011, the county rates were frozen at 2010 levels. Beginning with 2012, the Affordable Care Act (ACA) specifies that MA county rates will be directly related to a percentage of average fee-for-service (FFS) costs, and establishes a transition during which a blended benchmark will be used to blend rates based on pre-ACA rules and rates based on ACA rules. As discussed in Section A, ACA rates are based on a function of FFS costs and the quality rating of the plan.

In conjunction with implementing the ACA's requirement to transition the county rates to be based only on a function of FFS costs, we have performed a detailed review of the current methodology used to develop these costs. Our review included both the calculation of the United States Per Capita Cost (USPCC) and the Average Geographic Adjustment (AGA) methodology. Adjustments to the AGA for a given county cause each county's share relative to the national average to change marginally. However, adjustments to the relative share of national expenditure as measured by the AGA have no effect on the overall USPCC. As part of this review, we identified several areas for improvement in the calculation and we are proposing to update the methodology as discussed below. *Exclude Hospice Claims:* When a beneficiary enrolled in a Part C plan enters Hospice, traditional Medicare claims are paid on a fee-for-service (FFS) basis and no payment is made to the Part C plan sponsor for these claims. Accordingly, the calculation of the USPCC excludes all claims for beneficiaries in Hospice status. Historically, all FFS claims, including those for beneficiaries in Hospice status, have been included in the FFS tabulations used in calculation of the average geographic adjustment (AGA) factors. For 2012, the county average FFS costs will be based on 2005 through 2009 FFS tabulations. CMS proposes to tabulate the 2009 FFS costs for members that are not in Hospice status for the 2012 rate calculation. For 2013 and subsequent years, we will compute each new year added to the historic cost base under the new method, thereby transitioning this change over a five year period. This change will have a negligible effect for most counties. For 2012, we expect 9 small counties would have an impact of more than 1%.

*Exclude Cost Plan Data:* Cost plan beneficiaries generally have Part A claims paid on fee-forservice (FFS) basis and certain Part B claims on a capitated basis. To date, all FFS claims, including those for beneficiaries enrolled in Cost plans, have been included in the FFS tabulations used in calculation of the average geographic adjustment (AGA) factors and in the calculation of the FFS USPCC. For 2012, the county average FFS costs will be based on 2005 through 2009 FFS tabulations. CMS proposes to tabulate the 2009 FFS costs for beneficiaries that are not enrolled in Cost plans for the 2012 rate calculation. For 2013 and subsequent years, we will to compute each new year added to the historic cost base under the new method, thereby transitioning this change over a five year period. In addition, starting with 2012, we will exclude FFS costs for Cost plan enrollees from the total FFS USPCC. This change will have a negligible effect for most counties. For 2012, we expect 30 counties would have an impact of more than 1%.

*County rates in Puerto Rico*: Medicare enrollment, cost and use in Puerto Rico is different than in the states. A far greater proportion of beneficiaries enroll in Medicare Advantage plans (67% in Puerto Rico vs 24% nationally) and those that do remain in fee-for-service are much less likely to enroll in Part B (46% in Puerto Rico vs 91% nationally). While most mainland beneficiaries are automatically enrolled in Part B, and must opt out to decline it, Puerto Rican beneficiaries are required to opt-in to Part B coverage. In addition, Medicare fee-for-service payment rates tend to be lower. We analyzed the FFS cost development to ensure that they adequately take into account the unique factors in Puerto Rico.

The tabulation of FFS payments in the Commonwealth is appropriate for determining FFS costs and serving as the basis for MA payment rates. However, the tabulation of FFS payments for Part A and/or Part B FFS beneficiaries may not be appropriate for basing payments to plans that serve Part A and Part B individuals. We performed a study to measure the effect on the standardized FFS per-capita costs separately for Part A and/or Part B beneficiaries and for Part A and Part B beneficiaries. The results of this study indicated that the standardized costs for Part A and Part B beneficiaries in Puerto Rico are on average 5% higher than Part A and/or Part B beneficiaries while there were only nominal differences between these populations in non-Puerto Rico counties. Since enrollment in Medicare Advantage is generally limited to beneficiaries enrolled in both Part A and Part B, we are proposing to tabulate FFS costs in Puerto Rico for beneficiaries enrolled in both Part A and Part B. Similar to the treatment of Hospice and Cost plan claims above, we are proposing to modify the 2009 FFS tabulation resulting in a transition over a five year period. This change will result in an average increase of 0.2% in the blended benchmark for Puerto Rico counties in 2012.

*Variations in Small Counties:* The current method for calculating fee-for-service (FFS) costs attempts to minimize the effect of random fluctuations by relying on five years' worth of cost in determining the average geographic adjustment (AGA) factor. Even following this approach, counties with small enrollment commonly experience a significant amount of cost variation each year. To address this issue, we performed a study on introducing credibility theory to the rate setting process.

Our study included evaluating counties with alternative minimum levels of FFS beneficiaries. Counties over this threshold would be considered fully credible while counties with fewer enrollees would be considered partially credible. The FFS experience for partially credible plans would be blended with the applicable manual rate. The applicable manual rate will be one of two values:

- 1) For counties that are part of a Core Based Statistical Area (CBSA) (either Metropolitan or Micropolitan Statistical Area), the applicable manual rate would be the weighted average of all of the counties in that Core Based Statistical Area in the same state.
- 2) For counties that are not part of a CBSA, the applicable manual rate would be the weighted average of all of the non-CBSA counties in that state.

The weighting used for the small counties experience was the square root of the average number of FFS enrollees over the five year period included in the AGA calculation divided by the threshold amount with the balance of the weight being applied to the manual rate. After calculating the revised rate for the low enrollment county, the low enrollment county rates for each state were restandardized so that each state's share of the AGA remains constant.

The results of the study are that incorporating such an approach greatly reduces the annual fluctuation in FFS cost for counties with low enrollment. Since there was a significant reduction in the fluctuation with the threshold set at 1,000 enrollees, we are proposing implementing this approach for calculating FFS costs for counties with less than 1,000 enrollees.

There are 380 counties with enrollment under 1,000. We expect 79 counties would have greater than a 1% impact and 29 very small counties would have an impact of more than 2%.

#### Section C. 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, we will first calculate 2012 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 2012 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, however, the maximum reduction for any specific county in 2012 is 1.8% of the FFS rate. To help plans identify the impact, CMS will separately identify the amount of IME for each county rate in the 2012 ratebook. We will also publish the rates with and without the IME reduction for the year.

#### Section D. Adjustment to FFS Per Capita Costs for VA-DOD Costs

Section 1853(c)(1)(D)(iii) of the Act directs the Secretary to make an appropriate adjustment to the payment rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense (DoD) or the Department of Veterans Affairs." In the 2010 Advance Notice, dated February 20, 2009, we concluded that there was insufficient evidence to incorporate any VA adjustment into the rate making process.

As stated in the 2011 Advance Notice, we have obtained TRICARE eligibility data from the DoD. TRICARE is the DoD's health care program that covers eligible Uniformed Services beneficiaries for medical care. The vast majority of TRICARE beneficiaries are enrolled in the TRICARE For Life (TFL) option, which pays secondary to Medicare. Another TRICARE option, available to TRICARE/Medicare dual-eligibles, is the Uniformed Services Family Health Plan (USFHP). The USFHP is available to TRICARE members who live near selected civilian medical facilities through which the plan delivers care. Non-emergency care must be obtained through the USFHP hospital and doctor network. USFHP is primary to Medicare (with very few exceptions) and bills are not generally submitted to Medicare.

In lieu of obtaining cost, use, and diagnosis data at the beneficiary level, the methodology used is the same as was used to analyze the VA data in 2010. The analysis was performed separately for all DoD and USFHP-only enrollees and compares the average FFS costs to determine if there are

significant differences between the DoD groups and the total Medicare population. To approximate an adjustment to the county fee for service (FFS) payment rates, we analyzed the cost impact of removing the dual-eligibles from the Medicare claims and enrollment<sup>3</sup>. Specifically, we calculated the ratio of standardized per capita costs of all Medicare beneficiaries excluding dual-eligibles (DoD) to all Medicare beneficiaries (or all beneficiaries) for each county. The calculations were based on FFS data for calendar years 2004-2006.

We analyzed the ratios in counties with at least 10 members in the respective groups and found that there was no statistical significance of the DoD ratios, but did find that the USFHP-only ratios were significant. Accordingly, adjustments will be made to counties with at least 10 USFHP members. CMS will adjust the FFS rates by the ratios calculated. Based on applying the adjustments to the 2009 FFS rates, the average monthly FFS rate will increase in 138 affected counties by approximately \$1.85, with a range of a decrease of \$0.10 to an increase of \$12.04; fifteen counties will experience increases in FFS rates of \$5.00 or more. This adjustment was also announced in the 2011 Advance Notice, but was not implemented because of the rate freeze that was mandated by the Affordable Care Act.

#### Section E. Clinical Trials

In 2012, we will continue the policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

#### Section F. ESRD Payments

Updates to the ESRD ratebook are discussed in this section. Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to establish "separate rates of payment" with respect to ESRD beneficiaries.

#### F1. Transition to New ESRD Payment

CMS concludes the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status in 2012. The transition schedule was first announced in the 2008 Advance Notice. The full transition schedule is as follows:

<sup>&</sup>lt;sup>3</sup> For this analysis, dual-eligibles are defined as those Medicare beneficiaries who are also eligible to receive care through the Department of Defense.

	Old Ratebook	Revised Ratebook
2008	75%	25%
2009	50%	50%
2010	25%	75%
2011	25%	75%
2012	0%	100%

#### F2. ESRD State Rates

For 2012, 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 2009 to determine the average geographic adjustment (AGA) for each State and to determine the 2009 national average per capita FFS dialysis cost. The State AGAs were standardized to the proposed 2012 ESRD risk adjustment model. CMS then adjusted the 2009 national average by each State AGA to determine revised 2009 State rates and trended these rates to 2012 using the ESRD dialysis growth trend. The final rate for 2012 will be the estimated 2012 fee-for-service amount. The final 2012 State rates will be developed by taking into account the MIPPA '08 carve-out of indirect medical education (IME) and the \$5.25 ESRD user fee.

#### **F3. Functioning Graft**

For 2012, CMS will pay Functioning Graft enrollees based on the blended benchmark for the county minus the amount of any rebate dollars (if any) allocated to reduce plan enrollees' Part B premium and/or Part D basic premium, where the blended benchmark depends on the quality bonus payment (QBP) for the contract within which the person is enrolled. For example, if a beneficiary is enrolled in a contract with 3 stars, the payment for that beneficiary will be the 3 star QBP benchmark for the beneficiary's county of residence, multiplied by the functioning graft risk score for that beneficiary.

#### Section G. Location of Network Areas for PFFS Plans in Plan Year 2013

Section 162(a)(1) of MIPPA amended section 1852(d) of the Social Security Act by creating a new requirement for 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, MIPPA requires that 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 no longer 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 the 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 2013 will appear in the *Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies* and will also be available on the CMS website at

<u>http://www.cms.hhs.gov/PrivateFeeforServicePlans/</u>. We will use January 1, 2011 enrollment data to identify the location of network areas for plan year 2013.

## Section H. End of Medicare Advantage Medical Savings Account (MSA) Plan Demonstration Program

In a July 13, 2006, Federal Register Notice (CMS-4123-N) we announced the availability of an opportunity to participate in an MA MSA demonstration project. In the Federal Register notice we said that waivers provided under our demonstration authority would allow interested entities to offer products that more closely resemble high deductible health plans that are offered in conjunction with health savings accounts to the non-Medicare population. We initially established a deadline of July 21, 2006, for applicants that wanted to participate in the MA MSA demonstration program for 2007. We also asked applicants that wanted to participate in the program in 2008 to submit a notice of intent to us as soon as possible.

Overall we had one applicant that participated in the MSA demonstration program in calendar year 2007. There has been no activity under this demonstration program since then. We are not seeking extension of this demonstration program and will not accept applications for participation in this program for plan years 2012 and thereafter.

## Section I. Employer Group Waiver Plan (EGWP)<sup>4</sup> Bidding

MedPAC's March 2009 Report to Congress notes that in 2009 the average bid for employer group plans was 109% of the FFS rate, whereas for all other MA plans the average bid was

<sup>&</sup>lt;sup>4</sup> Employer Group Waiver Plans (EGWPs) are defined in Chapter 9 of the Medicare Managed Care Manual - <u>http://www.cms.gov/manuals/downloads/mc86c09.pdf</u> - as Customized employer group MA plans offered exclusively to employer/union group health plan sponsors [that] include: (1) plans offered by MAOs to employers/unions (these plans are hereinafter referred to as "800 series" plans because their plan benefit packages are enumerated in the CMS Health Plan Management System (HPMS) with identifiers in the 800s to distinguish them from individual plans offered by MAOs); and (2) plans offered by employers/unions that directly contract with CMS (hereinafter referred to as "Direct Contract" plans). These "800 series" and Direct Contract MAOs are referred to collectively as employer/union-only group waiver plans ("EGWPs").

100% of the FFS rate. MedPAC also notes that "[e]mployer group plans consistently bid higher than plans open to all Medicare beneficiaries." They also state that "conceptually, the closer the bid is to the benchmark the better it is for the plans and employer, because a higher bid brings in more revenue for Medicare, potentially offsetting expenses that would have required a higher pay-in from employers." Further, MedPAC says one would expect "economies of scale" in employer group plans, from the perspective of enrollment and marketing costs. MA plans that exclusively serve employer/union groups do not compete in the open market, but are offered privately to only those groups pre-selected by the MAO.

CMS has found, in reviewing bids from recent years, that the projected medical costs for EGWP members exceed those of members in individual market plans while the projected risk of EGWP members is lower than for individual MA plan enrollees.

CMS invites public comments on the factors that may explain the discrepancy between the bidding behavior of EGWPs and other types of MA plans. Further, we solicit public comments on potential ways to address these differences.

In the following chart we document the bid ratios and average risk scores in MA EGWP and individual enrollment plans over the last three years.

Risk Scores and Bid Ratios			
EGWP vs. Non-EGWP <sup>5</sup>	2008	2009	2010
Weighted Average Projected Risk Score (EGWP)	0.964	0.951	0.949
Weighted Average Projected Risk Score (Non-EGWP)	1.002	1.002	0.986
EGWP over Non-EGWP	-3.81%	-5.09%	-3.75%
Weighted Average Plan A/B Bid (EGWP)	\$725.46	\$744.10	\$752.26
Weighted Average Plan A/B Bid (Non-EGWP)	\$687.85	\$720.72	\$726.99
EGWP over Non-EGWP	5.47%	3.24%	3.48%
Weighted Average Standardized Plan A/B Bid (EGWP)	\$753.23	\$784.40	\$803.74
Weighted Average Standardized Plan A/B Bid (Non-EGWP)	\$671.47	\$708.74	\$733.96
EGWP over Non-EGWP	12.18%	10.67%	9.51%

#### **RISK ADJUSTMENT**

#### Section J. CMS-HCC Risk Adjustment Model

In the 2011 Announcement, CMS indicated that it intended to implement an updated version of the CMS-HCC risk adjustment model in 2012. CMS also provided information on this model.

<sup>&</sup>lt;sup>5</sup> Note that we have not adjusted for differences in service areas between EGWP and non-EGWP plan bids to account for theoretical distortions caused by ratebook rules that set benchmarks far above FFS costs in some areas.

However, CMS is proposing not to implement the new model for Part C for 2012 in order to minimize change during 2012, the first year of the blended benchmarks under the Affordable Care Act.

#### Section K. Recalibration of the ESRD Risk Adjustment Model

In 2012, CMS will implement an updated version of the ESRD risk adjustment model. The ESRD model dialysis segment is calibrated using the appropriate ESRD population. Therefore, the resulting coefficients reflect the relative cost and diagnosis coding for this subgroup of beneficiaries.<sup>6</sup> All of the components of the ESRD model were recalibrated for 2012:

- Dialysis: The ESRD dialysis risk adjustment model is a single set of coefficients for both community and institutional enrollees in dialysis status. The ESRD dialysis model is calibrated using diagnoses and expenditure data for all beneficiaries in FFS who are in dialysis status.
- Dialysis new enrollee: The dialysis new enrollee factors are estimated using data from all FFS beneficiaries in dialysis status. These factors represent the average projected spending based on demographic factors. The set of demographic-only new enrollee factors are applied to beneficiaries in dialysis status that do not have 12 months of Part B in the data collection year.
- Transplant: Transplant factors are estimated for the first three months following a transplant. The first month's factor is the largest, as that is the month within which the transplant takes place, with months 2 and 3 smaller for post-transplant recovery.
- Functioning graft: A number of the HCC relative factors in both the functioning graft community and institutional segments of the ESRD model are constrained. First, kidney-related conditions are constrained to zero. The HCC for Dialysis Status (HCC134) is constrained to zero, since this is a population defined by having a functioning kidney and not being in dialysis status. We have also constrained nephritis (HCC134), and acute and chronic kidney conditions (HCC134 through HCC 140,) to be zero since there is concern that the functioning graft population is more likely to be inconsistently coded with these conditions without any real health difference. Second, there is a set of functioning graft "add on" factors which vary depending on the amount of time that has elapsed since kidney transplant. These "add on" factors take into account the cost of additional treatment and immunosuppressant drugs.

*Disabled-Disease Interactions:* The Disabled-Disease Interactions in the ESRD dialysis model have increased from six to seven as a result of adding two Disabled-Disease Interactions and removing one Disabled-Disease Interaction. The two additional disabled-disease interactions

<sup>&</sup>lt;sup>6</sup> The recalibrated ESRD model has a different numbering system than prior versions.

are: Disabled\*Chronic Pancreatitis and Disabled\*Complications of Specified Implanted Device or Graft. The disabled-disease interaction that was removed is: Disabled\*Disorders of immunity.

*Disease Interactions:* The Disease Interactions in the ESRD dialysis model have increased from four to five as a result of adding four Disease Interactions and removing three Disease Interactions. The four additional disease interactions are:

Sepsis \* Cardiorespiratory Failure Cancer \* Immune Disorders Diabetes \* Congestive Heart Failure Chronic Obstructive Pulmonary Disease \* Cardiorepiratory Failure

The three disease interactions that were removed are:

Diabetes Mellitus \* Congestive Heart Failure Diabetes Mellitus \* Cerebrovascular Disease Chronic Obstructive Pulmonary Disease \* Cerebrovascular Disease \* Coronary Artery Disease

#### Data Submission

CMS will post mappings of ICD-9 codes to the new ESRD model HCCs with the publication of the Advance Notice. MA organizations and PACE organizations will be required to submit all ICD-9 codes mapped to the payment model HCCs for dates of service starting January 1, 2011, and may choose to submit all these ICD-9 codes for dates of services starting July 1, 2010, so that they can be included in the calculation of the initial 2012 risk scores.

#### Section L. Adjustment for MA Coding Pattern Differences

CMS is proposing an MA coding pattern difference adjustment of 3.41% for payment year 2012.

#### Section M. Frailty Adjustment

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

As noted in the 2008 Announcement (published April 2, 2007), CMS will fully transition to the new frailty factors in 2012 for PACE organizations. CMS will use the results from each PACE organization's 2011 Health Outcome Survey-Modified (HOS-M) survey to calculate each contract-level frailty score for CY2012. CMS will not apply negative contract-level frailty score will be set to zero).

Eligible individuals who wish to participate in a PACE organization must voluntarily enroll. The PACE service package must include all Medicare and Medicaid services provided by that State. PACE enrollees also must: 1) be at least 55 years of age, 2) live in the PACE service area, 3) be screened by a team of doctors, nurses, and other health professionals as meeting that state's nursing facility level of care, and 4) at the time of enrollment, be able to safely live in a community setting.

The ADL distribution of the enrollees in all PACE organizations is shown below. As shown, 40 percent of enrollees had 5-6 ADL limitations in 2010.

Percent of Enrollees with:	2009	2010
0 ADLs	13.6%	12.9%
1-2 ADLs	23.1%	23.3%
3-4 ADLs	24.3%	23.4%
5-6 ADLs	39.0%	40.4%

#### 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.

CMS requires MA organizations to collect Health Outcome Survey data at the contract level for quality reporting purposes. Historically, we have used this contract level data to calculate frailty for PACE organizations and dual-eligible demonstrations. However, this approach must be modified to measure frailty in dual eligible SNPs because SNPs are organized at the plan benefit package level rather than the contract level. This means that dual eligible SNPs co-exist within the same contract with other types of SNP plans and non-SNP plans. Because the frailty level of individual PBPs may not be similar to the contract-level frailty, valid PBP-level frailty scores cannot be calculated using the current sampling methodology. Therefore, MA organizations will need to contract with a vendor to field the survey 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.

CMS has allowed MAOs that anticipate offering a FIDE SNP in 2012 to field the HOS at the PBP level in 2011. This will allow CMS to calculate the FIDE SNP's frailty score. These HOS data will be collected in early 2011.

CMS invites comments on the appropriate criteria that should be used to determine if a FIDE SNP has "similar average levels of frailty (as determined by the Secretary) as the PACE program", as required by the Affordable Care Act. We are considering using distributions of ADLs, or perhaps average frailty scores, to implement this portion of the statute. CMS is also considering using multivariate analyses to model the relationship of disease scores and frailty. In the final rate announcement, we will establish our methodology for determining if a FIDE SNP has a level of frailty that is similar to the PACE program.

We also invite comment on how to calculate frailty scores for very low enrollment SNPs (under 30 members) and for "new" dual eligible SNPs. In this context "new" indicates SNPs in MA contracts that have been in existence less than 3 years and have had no dual eligible SNPs in the contract in that time.

#### Section N. 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 2012 Announcement, to be released April 4, 2011.

## N1. Normalization Factor for the CMS-HCC Model

The preliminary 2012 normalization factor for the aged-disabled model is 1.079, which will adjust for risk score growth over the five years from the denominator year of 2007 to the payment year of 2012.

## N2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2012 normalization factor for the ESRD dialysis model is 1.012, which will adjust for risk score growth over the three years from the denominator year of 2009 to the payment year of 2012.

## N3. Normalization Factor for Functioning Graft Enrollees' Risk Scores

The preliminary 2012 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model is: 1.051, which will adjust for risk score growth over the three years from the denominator year of 2009 to the payment year of 2012.

#### N4. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

The preliminary 2012 normalization factor for the RxHCC model is 1.032, which will adjust for risk score growth over the three years from the denominator year of 2009 to the payment year of 2012.

#### Section O. ESRD MSP Factor

CMS has recalculated the MSP adjuster for ESRD beneficiaries. The current ESRD MSP adjustment factor of 0.215 will be revised; the preliminary 2012 ESRD MSP factor is 0.189. CMS will continue to apply the ESRD MSP adjustment to individual-level payments.

#### Section P. Affordable Care Act-Mandated Risk Adjustment Evaluation

The Affordable Care Act amended section 1853(a)(1)(C)(iii)(III) and (IV) of the Social Security Act to require CMS to periodically evaluate and revise its risk adjustment system "to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentration of beneficiaries with those conditions." In addition, the statute requires that CMS shall publish, as part of a Rate Announcement, a description of any evaluation conducted under this requirement during the preceding year and any revisions made to the model as a result of such evaluation.

CMS is currently conducting an analysis of the risk adjustment system, as required under section 1853, and will publish our results in the 2012 Rate Announcement, to be published April 4, 2011.

#### Section Q. Encounter Data Collection

In the final 2009 inpatient prospective payment system (IPPS) rule, published August 19, 2008 - 73 FR 48434 ff – we revised 42 CFR 422.310(d) to clarify that CMS has the authority to require MA organizations to submit encounter data for each item and service provided to MA plan enrollees. Consistent with this authority, we will require MA organizations to submit encounter data for dates of service January 1, 2012, and later.

With the exception of encounter data on Durable Medical Equipment (DME) encounters, which CMS will begin collecting on May 7, 2012, MA plans will be required to submit data for all other types of institutional and professional services provided to MA plan enrollees on or after January 1, 2012. MA plans will see significant differences between the current Risk Adjustment System (RAS) and the new Encounter Data Processing System (EDPS). Most notably, data collection changes from the 5 elements currently collected to all of the elements on the HIPAA 5010 version of the X12 standards. Use of the HIPAA 5010 format is required to align with

federal law that mandates use of the HIPAA 5010 format as of January 1, 2012. In addition, the timing of required data submissions for MA plans will change from quarterly to a more frequent schedule to accommodate the increase in volume of data and more complex editing and reporting. MA plans will be required to enter into new EDI agreements with the Encounter Data Front-end System, in addition to the EDI agreements already present in the Front-end Risk Adjustment System (FERAS).

To mitigate risk, CMS will maintain parallel systems and continue running the current RAS until testing of the EDPS is 100 percent complete. CMS will provide outreach and education to assist the industry in its transition to the new process. CMS will capture industry feedback throughout the design and implementation phase of the EDPS. CMS will host 13 workgroup sessions. These sessions will allow the industry to participate in knowledge sharing and problem solving as CMS identifies best practices in the areas of third party submission, chart reviews and audits, capitated and staff model plans, PACE organizations, and the editing and storing of data. In addition, CMS will host industry-wide meetings to provide updates throughout 2011on its progress of implementing EDPS. CMS will also be preparing quarterly newsletters for the industry to provide updates and new information.

# *§1876 Cost HMO/Competitive Medical Plan (CMP) and §1833 Health Care Pre-Payment Plan (HCPP) Diagnostic and Encounter Data Submission*

In a memorandum dated September 30, 2004, we notified §1876 Cost contracting HMOs/CMPs that they were required to submit diagnostic data (medical and drug-related) for dates of service after July 1, 2004. We informed HMOs/CMPs that we would provide payment for the full reasonable cost for gathering and transmitting such data to CMS, consistent with 42 CFR 417.550 et seq.

As indicated elsewhere in this notice, we will begin collecting encounter data in 2012.

While our authority to collect encounter data from MA organizations derives from the authority in §1853(a)(3)(B) to collect encounter data for purposes of risk adjustment, we are requiring §1876 Cost HMOs/CMPs and §1833 HCPPs to submit such data under our authority in §1876(h)(3), §1833(a)(1)(A) and §1861(v) to determine "reasonable costs." Specifically, in the case of HMOs/CMS, we are requiring the submission of encounter data under our authority in 42 C.F.R. §417.568(b)(1) to require submission of "adequate cost and statistical data. . . that can be verified by qualified auditors," and 42 C.F.R. §427.576(b)(2)(iii) to require "[a]ny other information required by CMS" for purposes of final settlement of payment amounts due. In the case of HCPPs under our authority in 42 C.F.R. §417.806(c) to access "records of the HCPP... that pertain to the determination of amounts payable for covered Part B services furnished its Medicare enrollees and 42 C.F.R. §417.871(b)(2)(iii) to require "other data as specified by CMS" for purposes of final settlement of payment amounts due. Data reflecting encounters will assist us in verifying the accuracy and validity of the costs claimed on cost reports.

We will require Cost plans to continue submitting diagnostic data and to begin submitting encounter data in a manner consistent with the risk mitigation strategy we will follow for MA plans. Thus, while both systems (diagnostic and encounter data) are in operation, we will provide payment for the full reasonable cost for gathering and transmitting such data to CMS under both systems, consistent with 42 CFR 417.550 et seq. Once we transition solely to encounter data, we will provide payment for the full reasonable cost solely of encounter data.

In addition to assisting us in verifying the accuracy and validity of cost reports, encounter data from HCPPs will assist us in calibrating the Part C and Part D risk adjustment models. In addition, in the absence of encounter data for HCPP enrollees, the risk scores for them under Part D would be inaccurate. Also, should HCPP enrollees later join a Part C plan, risk adjusted payments to that plan would also be inaccurate.

Therefore, beginning in 2012, we will reimburse HCPPs for the full reasonable cost for gathering and transmitting encounter data to CMS, consistent with 42 CFR 417.550 et seq., in order to mitigate the administrative burden of this requirement on them.

#### Section R. Risk Adjustment Processing System (RAPS) File Changes

On January 16, 2009, the U.S. Department of Health and Human Services (HHS) released the final rule (45 CFR Part 162) mandating that all entities covered by the Health Insurance Portability and Accountability Act (HIPAA) must implement medical coding sets using the International Classification of Diseases, Tenth Revision (ICD-10) on **October 1, 2013**.

In a related action released the same day, HHS mandated that transaction standards for all electronic health care claims must switch from the X12 standard version 4010/40101A to version 5010 by **January 1, 2012**. Among the changes in version 5010, it will now accommodate the use of the ICD-10 code sets, which are not supported in the current X12 version 4010/40101A.

Effective **January 1, 2012**, CMS is modifying the format of the RAPS file currently used in the risk adjustment data collection and storage process, to accommodate the ICD-10 mandate.

Two changes will be made to the file. First, the Diagnosis field currently using the International Classification of Diseases, 9<sup>th</sup> Revision, Clinical Modification (ICD-9-CM), 5 character codes, will be changed to 7 character codes to accommodate the expanded ICD-10 clinical modification (CM) codes. Second, there will be a new field added to the RAPS file. This field will indicate which version of the diagnosis codes, revision 9 or revision 10, is stored in the diagnosis field. While the change from ICD-9 to ICD-10 will be a complete cutover on October 1, 2013, the

diagnosis type indicator is required to allow the processing of adjustments to previously submitted data.

CMS will provide further information regarding implementation of the updated RAPS file (formatting and requirements for testing and certification through our regular outreach and communication channels).

## Section S. Risk Adjustment Data Validation (RADV)

CMS will continue conducting contract-level Risk Adjustment Data Validation audits on Medicare Advantage (MA) organizations in 2012. To facilitate automated RADV audit activity, all MA organizations must have systems and telecommunications capabilities consistent with the following standards:

- Microsoft Internet Explorer (IE) 7.x or 8.x
- Configuration of security settings in Internet Explorer to:
  - Add the cms.radvcdat.com domain to the list of trusted sites
  - Prompt for file downloads
  - Enable native XMLHTTP support
  - Enable SSL 2.0 & 3.0 / TLS 1.0
  - Disable pop-up blocker for cms.radvcdat.com domain
- An active land-line telephone number

#### Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2012

#### Section A. Prospective Coverage Gap Discount Program (CGDP) Payments

#### Overview

Section 3301 of the Affordable Care Act (ACA) established the Coverage Gap Discount Program (CGDP) in contract year 2011. Under this program, pharmaceutical manufacturers generally provide an approximately 50% discount to non-low income subsidy eligible (non-LIS) beneficiaries receiving applicable (brand) drugs in the coverage gap phase of the Part D benefit. The discounts made available under this program are considered incurred costs and therefore, are applied towards each beneficiary's true out-of-pocket costs (TrOOP).

For additional information regarding this program, please see the May 21, 2010 HPMS memorandum entitled, "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Response to Summary Public Comments on the Draft Guidance."

#### Calculation Methodology for 2012 Prospective CGDP Payments

CMS will provide monthly prospective payments to Part D sponsors for the manufacturer discounts made available to their enrollees under the CGDP. These prospective CGDP payments will be determined based on the projections in each Part D sponsor's bid and their current enrollment. In Worksheet 6A of the Part D bids, "Gap Coverage," Part D sponsors will project the brand drug cost sharing amounts for 2012 for non-LIS beneficiaries in the coverage gap. The monthly prospective CGDP payment for each enrollee will be calculated by dividing the total projected non-LIS brand cost sharing amounts by the non-LIS enrollment projected in each sponsor's bid and multiplying the resulting quotient by 50%. Once the bids are finalized, the prospective CGDP payment amount for each plan will be made available to Part D sponsors on the Part C & D Bid and Premium Information page in the Health Plan Management System (HPMS).

CMS will determine the monthly prospective CGDP payments for each plan by multiplying the plan-specific prospective CGDP payment amount estimated in the Part D bid by the number of non-LIS beneficiaries enrolled in the Part D plan. We invite public comment on whether the calculation of the prospective coverage gap discount payment to Part D sponsors should be adjusted to account for fill fees. Please note that prospective CGDP payments will not be provided to EGWPs because these plans do not submit Part D bids. Program of the All Inclusive Care for the Elderly (PACE) organizations will also not receive prospective CGDP payments due to LIS enrollment in Dual Eligible PACE plans and the absence of beneficiary cost sharing in Medicare-only PACE plans.

#### Section B. Cost Sharing for Applicable Beneficiaries in the Coverage Gap

The Affordable Care Act, as enacted in section 3301 and amended by section 1101, phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit. This reduction in cost sharing begins 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 cost sharing reductions, 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.

Thus, in 2012, the coinsurance under basic prescription drug coverage for certain beneficiaries is reduced 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 86% or actuarially equivalent to an average expected payment of 86%. To be eligible for this reduced cost sharing, 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 86% coinsurance for non-applicable drugs in the coverage gap represents an increase in plan liability and a reduction in beneficiary cost sharing. Therefore, the 14% plan liability for non-applicable drugs in the coverage gap will not count toward TrOOP. Part D sponsors must account for this reduced cost sharing and increased plan liability when developing their Part D bids for contract year 2012. In 2012, there will be no reduction in cost sharing for applicable drugs purchased in the coverage gap with the exception of the manufacturer discounts from the coverage gap discount programs. Thus, there will be no change in plan liability for applicable drugs in the coverage gap in 2012.

#### Section C. Update of the Rx-HCC Model

The RxHCC risk adjustment model, which predicts plan liability, has separate segments for LIS and non-LIS, while the denominator across all segments is a uniform industry average. CMS anticipates that the impact of increased plan liability as a result of the cost sharing reduction for non-applicable (generic) drugs described in section B above will result in differential risk scores changes for LIS and non-LIS beneficiaries. This is because plan liability for non-LIS populations, relative to LIS populations, will likely increase as the reduction of non-applicable

drug cost sharing is only for non-LIS beneficiaries. Therefore, the RxHCC model will be recalibrated to factor in the impact of the new Medicare Part D benefit structure. Specifically, for non-LIS beneficiaries, CMS will calculate plan liability using data from the 2008 prescription drug event (PDE) records as follows:

 $(CPP - 0.8 \times GDCA) + (0.14 \times GDCB \text{ for non-applicable drugs in the gap})$ 

CPP refers to the aggregate amounts paid by Part D sponsors for covered Part D drugs under the defined standard benefit as reported on the "Covered D Plan Paid Amount" field on the PDE records. GDCA and GDCB refer to the gross drug costs incurred above and below the out-of-pocket threshold respectively as reported on the PDE records. The first term in the equation above reflects our current definition of plan liability: CPP minus the reinsurance subsidy provided by CMS for covered Part D drug costs in the catastrophic phase of the Part D benefit. The second term signifies the addition of a factor reflecting 14% of the gross drug costs for non-applicable drugs in the gap. While beneficiary behavioral changes in response to the cost sharing changes are unknown at this point, CMS will take into account changes in plan liability for non-applicable drugs that are purchased in the coverage gap in the RxHCC model for 2012.

When we recalibrated the RxHCC risk adjustment model for 2012, we also updated the denominator used across all segments of the RxHCC model from 2008 to 2009. The new denominator is \$1,107.82.

#### Section D. De Minimis Premium Policy

Under the Affordable Care Act (ACA) §3303(a), a PDP or MA-PD may volunteer to waive the portion of the monthly adjusted basic beneficiary premium that is a *de minimis* amount above the low-income benchmark for a subsidy eligible individual. CMS is prohibited from reassigning LIS members from plans who volunteer to waive the de minimis amount based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

The purpose of the *de minimis* premium policy is to permit LIS beneficiaries to remain enrolled in their current plans without paying a premium, even if the plan's premium exceeded the LIS benchmark by a de minimis amount. Because partial-subsidy-eligible beneficiaries pay more than a de minimis premium, and because non-LIS beneficiaries are not entitled to a waiver of premium under section 3303, Part D sponsors may not rely on the de minimis policy to waive any part of their Part D premiums for partial subsidy or non-LIS beneficiaries.

#### 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

contract year 2012. The risk sharing payments provided by CMS limit Part D sponsors' exposure to unexpected drug expenses. Establishing higher Part D risk percentages would increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS.

CMS has evaluated the risk sharing amounts provided by CMS for 2006 – 2009 to assess whether they have decreased or stabilized. A steady decline or stabilization in the Part D risk sharing amounts would suggest that Part D sponsors have significantly improved in their ability to predict Part D expenditures. However, CMS has found that risk sharing amounts continue to vary significantly for Part D sponsors. In addition, the aggregate risk sharing amount paid by CMS varies significantly from year to year. Therefore, CMS will apply no changes to the current risk percentages for contract year 2012. We will continue to evaluate the risk sharing amounts each year to determine if higher risk percentages should be applied for Part D risk sharing.

Thus, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2011. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2012. 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 2012.

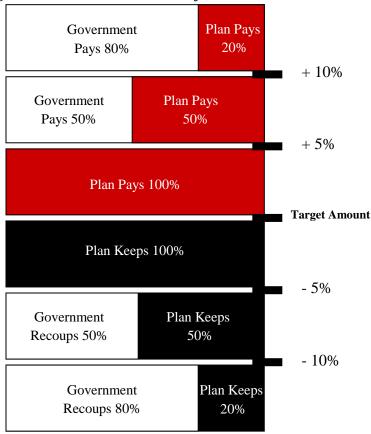


Figure 1. Part D Risk Corridors for 2012

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.

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 2012

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-ofpocket (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 3.34% for 2012 as summarized by Table III-1 below. This increase reflects the 2011 annual percentage trend of 4.67% as well as a

multiplicative update of -1.27% 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 3.34% from their 2011 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 0.98% for 2012 as summarized in Table III-1 below.

This increase reflects the 2011 annual percentage trend in CPI of 1.42%, as well as a multiplicative update of -0.43% 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% 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 is estimated based on 100% cost sharing in the deductible, 25% in the initial coverage phase, and in the coverage gap, 86% for non-applicable

(generic) drugs and 100% 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 Outof-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
	Annual		percentage
	percentage trend	Prior year	increase for
	for 2011	revisions	2011
Applied to all parameters but (1)	4.67%	-1.27%	3.34%
CPI (all items, U.S. city average): Applied to (1)	1.42%	-0.43%	0.98%

#### **Annual Percentage Increases**

# **Part D Benefit Parameters**

	2011	2012
Standard Benefit		
Deductible	\$310	\$320
Initial Coverage Limit	\$2,840	\$2,930
Out-of-Pocket Threshold	\$4,550	\$4,700
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable		
Beneficiaries (2)	\$6,447.50	\$6,657.50
Estimated Total Covered Part D Spending for Applicable Beneficiaries (3)	\$6,483.72	\$6,730.3
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	\$2.50	\$2.6
Other	\$6.30	\$6.50
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	\$0.00	\$0.00
Copayments for Institutionalized Beneficiaries (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	\$1.10
Generic/Preferred Multi-Source Drug (4)	\$3.30	\$3.30
Other (4)	\$0.00	\$0.00
Above Out-of-Pocket Threshold	<b>\$0.00</b>	¢0.0
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold	\$2.50	\$2.6
Generic/Preferred Multi-Source Drug	\$6.30	\$6.5
Other	φ0.50	φ0.50
Above Out-of-Pocket Threshold	\$0.00	\$0.00
Full Subsidy-Non-FBDE Individuals	φ0.00	\$0.0
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and		
resources $\leq$		
\$6,680 (individuals) or $\leq$ \$10,020 (couples) (5)(category code 1)		
Deductible	\$0.00	\$0.0
	\$0.00	\$ <b>0.</b> 0
Maximum Copayments up to Out-of-Pocket Threshold Generic/Preferred Multi-Source Drug	\$2.50	\$2.6
Other	\$2.30 \$6.30	\$6.5
Maximum Copayments above Out-of-Pocket Threshold		
	\$0.00	\$0.0
Partial Subsidy		
Applied and income below 150% FPL and resources below \$11,140 (individual) or		
\$22,260 (couple)(category code 4)	¢ (2,00	¢ < 7 0
Deductible	\$63.00	\$65.0
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold	**	** -
Generic/Preferred Multi-Source Drug	\$2.50	\$2.6
Other	\$6.30	\$6.5
Retiree Drug Subsidy Amounts		
Cost Threshold	\$310	\$320
Cost Limit	\$6,300	\$6,50

(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 therefore are not eligible for the coverage gap discount program (i.e. LIS beneficiaries), this is the amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if the beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage plans to the defined standard benefit, for the purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.

(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and therefore are eligible for the coverage gap discount program (i.e. non-LIS beneficiaries), this is the estimated average amount of total drug spending required to attain the out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage to the defined standard benefit, for purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.

(4) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2011 values of \$63.12, \$1.10, and \$3.31, respectively.

(5) The actual amount of resources allowable will be updated for contract year 2012.

# Attachment IV. Medicare Part D Benefit Parameters for the Defined Standard Benefit: Annual Adjustments for 2012

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2012, 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 \$310 in 2011 and rounded to the nearest multiple of \$5.

Initial Coverage Limit: From \$2,840 in 2011 and rounded to the nearest multiple of \$10.

**Out-of-Pocket Threshold:** From \$4,550 in 2011 and rounded to the nearest multiple of \$50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From \$2.50 per generic or preferred drug that is a multi-source drug, and \$6.30 for all other drugs in 2011, 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 \$2.50 per generic or preferred drug that is a multi-source drug, and \$6.30 for all other drugs in 2011, and rounded to the nearest multiple of \$0.05.
- **Deductible for Low Income (Partial) Subsidy Eligible Enrollees:** From \$63<sup>7</sup> in 2011 and rounded to the nearest \$1.
- Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From \$2.50 per generic or preferred drug that is a multisource drug, and \$6.30 for all other drugs in 2011, 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 2011<sup>8</sup>, and rounded to the nearest multiple of \$0.05 and \$0.10, respectively.

III. Calculation Methodology

## Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2012 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

 $<sup>^{7}</sup>$  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 2011 value of \$63.12.

<sup>&</sup>lt;sup>8</sup> Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2011 values of \$1.10 per generic or preferred drug that is a multi-source drug, and \$3.31 for all other drugs.

$$\frac{August 2010 - July 2011}{August 2009 - July 2010} = \frac{\$2,924.44}{\$2,793.88} = 1.0467$$

In the formula, the average per capita cost for August 2009 – July 2010 (\$2,793.88) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2010 – July 2011 (\$2,924.44) is calculated based on actual Part D PDE data incurred from August – December, 2010 and projected through July, 2011.

The 2012 benefit parameters reflect the 2011 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-2.

	Prior Estimates of	
	Annual Percentage	Revised Annual
Year	Increases	Percentage Increases
2007	6.48%	6.74%
2008	5.12%	5.36%
2009	4.42%	4.44%
2010	3.22%	3.07%
2011	4.63%	2.96%

 Table III-2. Revised Prior Years' Annual Percentage Increases

Accordingly, the 2012 benefit parameters reflect a multiplicative update of -1.27% for prior year revisions. In summary, the 2011 parameters outlined in section I are updated by 3.34% for 2012 as summarized by Table III-3.

Annual percentage trend for July 2011	4.67%
Prior year revisions	-1.27%
Annual percentage increase for 2012	3.34%

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

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

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2012, the September 2011 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 2011 CPI based on the projected amount included in the President's FY2012 Budget. The September 2010 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2012 is calculated as follows:

 $\frac{\text{ProjectedSeptember 2011CPI}}{\text{Actual September 2010 CPI}} \text{ or } \frac{221.550}{218.439} = 1.0142$ 

(Source: President's FY2012 Budget and Bureau of Labor Statistics, Department of Labor)

The 2012 benefit parameters reflect the 2011 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2010 annual percentage increase. The 2011 parameter update reflected an annual percentage trend in CPI of 1.58%. Based on the actual reported CPI for September 2010, the September 2010 CPI increase is now estimated to be 1.14%. Thus, the 2012 update reflects a multiplicative -0.43% correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 1.01% for 2012 as summarized by Table III-4.

#### Table III-4. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2011	1.42%
Prior year revisions	-0.43%
Annual percentage increase for 2011	1.01%

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

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

For 2012, the Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is \$6,730.39. The Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is calculated as the ICL plus 100% beneficiary cost sharing in the coverage gap divided by the weighted gap coinsurance factor. This value is calculated assuming 100% cost sharing in the deductible phase, 25% in the initial coverage phase, and in the coverage gap, 86% for non-applicable (generic) drugs and 100% for applicable (brand) drugs.

Total Covered Part D Spending at OOP Threshold for Applicable Beneficiaries is calculated for 2012 as follows:

 $ICL + \frac{100\% \text{ beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \qquad or \qquad \$2930 + \frac{\$3727.50}{98.082\%} = \$6,730.39$ 

where 100% of the beneficiary cost sharing in the gap is the estimated total drug spending in the gap assuming 100% coinsurance.

100% beneficiary cost sharing in the gap is calculated as follows for 2012:

OOP threshold – OOP costs up to the ICL or \$4,700 - \$972.50 = \$3,727.50

Weighted gap coinsurance factor is calculated for 2012 as follows:

(Brand GDCB % for non-LIS  $\times$ 100% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS  $\times$  86% cost sharing for non-applicable drugs) or (86.3%  $\times$  100%) + (13.7%  $\times$  86%) = 98.082%

where:

- 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 2010 PDE records;
- Gap cost sharing for applicable drugs is the coinsurance incurred by applicable beneficiaries for applicable (brand) drugs in 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 2010 PDE records; and
- Gap cost sharing for non-applicable drugs is the coinsurance incurred by applicable beneficiaries for non-applicable (generic) drugs in coverage gap.

### IV. 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 2010, and, as \$310 and \$6,300, respectively, for plans that end in 2011. For 2012, the cost threshold is \$320 and the cost limit is \$6,500.

# Attachment V. Preliminary ESRD, and Rx-HCC Risk Adjustment Factors

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# Table 1. Preliminary ESRD Model Continuing Enrollee Dialysis Relative Factors

	0.598
	0.598
	0.598
	0.606
	0.619
	0.686
	0.702
	0.717
	0.739
	0.745
	0.745
	0.745
	0.700
	0.589
	0.589
	0.589
	0.599
	0.609
	0.661
	0.686
	0.695
	0.736
	0.752
	0.752
	0.752
d, and Originally ESRD Interactions with Age and Sex	
	0.052
Age <65)	0.057
	0.065
ge <65)	0.033
	0.049
	0.045
	-0.062
	-0.045
Description Label	RelativeFactors
HIV/AIDS	0.171
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.077
	0.080
	0.251
	0.172
	0.106
	0.058
	0.031
	0.202
	0.087
	0.075
	0.037
	0.132
	0.004
•	0.201
5	0.085
	0.053
	0.053
	0.039
Inflammatory Bowel Disease	0.055
Bone/Joint/Muscle Infections/Necrosis	() ()6X
Bone/Joint/Muscle Infections/Necrosis Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.068
Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.075
	ed, and Originally ESRD Interactions with Age and Sex Age <65) ge <65)

Disease Group	Description Label	RelativeFactors
HCC51	Dementia With Complications	0.127
HCC52	Dementia Without Complication	0.060
HCC54	Drug/Alcohol Psychosis	-
HCC55	Drug/Alcohol Dependence	-
HCC57	Schizophrenia	0.136
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.084
HCC70	Quadriplegia	0.206
HCC71	Paraplegia	0.206
HCC72	Spinal Cord Disorders/Injuries	0.105
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	-
HCC74	Cerebral Palsy	0.068
HCC75	Polyneuropathy	0.056
HCC76	Muscular Dystrophy	-
HCC77	Multiple Sclerosis	0.069
HCC78	Parkinson's and Huntington's Diseases	0.055
HCC79	Seizure Disorders and Convulsions	0.069
HCC80	Coma, Brain Compression/Anoxic Damage	0.118
HCC82	Respirator Dependence/Tracheostomy Status	0.295
HCC83	Respiratory Arrest	0.114
HCC84	Cardio-Respiratory Failure and Shock	0.062
HCC85	Congestive Heart Failure	0.072
HCC86	Acute Myocardial Infarction	0.092
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.092
HCC88	Angina Pectoris	0.044
HCC96	Specified Heart Arrhythmias	0.071
HCC99	Cerebral Hemorrhage	0.077
HCC100	Ischemic or Unspecified Stroke	0.077
HCC103	Hemiplegia/Hemiparesis	0.076
HCC104	Monoplegia, Other Paralytic Syndromes	0.076
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.279
HCC107	Vascular Disease with Complications	0.084
HCC108	Vascular Disease	0.051
HCC110	Cystic Fibrosis	0.065
HCC111	Chronic Obstructive Pulmonary Disease	0.065
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.054
HCC114	Aspiration and Specified Bacterial Pneumonias	0.081
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.015
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	-
HCC124	Exudative Macular Degeneration	-
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.171
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.171
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.171
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.171
HCC161	Chronic Ulcer of Skin, Except Pressure	0.118
HCC162	Severe Skin Burn or Condition	0.049
HCC166	Severe Head Injury	0.118
HCC167	Major Head Injury	0.015
HCC169	Vertebral Fractures without Spinal Cord Injury	0.050
HCC170	Hip Fracture/Dislocation	0.040
HCC173	Traumatic Amputations and Complications	0.041
HCC176	Complications of Specified Implanted Device or Graft	-
HCC186	Major Organ Transplant or Replacement Status	0.159
HCC188	Artificial Openings for Feeding or Elimination	0.047
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.114
Disease Interactions		
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.100
CANCER_IMMUNE	Cancer*Immune Disorders	0.093
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.020
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.018
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.013

Disease Group	Description Label	RelativeFactors
NonAged (Age <65)/Diseas	e Interactions	
NONAGED_HCC6	NonAged, Opportunistic Infections	0.074
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.116
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.038
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.166
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.166
NONAGED_HCC110	NonAged, Cystic Fibrosis	0.369
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft	0.046

#### NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is \$75,564.91.

<sup>2</sup> Originally Disabled indicates beneficiary originally entered Medicare due to a condition other than ESRD.

<sup>3</sup> Originally ESRD indicates beneficiary originally entered Medicare due to ESRD. Beneficiaries that are Originally ESRD cannot be Originally Disabled.

The estimate for HCC 160 is based on pressure ulcer, any stage, for all anatomical sites codes. The estimated coefficient for HCC 160 is also assigned to HCCs 157, 158, and 159 in the constrained regression because the ICD9 codes for the stages of pressure ulcers are not implemented until FY09.

In the "disease interactions," the variables are defined as follows:

Sepsis = HCC 2. Cardiorespiratory Failure = HCCs 82-84. Cancer = HCCs 8-12. Immune Disorders = HCC 47. Diabetes = HCCs 17, 18, 19. Congestive Heart Failure = HCC 85. Chronic Obstructive Pulmonary Disease = HCCs 110-111.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.848	0.966	1.075	1.193
35-44 Years	0.848	0.966	1.075	1.193
45-54 Years	0.848	0.966	1.075	1.193
55-59 Years	0.883	1.001	1.110	1.228
60-64 Years	0.902	1.020	1.128	1.246
65-69 Years	1.021	1.120	1.248	1.347
70-74 Years	1.065	1.165	1.292	1.392
75-79 Years	1.123	1.222	1.350	1.449
80-84 Years	1.128	1.227	1.354	1.454
85 Years or Over	1.142	1.241	1.369	1.468
Male				
0-34 Years	0.735	0.842	0.957	1.065
35-44 Years	0.775	0.883	0.998	1.105
45-54 Years	0.811	0.919	1.034	1.141
55-59 Years	0.843	0.951	1.066	1.173
60-64 Years	0.867	0.975	1.090	1.197
65-69 Years	0.974	1.088	1.197	1.311
70-74 Years	1.030	1.144	1.253	1.367
75-79 Years	1.072	1.186	1.295	1.409
80-84 Years	1.105	1.219	1.327	1.441
85 Years or Over	1.120	1.234	1.342	1.456

#### Table 2. Preliminary ESRD Model Demographic Relative Factors for New Enrollees in Dialysis Status

#### NOTES:

1. The CMS ESRD Dialysis Denominator used to calculate the relative factors is \$75,564.91.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

#### Table 3. Preliminary ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries

	Beneficiaries	Kidney Transplant Actual Dollars	Kidney Transplant Relative Risk Factor
Month 1 Months 2 and 3	8,412 16,188	36,618.30 5,540.51	5.815 0.880
Total (Actual Months 1-3)		47,569.19	

#### NOTES:

1. Kidney transplant is identified by DRG 302 for discharge dates through September 30, 2007 and by MS-DRG 652 for discharge dates from October 1, 2007 on.

2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.

3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator)\*12. The CMS ESRD Dialysis Denominator value used was \$75,564.91.

#### SOURCE: RTI International analysis of 2006/2007 Medicare 100% ESRD sample claims and enrollment data.

# Table 4. Preliminary ESRD Model Functioning Graft Relative Factors for Community Population

Variable		<b>Relative Factor</b>
Functioning Graft Factors		
Aged 65+, with duration since tran		2.635
Aged <65, with duration since tran		2.582
Aged 65+, with duration since tran		1.268
Aged <65, with duration since tran	nsplant of 10 months or more	1.170
Female		
0-34 Years		0.198
35-44 Years		0.212
45-54 Years		0.274
55-59 Years		0.359
60-64 Years		0.416
65-69 Years		0.283
70-74 Years		0.346
75-79 Years		0.428
80-84 Years		0.517
85-89 Years		0.632
90-94 Years		0.755
90-94 Years 95 Years or Over		0.735
		0.775
Male		0.050
0-34 Years		0.079
35-44 Years		0.119
45-54 Years		0.165
55-59 Years		0.292
60-64 Years		0.332
65-69 Years		0.309
70-74 Years		0.378
75-79 Years		0.464
80-84 Years		0.565
85-89 Years		0.647
90-94 Years		0.776
95 Years or Over		0.963
	ed Interactions with Age and Sex	0.705
Medicaid_Female_Aged	eu interactions with Age and Sex	0.213
Medicaid_Female_NonAged (Age	~ <i>(</i> ( <b>5</b> )	0.213
	e < 05)	
Medicaid_Male_Aged		0.210
Medicaid_Male_NonAged (Age <		0.113
Originally Disabled Female Age	2265	0.244
	≥65 65	0.244
Originally Disabled_Female_Age Originally Disabled_Male_Age ≥0	≥265 65 Description Label	
Originally Disabled Female Age	65	0.171
Originally Disabled_Female_Age Originally Disabled_Male_Age ≥t Disease Group HCC1	65 Description Label HIV/AIDS	0.171  Relative Factor  0.492
Originally Disabled_Female_Age Originally Disabled_Male_Age ≥ℓ Disease Group HCC1 HCC2	65	0.171  Relative Factor 0.492 0.520
Originally Disabled Female Age Originally Disabled Male Age ≥t Disease Group HCC1 HCC2 HCC6	65	0.171 <b>Relative Factor</b> 0.492 0.520 0.557
Originally Disabled Female Age Originally Disabled Male Age ≥ Disease Group HCC1 HCC2 HCC6 HCC8	65	0.171 <b>Relative Factor</b> 0.492 0.520 0.557 2.425
Originally Disabled Female Age Originally Disabled Male Age ≥e Disease Group HCC1 HCC2 HCC6 HCC8 HCC9	65	0.171 <b>Relative Factor</b> 0.492 0.520 0.557 2.425 1.006
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10	65	0.171 Relative Factor 0.492 0.520 0.557 2.425 1.006 0.695
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC11	65	0.171 Relative Factor 0.492 0.520 0.557 2.425 1.006 0.695 0.330
Originally Disabled Female Age Originally Disabled Male Age ≥ Disease Group HCC1 HCC2 HCC6 HCC8 HCC9 HCC10 HCC10 HCC11 HCC12	65	0.171 Relative Factor 0.492 0.520 0.557 2.425 1.006 0.695 0.330 0.180
Originally Disabled Female Age Originally Disabled Male Age ≥e Disease Group HCC1 HCC2 HCC6 HCC8 HCC9 HCC10 HCC10 HCC11 HCC12 HCC17	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC13         HCC14	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC13         HCC14	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124
Originally Disabled Female Age         Originally Disabled Male Age ≥e         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC13         HCC19         HCC17         HCC18         HCC19         HCC12	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC17         HCC18         HCC19         HCC211	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC17         HCC18         HCC19         HCC21         HCC23	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC19         HCC17         HCC18         HCC21         HCC23         HCC23         HCC23	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC17         HCC18         HCC19         HCC21         HCC23	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240
Originally Disabled Female Age         Originally Disabled Male Age ≥         Disease Group         HCC1         HCC2         HCC6         HCC9         HCC10         HCC12         HCC19         HCC17         HCC18         HCC21         HCC23         HCC23         HCC23	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders           End-Stage Liver Disease	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240
Originally Disabled Female AgeOriginally Disabled Male Age $\geq d$ Disease GroupHCC1HCC2HCC6HCC9HCC10HCC11HCC12HCC17HCC18HCC19HCC21HCC23HCC27HCC28HCC29	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders           End-Stage Liver Disease           Cirrhosis of Liver	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240           1.003
Originally Disabled Female AgeOriginally Disabled Male Age $\geq$ Disease GroupHCC1HCC2HCC6HCC9HCC10HCC11HCC12HCC17HCC18HCC19HCC21HCC22HCC23HCC23HCC27HCC28HCC29HCC21HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC33	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders           End-Stage Liver Disease           Cirrhosis of Liver           Chronic Hepatitis           Intestinal Obstruction/Perforation	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240           1.003           0.425           0.313
Originally Disabled Female AgeOriginally Disabled Male Age $\geq$ Disease GroupHCC1HCC2HCC6HCC9HCC10HCC11HCC12HCC17HCC18HCC19HCC21HCC23HCC23HCC27HCC28HCC29HCC33HCC34	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders           End-Stage Liver Disease           Cirrhosis of Liver           Chronic Hepatitis           Intestinal Obstruction/Perforation           Chronic Pancreatitis	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240           1.003           0.425           0.313           0.337           0.257
Originally Disabled Female AgeOriginally Disabled Male Age $\geq$ Disease GroupHCC1HCC2HCC6HCC9HCC10HCC11HCC12HCC17HCC18HCC19HCC21HCC22HCC23HCC23HCC27HCC28HCC29HCC21HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC23HCC33	Description Label           HIV/AIDS           Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock           Opportunistic Infections           Metastatic Cancer and Acute Leukemia           Lung and Other Severe Cancers           Lymphoma and Other Cancers           Colorectal, Bladder, and Other Cancers           Breast, Prostate, and Other Cancers and Tumors           Diabetes with Acute Complications           Diabetes with Chronic Complications           Diabetes without Complication           Protein-Calorie Malnutrition           Morbid Obesity           Other Significant Endocrine and Metabolic Disorders           End-Stage Liver Disease           Cirrhosis of Liver           Chronic Hepatitis           Intestinal Obstruction/Perforation	0.171           Relative Factor           0.492           0.520           0.557           2.425           1.006           0.695           0.330           0.180           0.344           0.344           0.124           0.653           0.342           0.240           1.003           0.425           0.313

Disease Group	Description Label	Relative Factor
HCC46	Severe Hematological Disorders	1.078
HCC47	Disorders of Immunity	0.306
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.258
HCC51	Dementia With Complications	0.616
HCC52	Dementia Without Complication	0.343
HCC54 HCC55	Drug/Alcohol Psychosis Drug/Alcohol Dependence	0.358
HCC57	· ·	
HCC57 HCC58	Schizophrenia Major Depressive, Bipolar, and Paranoid Disorders	0.471
HCC70	Quadriplegia	1.075
HCC71	Paraplegia	0.868
HCC72	Spinal Cord Disorders/Injuries	0.441
НСС72	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	1.016
HCC74	Cerebral Palsy	0.036
HCC75	Polyneuropathy	0.281
HCC76	Muscular Dystrophy	0.460
HCC77	Multiple Sclerosis	0.482
HCC78	Parkinson's and Huntington's Diseases	0.555
HCC79	Seizure Disorders and Convulsions	0.252
HCC80	Coma, Brain Compression/Anoxic Damage	0.533
HCC82	Respirator Dependence/Tracheostomy Status	1.732
HCC83	Respiratory Arrest	0.769
HCC84	Cardio-Respiratory Failure and Shock	0.326
HCC85	Congestive Heart Failure	0.361
HCC86	Acute Myocardial Infarction	0.283
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.283
HCC88	Angina Pectoris	0.210
HCC96	Specified Heart Arrhythmias	0.276
HCC99	Cerebral Hemorrhage	0.371
HCC100	Ischemic or Unspecified Stroke	0.333
HCC103 HCC104	Hemiplegia/Hemiparesis	0.481
HCC104 HCC106	Monoplegia, Other Paralytic Syndromes Atherosclerosis of the Extremities with Ulceration or Gangrene	0.212
HCC100 HCC107	Vascular Disease with Complications	0.417
HCC108	Vascular Disease Vascular Disease	0.288
HCC110	Cystic Fibrosis	0.388
HCC111	Chronic Obstructive Pulmonary Disease	0.388
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.294
HCC114	Aspiration and Specified Bacterial Pneumonias	0.691
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.212
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.223
HCC124	Exudative Macular Degeneration	0.248
HCC134	Dialysis Status	_
HCC135	Acute Renal Failure	_
HCC136	Chronic Kidney Disease, Stage 5	—
HCC137	Chronic Kidney Disease, Severe (Stage 4)	—
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	—
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	
HCC140	Unspecified Renal Failure	
HCC141	Nephritis	
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	1.071
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.071
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	1.071
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	1.071
HCC161	Chronic Ulcer of Skin, Except Pressure	0.473
HCC162	Severe Skin Burn or Condition	0.458
HCC166	Severe Head Injury	0.533
HCC167 HCC169	Major Head Injury	0.141
HCC169 HCC170	Vertebral Fractures without Spinal Cord Injury Hip Fracture/Dislocation	0.441
HCC170 HCC173	Traumatic Amputations and Complications	0.363
HCC175	Complications of Specified Implanted Device or Graft	0.579
11001/0	Major Organ Transplant or Replacement Status	0.008
HCC186	Major Organ Transplant or Replacement Statue	

Disease Group	ease Group Description Label		
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.804	
Disease Interactions			
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.634	
CANCER_IMMUNE	Cancer*Immune Disorders	1.101	
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.237	
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.255	
CHF_RENAL	Congestive Heart Failure*Renal Disease		
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.420	
NonAged (Age <65)/Disease Interaction	Dns		
NONAGED_HCC6	NonAged, Opportunistic Infections	0.564	
NONAGED_HCC34	NonAged, Chronic Pancreatitis	0.757	
NONAGED_HCC46	NonAged, Severe Hematological Disorders	0.818	
NONAGED_HCC54	NonAged, Drug/Alcohol Psychosis	0.432	
NONAGED_HCC55	NonAged, Drug/Alcohol Dependence	0.147	
NONAGED_HCC110	NonAged, Cystic Fibrosis	2.397	
NONAGED_HCC176	NonAged, Complications of Specified Implanted Device or Graft		

#### NOTES:

1. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

3. The Denominator used to calculate the relative factors is \$8,034.71.

In the "disease interactions," the variables are defined as follows: Sepsis = HCC 2. Cardiorespiratory Failure = HCCs 82-84. Cancer = HCCs 8-12. Immune Disorders = HCC 47. Diabetes = HCCs 17, 18, 19. Congestive Heart Failure = HCC 85. Chronic Obstructive Pulmonary Disease = HCCs 110-111. Renal Disease = HCCs 134-141.

# Table 5. Preliminary ESRD Model Functioning Graft Relative Factors for Institutionalized Population

Variable		Relative Factor
Functioning Graft Factors		
Aged 65+, with duration since transplan	t of 4-9 months	2.635
Aged <65, with duration since transplan	t of 4-9 months	2.033
Aged 65+, with duration since transplan		1.268
Aged <65, with duration since transplan		1.170
Female		
0-34 Years		0.783
35-44 Years		0.723
45-54 Years		0.700
55-59 Years		0.805
60-64 Years		0.773
65-69 Years 70-74 Years		1.004
75-79 Years		0.874
80-84 Years		0.792
85-89 Years		0.699
90-94 Years		0.594
95 Years or Over		0.465
Male		
0-34 Years		0.994
35-44 Years		0.658
45-54 Years		0.687
55-59 Years 60-64 Years		0.814 0.877
65-69 Years		1.148
70-74 Years		1.140
75-79 Years		1.168
80-84 Years		1.104
85-89 Years		1.046
90-94 Years		0.928
95 Years or Over		0.842
Medicaid and Originally Disabled Int	eractions with Age and Sex	
Medicaid Originally Disabled Age ≥65		0.126
Originally Disabled_Age 203		
Disease Group	Description Label	Relative Factor
HCC1	HIV/AIDS	1.374
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.471
HCC6	Opportunistic Infections	0.541
HCC8	Metastatic Cancer and Acute Leukemia	0.928
HCC9	Lung and Other Severe Cancers	0.610
HCC10	Lymphoma and Other Cancers	0.363
HCC11 HCC12	Colorectal, Bladder, and Other Cancers Breast, Prostate, and Other Cancers and Tumors	0.255 0.165
HCC12 HCC17	Diabetes with Acute Complications	0.434
HCC18	Diabetes with Treate Compleations	0.434
HCC19	Diabetes without Complication	0.187
HCC21	Protein-Calorie Malnutrition	0.343
HCC22	Morbid Obesity	0.353
HCC23	Other Significant Endocrine and Metabolic Disorders	0.248
HCC27 HCC28	End-Stage Liver Disease Cirrhosis of Liver	0.637
HCC28 HCC29	Chronic Hepatitis	0.343
HCC33	Intestinal Obstruction/Perforation	0.343
HCC34	Chronic Pancreatitis	0.175
HCC35	Inflammatory Bowel Disease	0.250
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.386
HCC40 HCC46	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.222
	Severe Hematological Disorders	0.638

Disease Group	Description Label	Relative Factor
HCC47	Disorders of Immunity	0.436
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.197
HCC51	Dementia With Complications	
HCC52	Dementia Without Complication	
HCC54	Drug/Alcohol Psychosis	0.051
HCC55	Drug/Alcohol Dependence	0.051
HCC57	Schizophrenia	0.274
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.274
HCC70	Quadriplegia	0.497
HCC71	Paraplegia	0.497
HCC72	Spinal Cord Disorders/Injuries	0.191
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.294
HCC74 HCC75	Cerebral Palsy	0.256
	Polyneuropathy	
HCC76	Muscular Dystrophy	0.247
HCC77	Multiple Sclerosis	0.110
HCC78	Parkinson's and Huntington's Diseases	0.110
HCC79	Seizure Disorders and Convulsions Coma, Brain Compression/Anoxic Damage	0.173
HCC80		0.103
HCC82 HCC83	Respirator Dependence/Tracheostomy Status	1.567
	Respiratory Arrest	0.611
HCC84 HCC85	Cardio-Respiratory Failure and Shock Congestive Heart Failure	0.346
HCC85 HCC86	Acute Myocardial Infarction	0.226
HCC80 HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.394
HCC87 HCC88	0	0.394
НСС96	Angina Pectoris	0.300
HCC96 HCC99	Specified Heart Arrhythmias Cerebral Hemorrhage	0.227
HCC100	Ischemic or Unspecified Stroke	0.175
HCC103	Hemiplegia/Hemiparesis	0.173
HCC104	Monoplegia, Other Paralytic Syndromes	0.063
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	0.773
HCC107	Vascular Disease with Complications	0.257
HCC108	Vascular Disease	0.146
HCC110	Cystic Fibrosis	0.323
HCC111	Chronic Obstructive Pulmonary Disease	0.323
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.252
HCC114	Aspiration and Specified Bacterial Pneumonias	0.239
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.194
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.366
HCC124	Exudative Macular Degeneration	0.178
HCC134	Dialysis Status	
HCC135	Acute Renal Failure	
HCC136	Chronic Kidney Disease, Stage 5	
HCC137	Chronic Kidney Disease, Severe (Stage 4)	
HCC138	Chronic Kidney Disease, Moderate (Stage 3)	
HCC139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)	
HCC140	Unspecified Renal Failure	
HCC141	Nephritis	
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	0.284
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	0.284
HCC159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	0.284
HCC160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	0.284
HCC161	Chronic Ulcer of Skin, Except Pressure	0.226
HCC162	Severe Skin Burn or Condition	
HCC166	Severe Head Injury	0.103
HCC167	Major Head Injury	
HCC169	Vertebral Fractures without Spinal Cord Injury	0.179
HCC170	Hip Fracture/Dislocation	
HCC173	Traumatic Amputations and Complications	0.067
HCC176	Complications of Specified Implanted Device or Graft	0.668
HCC186	Major Organ Transplant or Replacement Status	0.203
HCC188	Artificial Openings for Feeding or Elimination	0.658

Disease Group	Description Label	Relative Factor
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.384
Disease Interactions		
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.159
CRFAIL_COPD	Cardiorespiratory Failure*Chronic Obstructive Pulmonary Disease	0.524
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	0.538
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	0.453
ARTIF_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	0.361
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.143
COPD_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	0.249
ASP_SPEC_BACT_PNEUM_PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	0.325
SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	0.387
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	0.187
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	0.220
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	0.303
NonAged (Age <65)/Disease Interactions		
NONAGED_HCC85	NonAged, Congestive Heart Failure	0.320
NONAGED_PRESSURE_ULCER	NonAged, Pressure Ulcer	0.421
NONAGED_HCC161	NonAged, Chronic Ulcer of the Skin, Except Pressure Ulcer	0.337
NONAGED_HCC39	NonAged, Bone/Joint Muscle Infections/Necrosis	0.624
NONAGED_HCC77	NonAged, Multiple Sclerosis	0.344
NONAGED_HCC6	NonAged, Opportunistic Infections	0.914

#### NOTES:

1. The coefficients estimated for this model are the Functioning Graft add-on factors for being in a month after the 3 months accounted for in the Transplant segment of the ESRD system. Early months post-transplant incur higher Medicare spending than later months. The model differentiates the six months, months 4-9, from months further from the transplant period.

2. Originally disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD.

3. The Denominator used to calculate the relative factors is \$8,034.71.

In the "Disease interactions" and "NonAged interactions," the variables are defined as follows:

Sepsis = HCC 2. Cardiorespiratory Failure = HCCs 82-84. Diabetes = HCCs 17, 18, 19. Congestive Heart Failure = HCC 85. Chronic Obstructive Pulmonary Disease = HCCs 110-111. Pressure Ulcer = HCCs 157-160. Artificial Openings for Feeding or Elimination = HCC 188. Aspiration and Specified Bacterial Pneumonias = HCC 114. Schizophrenia = HCC 57. Seizure Disorders and Convulsions = HCC 79. Chronic Ulcer of Skin, except Pressure = HCC 161. Bone/Joint/Muscle Infections/Necrosis = HCC 39. Multiple Sclerosis = HCC 77. Opportunistic Infections = HCC 6.

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	3.033	3.362	-	_
35-44 Years	3.180	3.509	-	_
45-54 Years	3.388	3.717	-	_
55-59 Years	3.554	3.883	_	_
60-64 Years	3.659	3.988	_	_
65 Years	3.133	3.644	3.753	4.263
66 Years	3.174	3.646	3.821	4.292
67 Years	3.210	3.682	3.857	4.328
68 Years	3.229	3.701	3.876	4.347
69 Years	3.256	3.727	3.902	4.373
70-74 Years	3.368	3.862	3.955	4.449
75-79 Years	3.571	3.994	4.130	4.553
80-84 Years	3.745	4.169	4.304	4.728
85-89 Years	3.908	4.332	4.467	4.891
90-94 Years	4.000	4.423	4.559	4.982
95 Years or Over	3.875	4.298	4.434	4.858
Male				
0-34 Years	2.824	3.241	_	-
35-44 Years	3.030	3.446	_	_
45-54 Years	3.212	3.628	_	-
55-59 Years	3.403	3.819	_	_
60-64 Years	3.533	3.950	_	-
65 Years	3.174	3.726	3.738	4.289
66 Years	3.232	3.783	3.751	4.302
67 Years	3.262	3.813	3.781	4.332
68 Years	3.290	3.842	3.809	4.361
69 Years	3.311	3.863	3.830	4.382
70-74 Years	3.449	4.000	3.965	4.515
75-79 Years	3.685	4.195	4.124	4.635
80-84 Years	3.904	4.414	4.343	4.853
85-89 Years	4.074	4.584	4.513	5.023
90-94 Years	4.249	4.759	4.688	5.198
95 Years or Over	4.315	4.826	4.754	5.265

 Table 6. Preliminary ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration

 Since Transplant of 4-9 Months

#### **NOTES:**

1. The table entries are derived from the Graft New Enrollee model. 2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

3. The Denominator used to calculate the relative factors is \$8,034.71.

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.621	1.951	_	_
35-44 Years	1.768	2.098	_	_
45-54 Years	1.976	2.306	_	_
55-59 Years	2.142	2.472	_	_
60-64 Years	2.247	2.577	_	_
65 Years	1.766	2.277	2.386	2.896
66 Years	1.808	2.279	2.454	2.925
67 Years	1.844	2.315	2.490	2.961
68 Years	1.862	2.334	2.509	2.980
69 Years	1.889	2.360	2.535	3.006
70-74 Years	2.001	2.495	2.588	3.082
75-79 Years	2.204	2.627	2.763	3.186
80-84 Years	2.378	2.802	2.938	3.361
85-89 Years	2.541	2.965	3.101	3.524
90-94 Years	2.633	3.056	3.192	3.615
95 Years or Over	2.508	2.931	3.067	3.491
Male				
0-34 Years	1.412	1.829	_	-
35-44 Years	1.618	2.035	_	-
45-54 Years	1.800	2.217	_	_
55-59 Years	1.991	2.408	_	_
60-64 Years	2.122	2.538	_	_
65 Years	1.807	2.359	2.371	2.922
66 Years	1.865	2.416	2.384	2.935
67 Years	1.895	2.446	2.414	2.965
68 Years	1.924	2.475	2.442	2.994
69 Years	1.944	2.496	2.463	3.015
70-74 Years	2.082	2.633	2.598	3.149
75-79 Years	2.318	2.829	2.757	3.268
80-84 Years	2.537	3.047	2.976	3.486
85-89 Years	2.707	3.217	3.146	3.657
90-94 Years	2.882	3.392	3.321	3.831
95 Years or Over	2.948	3.459	3.387	3.898

 Table 7. Preliminary ESRD Model Demographic Relative Factors for Functioning Graft New Enrollees Duration

 Since Transplant of 10 Months or More

#### **NOTES:**

1. The table entries are derived from the Graft New Enrollee model. 2. Originally Disabled terms refer to people originally entitled to Medicare for reasons of disability other than ESRD. In this model, Originally Disabled is defined only for beneficiaries age 65 and greater.

3. The Denominator used to calculate the relative factors is \$8,034.71.

#### Table 8. Preliminary list of Disease Hierarchies for the Revised ESRD Model

Hierarchical	If the Disease Group is Listed in this column	Then drop the HCC(s)
Condition		listed in this column
Category (HCC)		
	Hierarchical Condition Category (HCC) LABEL	
8	Metastatic Cancer and Acute Leukemia	9,10,11,12
9	Lung and Other Severe Cancers	10,11,12
10	Lymphoma and Other Cancers	11,12
11	Colorectal, Bladder, and Other Cancers	12
17	Diabetes with Acute Complications	18,19
18	Diabetes with Chronic Complications	19
27	End-Stage Liver Disease	28,29,80
28	Cirrhosis of Liver	29
46	Severe Hematological Disorders	48
51	Dementia With Complications	52
54	Drug/Alcohol Psychosis	55
57	Schizophrenia	58
70	Quadriplegia	71,72,103,104,169
71	Paraplegia	72,104,169
72	Spinal Cord Disorders/Injuries	169
82	Respirator Dependence/Tracheostomy Status	83,84
83	Respiratory Arrest	84
86	Acute Myocardial Infarction	87,88
87	Unstable Angina and Other Acute Ischemic Heart Disease	88
99	Cerebral Hemorrhage	100
103	Hemiplegia/Hemiparesis	104
106	Atherosclerosis of the Extremities with Ulceration or	
	Gangrene	107,108,161,189
107	Vascular Disease with Complications	108
110	Cystic Fibrosis	111,112
111	Chronic Obstructive Pulmonary Disease	112
114	Aspiration and Specified Bacterial Pneumonias	115
134	Dialysis Status	135,136,137,138,139,140,141
135	Acute Renal Failure	136,137,138,139,140,141
136	Chronic Kidney Disease, Stage 5	137,138,139,140,141
137	Chronic Kidney Disease, Severe (Stage 4)	138,139,140,141
138	Chronic Kidney Disease, Moderate (Stage 3)	139,140,141
139	Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or	
	Unspecified)	140,141
140	Unspecified Renal Failure	141
157	Pressure Ulcer of Skin with Necrosis Through to Muscle,	
	Tendon, or Bone	158,159,160,161
158	Pressure Ulcer of Skin with Full Thickness Skin Loss	159,160,161
159	Pressure Ulcer of Skin with Partial Thickness Skin Loss	160,161
160	Pressure Pre-Ulcer Skin Changes or Unspecified Stage	161
166	Severe Head Injury	80,167

#### **DISEASE HIERARCHIES**

**How Payments are Made with a Disease Hierarchy EXAMPLE:** If a beneficiary triggers HCCs 140 (Unspecified Renal Failure) and 141 (Nephritis), then HCC 141 will be dropped. In other words, payment will always be associated with the HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 140 rather than HCC 141.

Continuing Enrollee (CE) RxHCC Model Segments					gments	
		Community,	Community,	Community,	Community,	
		Non-Low	Non-Low	Low	Low	
		Income,	Income,	Income,	Income,	
Variable	Disease Group	Age>=65	Age<65	Age>=65	Age<65	Institutional
Female			n	n	1	
0-34 Years		-	0.260	-	0.397	1.525
35-44 Years		-	0.471	-	0.587	1.546
45-54 Years		-	0.579	-	0.659	1.461
55-59 Years	-	-	0.568	-	0.630	1.384
60-64 Years		-	0.570	-	0.606	1.331
65 Years		0.410	-	0.440	-	1.422
66 Years	_	0.410	-	0.440	-	1.422
67 Years	_	0.410	-	0.440	-	1.422
68 Years	_	0.410	-	0.440	-	1.422
69 Years	_	0.410	-	0.440	-	1.422
70-74 Years		0.406	-	0.430	-	1.343
75-79 Years		0.413	-	0.428	-	1.287
80-84 Years		0.423	-	0.423	-	1.234
85-89 Years		0.432	-	0.414	-	1.181
90-94 Years		0.430	-	0.391	-	1.110
95 Years or Over		0.405	-	0.322	-	0.965
Male						
0-34 Years		-	0.240	-	0.426	1.552
35-44 Years		-	0.395	-	0.552	1.512
45-54 Years		-	0.522	-	0.592	1.443
55-59 Years		-	0.517	-	0.560	1.350
60-64 Years		-	0.531	-	0.531	1.299
65 Years		0.416	-	0.360	-	1.360
66 Years		0.416	-	0.360	-	1.360
67 Years		0.416	-	0.360	-	1.360
68 Years		0.416	-	0.360	-	1.360
69 Years		0.416	-	0.360	-	1.360
70-74 Years		0.407	-	0.352	-	1.316
75-79 Years		0.398	-	0.347	-	1.274
80-84 Years		0.392	-	0.336	-	1.246
85-89 Years		0.394	-	0.336	-	1.225
90-94 Years		0.419	-	0.357	-	1.182
95 Years or Over		0.423	-	0.350	-	1.079
Originally Disabled Interactions with Sex	<u> </u>		•	•	•	
Originally Disabled		-	-	-	-	0.027
Originally Disabled_Female		0.070	-	0.100	-	-
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		0.021	-	0.089	-	-
Originally Disabled_Male_Age 65		-	-	-	-	-
Originally Disabled_Male_Age 66-69		-	-	-	-	-
Originally Disabled_Male_Age 70-74		-	-	-	-	-
Originally Disabled_Male_Age 75+		-	-	-	-	-

# Table 9. Preliminary RxHCC Model Relative Factors for Continuing Enrollees

		Community,		Community,		
		Non-Low	Non-Low	Low	Low	
		Income,	Income,	Income,	Income,	
Disease Coefficients	Description Label	Age>=65	Age<65	Age>=65	Age<65	Institutional
RXHCC1	HIV/AIDS	1.599	2.337	2.082	2.496	1.058
RXHCC5	Opportunistic Infections	0.118	0.130	0.082	0.176	0.083
RXHCC8	Chronic Myeloid Leukemia	1.651	2.073	2.059	2.329	1.037
RXHCC9	Multiple Myeloma and Other Neoplastic					
	Disorders	1.095	1.278	0.997	1.192	0.546
RXHCC10	Breast, Lung, and Other Cancers and					
	Tumors	0.206	0.209	0.233	0.249	0.101
RXHCC11	Prostate and Other Cancers and Tumors	0.039	0.052	0.114	0.062	0.082
RXHCC14	Diabetes with Complications	0.251	0.188	0.270	0.266	0.154
RXHCC15	Diabetes without Complication	0.175	0.152	0.209	0.218	0.110
RXHCC18	Diabetes Insipidus and Other Endocrine					
	and Metabolic Disorders	0.247	0.577	0.183	0.612	0.124
RXHCC19	Pituitary, Adrenal Gland, and Other					
	Endocrine and Metabolic Disorders	0.045	0.065	0.029	0.059	0.061
RXHCC20	Thyroid Disorders	0.038	0.095	0.045	0.102	0.037
RXHCC21	Morbid Obesity	0.042	0.016	0.045	0.048	0.067
RXHCC23	Disorders of Lipoid Metabolism	0.119	0.131	0.139	0.178	0.063
RXHCC25	Chronic Viral Hepatitis	0.077	0.041	0.216	0.109	0.005
RXHCC23	Chronic Vital Hepatitis	0.091	0.041	0.045	0.109	0.021
	Pancreatic Disorders and Intestinal	0.091	0.174	0.043	0.074	0.021
RXHCC31		0.034	0.075	0.024	0.074	0.021
RXHCC32	Malabsorption, Except Pancreatitis	0.034	0.073	0.034 0.186	0.074	0.021
	Inflammatory Bowel Disease	0.208	0.237	0.180	0.309	0.075
RXHCC33	Esophageal Reflux and Other Disorders of	0.126	0.114	0.150	0.170	0.074
DVIICC20	Esophagus	0.136	0.114	0.158	0.172	0.074
RXHCC38	Aseptic Necrosis of Bone	0.056	0.166	0.043	0.229	0.068
RXHCC40	Psoriatic Arthropathy	0.321	0.449	0.560	0.992	0.374
RXHCC41	Rheumatoid Arthritis and Other	0.450	0.044	0.400	0.000	0.005
	Inflammatory Polyarthropathy	0.172	0.264	0.193	0.383	0.095
RXHCC42	Systemic Lupus Erythematosus, Other					
	Connective Tissue Disorders, and	0.105	0.040	0.150	0.0(1	0.000
	Inflammatory Spondylopathies	0.125	0.249	0.158	0.261	0.086
RXHCC45	Osteoporosis, Vertebral and Pathological	0.000	0.160	0.100	0.170	0.000
	Fractures	0.093	0.162	0.123	0.178	0.028
RXHCC47	Sickle Cell Anemia	0.140	0.089	0.131	0.425	0.035
RXHCC48	Myelodysplastic Syndromes, Except High-	0.000	0.071	0.000	0.001	0.400
577776640	Grade	0.209	0.371	0.293	0.226	0.420
RXHCC49	Immune Disorders	0.151	0.255	0.128	0.271	0.142
RXHCC50	Aplastic Anemia and Other Significant	0.045	0.000	0.0.70	0.070	0.005
	Blood Disorders	0.045	0.089	0.058	0.072	0.035
RXHCC54	Alzheimer`s Disease	0.471	0.264	0.304	0.181	0.015
RXHCC55	Dementia, Except Alzheimer`s Disease	0.253	0.098	0.141	0.048	
RXHCC58	Schizophrenia	0.433	0.574	0.633	0.940	0.334
RXHCC59	Bipolar Disorders	0.364	0.442	0.419	0.664	0.287
RXHCC60	Major Depression	0.274	0.350	0.302	0.430	0.202
RXHCC61	Specified Anxiety, Personality, and					
	Behavior Disorders	0.163	0.224	0.215	0.430	0.172
RXHCC62	Depression	0.139	0.177	0.143	0.226	0.115
RXHCC63	Anxiety Disorders	0.057	0.127	0.086	0.179	0.115
RXHCC65	Autism	0.180	0.325	0.486	0.648	0.172
RXHCC66	Profound or Severe Mental					
	Retardation/Developmental Disability	0.028	0.325	0.486	0.393	—
RXHCC67	Moderate Mental					
	Retardation/Developmental Disability	0.028	0.173	0.396	0.288	—
RXHCC68	Mild or Unspecified Mental					
	Retardation/Developmental Disability	0.011	0.051	0.234	0.141	—
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral					
	Sclerosis and Other Motor Neuron Disease	0.185	0.306	0.156	0.308	0.059
RXHCC72	Spinal Cord Disorders	0.064	0.170	0.071	0.094	—
RXHCC74	Polyneuropathy	0.089	0.215	0.081	0.179	0.059
B URLAGE F	Multiple Sclerosis	0.448	0.796	0.485	1.313	0.121
RXHCC75		0.110				
RXHCC75 RXHCC76 RXHCC78	Parkinson's Disease Intractable Epilepsy	0.420	0.501	0.290	0.286 0.897	0.154

				Community,		
		Non-Low	Non-Low	Low	Low	
		Income,	Income,	Income,	Income,	
Disease Coefficients	Description Label	Age>=65	Age<65	Age>=65	Age<65	Institutional
RXHCC79	Epilepsy and Other Seizure Disorders,	0.221	0.000	0.166	0.262	0.077
	Except Intractable Epilepsy	0.221	0.269	0.166	0.363	0.077
RXHCC80	Convulsions	0.110	0.129	0.097	0.225	0.039
RXHCC81	Migraine Headaches	0.115	0.229	0.109	0.197	0.144
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.095	0.179	0.105	0.151	0.081
RXHCC86	Pulmonary Hypertension and Other	0.052	0.205	0.000	0.220	0.100
D.///0007	Pulmonary Heart Disease	0.253	0.395	0.286	0.338	0.122
RXHCC87	Congestive Heart Failure	0.177	0.091	0.242	0.106	0.098
RXHCC88	Hypertension	0.168	0.077	0.215	0.094	0.063
RXHCC89	Coronary Artery Disease	0.146	0.083	0.130	0.045	0.017
RXHCC93	Atrial Arrhythmias	0.062	0.046	0.022		0.013
RXHCC97	Cerebrovascular Disease, Except	0.045		0.040		
	Hemorrhage or Aneurysm	0.065		0.049		
RXHCC98	Spastic Hemiplegia	0.146	0.241	0.055	0.146	0.013
RXHCC100	Venous Thromboembolism	0.014	0.048		0.083	
RXHCC101	Peripheral Vascular Disease	0.057	0.030	0.091	0.063	—
RXHCC103	Cystic Fibrosis	0.199	0.692	0.219	1.320	0.114
RXHCC104	Chronic Obstructive Pulmonary Disease					
	and Asthma	0.199	0.125	0.217	0.200	0.114
RXHCC105	Pulmonary Fibrosis and Other Chronic					
	Lung Disorders	0.113	0.125	0.096	0.199	0.038
RXHCC106	Gram-Negative/Staphylococcus Pneumonia					
	and Other Lung Infections		0.079	—	0.042	0.027
RXHCC111	Diabetic Retinopathy	0.094	0.082	0.078	0.038	0.034
RXHCC113	Open-Angle Glaucoma	0.142	0.101	0.152	0.122	0.100
RXHCC120	Kidney Transplant Status	0.275	0.165	0.379	0.399	0.329
RXHCC121	Dialysis Status	0.220	0.295	0.278	0.526	0.211
RXHCC122	Chronic Kidney Disease Stage 5	0.118	0.138	0.128	0.164	0.108
RXHCC123	Chronic Kidney Disease Stage 4	0.118	0.138	0.128	0.164	0.108
RXHCC124	Chronic Kidney Disease Stage 3	0.100	0.138	0.113	0.164	0.080
RXHCC125	Chronic Kidney Disease Stage 1, 2, or					
	Unspecified	0.040	0.059	0.035	0.070	0.041
RXHCC126	Nephritis	0.040	0.034	0.035	0.068	0.013
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.042	0.060	0.027	0.060	
RXHCC145	Pemphigus	0.111	0.146	0.120	0.254	
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.186	0.202	0.284	0.124
RXHCC156	Narcolepsy and Cataplexy	0.274	0.344	0.161	0.432	0.102
RXHCC166	Lung Transplant Status	0.948	0.912	0.949	1.093	0.696
RXHCC167	Major Organ Transplant Status, Except					
	Lung, Kidney, and Pancreas	0.415	0.378	0.409	0.471	0.329
RXHCC168	Pancreas Transplant Status	0.275	0.165	0.379	0.345	0.329
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.074
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.382
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.238
NonAged_RXHCC60	Major Depression	-	-	-	-	0.112
NonAged_RXHCC61	Specified Anxiety, Personality, and					
_	Behavior Disorders	-	-	-	-	0.112
NonAged_RXHCC62	Depression	-	-	-	-	0.056
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.032
NonAged_RXHCC65	Autism	-	-	-	-	0.112
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.467
NonAged_RXHCC78	Intractable Epilepsy	_	-	_	_	0.199
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders,		1		ł	5.177
	Except Intractable Epilepsy	-	-	_	_	0.040
NonAged_RXHCC80	Convulsions	-	-	-	-	0.040
	0011101010	-	-	-	-	0.034

#### Note:

The relative risk scores in this table were calculated by dividing the parameter estimates by the Part D national average predicted expenditures (CMS Part D Denominator). The Part D Denominator value used was \$1,107.82. This Part D Denominator is based on the combined PDP and MA-PD populations, and it includes adjustments for new model diagnoses not yet submitted by the MA-PD population.

#### Source: RTI Analysis of 100% 2008 PDE, 2007 NCH, 2008 HPMS, 2008 CME, and 2007-2008 Denominator.

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	0.476	0.908	_	_
35-44 Years	0.793	1.225	-	
45-54 Years	1.061	1.493	-	
55-59 Years	1.124	1.556	_	-
60-64 Years	1.170	1.601	_	-
65 Years	0.755	1.187	1.151	1.583
66 Years	0.751	1.183	0.899	1.330
67 Years	0.751	1.183	0.899	1.330
68 Years	0.751	1.183	0.899	1.330
69 Years	0.751	1.183	0.899	1.330
70-74 Years	0.737	1.168	0.737	1.168
75-79 Years	0.674	1.106	0.674	1.106
80-84 Years	0.646	1.078	0.646	1.078
85-89 Years	0.566	0.997	0.566	0.997
90-94 Years	0.566	0.997	0.566	0.997
95 Years or Over	0.566	0.997	0.566	0.997
Male				
0-34 Years	0.322	0.754	-	-
35-44 Years	0.608	1.040	-	-
45-54 Years	0.874	1.306	-	-
55-59 Years	0.926	1.358	-	-
60-64 Years	1.013	1.445	-	
65 Years	0.771	1.203	1.020	1.451
66 Years	0.757	1.188	0.757	1.181
67 Years	0.757	1.188	0.757	1.188
68 Years	0.757	1.188	0.757	1.188
69 Years	0.757	1.188	0.757	1.188
70-74 Years	0.719	1.151	0.719	1.151
75-79 Years	0.638	1.070	0.638	1.070
80-84 Years	0.540	0.972	0.540	0.972
85-89 Years	0.462	0.894	0.462	0.894
90-94 Years	0.462	0.894	0.462	0.894
95 Years or Over	0.462	0.894	0.462	0.894

#### Table 10. Preliminary RxHCC Model Relative Factors for New Enrollees, Non-Low Income

#### NOTES:

1. The Part D Denominator used to calculate relative factors is \$1,107.82. 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 of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

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	0.875	1.413	-	-
35-44 Years	1.217	1.755	-	-
45-54 Years	1.253	1.792	-	-
55-59 Years	1.142	1.681	-	-
60-64 Years	1.116	1.654	-	-
65 Years	0.851	1.390	1.040	1.579
66 Years	0.587	1.126	0.742	1.280
67 Years	0.587	1.126	0.742	1.280
68 Years	0.587	1.126	0.742	1.280
69 Years	0.587	1.126	0.742	1.280
70-74 Years	0.598	1.137	0.753	1.291
75-79 Years	0.652	1.191	0.807	1.345
80-84 Years	0.684	1.222	0.839	1.377
85-89 Years	0.683	1.221	0.837	1.376
90-94 Years	0.683	1.221	0.837	1.376
95 Years or Over	0.683	1.221	0.837	1.376
Male				
0-34 Years	0.820	1.358	-	-
35-44 Years	1.093	1.632	_	-
45-54 Years	1.054	1.592	-	-
55-59 Years	0.914	1.452	-	-
60-64 Years	0.866	1.404	-	-
65 Years	0.674	1.212	0.772	1.311
66 Years	0.437	0.975	0.538	1.077
67 Years	0.437	0.975	0.538	1.077
68 Years	0.437	0.975	0.538	1.077
69 Years	0.437	0.975	0.538	1.077
70-74 Years	0.449	0.987	0.550	1.089
75-79 Years	0.477	1.016	0.477	1.016
80-84 Years	0.470	1.009	0.470	1.009
85-89 Years	0.507	1.045	0.507	1.045
90-94 Years	0.507	1.045	0.507	1.045
95 Years or Over	0.507	1.045	0.507	1.045

#### Table 11. Preliminary RxHCC Model Relative Factors for New Enrollees, Low Income

#### NOTES:

1. The Part D Denominator used to calculate relative factors is \$1,107.82. 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 of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

Variable	Baseline –	Concurrently
Variable	Not Concurrently ESRD	ESRD
Female		
0-34 Years	2.095	2.326
35-44 Years	2.095	2.326
45-54 Years	2.012	2.243
55-59 Years	1.975	2.205
60-64 Years	1.917	2.148
65 Years	1.988	2.218
66 Years	1.783	2.013
67 Years	1.783	2.013
68 Years	1.783	2.013
69 Years	1.783	2.013
70-74 Years	1.616	1.846
75-79 Years	1.551	1.781
80-84 Years	1.378	1.609
85-89 Years	1.214	1.445
90-94 Years	1.214	1.445
95 Years or Over	1.214	1.445
Male		
0-34 Years	2.118	2.348
35-44 Years	2.118	2.348
45-54 Years	2.059	2.289
55-59 Years	1.938	2.169
60-64 Years	1.792	2.023
65 Years	1.790	2.020
66 Years	1.683	1.914
67 Years	1.683	1.914
68 Years	1.683	1.914
69 Years	1.683	1.914
70-74 Years	1.573	1.804
75-79 Years	1.539	1.769
80-84 Years	1.505	1.736
85-89 Years	1.293	1.523
90-94 Years	1.293	1.523
95 Years or Over	1.293	1.523

### Table 12. Preliminary RxHCC Model Relative Factors for New Enrollees, Institutional

#### **NOTES:**

1. The Part D Denominator used to calculate relative factors is \$1,107.82. 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 of ESRD status—dialysis (D), transplant (1, 2, 5, 6 or N), or post-graft (G, R or Y) in the payment year (2008 in the model calibration).3. The Part D New Enrollee Institutional sample does not have an Originally Disabled add-on (set to \$0 because of regression results).

Source: RTI Analysis of 100% 2008 PDE SAF, 2007-2008 HPMS, 2008 CME, and 2007-2008 Denominator.

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		

# Table 13. Preliminary list of Disease Hierarchies for the Revised RxHCC Model

SOURCE: RTI International.

# Attachment VI: 2012 Call Letter

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# How to Use This Call Letter

The 2012 Call Letter contains information on the Part C and Part D programs. Also, we indicate when certain sections apply to cost-reimbursed HMOs, PACE programs, and employer and union-sponsored group 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 and prescription drug plans. As part of this effort, CMS published a proposed regulation (4144-P) on November 22, 2010 that 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.

Since this year's final Call Letter will be released close to the expected final publication of the final rule (4144-F), the content is limited to clarification of current policy and operational guidance. However, requirements contained in the final rule may be included in this year's final Call Letter, even if they have not been included in this draft Call Letter. The Call Letter is divided into three sections: Program Updates, Improving Information Sharing & Transparency with Sponsors, and Improving the Beneficiary Experience. These three sections contain information about Part C and Part D. 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, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

Also note that this year some of the calendar items have dates that are earlier than for the 2011 contract year. This is as a result of the earlier Annual Enrollment Period (AEP) as compared to years past. Items with earlier due dates are indicated in the chart. Organizations and CMS need to work together to ensure contracting deadlines are met.

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 <u>Heather.Rudo@cms.hhs.gov</u> (Part C issues) and Julie Gover at <u>Julie.Gover2@cms.hhs.gov</u> (Part D issues).

# Section 1 - Program updates

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)					
<b>MA-PD</b> plans	ates listed under Part C include MA and s. The dates listed under Part D sponsors MA and cost-based plans offering a Part D	*Part C	*Part D sponsors	Cost	Date earlier than last year
January 4, 2011	Release of the 2012 MAO/MAPD/PDP/SAE Applications in the Health Plan management System (HPMS)	~	<b>√</b>	~	
January 5 & 12, 2011	Industry training on 2012 Applications	~	~	~	
February 24, 2011	2012 Applications are due to CMS	~	~	~	
March 2011	CMS releases guidance concerning updates to Parent Organization designations in HPMS	~	~	~	$\checkmark$
March 4, 2011	Initial Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010.	<b>√</b>		~	
March 25, 2011	Release of the 2012 Formulary Submission Module in HPMS	~	~		
March 25 2011	Release of the 2012 Medication Therapy Management Module (MTMP) in HPMS		~		
Early April 2011	CY 2012 OOPC estimates for each plan and an OOPC model will be made available to plan sponsors in SAS to download from the CMS website that will assist plans in meeting meaningful difference and total beneficiary cost requirements prior to bid submission.	✓ 	✓ 		
Early April 2011	Release additional guidance regarding potentially duplicative plans, low enrollment plans and benefits review standards for 2012 bid submission.	~	<b>√</b>		
TBD	Conference call with industry to discuss the 2012 Call Letter.	~	~	~	
Early April 2011	Information about renewal options for contract year 2012 (including HPMS crosswalk charts) will be provided to plans.	√	<b>√</b>		
April 4, 2011	2012 Final Call Letter released. Announce CY 2011 MA Capitation Rates and MA and Part D Payment Policies. (applies to Part C and Part D sponsors only)	~	×	✓	
April 4, 2011	2012 MTMP submission deadline		~		
April 8, 2011	Release of the 2012 Plan Creation, Plan Benefit Package (PBP), and Bid Pricing Tool (BPT) Software of HPMS.	✓	✓		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)					
MA-PD plan	ates listed under Part C include MA and s. The dates listed under Part D sponsors MA and cost-based plans offering a Part D	*Part C	*Part D sponsors	Cost	Date earlier than last year
April 15, 2011	Release of the 2012 PBP online Training Module	~	✓		
April 15, 2011	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released on March 25, 2011)	<ul> <li>✓</li> </ul>	✓	~	✓
April 18, 2011	2012 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT). Transition Attestations due to CMS ( <i>Part D</i> <i>sponsors only</i> )	~	×		
April 12-13, 2011	Medicare Advantage and Part D Spring Conference	~	~	~	~
April/May 2011	CMS contacts MAOs with low enrollment plans	~	~	~	
May 2011	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2012 will be available for all organizations. (Models containing significant revisions will be released for public comment prior to this date).	✓ 	✓ 		
May 2, 2011	Voluntary Non-Renewal. CMS strongly encourages MA and MA-PD plans to notify us of an intention to non-renew a county or counties for individuals, but continue the county for "800 series" EGWP members, by May 2, 2011.	<b>√</b>		~	
May 2, 2011	<i>Voluntary non-renewal</i> : CMS strongly encourages Part D sponsors to notify us of any type of service area reduction, or conversion to offering employer-only contracts by May 2, 2011, so that we can make the required changes in HPMS to facilitate sponsors' ability to correctly upload their bids in June.		~		
May 13, 2011	Release of the 2012 Bid Upload Functionality in HPMS	~	✓	~	
Late- May/June 2011	CMS sends eligibility determinations to applicants based on review of the 2012 applications for new contracts or service area expansions.	~	V	~	

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)					
<b>MA-PD</b> plans	ates listed under Part C include MA and s. The dates listed under Part D sponsors MA and cost-based plans offering a Part D	*Part C	*Part D sponsors	Cost	Date earlier than last year
Late May, 2011	Release of HITECH identifying information for MA EPs and MA-affiliated hospitals and for attestation of qualifying MA organizations not offering MA HMO plans in HPMS.	~	~	~	
Late Spring/Early Summer 2011	Update Medicare Marketing Guidelines for CY 2012.	~	<b>√</b>	<b>√</b>	
June 1, 2011	Final date to submit 2011 HITECH methodology for estimating portion of MA EP salary attributable to providing Part B services.	~	~	~	
June 3, 2011	Release of the 2010 DIR Submission Module in HPMS		~		
June 3, 2011	2012 MTMP Annual Review completed	~	~	~	
June 6, 2011	Release of the 2012 Marketing Module in HPMS	~	~	~	
June 6, 2011	Release of the 2012 Actuarial Certification Module in HPMS	~	~	~	
June 6, 2011	Deadline for submission of CY 2012 bids for all MA plans, MA-PD plans, PDPs, 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 2011 Medicare Options Compare to submit PBPs (11:59 p.m. PDT).	~	✓	~	
	Voluntary Non-Renewal. Deadline for MA, MA-PD p, PDPs and Cost-Based organizations to submit a contract non- renewal, service area reduction, or Plan Benefit Package (PBP) level non-renewal notice to CMS for CY 2012.				
June to Early September, 2011	CMS completes review and approval of 2012 bid data. Submit attestations, contracts, and final actuarial certifications.	×	V		

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)					
<b>MA-PD</b> plans	ates listed under Part C include MA and s. The dates listed under Part D sponsors MA and cost-based plans offering a Part D	*Part C	*Part D sponsors	Cost	Date earlier than last year
June 13, 2011	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.	~	~		
Late June, 2011	Release of the 2012 SB hardcopy Change Request Module) on HPMS.	~	~	~	
June 30, 2011	Final date to submit CY 2012 marketing materials for assured CMS' review and approval. NOTE: This date does not apply to CY 2012 file and use materials since these may be filed with the appropriate CMS regional office five calendar days prior to their use.	~	~	V	
Late June 2011	Non-Renewal. CMS to issue an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that have notified CMS they are non-renewing or reducing their service area.	~	~	~	
Late June 2011	Industry training on revised Medicare Marketing Guidelines and model documents.	~	~	~	
July1, 2011	Submission date for contracting MAOs (new and expanding) to provide CMS with a ratified contract with the State in order to operate a Medicaid dual eligible SNP for CY 2012.	~			
July 5, 2011	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the regional office for review.		<b>v</b>		
July 25, 2011	Submission deadline for agent/broker compensation structures due to CMS.	~	~	~	
Late July/Early August, 2011	Release of the 2012 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. Rebate reallocation period begins after release of the above amounts.	~	~	✓	×

	2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)				
MA-PD plans	ates listed under Part C include MA and s. The dates listed under Part D sponsors MA and cost-based plans offering a Part D	*Part C	*Part D sponsors	Cost	Date earlier than last year
Late July/Early August, 2011	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 Options Compare" and the <i>Medicare &amp; You</i> handbook. SBs must be submitted by this date to be assured of being included.			✓	
August 1, 2011	Plans are expected to submit model Low Income Subsidy (LIS) riders to the regional office for review.		~		
Mid – August, 2011	CMS will release model final beneficiary notification letters.				~
August 25 – August 29, 2011	If applicable, plans preview the 2012 <i>Medicare &amp; You</i> plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	~	~	~	✓ 
Late August 2011	Contracting Materials submitted to CMS	✓	~	~	
End of August/Early September 2011	Plan preview period of star ratings in HPMS	✓	V		
August 31 – September 2, 2011	First CY 2012 Medicare Plan Finder (MPF) Preview and (Out-of-Pocket Cost) OOPC Preview	~	~	~	~
September, 2011	CMS begins accepting plan correction requests upon contract approval.	~	~	~	
September 2, 2011	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2010 through June 30, 2011.	~		~	
September 13 - September16, 2011	Second CY 2012 Medicare Plan Finder (MPF) Preview and (Out-of-Pocket Cost) OOPC Preview	✓	~	~	~
Mid- September 2011	All 2012 contracts fully executed (signed by both parties: Part C/Part D sponsor and CMS)	√	✓	~	
Sept 15 – Sept 30, 2011	CMS mails the 2012 <i>Medicare &amp; You</i> handbook to Medicare beneficiaries.	~	✓	✓	✓ 

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)						
2011 *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 D sponsors	Cost	Date earlier than last year	
September 30, 2011	CY 2012 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. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request. Exception: Dual eligible SNPs that are fully integrated with the State must mail an ANOC with the SB for member receipt by September 30, 2011 and then send the EOC for member receipt by December 31, 2011. Dual eligible SNPs that send a combined, standardized ANOC/EOC for member receipt by September 30, 2011 are not required to send an SB to current members; however, the SB must be made available upon request. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies before this date to ensure receipt by members by September 30 <sup>th</sup> . Note: Plan sponsors must send the ANOC/EOC to enrollees for receipt by September 30th. No additional materials may be sent prior to the beginning of when marketing activities may begin on October 1.					

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)						
MA-PD plan	ates listed under Part C include MA and s. The dates listed under Part D sponsors MA and cost-based plans offering a Part D	*Part C	*Part D sponsors	Cost	Date earlier than last year	
October 1, 2011	Plans may begin CY 2012 marketing activities. Once an organization begins marketing CY 2012 plans, the organization must cease marketing CY 2011 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2011 materials upon request, conduct one-on-one sales appointments and process enrollment applications. Plans are required to include information in CY 2011 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2012. Last day for Part D sponsors to request plan benefit package (PBP) plan corrections via HPMS.	~		✓ 		
October 1, 2011	Deadline for cost-based, MA, and MA-PD organizations to request a plan correction to the plan benefit package (PBP). Deadline for cost-based, MA and MA-PD organizations to request of a SB hard copy change.	~		V		
October 3, 2011	Non-Renewal. The final beneficiary non- renewal notification letter must be a personalized letter and received by PDP, MA, MA-PD enrollees by October 3, 2011. PDP, MA, MA-PD organizations may not market to beneficiaries of non-renewing plans until after October 3, 2011.	✓ 	✓ 	✓		
October 6, 2011	Plan ratings go live on Medicare Plan Finder	~	~			
October 6, 2011	Tentative date for 2012 plan benefit data and plan drug beneit information to be displayed on Medicare Plan Finder (not applicable to EGWPs).	~	✓	~		
October 15, 2011	Part D sponsors must post PA and ST criteria on their websites for the 2012 contract year.		✓			

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)						
2011 *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 D sponsors	Cost	Date earlier than last year	
October 15, 2011	2012 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). Medicare Marketing Guidelines require that all plans mail a CY 2012 EOC to each new member no later than when they notify the new member of acceptance of enrollment. Organizations offering Part D must mail their Low Income Subsidy Rider (LIS) and abridged or comprehensive formularies with the EOC for new members. New members with an effective date of January 1, 2012 or later do not need to (but may) receive the ANOC portion of the standardized/combined ANOC/EOC.	~	~	•	~	
November 2, 2011	Cost-Based organizations must mail the personalized final beneficiary non-renewal notification in time to be received by enrollees by November 2, 2011.			✓		
November 11, 2011	Notices of Intent to Apply (NOIA) for CY 2013 due for MA, MA-PD, PDPs, and "800 series" EGWPS and Direct Contract EGWPs.	~	~	~		
November – December, 2011	Non-Renewal. CMS to issue "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, 2011	Medicare cost-based plans not offering Part D must send the combined ANOC/EOC for receipt by members by December 1, 2011.			~		
December 1, 2011	Non-Renewal. Cost-based plans must publish notice of non-renewal.			~		
December 7, 2011	Annual Coordinated Election Period Ends.	✓	~		✓	
December 31, 2011	Dual eligible SNPs that are fully integrated with the State and did not send an EOC with the ANOC by September 30, 2011, must send the EOC by December 31, 2011.	~				

2012 MA, MA-PD, Part D and Cost-Based Plan Calendar (All dates, unless identified as statutory, are subject to change)						
2011 *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 D sponsors	Cost	Date earlier than last year	
December 31, 2011	MAOs must disenroll members who enrolled prior to January 1, 2010, into a SNP that was previously designated as a "disproportionate share" SNP and who did not meet the special needs criteria as of December 31, 2009 and members who enrolled prior to January 1, 2010, into a C-SNP that no longer targeted the individual's chronic condition(s) as of January 1, 2010.	~				
2012						
January 1, 2012	Plan Benefit Period Begins.	~	~	~		
January 1 – February 14, 2012	MA Annual 45 Day Disenrollment Period (ADP).	~				
January 4, 2012	Release of CY 2013 MAO/MAPD/PDP/SAE/EGWP applications.	~	~	~		
Mid January, 2012	Industry training on CY 2013 applications.	~	~	~		
January 31, 2012	Final Submission deadline for risk adjustment data with dates of service January 1, 2010 through December 31, 2010	~		~		
February 23, 2012	Applications due for CY 2013.	~	<b>√</b>	~		
March 2, 2012	Initial Submission deadline for risk adjustment data with dates of service January 1, 2011 through December 31, 2011	~		~		
September 7, 2012	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2011 through June 30, 2012	✓		✓		

#### Part D Sponsor Bids and the Platino Program

When Part D sponsors seek to offer a plan in the Commonwealth of Puerto Rico as part of the Platino program, the Part D bids must reflect only basic benefits. Any supplemental benefits required by the Commonwealth (the Platino program's coverage of excluded drugs and/or costsharing buy-downs) should not be included as part of the plan sponsor's Part D bid. As discussed previously in our Call Letter for calendar year 2010, the supplemental benefits are negotiated between the Commonwealth and the Part D sponsor and are never part of the

Medicare Part D bid submitted to CMS. CMS does not evaluate nor approve the Commonwealth's benefits provided by the Platino program.

CMS will revise the Health Plan Management System's (HPMS) Plan Benefit Package to reflect submissions of bids specific to the Platino program for 2012. Plan sponsors will not be able to validate bids for enhanced plans that apply to Platino programs.

# Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for certain benefit coordination activities between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with such COB activities. For contract year 2011, the Part D COB user fee was decreased to \$1.17 per enrollee per year. In April 2011, CMS will implement the MARx Redesign and Modernization project which, among other changes, will enable daily enrollment transaction processing and reporting, multiple 4Rx spans within the beneficiary enrollment history, and reinstatement of erroneous disenrollments. These changes will significantly improve the timeliness and accuracy of information on beneficiary coverages. Some of the other functions financed through these fees include the operations of the TrOOP Facilitation Contractor (supporting real-time electronic E1, Nx and FIR transactions), the Coordination of Benefits Contractor (supporting exchange and collection of information on other insurance or liability coverages for Medicare beneficiaries, and the facilitation of information on coverage gap discount program Part D drug cost reimbursements. Our projection of the incremental on-going costs of related activities in 2012 indicates the Part D COB user fee must be increased to \$1.62 per enrollee per year for contract year 2012. The 2012 COB user fee will be collected at a monthly rate of \$0.18 for the first 9 months of the coverage year (for an annual rate of \$0.135 per enrollee per month) for a total user fee of \$1.62 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2012 bids. 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.

## **ESRD** Drugs

Effective January 1, 2011, the bundled prospective payment system (PPS) for renal dialysis services provided by an end-stage renal disease (ESRD) dialysis facility includes the limited number of oral equivalents of injectable drugs and biologics used in the treatment of ESRD that were formerly reimbursed under Part D. Therefore, sponsors are reminded that the costs related to these oral drugs with injectable equivalents must be excluded from the 2012 plan bids.

# Submission of Quality Improvement Projects (QIPs) and Chronic Care Improvement Programs

Each MA organization that offers one or more MA plan must, for each of those plans, have an ongoing Quality Improvement (QI) Program that meets the applicable requirements of 42 CFR §422.152. CMS will request, on an annual basis, that QIPs and CCIPs be submitted for purposes of ongoing quality improvement monitoring. To ensure that these projects are evaluated in a consistent manner, CMS will require all plans, including those that have been deemed by an accrediting organization, to submit the QIPs and CCIPs for CY2012 on the appropriate templates.

Guidance describing the QIP and CCIP templates, scoring methodology, benchmarks, and any CMS identified QIP and/or CCIP topics will be forthcoming. The guidance will also specify that in future years we anticipate that the project submission date may be earlier in the calendar year to allow sufficient time for CMS review.

# **Proposed Initiative to Promote Enrollment in Fully Integrated SNPs**

CMS is now considering an initiative to promote enrollment of dual eligible beneficiaries in fully integrated, high quality Special Needs Plans (SNPs). The initiative would test the impact of certain plan design flexibilities in the 2013 contract year. To qualify, SNPs would have to be an existing plan in the 2011 and 2012 plan years, be of high quality, and demonstrate that they offer a truly integrated product, e.g., a capitated contract for the full array of Medicaid services, including primary, acute, behavioral, and long term.

We are interested in comments on this proposed initiative, including specifically:

- What criteria should be used for a SNP to be considered "high quality?"
- What specific plan design flexibilities would promote improved care delivery and streamlined administration?
- What incentives (such as seamless enrollment transitions) would best promote plan participation in this initiative?
- What additional care coordination or beneficiary protection requirements would be appropriate for participating SNPs?

## All Dual Eligible SNPs Required to Contract with State Medicaid Agencies

As required by section 164 of MIPPA and revised by section 3205 of the Affordable Care Act, all Dual Eligible Special Needs Plans will be required to have contracts with the state Medicaid

agencies in the states within which they operate starting in Contract Year 2013. However, pursuant to section 3205 of the Affordable Care Act, existing D-SNPs that are not expanding their service areas can continue to operate without a state contract through December 31, 2012. The contract between the MA dual eligible SNP and the State Medicaid agency must document each entity's roles and responsibilities with regard to dual eligible individuals. The required elements of the contract are discussed in 42 CFR § 422.107.

• Proposed Contract Submission Requirements:

Effective for the CY 2013 MA Application, CMS is working to align the contract submission deadline with the MA Application deadline in late February so SNP approval can occur simultaneously with the MA contracting process. As such, CMS is considering an earlier contract submission date.

#### Involuntary Disenrollment of Ineligible or "Disproportionate Share" SNP Enrollees

As provided under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Special Needs Plans (SNPs) may only enroll individuals who meet the plan's specific eligibility criteria. They may no longer enroll and serve a "disproportionate share" of individuals who do not meet the targeted criteria or condition. Similarly, MIPPA limits enrollment in chronic care SNPs (C-SNPs) to individuals with certain chronic conditions, as specified by CMS. Rather than require MA organizations offering these SNPs to involuntarily disenroll these members as of December 31, 2009, because they did not meet the SNP's targeted criteria, CMS required the MAOs to allow these individuals to continue to be enrolled through 2011, in order to provide affected beneficiaries sufficient time to review and understand their options and to make another election. Details of current guidance can be found in a September 9, 2010, memorandum entitled "Transition Guidance for Non-Special Needs Enrollees in MA Special Needs Plans (SNPs) beyond January 1, 2010." Additionally, the requirement to disenroll individuals who do not meet SNPs' targeted criteria does not apply to enrollees who are in a designated grace period after losing special needs status. These individuals, however, will have to be disenrolled at the end of their grace period in accordance with existing CMS policy.

SNPs that include members who enrolled under the two circumstances described above will be required to disenroll those individuals if they do not request enrollment in a different plan prior to January 1, 2012. In order to facilitate this process, MAOs offering SNPs will be required to provide their CMS account manager with information regarding the total number of non-special needs individuals enrolled in these SNPs as of January 1, 2010. The deadline for providing this information to CMS is June 30, 2011. This accounting will assist MAOs with notifying and disenrolling these individuals for the 2012 plan benefit year. MAOs must notify each individual on or before October 1, 2011, that he/she will be disenrolled effective January 1, 2012, and will need to enroll in another plan prior to that date if he/she wants MA coverage for 2012. MAOs

will not be permitted to transition these current enrollees into other non-SNP MA plans offered by the organization, but are permitted to market other plans to these individuals, consistent with Medicare Marketing Guidelines. CMS will provide a model beneficiary disenrollment notice as part of the annual non-renewal and service area reduction guidance. MAOs must retain any of these enrollees whose circumstances change and who attain special needs status prior to CY 2012.

Enrollees who lose special needs status in 2011 must be notified and disenrolled, if necessary, in accordance with the requirements in section 50.2.5 of the MA Enrollment and Disenrollment Guidance.

## MAO and PDP Sponsor Renewal/Non-Renewal Options for CY 2012

In this Call Letter, we provide comprehensive guidance regarding the plan renewal and nonrenewal options available to MAOs and PDP sponsors for CY 2012. In addition, we clarify aspects of our non-renewal policies with respect to section 1876 cost contract plans.

As a result of business decisions, or pre- or post-bid discussions with CMS, MAOs and PDP sponsors may choose to change their current year offerings for the following contract year. Each year, current MAOs and PDP sponsors 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. MAOs and Part D 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 Appendices A-1, A-2, B-1 and B-2 of this Call Letter.

Overall, this renewal and non-renewal guidance is based on two underlying principles: (1) the maximization of beneficiary choice; and (2) the protection of enrollment choices beneficiaries have previously made. We believe that beneficiaries should have the opportunity to make active enrollment elections into Original Medicare, a 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 benefit packages offered in a service area are substantially different from others offered by the organization or sponsor in the same 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 2012.

Although many of the renewal options outlined in this guidance are permissible despite year-toyear 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 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. CMS is currently undergoing notice-and-comment rulemaking to implement this provision for CY 2012.

Appendices A-1, A-2, B-1 and B-2 outline all permissible renewal and non-renewal options for CY 2012 for MAOs and PDP sponsors including their method of effectuation, systems enrollment activities, enrollment procedures, and required beneficiary notifications. MAOs offering special needs plans (SNPs) should note the options for SNP transitions, such as those involving renewing SNPs with ineligible or "disproportionate share" members and other transitions potentially affected by State contracting efforts. 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 on May 13, 2011. Organizations and sponsors should note that we have eliminated some exceptions that were allowed in previous years and modified previous options available under the HPMS Plan Crosswalk based on our previously articulated principles. Organizations and sponsors should also be aware that an 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. **If a renewal or non-renewal scenario is not outlined in Appendices A-1, A-2, B-1, or B-2, it is not a permissible renewal option for CY 2012.** 

Each renewal and non-renewal option outlined in Appendices A-2 and 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. To ensure smooth year-to-year transitions, organizations and sponsors should communicate early with CMS staff and comply with all established deadlines. Organizations and sponsors will *not* be able to make changes to their HPMS Plan Crosswalks once bids are submitted to CMS in June 2011. 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 manual enrollment transactions must be completed both correctly and completely pursuant to instructions that CMS will release later this year.

#### Section 2 – IMPROVING INFORMATION sharing & transparency with sponsors

#### **Clarification of Parent Organization Information for MA Organizations and PDP Sponsors**

CMS is increasingly focused on the relationship between MA organizations and PDP sponsors and their parent organizations in our administration of the Part C and D programs. For example, CMS makes auto-enrollment and reassignment determinations by allocating enrollees among PDP sponsors' parent organizations, not among the sponsors themselves. Also, in certain situations, CMS will look to an MA organization's parent organization to make a determination concerning its qualification for quality bonus payments. Therefore, it is crucial that all MA organizations and PDP sponsors accurately report their parent organization status to CMS and keep such information up-to-date in CMS records.

CMS considers a parent organization to be the legal entity that owns a controlling interest in a PDP sponsor or MA organization (both referred to as "contracting organizations"). More specifically, for Part C and D reporting purposes, the parent organization is the "ultimate" parent, or the top entity in a hierarchy (which may include other parent organizations) of subsidiary organizations which is not itself a subsidiary of any corporation.

CMS is providing this clarification in part because there have been instances where contracting organizations have reported information concerning their immediate parent rather than their ultimate parent. Such inaccuracies create the risk that CMS makes incorrect program implementation determinations or conducts duplicative work.

CMS acknowledges that in fact many contracting organizations are not subsidiaries to a parent company. However, for purposes of program administration, CMS must have a parent organization name associated with each contracting organization. Therefore, when applicable, contracting organizations should identify themselves as their own "parent organization" in CMS records.

All contracting organizations are required to report parent organization information to CMS as part of their applications for qualification for a Medicare contract. CMS has also provided guidance through HPMS to organizations alerting them to their obligation to keep such information up-to-date in our records. As part of this effort, contracting organizations must pay special attention to the impact of changes of ownership among entities in their corporate ownership chain that may have an effect on the identity of the contracting organization's ultimate parent. Also, contracting organizations should always be prepared to provide the most conclusive documentation available to them of their relationship to their parent organization upon request from CMS. Such documentation may consist of financial statements, articles of incorporation, contracts, or filings with regulatory authorities.

Contracting organizations can view their parent organization assignments within the Basic Contract Management Module in HPMS. The parent organization assignment can be accessed using the following navigation path: Contract Management > Basic Contract Management > Select Contract Number > Plan Management Data. Parent organization data is also available in the General Information Report under Contract Reports and in the Plan Version of the Contract Information Data Extract. Contracting organizations do not have access rights to change the parent organization designation, but rather must report changes to CMS.

While CMS will continue to issue annual requests to contracting organizations to provide updates to CMS concerning the name of the parent organization, effective immediately, we are now requiring contracting organizations to proactively report all parent organization changes to CMS within 30 days of the effective date of such a change. All such change requests must be emailed to <u>drugbenefitimpl@cms.hhs.gov</u> with the subject line of "Parent Organization Update." Contracting organizations should include with the email supporting documentation, such as one or more of the items listed above. CMS may request additional supporting documentation, if necessary. Of note, due to character limitations, CMS will not necessarily agree to all minor changes, such as requests to expand abbreviations.

#### **Prescriber Identifiers**

This section provides guidance regarding how Part D sponsors handle prescriber identifiers on Part D claims and PDE records; the first section responds to questions we have received on how sponsors should currently handle identifiers for prescribers from jurisdictions other than U.S states and territories, where allowed under state law; the remaining sections concern permissible prescriber identifiers on Part D claims and PDE records in 2012 and 2013.

**Foreign Prescriber Identifers:** In an August 13, 2010 memorandum on the use of prescriber identifiers on Medicare Part D drug claims, we reiterated the CMS guidance that specifies that the NPI is intended to uniquely identify a health care provider in standard transactions, such as health care claims. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities use NPIs in standard transactions by the specified compliance dates. The NPI is the only health care provider identifier that covered entities may use to identify health care providers. Although HIPAA requires pharmacies to use the NPI on HIPPA standard transactions, we recognize that pharmacies cannot always obtain the prescriber NPI at the time of dispensing. Therefore, to ensure Part D enrollees do not experience service interruptions, CMS guidance permits Part D sponsors to accept alternative prescriber identifiers, such as DEA registration numbers or state license numbers. However, we clarified that it is our intention that whatever type of prescriber identifier (i.e., NPI, DEA number, unique provider identification number (UPIN) or state license number) is used, it must be a valid number.

After this guidance was issued, we received comments indicating that a number of States permit pharmacies to fill prescriptions written by foreign (i.e., non-U.S. - licensed) prescribers. We have been asked what prescriber identifier should be required on the Part D claim and submitted on the prescription drug event (PDE) record. If a prescription has been written by a foreign prescriber, the sponsor should require the use of the license number assigned by an appropriate licensing board in the foreign jurisdiction in which the prescriber practices/resides on the claim with the State license qualifier. We understand that the use of this qualifier is not inconsistent with the National Council for Prescription Drug Programs (NCPDP) data dictionary, which defines a State license number as a number assigned and required by a State Board or other State regulatory agency. In the absence of a reference to "U.S." in the NCPDP definition and given the Webster's dictionary definition of "state" as one of the territorial and political units constituting a federal government, we believe State license is the most appropriate qualifier to use for foreign prescribers.

**Permissible Prescriber Identifiers in 2012**: For 2012, CMS will continue to permit Part D sponsors to accept on Part D claims and report on the PDE records any one of the four currently acceptable types of prescriber identifiers; that is NPI, DEA number, UPIN or state license number. Whichever type of identifier is used, however, the identifier must be valid. We will likewise extend to non-standard format claims, such as paper claims submitted by Medicare beneficiaries, the requirement for a valid prescriber identifier to be on the Part D claim and reported on the PDE record. CMS will begin validating the format of all prescriber identifiers on PDEs that are coded as an NPI and will exclude from payment reconciliation PDEs with invalid NPIs. We will also be assessing each sponsor's performance regarding NPI use and validity and will be notifying plan sponsors of their performance level.

In 2012, we will also impose additional requirements on plan sponsors with regard to Part D claims for Schedule II drugs. We believe that resources are currently available to enable sponsors to buy or build appropriate internal controls to enforce the submission of valid prescriber identifiers from their network pharmacies for these drugs. We also believe that sponsors should ensure that their network pharmacies enforce state and federal laws concerning prescriber scope of practice with respect to authority to prescribe controlled substances. As a result, effective January 1, 2012 Part D sponsors will be required to confirm the validity of DEA numbers on Schedule II drug claims or map NPIs on these claims to the prescriber's DEA. In addition, sponsors will be required to confirm that the controlled substance is within the prescriber's scope of practice to prescribe. Plan sponsors may elect to comply with these requirements by engaging a commercial vendor that provides validation/mapping services or by executing a Memorandum of Understanding with the DEA to access the DEA's Controlled Substance Registration File.

**Permissible Prescriber Identifiers in 2013**: Finally, we are considering proposing a regulatory change that will limit acceptable prescriber identifiers on Part D claims and PDE records in 2013 to only the individual NPI. In other words, a prescription written by an individual prescriber

who did not acquire an individual NPI and disclose it to the pharmacy on the prescription or otherwise would not be filled under the Part D program. Since all practitioners who are authorized to prescribe Part D drugs under applicable state laws can acquire an individual NPI from CMS, we do not believe that this will present a significant barrier to access to Part D drugs for Medicare beneficiaries. Moreover, consistent use of a single validated identifier will enable CMS to provide better oversight over possible fraudulent activities.

#### **Supplemental Formulary File Submission**

The regulation at 42 CFR § 423.272(b)(2) requires that CMS review bids to ensure that the plan designs are not likely to substantially discourage enrollment by certain Part D eligible individuals. Part D sponsors offering partial tier gap coverage, free first fill coverage, home infusion bundling under Part C, coverage of excluded drugs, or coverage of over-the-counter (OTC) drugs under utilization management programs must submit the corresponding required supplemental formulary file(s) as part of their bid submission so that CMS can assess whether or not the plan design meets the non-discrimination requirements as described under 42 CFR § 423.272(b)(2). We are requesting that these supplemental formulary files be submitted no later than June 13, 2011. Given the reduced time frame for review and approval of bids, CMS will not have sufficient information to fully evaluate whether a plan's benefit design meets the non-discrimination requiremental files in a timely manner. Therefore CMS will assume that if a sponsor does not submit the appropriate supplemental files by the June 13<sup>th</sup> deadline, then the sponsor does not intend to offer these supplemental benefits and will be asked to revise their bids accordingly. In addition these plans will be subject to a compliance action and will be at risk of having their bids disapproved.

## **Preventing Part D Payment for Hospice Drugs**

Hospice programs, as specified in section 1861(dd) of the Social Security Act and in Federal regulations at Part 418, must provide individuals under hospice care with drugs and biologicals related to the palliation and symptom management of the terminal illness as defined in the hospice plan of care. The only drugs covered by the hospice program are those used primarily for relief of pain and symptom control related to the individual's terminal illness. However, because hospice care is a Medicare Part A benefit, the drugs provided by the hospice and covered under the Medicare per-diem payment to the hospice program are not covered under Part D.

Our October 23, 2010 memorandum entitled, "Preventing Part D Payment for Hospice Drugs," incorrectly stated that all Part D sponsors currently do not have the ability to identify any Medicare enrollees who have elected hospice. In fact, CMS has been sending beneficiary-level hospice data to all Part D sponsors. These data are currently sent on the transaction reply report (TRR) at the time of the beneficiary's enrollment and subsequently whenever the hospice

information changes. As specified in the Plan Communications User Guide, the TRR includes a hospice indicator in position 54 and, in positions 85-96, a hospice start date and, if applicable, hospice termination date. The associated transaction reply codes are 071- Hospice status set and 72- Hospice status terminated. Sponsors need to ensure their claims processor is notified of an enrollee's hospice election and that processes are in place to prevent Part D payment for hospice drugs.

#### **Employer Group Waiver Plans and Application of the Manufacturer Discount**

CMS announced in a June 2, 2010 HPMS memorandum to all Part D sponsors that the value of supplemental benefits provided as part of a Part D enhanced benefit, including benefits negotiated between EGWP sponsors and employers, must be calculated prior to the application of the Medicare manufacturer coverage gap discount. Since CMS does not collect supplemental benefits information as part of the EGWP PBP, a Part D sponsor of EGWPs is required to attest, as part of its contract with CMS for CY 2011, that if the sponsor provides supplemental coverage via any of its enhanced benefit plans, it will apply the manufacturer coverage gap discount only after the plan's supplemental benefits have been applied. Sponsors are also required to attest to the accuracy of the discount amounts submitted on the prescription drug event (PDE) data and provide documentation, upon request, to CMS's third party administrator (TPA) when required.

CMS will be developing an information collection effort to ensure Part D EGWP sponsors have correctly applied the manufacturer discounts to covered Part D drugs. This information collection effort would require Part D sponsors submit the Part D supplemental benefits negotiated between employers and EGWPs. The information collected by CMS would be available in the event CMS received other indications that an EGWP was not compliant with the administration of the manufacturer discount. More information will be communicated to Part D sponsors regarding the information collection process, including any modifications to existing EGWP waivers, in upcoming memoranda.

## **Quality Reporting Requirements for Employer/Union-Only Direct Contracts**

Currently, Medicare Advantage (MA) contracts are required to collect and report to CMS quality measurement data from the Healthcare Effectiveness Data and Information Set (HEDIS), Medicare Health Outcome Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS). All stand-alone Prescription Drug Plans (PDPs) are required to collect and report CAHPS data to CMS. To date, the Employer/Union Only Direct contracts have been excluded from the quality reporting requirements. Beginning in 2012 all Employer/Union Only Direct contracts will be required to meet the same reporting requirements as MA or PDP contracts. For example, the Employer/Union Only Direct Private Fee-for-Service (PFFS) contracts will be required to collect and report HEDIS, HOS and CAHPS data to CMS. Employer/Union Only Direct MA contracts can see the HPMS memo "2011 HEDIS, HOS and

CAHPS Measures for Reporting on Medicare Advantage Organizations" dated November 4, 2010 as an example of the MA reporting requirements for 2011. Employer/Union Only Direct PDPs can view the CAHPS reporting requirements at <u>www.ma-pdpcahps.org</u>.

## **Improvements to Plan Ratings**

CMS is committed to continuing to improve the Part C and D quality performance measurement system to increase focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. To that end, CMS has been working on developing a more robust system to measure quality and performance of Part C and 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.

CMS views 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. As we add measures to the Plan Ratings over time, we will consider the following principles:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, CMS seeks to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS seeks to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Our strategy is to continue to adopt measures that are nationally endorsed and are in alignment with the private sector as we do today through the use of measures developed by the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), and the use of measures that are endorsed by the National Quality Forum (NQF).

As we modify the calculation approaches for the Plan Ratings, we are incorporating the following principles:

- Plans should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

Using the principles discussed above, CMS has identified a set of enhancements for the 2012 and 2013 Plan Ratings. For the 2012 Plan Ratings we are proposing to add the following measures to the existing set used in the 2011 Plan Ratings:

- All-Cause Readmission rates. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Advising Smoker and Tobacco Users to Quit. This information is collected through the CAHPS survey. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Body Mass Index. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Special Needs Plan (SNP)-specific measures. This would include the four rates included as part of the Care for Older Adults measure. These would only apply to contracts that have a SNP plan. (For more information about this measure, please see HEDIS® 2011 Technical Specifications, Volume 2.)
- Voluntary Disenrollment Rates. <u>www.cms.gov/PrescriptionDrugCovGenIn/06\_PerformanceData.asp</u> (see 2011 Display Measures – Technical Notes)
- One or more measures from the Hospital Inpatient Quality Reporting program (formerly known as Reporting Hospital Quality Data for Annual Payment Update). (See <a href="http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473">http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473</a> for a list of measures.) CMS is exploring whether the individual-level hospital data can be associated with individual MA contracts.
- Appropriate implementation of Part D transition processes by plans to ensure continuity of care for beneficiaries. Additional information on this measure will be provided as it becomes available.

 Part D Medication Adherence. This measure would use the proportion of days covered methodology as endorsed by the Pharmacy Quality Alliance. (Several potential adherence measures are currently posted on the display measures page at <u>http://www.cms.gov/PrescriptionDrugCovGenIn/06\_PerformanceData.asp#TopOfPage.</u>)

For SNP-specific measures, CMS is seeking comment on the feasibility of creating a methodology to incorporate SNP-specific measures into plan ratings, particularly in cases where CMS applies differential weighting to individual measures.

For all of the measures, CMS will be examining the quality of the data, variation among plans, and the measure's accuracy and validity. For example, for the all-cause readmission rate we will look at the quality of the data reported in June 2011 to make a final decision about whether this measure is incorporated into the 2012 plan ratings or the 2013 plan ratings. For those measures that are not proven to be reliable and valid, CMS will determine whether such measures may be appropriate "display measures", which would not be used in the plans' star ratings.

CMS is also considering using the same 4-star thresholds that were set for the 2011 Part C and D plan ratings. (See <u>http://www.cms.gov/PrescriptionDrugCovGenIn/06 PerformanceData.asp</u> for the current thresholds.) For the 2011 plan ratings, measures that were new or were not part of the plan ratings for at least two years did not receive a 4-star threshold. For 2012 and beyond, CMS will be setting 4-star thresholds for measures with at least a two year data history. For example, (through an HPMS memo) we will be providing sponsors with the 4-star thresholds for the following measure: availability of TTY/TDD services and foreign language interpretation and accuracy of information members get when they call the health plan.

Additional enhancements under consideration for the 2012 Part C and D plan ratings include:

- weighting of the measures to provide greater weight to clinical outcomes and lesser weight to process measures such as call center measures,
- controlling for the concentration of providers in a geographic area, such as a Health Professional Shortage Areas (HPSA),
- rewarding contracts for quality improvement, and
- reducing the overall and/or summary plan ratings for contracts with serious compliance issues.

For the 2013 Plan Ratings we are considering adding the following measures:

• Survey measures of care coordination, care transitions and patient activation. We are considering adding a set of survey items to the CAHPS survey that will be administered in 2012. We will let sponsors know the set of items through an HPMS memo once they are finalized.

- Case-mix adjusted mortality rates.
- Preventable hospitalizations.
- Serious Reportable Adverse Events, including Hospital Acquired Conditions. (See the Part C Reporting Requirements posted at <a href="https://www.cms.gov/HealthPlansGenInfo/16\_ReportingRequirements.asp">www.cms.gov/HealthPlansGenInfo/16\_ReportingRequirements.asp</a>.)
- Grievances. (See the Part C Requirements posted at <u>www.cms.gov/HealthPlansGenInfo/16\_ReportingRequirements.asp</u> and Part D Reporting Requirements posted at <u>http://www.cms.gov/PrescriptionDrugCovContra/08\_RxContracting\_ReportingOversight</u> <u>.asp#TopOfPage</u>.
- Use of highly rated hospitals by plan members. This will 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.
- Medication therapy management (MTM) measures related to comprehensive medication reviews.
- Evaluation of a contract's Chronic Care Improvement Program (CCIP) and Quality Improvement Project (QIP).

We will provide as much advance notice of these changes as possible, but sponsors are encouraged to take proactive steps to put in place quality assurance efforts in these areas in order to have a head start in effecting improved outcomes.

# Section 3 – improving beneficiary protections

## I. General

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

CMS has previously stated publicly 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. For example, in the preamble to our notice of proposed rulemaking published in the <u>Federal Register</u> on October 22, 2009, we stated that, "organizations and sponsors with less than 'good' ratings should expect to be the subject of our monitoring and compliance actions." We also made a similar statement in the 2009 Call Letter.

CMS cannot 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 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 over a significant period of time their obligation to meet program requirements and to be substantially out of compliance with their Medicare contracts. These organizations should 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.

#### **Special Election Period for Enrollment in 5-Star MA plans**

On November 19, 2010, in an HPMS memorandum entitled "Establishing a Special Election Period (SEP) to Enroll in 5-star Medicare Advantage Plans in Plan Year 2012," CMS announced the establishment of an SEP that will allow Medicare beneficiaries eligible for MA plans to enroll in 5-star MA plans at any point during the year. As indicated in the November 19 memorandum, we are providing additional guidance about the new SEP through this call letter, based on questions we have received since publication of the memorandum on the SEP. The general parameters of the SEP are as follows:

- For purposes of the SEP, an MA plan must have 5 stars as of the 2011 Annual Enrollment Period (AEP), regardless of the rating used for purposes of 2012 quality bonus payments.
- As currently constituted, the new SEP will apply only for purposes of enrolling in a 5-star MA plan; it will not permit an individual to enroll in 5-star stand-alone Part D, 1876, 1833 or any other Medicare health plan other than an MA plan. (See below for further information on this point.)
- Individuals will be eligible for this SEP only if they are either enrolled in MA plans with a star rating of 4.5 or less, or enrolled in Original Medicare and meet the MA eligibility requirements. Individuals already enrolled in 5-star MA plans are not eligible for the SEP.
- The SEP will begin on December 8, 2011, that is, the day after the end of the Fall 2011 AEP, which will be December 7. Enrollment requests made using this SEP will be effective the first of the month following the month the enrollment request is received. Once an individual enrolls in a 5-star MA plan, the individual's SEP ends for that plan year, and the individual will be limited to making changes only during other applicable election periods (e.g., annual enrollment period or another valid SEP). Individuals will be able to enroll in 5-star MA plans directly through the plan, or through 1-800-MEDICARE or Medicare.gov.

- MA plans that have received an overall 5-star rating will be required to accept these SEP requests, similar to any other SEP or initial enrollment for a newly eligible individual, unless the plan is closed per a CMS-approved capacity limit.
- The SEP is applicable only to those MA plans with an **overall** 5-star rating. The SEP is not available to enroll in a plan that does not have an overall 5-star rating, even if the plan receives 5 stars in some rating categories. While the SEP can be used by an individual who is enrolled in a plan with fewer than 5 stars to join a 5-star plan offered by the same organization, it cannot be used to enroll in other MA plans in the organization with less than a 5 star rating.
- Individuals enrolled in an MA-PD plan enrolling in a 5-star MA-only plan will be
  provided an SEP to join a stand-alone PDP, only if the MA-only plan is a Private Fee-forService (PFFS) plan. If the MA-only plan is not PFFS, the individual will forgo Part D
  coverage and may elect to enroll in a stand-alone PDP during a valid enrollment period.
  Individuals enrolled in Original Medicare will not be provided an additional SEP to
  enroll in Part D since enrollment in an MA-only plan will not affect their current standalone Part D drug coverage.
- CMS plans to create a new SEP indicator to be used for plan submitted enrollment transactions and to track the utilization of this SEP. Details on the new indicator will be included in a future CMS system release announcement later in 2011.

As noted above, the 5-star SEP at this point is designed to apply only to MA plans; however, we are considering whether the SEP should be expanded to also allow enrollment at any time into a 5-star PDP. We have already received some comments indicating that the SEP would provide added incentive for improved PDP performance and thus should be expanded to include PDPs. We welcome additional feedback on this issue. We anticipate releasing further guidance on the new SEP later this year in advance of the 2011 AEP.

## II. Part C

## **Benefit Design**

The guidance in this memorandum advances CMS' goals of establishing a more transparent and predictable process so that beneficiaries can select a plan that best meets their health care needs, while also being protected from high unexpected or discriminatory cost sharing. This memorandum provides policy guidance and sets forth cost sharing standards for CY 2012 for MAOs to use to evaluate their bids prior to submission in order to ensure that their plan offerings in the same area are meaningfully different from one another, are not significantly more costly to enrolled beneficiaries than they were in CY 2011 and have sufficient enrollment. Finally, the guidance includes clarifications of our benefits and cost sharing policies and instructions for proper CY 2012 Plan Benefits Package (PBP) preparation.

This guidance references our recently updated Chapter 4 of the Medicare Managed Care Manual (Benefits and Beneficiary Protections). Therefore, we recommend that MAOs and other Medicare health plans review Chapter 4 while designing their plans for CY 2012. Chapter 4 clarifies current Part C benefits policy and incorporates new policy topics in order to address issues that arose in prior bid seasons. Examples include: clarification of items and services that can be classified as supplemental benefits and multi-year benefits. The link to Chapter 4 is: <a href="http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf">http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf</a>

# **Duplicative Plans and Plans with Low Enrollment**

The large number of MA plan options that have been offered in many areas has made it difficult and confusing for beneficiaries to distinguish between these plans and to choose the best option to meet their needs. MAOs should not submit CY 2012 bids for plans that have insufficient enrollment and/or are not meaningfully different from their other plan offerings in the area. CMS discussed this issue in our CY 2010 Call Letter, worked with MAOs to improve beneficiary choice for CY 2010 and CY 2011 bid submissions, and addressed this in our April 15, 2010 final rule.

In 42 CFR § 422.254(a)(5) and 422.256(b)(4)(i), we specify that CMS reviews bids to ensure that an MAO's plans in a given service area are meaningfully different from one another in terms of key benefits or plan characteristics such as cost sharing, benefits offered, or plan type. Using our authority under section 1857(c)(2)(B) of the Act and 42 CFR §422.506(b)(1)(iv), CMS may non-renew plans that do not have sufficient enrollment after a specified length of time. CMS will address low enrollment and duplicative plans for CY 2012 with two separate processes, as described below.

The following guidance applies to non-employer MA plans, including Special Needs Plans (SNPs). Note: We reserve the right to review employer plans for low enrollment and/or meaningful difference in future years.

## A. Plans With Low Enrollment

During April or May 2011, CMS will send each MAO a list of low enrollment plans that have been in existence for three or more years but, as of April 2011, have fewer than 500 enrollees for non-SNP plans and 100 enrollees for SNP plans. The lists will not include low enrollment plans that CMS determines are located in service areas that do not have a sufficient number of competing options of the same plan type.

For each identified plan, MAOs must provide justification for low enrollment under the standards in the final rule or confirm through return email that the plan will be eliminated or consolidated with another of the organization's plans for CY 2012. If CMS does not find that

there is a unique or compelling reason for maintaining a plan with low enrollment, CMS will non-renew the plan. Instructions for how to submit business cases, the timeframe for submissions, and what information is required in those submissions will be included with the list of low enrollment plans sent to the MAO.

CMS recognizes there may be reasonable factors, such as specific populations served and geographic location, which lead to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because of their focus on a subset of enrollees with certain medical conditions. We will consider all such information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs are to follow the CY 2012 renewal/non-renewal guidance in this Call Letter to determine whether a low enrollment plan may be consolidated with another plan(s).

# B. Duplicative Plan Offerings

MAOs offering more than one plan in a given service area should ensure that beneficiaries can easily identify the differences between the plans and determine which plan provides the highest value at the lowest cost based on their needs. For CY 2012, CMS will use plan-specific out-of-pocket cost (OOPC) estimates to identify meaningful differences among similar plan types. OOPC estimates are based on a nationally representative cohort of more than 13,000 Medicare beneficiaries represented in the 2004 and 2005 Medicare Current Beneficiary Survey data and are used to provide estimated plan cost information to beneficiaries on Medicare Options Compare. Estimated out-of-pocket costs for each plan benefit package are calculated on the basis of utilization patterns for that cohort. The calculation includes Parts A, B, and D services and certain mandatory supplemental benefits, but not optional supplemental benefits. For purposes of evaluating meaningful differences among MA plans, CMS will exclude premiums from the OOPC calculation. Current enrollment and risk scores will not affect the OOPC calculation. A summary of the OOPC estimates is available at: <a href="http://www.medicare.gov/MPPF/Include/DataSection/OOPC/OOPCCalculations.asp?language=English">http://www.medicare.gov/MPPF/Include/DataSection/OOPC/OOPCCalculations.asp?language=English.</a>

MAOs will have access to CY 2011 OOPC estimates for each of their current plans and an OOPC model available in SAS from the CMS website. Instructions on how to download the files and a User Guide for the model will also be made available to MAOs. Organizations can use this information to develop CY 2012 plan bids that comply with CMS requirements. CMS will evaluate meaningful differences among non-employer plans offered by the same MAO, in the same county, as follows:

 Non-SNP plan offerings will be separated into five plan-type groups on a county basis: (1) HMO (2) HMOPOS; (3) Local PPO; (4) Regional PPO; and (5) PFFS. SNP plans will be further separated into groups representing the specific target populations served by the SNP. Chronic Care SNPS will be separated by the chronic disease served, Institutional SNPs will be separated into institutional-based SNPs and community-based SNPs, and Dual-Eligible SNPs will be separated by enrollment category: all dual, full dual, zero cost share, Medicaid subset, and fully integrated types. Please note that using different providers or serving different ethnic populations are not considered meaningfully different characteristics between two plans.

- 2. Plans within each plan-type group will be further divided into MA-only and MA-PD subgroups for evaluation. That is, the presence or absence of a Part D benefit is considered a meaningful difference.
- 3. The <u>combined</u> Part C and Part D OOPC estimate will be calculated for each plan within the plan-type groups and sorted from high to low. There must be a total OOPC difference of at least \$22.00 per member per month between each plan to be considered meaningfully different.

(Note: Employer plans are not included in this evaluation for CY 2012.)

CMS expects MAOs to submit CY 2012 plan bids that meet the meaningful difference requirements but will not prescribe how the MAOs should redesign benefits packages to achieve the differences. Since MAOs will have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission, CMS may not permit revised submissions if a plan's initial bid does not comply with meaningful difference requirements. Ultimately, plan bids that do not meet these requirements will not be approved by CMS. MAOs are to follow the CY 2012 renewal/non-renewal guidance in this Call Letter to determine if their plans may be consolidated with other plans.

## CY 2012 Cost Sharing Standards

# A. Maximum Out-of-Pocket (MOOP) Limits

CMS strives to ensure that MAOs develop more transparent plan benefit designs so that beneficiaries are better able to predict their out-of-pocket costs and also are protected from excessively high or unexpected cost sharing. As provided at 42 CFR § 422.100(f)(4), all local MA plans (employer and non-employer), including HMOs, HMOPOS, local PPO (LPPO) plans, special needs plans (SNPs) (including Dual-eligible SNPs), and PFFS plans must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which will be set annually by CMS.

In addition, as provided at 42 CFR § 422.100(f)(5), LPPO plans were required to have a "catastrophic" limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the dollar amount of which also will be set annually by CMS. All cost sharing (i.e., deductibles, coinsurance, and copayments) for Parts A and B services must be included in plans' MOOPs. The "catastrophic" maximum out-of-pocket limit is the term used in regulation (§

422.100(f)(5)) and is synonymous with "combined" maximum out-of-pocket limit used in the PBP and beneficiary marketing materials.

For CY 2012, we do not want to eliminate incentives for organizations to establish lower voluntary MOOP thresholds. Therefore, we will continue to allow MAOs the option of adopting lower, voluntary MOOP limits. MAOs that adopt voluntary MOOP amounts will have more flexibility in establishing cost-sharing amounts for Parts A and B services than those that do not elect the voluntary MOOP.

Like all other local MA plans, D-SNPs must establish a MOOP limit to provide this enrollee protection even though the State Medicaid program is usually paying those costs on the enrollee's behalf. Enrollees' eligibility for Medicaid may change during the year, leaving the enrollee liable for cost sharing. We strongly encourage D-SNPs to establish MOOP amounts that are greater than \$0 to protect the plan from full liability for the cost sharing amounts in the event that an enrollee's Medicaid coverage is discontinued for some period of time. However, adoption of a \$0 MOOP is permitted.

Second, although it may be rare that an enrollee of a D-SNP would be responsible for paying any cost sharing because the State Medicaid program is making those payments on his behalf, the PBPs for D-SNPs must reflect the plan's actual out-of-pocket cost sharing charges for covered services as well as a valid MOOP amount. Additionally, the plan must track each enrollee's cost sharing expenditures. The PBP will not be acceptable without entry of a valid MOOP amount.

For purposes of tracking out-of-pocket spending relative to its MOOP limit, a D-SNP must count only the enrollee's actual out-of-pocket spending. Thus, for any D-SNP enrollee, MA plans must count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package. Effectively, this means that D-SNP enrollees who are not responsible for paying the Medicare Parts A and B cost sharing will rarely reach the MOOP limit.

Since implementation of the Medicare Modernization Act of 2003, RPPOs have been required to establish a MOOP for in-network cost sharing and a catastrophic limit inclusive of both in- and out-of-network cost sharing for Parts A and B services; however, those amounts are at the discretion of MAOs offering RPPO plans. For CY 2011, RPPOs were permitted to establish their own in-network MOOP and catastrophic limits, but we encouraged them to adopt either the mandatory or voluntary MOOPs established by CMS.

We proposed in our November 22, 2010 Notice of Proposed Rulemaking (75 FR 71233) to require RPPOs to establish MOOP amounts that are consistent with the limits established each year by CMS. If this proposal is finalized, RPPOs would be required to establish both in-

network and catastrophic MOOP limits like LPPOs for CY 2012 consistent with the voluntary and mandatory MOOP levels established by CMS for all Parts A and B covered services.

The dollar amounts for the **mandatory**, **voluntary** and **catastrophic** MOOPs will be set annually by CMS.

**Mandatory MOOP** The amount CMS sets as the highest limit for enrolled beneficiary in-network cost sharing for Parts A and B services for the contract year.

**Voluntary MOOP** An amount lower than the CMS established mandatory MOOP. Plans may voluntarily adopt this lower limit in exchange for increased flexibility in establishing cost sharing amounts for Parts A and B services.

**Catastrophic MOOP** The amount CMS sets as the highest limit charged by LPPOs and if the proposal to extend the MOOP requirements to RPPOs in our November 22, 2010 proposed rule is finalized for RPPOs, for the combined in-and out-of-network cost sharing for Parts A and B services for the contract year. The catastrophic MOOP amount is calculated as 1.5 times the mandatory or voluntary MOOP amount, as applicable to the plan.

Plans are responsible for tracking enrolled beneficiaries' out-of-pocket spending and to alert them and plan providers when the spending limit is reached. As stated above, D-SNPs also must track enrollee cost sharing but should include only those amounts the enrollee is responsible for paying net of any State responsibility or exemption from cost sharing.

The chart below provides the CY 2012 mandatory MOOP amount that MA plans may not exceed, the voluntary MOOP amount that, if adopted, would result in less scrutiny of individual service category cost sharing, and the catastrophic MOOP amounts applicable to LPPOs and proposed for RPPOs (if the proposal to extend the MOOP requirements to RPPOs in our November 22, 2010 proposed rule is finalized).

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

CY 2012 Voluntary and Mandatory MOOP Amounts By Plan Type

\*Catastrophic MOOP is inclusive of in- and out-of-network Parts A and B services.

The MA MOOP amounts are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The mandatory MOOP amount represents approximately the 95<sup>th</sup> percentile of projected beneficiary out-of-pocket spending for CY 2012. Stated differently, 5 percent of Original Medicare beneficiaries are expected to incur \$6,700 or more in Parts A and B deductibles, copayments and coinsurance in CY 2012. The CY 2012 voluntary MOOP amount will be \$3,400. This level was established for CY 2012 because, consistent with established methodology, it represents approximately the 85<sup>th</sup> percentile of projected Original Medicare out-of-pocket costs.

We determined the catastrophic MOOP amounts applicable to LPPOs and proposed for RPPOs, by multiplying the respective MOOP amounts by 1.5 for the relevant year. Thus, the voluntary catastrophic MOOP amount for CY 2012 is calculated as  $3,400 \times 1.5 = 5,100$ . Similarly, the mandatory catastrophic MOOP amount for CY 2012 is calculated as  $6,700 \times 1.5 = 10,000$  (with rounding).

For further discussion on MOOP and how it is shown in D-SNPs' Summary of Benefits (SB), please refer to the section entitled "Changes to 2012 Summary of Benefits Regarding Dual Eligible SNP Cost Sharing" on page 105 of this Call Letter.

B. Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Affordable Care Act to deny bids that propose significant increases in cost sharing or decreases in benefits from one plan

year to the next. We note that we proposed to codify this authority in our November 22, 2010 proposed rule (75 FR 71200-71201) and may provide further guidance following the finalization of that rule.

For CY 2011, CMS established the Total Beneficiary Cost (TBC) metric as a means of evaluating changes in plan benefits from one year to the next, and whether such changes imposed significant increases in cost-sharing or decreases in benefits. TBC is the sum of plan-specific premium and estimated beneficiary out-of-pocket costs; the change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost-sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits. (See Section II; Duplicative Plans; B. Duplicative Plan Offerings of this draft call letter for additional information regarding estimated beneficiary out-of-pocket costs). By limiting the change in the TBC from one year to the next, CMS is able to ensure that beneficiaries are not exposed to significant cost increases from one plan year to the next. In CY 2012, for plans that include a Part B premium buy-down as part of their benefit package, the TBC calculation for that plan will include a factor to account for this additional benefit.

For CY 2011, CMS established TBC requirements for all non-employer plans that existed in CY 2010 and CY 2011 based on an outlier analysis that was conducted after bids were submitted, and negotiated with those plans that were identified as outliers. From CY 2010 to CY 2011, plan payment rates were frozen. Therefore, all plans were on a "level playing field" with respect to TBC.

For CY 2012, CMS will establish TBC requirements that will again apply to all non-employer MA plans that existed in 2011 and 2012, but also apply to plan consolidations into existing and new CY 2012 plans. CMS believes that the MA program is best served when MAOs provide their best package of benefits and premiums in their initial bid submission, and recognizes that MAOs need as much information about CMS' requirements in advance as possible in order to prepare their best initial bid. Therefore, CMS is considering two approaches with regard to establishing the TBC requirement for CY 2012. The first approach would be similar to the CY 2011 process, and include analyzing the distribution of TBC changes after bid submission and identifying outliers. CMS would notify those MAOs with outlier plans that they would need to re-submit an acceptable bid within a limited period of time for that bid to be considered for CY 2012.

Alternatively, CMS would establish an adjusted TBC change amount, based on historical data, and plan bids whose TBC was at or below this amount would not be subject to further scrutiny with respect to TBC. Bids with a TBC above the established amount would be subject to further scrutiny by CMS and MAOs might be required to resubmit these bids within a very limited time period. Under this approach, CMS would set the TBC change amount at approximately \$36 PMPM from CY 2011 to CY 2012. CMS believes this amount, which is an increase of about

10% in TBC between CY 2011 and CY 2012, represents a reasonable increase in TBC based on MA program changes for CY 2012, such as benchmarks and quality bonus payments. CMS would reserve the ability to adjust this amount following bid submission if the distribution of all bids increase program costs more than anticipated.

We note that, under either approach, plans would be required to apply a plan specific adjustment factor to account for geographic and quality bonus payment related changes in each plan's payment rates. For CY 2012, effective plan payment rates will change and quality bonus payments will be introduced; this was not the case for CY 2011. Therefore, an adjustment is needed to return the TBC to the "level playing field" that existed in CY 2011, when plan payment rates were frozen. CMS has determined that the projected change in rebate amount from CY 2011 to CY 2012 for a plan's CY 2011 service area will serve as this adjustment amount. CMS will calculate and provide to each plan the rebate adjustment factor will be applied to the plan's TBC calculation and then compared to the CMS requirement amount for TBC. We note that the adjustment factor will reflect changes in both MA payment rates and quality bonus payments.

CMS is soliciting comments regarding the two approaches discussed above, as well as the proposed TBC change amount discussed under the second option above. CMS may choose the first approach or the second approach using either the proposed adjusted TBC change amount or a different adjusted TBC change amount. CMS will provide guidance regarding the TBC analysis in the final Call Letter after consideration of public comments. CMS may also consider further rulemaking regarding the evaluation of significant increases in cost sharing or decreases in benefits.

As CMS has previously communicated, the amount of time available for review of CY 2012 bids and any required MAOs corrections has been reduced significantly due to the change in the dates for the Annual Coordinated Election Period. In an effort to ensure that plan bids comply with all applicable requirements, CMS intends to make as much data and information about bid requirements available in advance as possible in order to assist MAOs in calculating an acceptable bid. This material is expected to be available in mid-April.

## C. Discriminatory Cost Sharing Assessments

For CY 2012, CMS has established three benefit discrimination assessments for <u>all MA plans</u> (employer and non-employer):

- 1. Per Member Per Month (PMPM) Actuarially Equivalent (AE) Cost Sharing Maximums;
- 2. Service Category Cost Sharing Standards; and
- 3. Discriminatory Pattern Analysis.

The PMPM actuarial equivalent cost sharing maximums and service category cost sharing standards described below are provided in advance of the bid submission deadline with the expectation that all CY 2012 plan bids will conform to these standards when submitted on or before June 6, 2011. CMS will perform a discriminatory pattern analysis following bid submission to identify and resolve discriminatory benefit design elements not anticipated by the standards.

Also note that benefit design and cost sharing amounts approved for CY 2011 will not be automatically acceptable for CY 2012 because a separate and distinct review is conducted each contract year.

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

Total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Original Medicare on an actuarially equivalent basis. CMS will also apply this requirement separately to the following service categories for CY 2012: Inpatient Facility, Skilled Nursing Facility (SNF), Home Health; Durable Medical Equipment (DME), and Part B drugs.

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the Bid Pricing Tool (BPT).

Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column 1) is compared to Original Medicare actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For inpatient facility and SNF services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

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

	#1	#2	#3	#4	#5	#6	#7
BPT Benefit Category	PMPM Plan Cost Sharing (Parts A&B) (BPT Col. l)	Original Medicare Allowed (BPT Col. m)	Original Medicare AE Cost sharing (Part A only) (BPT Col. n)	Part B Adjustment. Factor to Incorporate Part B Cost Sharing (Based on FFS data)	Comparison Amount (#3 × #4)	Excess Cost Sharing (#1 – #5)	Pass /Fail
Inpatient	\$33.49	\$331.06	\$25.30	1.366	\$34.56	\$0.00	Pass
SNF	\$10.83	\$58.19	\$9.89	1.073	\$10.61	\$0.22	Fail
Home							TB
Health	TBD	TBD	TBD	TBD	TBD	TBD	D
DME	\$3.00	\$11.37	\$2.65	1.000	\$2.65	\$0.35	Fail
Part B-Rx	\$0.06	\$1.42	\$0.33	1.000	\$0.33	\$0.00	Pass

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

#### 2. Service Category Cost Sharing Standards

As provided under 42 CFR § 422.100(f)(6), we may specify service categories for which the cost sharing charged by MA plans may not exceed levels annually determined by CMS to be discriminatory. For purposes of setting cost sharing thresholds for Parts A and B services, CMS reviews the prior year's bid data, as well as actuarial equivalency relative to Original Medicare, in order to identify cost sharing requirements.

Similar to last year, CMS is focusing these standards on those Parts A and B services that are more likely to have a discriminatory impact on sicker beneficiaries. The standards are based on a combination of patient utilization scenarios and Original Medicare. The scenarios reflect factors such as hospital lengths of stay and the number of physician office visits generated by average-to-sicker patients. Some service categories have multiple utilization scenarios in an effort to ensure that plans will consistently distribute cost sharing amounts in a manner that does not discriminate.

We are continuing our current policy of offering MA plans the option to have greater flexibility in establishing Parts A and B cost sharing than is available for plans that adopt the mandatory MOOP by adopting a lower voluntary MOOP limit.

The chart below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local 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.

		Voluntary MOOP	Mandatory MOOP
Service Category	PBP Section B data entry field	Cost Sharing Limits	Cost Sharing Limits
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 <sup>1</sup>	2a	\$100/day	\$50/day
Skilled Nursing Facility – Days 21 through 100 <sup>1</sup>	2a	\$146/day	\$146/day
Home Health	6a	TBD	TBD
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 copay
Renal Dialysis	12	20% or \$30 co-pay	20% or \$30 co-pay
Part B Drugs-Chemotherapy <sup>2</sup>	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

CY 2012 In-Network Service Category Cost Sharing Requirements

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. Home health cost sharing policy for CY 2012 will be determined in the current notice and comment rulemaking process (75 FR 71190)
- 3. Chemotherapy includes administration services. Chemotherapy drugs and administration services in an inpatient setting are covered under the MA plan's inpatient benefit coverage.
- 3. Discriminatory Pattern Analysis

Following CY 2012 plan bid submissions, CMS will ensure that MA plans conform to the cost sharing requirements. In addition, CMS will analyze bids to ensure that discriminatory benefit designs are identified and corrected. This could include bids that meet standards but have cost sharing amounts that are distributed in a manner that may discriminate against sicker, higher-cost patients. This analysis may also evaluate the impact of benefit design on patient health status and/or certain disease states. CMS will contact plans to discuss and correct any issues that are identified as a result these analyses.

# **Other Cost Sharing Policy Issues**

# A. Multi-Year Benefits

CMS is concerned that allowing MA plans and section 1876 cost contract plans to offer benefits and cost sharing that span multiple contract years, multi-year benefits, is inconsistent with its goal to provide beneficiaries with plan choices that are easy to understand. We believe that abenefit that spans multiple contract years is confusing to many enrolled beneficiaries because it requires them to keep track of which services have been received and which are unused, across years. In addition, we believe that multi-year benefits complicate the comparison of plans by beneficiaries during the open enrollment periods.

To address these concerns, beginning with CY 2012, we strongly encourage plans to limit benefits to one contract year rather than a longer period and are contemplating future rulemaking to limit plans' flexibility to offer benefits over more than one contract year. We understand that plans have become accustomed to pricing some benefits across multiple years and cannot be expected to make immediate changes to those practices, but to the extent possible, we encourage plans to limit or discontinue offering benefits over a period that spans more than one contract year.

# B. Copayment and Coinsurance for the Same Service

We have found that, as is allowed for PBP data entry, a small number of plans enter both coinsurance and copayment amounts for the same service categories, presumably to capture variation in the plan's contracting agreements. We want to enable plans to accurately reflect their benefit packages in the PBP but also are committed to ensuring that plan benefits and cost sharing are easily understood by beneficiaries and that an enrollee is not charged both a coinsurance and a copayment for the same service. In our work to revise the PBP for CY 2012, we performed analyses to see how often plans were entering both coinsurance and copayment amounts for the same service categories. We were pleased to find that very few plans entered both types of cost sharing values for any service category in the CY 2011 bids and determined that we would be interested in simplifying the PBP by enabling plans to enter only one type of cost sharing for each of the service categories.

For CY 2012, we discourage plans from entering both types of cost sharing for any service category, but will not disallow those entries. For future contract years, we are considering rulemaking to revise the PBP to limit plans' ability to enter both copayment and coinsurance.

#### C. PBP Notes

CMS' longstanding policy requires that the Notes sections in the PBP may be used to provide additional information about the benefit that is being offered. The information in the note must not contain any cost sharing for the benefit/service that is not reflected in the PBP data entry field for the benefit/service. Any information in a note must be consistent with the benefit/service as it is reflected in the PBP data entry fields. The Notes must not be used to enter additional benefits, conditions for coverage or cost sharing charges.

## D. Supplemental Benefits for Section 1876 Cost Plans

Although cost contracts are prohibited from offering mandatory supplemental benefits, CMS has 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. CMS does 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, CMS does not consider this a termination of a PBP. Any cost optional supplemental package marked as "terminated" for Contract Year (CY) 2012 will be required to be crosswalked via the plan crosswalk to another supplemental package offered by the cost contract. Cost contracts in this situation must transition enrollees to the cost contract'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 Call Letter.

As outlined in the Medicare Managed Care Manual (MMCM) Chapter 17, Subchapter F, all benefits that are part of the 1876 Cost Plan must be offered uniformly to all enrollees. Because of this, CMS is also adding a new edit rule to the Health Plan Management System (HPMS) requiring that all Cost plan benefit packages must cover the entire cost contract's service area. This may mean that some cost plan benefit packages will have to expand their service area for CY 2012.

## Changes to 2012 Summary of Benefits Regarding Dual Eligible SNP Cost Sharing

CMS is changing the structure of the Summary of Benefits (SB) to address an issue related to how the Maximum Out-of-Pocket (MOOP) limit is reflected for DE SNP enrollees. For contract year 2010, CMS added a new requirement in the bid submission, whereby plans were required to have a MOOP limit in their bids, resulting in a MOOP value appearing in the SB (in column 3 under the plan benefit information).

For contract year 2011, CMS provided a temporary solution by allowing plans to submit a hard copy change to add qualifying language via an asterisk, indicating that the amount beneficiaries may have to pay is based on their level of state Medicaid assistance.

For contract year 2012, CMS is making programming changes to the SB sentences to ensure that cost sharing amounts are displayed accurately.

#### **Renewal Material Timelines Given AEP Changes**

Due to the statutory changes to the Annual Enrollment Period (AEP) the CY 2012 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) documents are due to current members of all MA plans, MA-PD plans, PDPs, and cost-based plans offering Part D by September 30, 2011. Organizations are not required to mail the Summary of Benefits (SB) to existing members when using the combined, standardized ANOC/EOC; however the SB must be available upon request.

In addition to the ANOC/EOC documents, organizations must provide the LIS rider and formulary, if applicable, to enrollees for receipt by September 30, 2011. Plan sponsors should note that no other materials regarding 2011 plan offerings may be sent prior to the beginning of marketing activities on October 1, 2011.

## III. Part D

#### Generic Samples Paid for Through Part D Sponsors' Administrative Costs

As described in section 60.2 of Chapter 7 of the Prescription Drug Benefit Manual, CMS allows Part D sponsors the option to provide OTCs as part of their administrative cost structure when a component of a cost-effective drug utilization management program and without any cost sharing on the part of the beneficiary at the point-of-sale. We have been asked whether the provision of generic samples in physician offices could be similarly treated under Part D and are now providing this guidance, effective immediately. Sponsors may incur expenses related to distribution of and reporting on generic drug samples, provided to members within a physician's office setting, under the plan's administrative cost structure if doing so is consistent with a cost effective drug utilization management program. Any provision of generic samples must be conducted consistent with the requirements of the Prescription Drug Marketing Act, 21 USC §353 and the Food and Drug Administration's implementing regulations at 21 CFR part 203. A drug sample, as defined by 21 CFR § 203.3(i), means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug. To clarify, for purposes of this analysis, a generic drug sample is a "unit of a prescription drug, limited to a drug subject to an application approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act, which is not intended to be sold and is intended to promote the sale of the drug." A brand drug

sample is "a unit of a prescription drug, limited to a drug subject to an application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, which is not intended to be sold and is intended to promote the sale of the drug." Drug samples do not meet the definition of a covered Part D drug under 42 CFR § 423.100 because they are not dispensed at a network pharmacy nor are they consistent with our out-of-network pharmacy coverage requirements stated at 42 CFR § 423.124. In other words, drug samples do not meet the emergency definition (42 CFR § 124 (a)(1)) and do not represent Part D drugs, unlike vaccines, which are appropriately dispensed and administered by physicians (42 CFR § 124 (a)(2)).

Given that generic samples do not meet the definition of a Part D drug, Part D sponsors cannot include the provision of samples as part of their benefit structure. Thus, such samples would not be placed on formulary tiers, and like similarly treated OTC products, such samples must be provided to enrollees without cost sharing requirements. However, in contrast to our related policy on the use of OTC products as part of a ulitilization management program (See Prescription Drug Manual, Chapter 7, Section 60.2), generic samples may not be incorporated into step-therapy protocols because all enrollees would not have equal access to such samples. More broadly, Part D sponsors may not require beneficiares to use generic samples under any conditions. CMS recognizes that generic drug samples may be an effective utilization management tool used to promote compliance with a new drug therapy. By facilitating access to trial supplies of less costly generic versions of Part D drugs, plan sponsors can enhance their enrollees' experience in Part D by reducing their current and future cost sharing expenses. In the case of low income subsidy entitled beneficiaries, facilitating medication starts on generic versions of drugs also helps to limit federal low income cost sharing subsidy reimbursements and overall program costs to the Trust Fund. Therefore, we believe that Part D sponsors may contract with vendors to provide access to and reporting on generic drug samples as part of their drug utilization management program as an incentive to reduce drug costs by promoting the use of lower cost generic medications (We expect that Part D sponsors will have the appropriate business associate agreements with the vendors providing generic sample to Part D beneficiaries. The business associate agreement should require that a beneficiary's protected health information only be used for transactions directly related to providing a generic sample to the Part D beneficiary and reporting the beneficiary's receipt of a generic sample to the Part D sponsor).

If desirable, Part D sponsors should account for such costs when developing their 2012 bids, but may also contract for such services in 2011 if they determine that doing so under their utilization management programs would be an offset to their prescription drug costs. CMS currently has no plans to require reporting on generic samples provided to Part D beneficiaries through PDE reporting, or otherwise.

In making this clarification, we specifically distinguish generic samples from brand samples. We believe that the provision of brand name drug samples would not be an appropriate use of administrative costs and would not be consistent with the requirements relating to drug

utilization management at 42 CFR § 423.153(b), which direct Part D sponsors to establish a drug utilization management program that includes incentives to reduce costs when medically appropriate.

# Applying Best Available Evidence Policy to Beneficiaries of Home and Community Based Waiver Services

Section 3309 of the Affordable Care Act extended the elimination of Part D cost sharing to full benefit dual eligibles who would be institutionalized individuals (or an institutionalized couple) if the individuals were not receiving home and community-based services under Title XIX of the Act. The effective date for this requirement will be no earlier than January 1, 2012. We have proposed an implementation date of January 1, 2012 in our November 15, 2010 proposed rule.

With the elimination of cost sharing for full benefit dual eligible individuals that receive home and community-based waiver services, we remind sponsors that once this requirement takes effect, they will need to have systems that can reflect zero cost sharing for these individuals when evidence is presented to the sponsor that the individual receives home and community-based waiver services, and the individual's cost-sharing is more than zero. Sponsors will be required to follow our Best Available Evidence policy as outlined in Chapter 13 of the Medicare Prescription Drug Benefit Manual. That is, on the date that this requirement takes effect (no earlier than January 1, 2012), a copy of a state document confirming full benefit dual eligible status and receipt of home and community-based waiver services is evidence that the beneficiary qualifies for zero cost-sharing.

## Monitoring the Implementation of Transition Policy

In CY 2011 CMS required Part D sponsors to complete transition attestations in HPMS and submit a transition policy and implementation statements through the CMS Part D transition mailbox. The CY 2011 review revealed many polices were deficient and did not adequately address all attestations. CMS spent a significant amount of time reviewing updated policies and providing technical assistance and guidance to Part D sponsors to bring the policies into compliance with the regulatory requirements. Despite CMS' efforts to work with plans to achieve approvable transition policies, subsequent audits revealed that Part D sponsors were not implementing the transition policies appropriately in their claims adjudication systems. Therefore, beneficiaries were not receiving their required transition supplies, which is a basic protection of the Part D program to ensure continuity of care. On August 27, 2010, CMS issued an HPMS memo to provide additional clarification to Part D sponsors on the transition benefit.

As a result of the audit findings, CMS remains concerned with whether Part D sponsors are appropriately implementing the transition policy. CMS is exploring several methods to determine if Part D sponsors are implementing their transition policy consistent with CMS'

guidance and applicable regulations. CMS will require that Part D sponsors provide documentation that their transition policy is correctly implemented in their claims system and that beneficiaries are receiving their required transition supplies. This documentation may require the sponsor to submit any or all of the following: (1) up to one quarter's worth of denied claims for 2012; (2) test claims for new beneficiaries; (3) identification of new beneficiaries and documentation of paid claims for transition supplies; or (4) evidence of transition supplies provided across contract years.

#### Medication Therapy Management (MTM) Services and Racial Disparities

In August 2010, Health Services Research (HSR), an organization that publishes findings from investigations in the field of health care to help improve the health of individuals and communities, published findings from a research study under the title "Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services." (Wang et al. 2010. "Disparity Implications of Medicare Eligibility Criteria for Medication Therapy Management Services." Health Services Research 45 (4): 1061-1082.) The objective of the research study was to determine if there were racial and ethnic disparities in meeting eligibility criteria for MTM services provided for Medicare Part D beneficiaries. The report findings suggest that Hispanic and African American beneficiaries could have a lower likelihood of meeting the MTM eligibility criteria when compared to whites based on the original MTM eligibility thresholds in 2006 and the new thresholds beginning in 2010. The study also found that there was disparity among beneficiaries with severe health problems. There are important implications for the Part D program considering these findings are consistent with other literature which suggests that minorities have lower utilization of drugs and health services in general, and the MTM eligibility criteria are based on utilization. The Part D benefit requires prescription drug sponsors to establish a MTM program to optimize therapeutic outcomes for targeted beneficiaries who meet high risk criteria, but currently a potentially vulnerable segment of the population may not be targeted accurately to receive MTM services.

CMS is conducting an analysis to verify the report's findings. As a first step of the analysis, CMS is replicating the analysis conducted in the HSR study using a larger sample of beneficiaries and will also investigate potential racial disparities using the plan-reported MTM data which reflects actual experience. If the report findings are validated, CMS may consider changes to the MTM eligibility thresholds in future rulemaking. Sponsors have had flexibility to determine the first two elements that make up the definition of MTM targeted beneficiaries, and CMS has put in place additional restrictions to define these elements beginning in 2010. CMS would like sponsors to provide comments on MTM eligibility criteria that could be used to target individuals who would otherwise receive a disparate level of care. Furthermore, CMS strongly encourages sponsors to examine their defined MTM targeting criteria and implement or pilot any changes to the criteria as needed to minimize racial disparities in MTM eligibility.

#### **Reassignment Policy for 2012**

In the fall of 2011, CMS will again reassign auto-enrolled low income subsidy (LIS) beneficiaries who are in a PDP that has a premium at or below the LIS benchmark in 2011, but above the LIS benchmark in 2012, as well as all LIS beneficiaries whose PDP is terminating for 2012. CMS will also reassign beneficiaries who remain LIS-eligible as of January 1, 2012, and are in Medicare Advantage plans that are terminating in 2012. Consistent with section 3303 of the Affordable Care Act (ACA), PDPs that volunteer to waive a de minimis amount of the premium will no longer lose LIS beneficiaries to reassignment based on the fact that their monthly premium exceeds the low-income benchmark; however, such PDPs will not receive reassignments and auto-enrollments. We anticipate establishing the de minimis amount in August 2011. Details of the reassignment process may be found in section 40.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, available on our website at: http://www.cms.gov/MedicarePresDrugEligEnrol/Downloads/FINALPDPEnrollmentandDisenro llmentGuidanceUpdateforCY2011.pdf.

Consistent with section 40.1.5 of the enrollment guidance, CMS will first reassign beneficiaries within the same organization if the organization offers another qualified PDP in the same region, either under the same contract number, or if that is not available, under a different contract number sponsored by the same parent organization. If the organization does not offer another qualifying PDP, CMS will randomly reassign affected beneficiaries to other PDP sponsors that have at least one qualifying PDP in that region. CMS will follow the two-step process used for auto-enrollment, i.e., random distribution first at the organization level, then randomly among qualifying PDPs within the organization (see section 40.1.4.C).

Note that organizations under an enrollment sanction will not receive reassignments, either from within their organization or through the random reassignment process. Thus, if a sanctioned organization offers a PDP with a 2011 premium below the low-income benchmark amount and that PDP's premium will be above this threshold for 2012—resulting in premium liability for LIS beneficiaries—affected enrollees in that PDP will be randomly reassigned to other PDPs in the region with a premium at or below the LIS benchmark amount.

#### Low Enrollment Plans (Stand-alone PDPs only)

CMS has the authority under to 42 CFR §423.507(b)(1)(iii) to non-renew plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. Consistent with that authority, we will again be scrutinizing low-enrollment plans during the bid review period and will expect that sponsors will have withdrawn or consolidated low-enrollment plans prior to submitting bids for CY 2012. This guidance applies to non-employer stand-alone Part D plans since CMS previously granted a waiver of 42 CFR

§423.512(a) (minimum enrollment requirements) for sponsors of employer group plans. We reserve the right to reconsider this waiver in the future.

We expect to particularly examine plans that constitute the lowest quintile (20%) per region of 2011 plans ranked by enrollment. As of February 2011, the lowest quintile was comprised of 173 plans, with an average of 5 plans per each of the 34 PDP regions. These plans had a total enrollment of 79,953 beneficiaries, with an average of 462 enrollees and a median enrollment of 273 per plan. The actual plan enrollments ranged from a low of 4 to a high of 2,490 beneficiaries. 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. Sponsors are strongly encouraged to view data on plan enrollment count at: <u>www.cms.hhs.gov/MCRAdvPartDenrolData/</u> to determine if any of their plans fall into the lowest quintile.

Before CMS would take any action to non-renew a plan pursuant to 42 CFR §423.507(b)(1)(iii), CMS would take into account all relevant factors, including, but not limited to: (1) whether the plan is a basic plan offered to meet the regulatory requirement in 42 CFR § 423.104(f)(2) that a PDP sponsor may not offer enhanced alternative coverage in a service area unless the sponsor also offers a basic drug plan in the area, in which case CMS would renew the basic plan;( 2) whether the plan was a new plan and if it has been in existence for three or more years; (3) whether the plan is offered nationally; (4) the total number of plan offerings in the applicable region; and (5) if the plan's premium currently falls at or below the low income benchmark premium amount.

#### **Benefit Design**

#### Cost-Sharing Out-of-Pocket (OOPC) Differential Analysis

For the CY 2011 bid submission, CMS used the cost-sharing OOPC amounts in establishing differences between basic and enhanced plans and between low and high value enhanced. Since then, CMS has received questions about our Cost-Sharing OOPC differential analysis. We employ this analysis to establish meaningful differences among basic and enhanced plans across the Part D program, not just between contract offerings. The purpose of the analysis and the setting of the target differential dollar amounts is to ensure that beneficiaries will receive a minimum additional value over basic coverage, and between enhanced coverage offerings, when they select and pay premiums for any enhanced plan. The analysis is not used to evaluate relative levels of all out-of-pocket costs that a beneficiary may incur, but rather, to establish the difference in cost-sharing incurred among plans as a measure of additional benefits available to the average consumer. For this reason, premiums are not included in the calculation because in the case of enhanced plans (as opposed to basic plans), any additional premium exactly offsets the additional benefits, by law. Thus, supplemental premiums cancel out the additional value of

the enhanced benefits and do not leave a comparable amount to be compared to the value of basic benefits.

In order to set a value for meaningful differences, CMS must be able to evaluate plan benefit packages (PBPs) on the same yardstick. This is accomplished by running the identical Medicare Current Beneficiary Survey (MCBS) data through each PBP. More specifically, CMS established the targets for differentiation by evaluating expected Cost-Sharing OOPC amounts under each 2011 plan offering by the same sponsor in a service area. For this relative analysis, CMS utilized a uniform market basket of drugs from a representative population of Medicare beneficiaries run through each plan's benefit design. Cost-sharing OOPC estimates were originally calculated using PBP and formulary data available during the 2011 bid review period, but were reevaluated using more recent PBP, formulary, and MCBS data (2005/6) as well as more precise calculations related to additional gap coverage for a subset of drugs on a particular tier or tiers (i.e. partial tier additional gap coverage). The latter calculation includes the MCBS data that will be used for the 2012 OOPC estimates. The chart below depicts a summary of the results of our analysis based on CY 2011 data:

	August Bid/	Formulary D	ata, 2004/5 M	ICBS Data		
Plan Comparison	# of Plans	Mean	25th	50th	75th	95th
1st Enhanced Plan vs. Basic Plan	886	-\$23.55	-\$23.48	-\$22.58	-\$22.16	-\$20.88
2nd Enhanced Plan vs. 1st Enhanced Plan	146	-\$15.41	-\$16.17	-\$16.17	-\$13.68	-\$13.35
	December Bio	l/Formulary	Data, 2005/6	MCBS Data		
Plan Comparison	# of Plans	Mean	25th	50th	75th	95th
1st Enhanced Plan vs. Basic Plan	886	-\$27.96	-\$32.36	-\$28.14	-\$25.63	-\$17.60
2nd Enhanced Plan vs. 1st Enhanced Plan	146	-\$12.29	-\$16.25	-\$15.93	-\$5.78	-\$5.78

#### 2011 Cost-Sharing OOPC Differential Analysis

Using the updated OOPC model with the most current formulary, PBP and MCBS data and a more precise calculation for partial gap coverage, the median monthly difference between basic and enhanced plan offerings increased to nearly \$28. However, to maintain consistency in this meaningful differences test while sponsors continue to gain experience calculating OOPC estimates, the minimum monthly threshold value between basic and enhanced plan offerings will remain at \$22 for CY 2012. Because the 2011 OOPCs considered partial gap coverage to be the same as full gap, the impact on the partial gap plans was greater as the OOPC differentials

decreased further away from the median. This was especially evident in the comparison between enhanced plan offerings (with adjusted OOPC differentials) that were not meaningfully different for these plans. Therefore, for CY 2012, CMS is also proposing using the median monthly cost-sharing OOPC difference of \$16 between 2 enhanced plans in the same service area.

#### Cost-Sharing Out-of-Pocket Cost (OOPC) Software

For CY 2012, CMS will make the Cost-Sharing Out-of-Pocket Cost model (Cost-Sharing OOPC) available in SAS via the CMS website which will allow plans to calculate Cost-Sharing OOPC estimates for each of their benefit offerings to prepare for meaningful difference negotiations with CMS (see below). Standalone Prescription Drug Plans (PDP), and Medicare Advantage Plans with Prescription Drug coverage (MA-PD) will be encouraged to run their plan benefit structures through the SAS Cost-Sharing OOPC model to ensure meaningful differences between their plan offerings as required by CMS regulations (see 42 CFR §§ 423.272(b)(3)(i) and 423.265(b)(2)). The SAS Cost-Sharing OOPC model will be available in the spring of 2011. Instructions for downloading the model and a User Guide will also be published via the CMS website.

CMS expects PDPs and MA-PDs to prepare CY 2012 plan bids that meet the meaningful difference requirements with their initial submissions, since there will be access to the necessary tools to consistently calculate Cost-Sharing OOPC estimates for each plan prior to bid submission. CMS might not permit revised submissions if a plan's initial bid does not comply with meaningful difference requirements. Ultimately, plan bids that do not meet these requirements will not be approved by CMS. Thus, plans should complete this analysis prior to submitting their bids for the 2012 contract year.

#### Meaningful Differences in Part D Coverage

As part of the bid negotiation process, CMS seeks to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. Part D regulations require that plan offerings by sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. 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. Section 423.265(b)(2) also requires that Part D sponsors' bid submissions in the same service area reflect differences in benefit packages or plan costs that we determine to represent substantial differences from each other.

Again for 2012, CMS will be waiving the meaningful differences requirements of sections 42 CFR 423.272(b)(3)(i) and 423.265(b)(2) to allow sponsors of employer group plans (800 series

and direct contract plans) to submit, and seek approval of, employer plan benefit packages that do not meet the meaningful differences requirements. We reserve the right to reconsider this waiver in the future.

As noted last year in the 2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions, CMS does not believe that sponsors can demonstrate meaningful differences based on expected Cost-Sharing OOPCs between two stand-alone basic Part D benefit designs and maintain both the statutory actuarial equivalence requirements and fulfill the requirement in §423.153(b) to maintain cost-effective drug utilization review programs. Therefore, sponsors again for the 2012 contract year should submit only 1 basic offering (where basic offering includes defined standard, actuarial equivalent and basic alternative drug benefit types) for a stand-alone prescription drug plan in a service area. As in prior years, CMS will negotiate with Part D sponsors to offer no more than 3 stand-alone prescription drug plan offerings in a service area, resulting in a mix of 1 basic and at most, 2 enhanced plans—subject to the following qualifications.

#### Cost-Sharing OOPC Differential Thresholds

To determine if cost sharing and formulary and benefit differences result in meaningful differences for the 2012 Contract Year, CMS expects the Cost-Sharing OOPC differential (exclusive of premium amounts) between a basic benefit offering and an enhanced offering of the same Part D sponsor in the same service area to be at least \$22 monthly (\$264 annually). In other words, the expected Cost-Sharing OOPCs of the basic plan should be higher by at least \$22 monthly than the enhanced offering. This amount has not changed from last year.

CMS will also continue its expectation that where 2 enhanced stand-alone drug plans are offered within the same service area, the second enhanced plan will have a higher value than the first and include coverage of at least some brand drugs in the gap (where "some" is defined as  $\geq 10\%$  - 65% of formulary drug entities labeled as brands). In addition, CMS expects that the Cost-Sharing OOPC differential between the two enhanced offerings will be at least \$16. In other words, the expected Cost-Sharing OOPCs of the first enhanced offering will be \$16 higher than the second enhanced offering. Assigning a value to the Cost-Sharing OOPC differential between two enhanced offerings is new this year.

#### **Co-pay Thresholds for Cost Shares**

According to 1860D-11(e) of the Medicare Modernization Act, the Secretary can only approve a plan if the design of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D eligible individuals. 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.

To implement these requirements, CMS will examine PDP and MA-PD bid (benefit package) data for 2012 to determine acceptable cost sharing thresholds. Consistent with prior years' review, we plan to conduct an analysis to identify drug tier cost sharing outliers relative to other sponsors' competing benefit packages submitted using the copay cost-sharing associated with the 95<sup>th</sup> percentile across all initially submitted bids consisting of three or more tiers. CMS believes that cost-sharing at the 95<sup>th</sup> percentile would reflect the level at which a beneficiary could easily identify outliers they would consider to be discriminatory based on other plan offerings. As part of this analysis, we will also take into consideration plan type (basic versus enhanced), the number of drug tiers within a PBP, cost structure (copayment versus coinsurance), tier content and differences between MA-PDs (including cost plans) as well as differences between MA-PDs and PDPs. The table below shows the results of the threshold analysis for the initial 2011 bid submissions.

	2011 Copay Distribution (Percentiles)								
Tier ID	Plan Count	20th	50th	70th	95th				
1	2846	\$2	\$5	\$6	\$10				
2	2696	\$15	\$35	\$40	\$45				
3	2570	\$40	\$70	\$80	\$95				

Copay Cost-Sharing Distribution for 2011 Bid Submissions with Three or More Tiers

Assuming similar benefit designs are submitted for 2012 as they were for 2011, sponsors can expect that CMS will establish 2012 thresholds that are reasonably consistent with the prior year's experience. Therefore, in constructing PBPs, Part D sponsors should consider the following thresholds that were used as part of the 2011 discrimination review for drug plans with three or more tiers:

Tier 1 over \$10 Tier 2 over \$45 Tier 3 over \$95

Based on the most common tier designs submitted by plans, tier 1 represents preferred generic cost-sharing, tier 2 represents preferred brand cost-sharing and tier 3 represents non-preferred brand cost-sharing. As in 2011, the established threshold for preferred generic, preferred brand and non-preferred brand cost-sharing still apply when the tier level for these categories are shifted based on variations in tier design. In addition, CMS will evaluate tier structures that include multiple generic and/or brand tiers to determine whether the weighted average of the retail cost-sharing for these tiers meets the established thresholds. It is important to note that in identifying drug tier outliers, CMS will consider specific benefit design aspects that could justify an exception for the purpose of our discrimination review. For instance, we may allow cost

sharing thresholds for plan benefit designs in which a particular tier represents the specialty tier such that if a plan has a 3 tier formulary which includes a specialty tier, the specialty tier will be held to the specialty tier thresholds, not the thresholds established by the 95<sup>th</sup> percentile. Atypical tiering structures, such as a two-tier formulary, will also be considered and with the additional standardization in tier design required for 2012, the benefits offered will have a distribution that is unique to each tier structures, thereby allowing CMS to refine the target costsharing thresholds. Therefore, we may also consider establishing alternative thresholds for 2012 plans with 4 and 5 tier formularies that follow the standardized models described in the next section.

During 2011, CMS will increase scrutiny of the expected cost sharing amounts incurred by beneficiaries under coinsurance tiers, in order to more consistently compare copay and coinsurance cost sharing impacts. We expect to derive average expected cost sharing amounts for a sponsor's 2012 coinsurance tiers using 2010 PDE drug cost data mapped to 2012 formulary tiers. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty formulary tiers that are greater than the standard benefit of 25% for non-specialty tiers, CMS may also request documentation from the sponsor on the average expected price for medications on the coinsurance tier(s) in order to better translate the coinsurance value into an average cost sharing amount for the purpose of our discrimination review.

Consistent with the meaningful difference review, CMS will notify plan sponsors whose benefit structures include drug tiers that exceed our discriminatory cost sharing threshold limits and conduct negotiation calls as applicable prior to bid approval. Sponsors not meeting our targets will be asked to amend or withdraw their PBPs.

#### **Tier Labeling and Hierarchy**

Over the last few years CMS has heard from various beneficiary and advocacy stakeholders and Part D sponsors that a large number of drug tiers, non-standardized labeling of those tiers and formularies using duplicative tier names or tier names that include multiple drug types in the label (e.g. Brand and Generic Drugs are confusing to beneficiaries especially when trying to compare plans. In order to improve the clarity and consistency of tier designs, CMS revised the PBP and formulary upload software in 2011 to accept a maximum of six drug tiers and established a uniform set of tier label description options based upon the most common tier names used by Part D sponsors. However, CMS believes that additional standardization of the tier structure and number could further improve the comparability of plan offerings by beneficiaries and will simplify the discriminatory cost-sharing analysis performed by CMS.

First, in order to keep drug benefits meaningful to beneficiaries while allowing sponsors adequate flexibility in the Part D benefit design, the 2012 PBP and formulary upload will continue to accept 6 formulary tiers. CMS continues to observe that the vast majority of Part D

plan benefit packages reflect benefit designs using five tiers or less, and those plans with six tier designs are similar to those submitted by five tier plans, but typically include an extra non-preferred cost-sharing tier that does not provide a clear additional value to the beneficiary. Therefore, CMS will only allow a 6<sup>th</sup> tier if it is an excluded- drug- only tier or a tier that provides a meaningful benefit offering such as a \$0 vaccine-only tier, a low or \$0 cost-sharing tier for special needs plans (SNP) targeting specific conditions (e.g., \$0 diabetic drug tier), or an injectable drug tier with cost-sharing that is at or below the cost sharing for specialty tier drugs in the other five tiers. Plans offering supplemental benefits for excluded drug coverage are not required to have this optional excluded-drug-only tier and may continue to offer excluded drugs on tiers that are shared by Part D covered drugs.

Second, CMS is establishing tier labels and hierarchy to reflect standards established by industry and assist in our analysis of discriminatory benefit practices. CMS updated its regulations at \$423.104(d)(2) by adding paragraph (iii) to specify that tiered cost-sharing for non-defined standard benefit designs may not exceed levels (or cost sharing thresholds) annually determined by CMS to be discriminatory. In order to accurately evaluate whether tiered cost-sharing is discriminatory, there needs to be a consistency between the tier labels adopted by the plan sponsors and the cost-sharing thresholds CMS established as part of its discriminatory analyses. Some of the variation in tier labeling that currently exists in Part D presents challenges for the discriminatory cost-sharing analyses, and does not lend itself to a common understanding of how competing plans compare in terms of tier offerings. As a result, beginning with the 2012 bid submissions, CMS is strongly encouraging sponsors to utilize certain tier labels and tiering hierarchy consistent with the industry standards already established in the market place. These standard tier labels and hierarchy reflect the common tier patterns utilized by the majority of sponsors in 2011 and will provide for a more comprehensible description of the overall tier offering as it relates to the drug content and assigned cost-sharing.

Below is a chart depicting the tier labels and hierarchy as observed currently in the industry. CMS will have difficulty determining whether a plan's tier cost-sharing structure is discriminatory if Part D sponsors submit plan benefit packages that do not reflect these industry standards. In addition because of the ACA provision that moved the annual enrollment period from November to October, CMS will have a shortened time frame for review and approval of 2012 Part D bids and may not have enough time to approve bids that are incomplete or otherwise challenging to evaluate. CMS strongly encourages Part D sponsors to ensure that their initial submissions due on June 7, 2011 are complete and consistent with CMS policy and guidance, to avoid the risk of being denied participation in the program. In addition, sponsors must ensure that the formularies submitted in advance of the bids only include a 6<sup>th</sup> tier that provides a meaningful offering. We further note that the tier labels submitted on the formularies should match those labels submitted in the PBP, with the exception of free text field names in the formulary submission module that are not available in the PBP. As in previous years, excluded-drug-only tiers will not be reflected on formulary submissions.

#### 2012 Tier Labels and Hierarchy

				2012 Tier I	Label		
2012 Tier Structure	2012 Option	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Optional Tier 6*
2 Tier	А	Generic or Preferred Generic	Brand or Preferred Brand				
3 Tier	А	Generic or Preferred Generic	Brand or Preferred Brand	Specialty Tier			
	В	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand			
4 Tier	А	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier		
	В	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non- Preferred Brand		
5 Tier	А	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non- Preferred Brand	Specialty Tier	optional
	В	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non- Preferred Brand	Injectables	optional
	С	Preferred Generic	Non-Preferred Generic	Preferred Brand	Injectables	Specialty Tier	optional
	D	Generic or Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectables	Specialty Tier	optional

\*The optional 6<sup>th</sup> tier can be used as an excluded-drug-only tier or for other meaningful offerings such as a \$0 vaccine-only tier.

#### **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 CMS determines to represent substantial differences relative to a sponsors other bid submissions. This being the case, CMS expects that the additional gap coverage of generic (non-applicable) drugs offered by plans to reflect meaningful enhancements over the standard prescription drug benefit, which provides 14% generic drug cost coverage in the gap for CY 2012.

To determine how much additional coverage in the coverage gap over the basic benefit would be recognized as substantially different, CMS considered the amount of additional coverage provided by the Part D sponsors in their plan benefit packages for CY 2011. CMS found that the majority of plans offering coverage in the gap had cost sharing levels for generics equal to 50%

coinsurance or less, and brand cost sharing at 60% coinsurance or less. Since the majority of plans reflect additional coverage of at least 50% in the gap for generics and 40% coverage of brands in the gap, CMS intends to scrutinize any 2012 plans that provide gap coverage at or below 30% of the cost of generic or brand drugs. In other words, the plan's benefit has beneficiary cost sharing during the coverage gap that is equal to or more than 70% coinsurance. For example, if a plan submits a basic benefit package which reflects the defined-standard benefit structure of 86% coinsurance for generics during the coverage gap and submits another enhanced plan that reflects more than 70% coinsurance for generics during the coverage gap, CMS will evaluate whether the enhanced plan is substantially different from what is offered under the sponsor's basic plan in accordance with our meaningfully different policies.

#### **Plan Corrections**

The plan correction module will be available in HPMS for 2012 PBPs for a limited period, from mid-September until October 1, 2011. Organizations may request a plan correction only after their contract has been approved. This limited timeframe will ensure that correct bid information will be available for review on the Medicare Prescription Drug Plan Finder in time for the open enrollment start date. Only changes to the PBP that are supported by the BPT are allowed during the plan correction period.

CMS expects that sponsors' requests for plan corrections will be very rare. A request for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and calls into question an organization's ability to submit correct bids and the validity of the final actuarial certification and bid attestation. Please be advised that an organization requesting a plan correction will receive a compliance notice.

#### **Specialty Tier Threshold**

For contract year 2012, we will maintain the \$600 threshold for drugs on the specialty tier. Thus, only Part D drugs with negotiated prices that exceed \$600 per month may be placed in the specialty tier, and the specialty tiers will be evaluated and approved in accordance with section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. In addition to cost calculations, CMS considers claims history in reviewing the placement of drugs on Part D sponsors' specialty tiers. Except for newly approved drugs for which Part D sponsors would have little or no claims data, CMS will approve specialty tiers that only include drugs on specialty tiers when their claims data demonstrates that the majority of fills exceed the specialty tier cost criteria. Part D sponsors should be prepared to provide CMS the applicable claims data during the formulary review process.

## Appendix A-1 – Contract Year 2012 Guidance for Medicare Advantage, Medicare Advantage Prescription Drug, and Section 1876 Cost Contract Plan Renewals

#### I. MA PBP Renewal and Non-Renewal Guidance

Each renewal/non-renewal option available to MAOs for CY 2012 is outlined in Appendix A-2 and summarized below. Some of these actions can be effectuated by MAOs in the HPMS Plan Crosswalk, while others require explicit prior approval from CMS. Note that CMS will not permit plan renewals across product types. For example, we will not permit MA-only plans to renew as, or consolidate into, MA-PD plans (and vice versa), Health Maintenance Organization (HMO) plans to renew as, or consolidate into, Preferred Provider Organization (PPO) plans (and vice versa); HMO plans or PPO plans to renew as, or consolidate into, Private-Fee-for-Service (PFFS) plans (and vice versa); Special Needs Plans (SNPs) to renew as, or consolidate into, non-SNP MA plans (and vice versa); and section 1876 cost contract plans to renew as, or consolidate into, MA plans (and vice versa). With limited exceptions (outlined below) CMS will not permit consolidation of PBPs, regardless of plan type, across contracts.

#### 1. New Plan Added

An MAO 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 MAO offering the MA plan must submit enrollment transactions to MARx.

### 2. Renewal Plan

An MAO may continue to offer a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for current 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

MAOs 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 so that all enrollees in the combined

plans are under one PBP with the same benefits in the following contract year. However, an MAO may not split a current PBP among more than one PBP for the following contract year. An MAO consolidating one or more entire PBPs with another PBP must designate which of the renewal PBP IDs will be retained following the consolidation. The renewal PBP ID will be used to transition current enrollees of the plans being consolidated into the designated renewal plan. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees.

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 organization will not submit enrollment transactions to MARx for those current members. However, the MAO 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 MAO 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 (SAE)

An MAO may continue to offer the same local MA PBP but add one or more new service areas (i.e., counties) to the plan's service area in the following contract year. This is known as a service area expansion, or SAE. Organizations that include any new service area additions to a PBP should have submitted an SAE application to CMS for review and approval. An MAO renewing a plan with a SAE in the HPMS Plan Crosswalk must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in the same plan in the following contract year.

Current enrollees of a PBP that is renewed with a SAE will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the MAO 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.

### 5a. Renewal Plan with a Service Area Reduction (SAR) and No Other MA Options Available

An MAO offering a local MA plan may reduce the service area of a current contract year's PBP. This is known as a service area reduction, or SAR. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions in MARx for these

current members. Current enrollees in the renewal portion of the service area must receive a standard ANOC notifying them of any changes to the renewing plan.

For the CY 2012 contract year, current plan enrollees in reduced service areas will be disenrolled at the end of 2011, regardless of whether the MAO has other plans available in the reduced area. These individuals affected by the SAR will need to elect another plan regardless of whether the MAO has other options available. The MAO will submit disenrollment transactions pursuant to instructions that CMS will release later this year.

The MAO will send a termination notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. Where there are no other MA options in the reduced service area, the MAO may offer current enrollees in the reduced portion of the service area the option of remaining enrolled in the renewal plan consistent with CMS continuation area policy as provided under 42 CFR § 422.74(b)(3)(ii). If an MAO elects to offer current enrollees in the reduced service area the option of remaining enrolled in the renewal plan, the MAO may provide additional information in the termination notice about the option to remain enrolled in the plan for CY 2012. However no specific CY 2012 plan information can be shared with any beneficiaries prior to October 1, 2011. Any current enrollees in the reduced portion of the service area who wish to continue their enrollment must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

# 5b. Renewal Plan with a Service Area Reduction (SAR) When the MAO Will Offer Another PBP in the Reduced Portion of the Service Area

An MAO offering a local MA plan may elect to reduce the service area of a current contract year's PBP and make the reduced area part of a new or renewal MA PBP service area in the following contract year. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for these current members. These individuals must receive a standard ANOC notifying them of any changes to the renewing plan.

Current enrollees in the reduced portion of the service area must be disenrolled, and the MAO must submit disenrollment transactions to MARx for these individuals, pursuant to instructions that CMS will release later this year. The MAO will send a termination notice to current enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. If the MAO offers one or more MA plans in the reduced portion of the service area, it may offer current enrollees in the reduced portion of the service area, it may offer current enrollees in the reduced portion of the service area that plan (or those plans). However, no specific CY

2012 plan information can be shared with any beneficiaries prior to October 1, 2011. Any current enrollees in the reduced portion of the service area who wish to enroll in another MA plan offered by the same organization in the reduced service area must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

#### 6. Terminated Plan (Non-Renewal)

An MAO may elect to terminate a current PBP for the following contract year. In this situation, the MAO will not submit disenrollment transactions to MARx for affected enrollees. CMS will disenroll these individuals from the MA plan at the end of the current contract year. These individuals must make a new election for their Medicare coverage for the following contract year. Regardless of whether these individuals elect to enroll in another plan offered by the same or another MAO, or to revert to Original Medicare and enroll in a PDP, they must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx. If these individuals do not make a new MA plan election prior to the beginning of the following contract year.

Enrollees in terminated PBPs will be sent a termination notice by the terminating plan that includes notification of a special election period and Medigap guaranteed issue rights. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming HPMS memorandum providing non-renewal and service area reduction guidance and model notices, to be released this summer.

# 7a, 7b, 8a, 8b, 9a, and 9c. Non-Network and Partial Network PFFS Plans Transitioning to Partial or Full Network PFFS Plans

As provided under 42 CFR § 422.114(a)(3), PFFS plans in certain counties ("network counties" with two network plans available) must operate with networks. We have historically required organizations to establish separate contracts for PFFS non-network, partial network, and network plans. CMS has not typically allowed plans to move members from one contract to another, and contract-to-contract moves are currently not possible in the HPMS Plan Crosswalk. However, CMS created an exception to this rule for CYs 2010 and 2011, which we will continue for CY 2012, in anticipation of a large number of transitions from non- or partial network PFFS plans to partial or full network PFFS plans due to the PFFS network requirements. The permissible PFFS transitions are outlined below. We note that some of these scenarios involve consolidations of whole PFFS PBPs and others involve transitions of some, but not all, counties of current non-network and partial network PFFS PBPs.

MAOs cannot complete the outlined PFFS renewal options in the HPMS Plan Crosswalk. An MAO must complete and submit a request to Sara Silver at <u>sara.silver@cms.hhs.gov</u> by June 6,

2011. She will coordinate the review of the request and, if approved, complete the renewal on behalf of the requesting MAO. In addition, for those transitions that will involve some, but not all, counties of current non-network and partial network PFFS PBPs, MAOs must submit enrollment transactions to MARx for individuals residing in consolidating counties (i.e., where the contract and PBP number will be different in 2012) following the instructions that CMS will release later this year. To request any of the PFFS exceptions outlined below, organizations must indicate in the subject line of the email "HPMS PFFS crosswalk exceptions request for <Organization Name>" and include the following information in the request.

2011	2011 Contract	2011 Plan	Whole or	2012	2012	2012 Plan
Contract	Name	ID	Partial	Contract	Contract	ID
Number			2011 PBP	Number	Name	
			Affected?			

NOTE: If a partial 2011 PBP is affected and you wish to submit enrollment transactions to move members to more than one 2012 plan, please list all 2012 plans in your request.

### 7a. Non-Network PFFS Plan Transitioning to a Partial Network PFFS Plan

An MAO with a PFFS non-network contract may consolidate one or more current non-network PFFS PBPs into a new or renewal partial network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS non-network plan or plans being consolidated into a new or renewal PFFS partial network plan will not be required to take any enrollment action, and the organization 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 MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS partial network plan must receive a standard ANOC.

# 7b. Some Counties of a Non-Network PFFS Plan Transitioning to a Partial Network PFFS Plan

An MAO with a PFFS non-network contract may consolidate some counties in the service area of a current non-network PFFS PBP into a single new or renewal partial network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the non-network PFFS PBP may remain in that non-network PBP in the following

contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing partial network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees as usual. Current enrollees transitioned to the PFFS partial network plan must receive a standard ANOC.

### 8a. Non-Network PFFS Plan Transitioning to a Full Network PFFS Plan

An MAO with a PFFS non-network contract may consolidate one or more current entire nonnetwork PFFS PBPs into a new or renewal full network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS non-network plan or plans being consolidated into a new or renewal PFFS full network plan will not be required to take any enrollment action, and the organization 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 MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS full network plan must receive a standard ANOC.

### 8b. Some Counties of a Non-Network PFFS Plan Transitioning to a Full Network PFFS Plan

An MAO with a PFFS non-network contract may consolidate some counties in the service area of a current non-network PFFS PBP into a single new or renewal full network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the non-network PFFS PBP may remain in that non-network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing full network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete

enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees transitioned to the PFFS full network plan must receive a standard ANOC.

### 9a. Partial Network PFFS Plan Transitioning to a Full Network PFFS Plan

An MAO with a PFFS partial network contract may consolidate one or more current partial network PFFS PBPs into a new or renewal full network PFFS PBP under a separate contract held by the same legal entity. HPMS will record the consolidation of one or more PBPs following the submission and approval of an exceptions request (per the instructions outlined above).

Current enrollees of a PFFS partial network plan or plans being consolidated into a new or renewal PFFS full network plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to MARx for those current members. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees of the consolidated PFFS full network plan must receive a standard ANOC.

# 9b. Some Counties of a Partial Network PFFS Plan Transitioning to a Full Network PFFS Plan

An MAO with a PFFS partial network contract may consolidate some counties in the service area of a current partial network PFFS PBP into a single new or renewal full network PFFS PBP under a separate contract held by the same legal entity. Current enrollees in the remaining counties in the partial network PFFS PBP may remain in that partial network PBP in the following contract year provided the MAO follows the rules for a renewal plan with a SAR described elsewhere in this guidance.

Following the submission of an exceptions request (per the instructions outlined above) and its approval, the MAO must submit enrollment transactions to MARx for current enrollees in the counties affected by the SAR who will be transitioned to a new or renewing full network PBP under a separate contract held by the same legal entity. CMS will provide specific instructions for the submission of these transactions later in the year. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees. Current enrollees transitioned to the PFFS full network plan must receive a standard ANOC.

# 10a. Renewal Dual Eligible SNP (D-SNP) with No State Contract that Converts to a New D-SNP with a Different Designation and a State Contract

An MAO currently offering a D-SNP PBP with no State contract that has requested conversion to a different D-SNP type under the same MAO contract may retain current eligible enrollees in the renewal D-SNP PBP. The renewing plan must retain the same PBP ID number as in the previous contract year.

Current enrollees who are eligible for the renewing D-SNP with the new designation and a State contract are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current eligible enrollees. The MAO must submit disenrollment transactions to MARx for current enrollees who are no longer eligible for the new D-SNP's designation, pursuant to instructions that CMS will release later this year.

Current eligible enrollees remaining in the D-SNP must receive an ANOC. Current enrollees whose enrollment is terminated because they are no longer eligible for the renewal D-SNP's designation must be sent a disenrollment notice that includes notification of plan options, a special election period, and, if appropriate, Medigap guaranteed issue rights. (CMS anticipates providing a model for this special disenrollment notice in the final Call Letter)

# 10b. Consolidation of a Renewal Dual Eligible SNP (D-SNP) with a D-SNP with a State Contract

An MAO currently offering one or more D-SNP PBPs with no State contracts may consolidate those PBPs into a single renewal PBP that is a D-SNP with a State contract (offered by the same MAO under the same contract and containing the applicable service area of all consolidating PBPs). The organization must retain one of the current year plan IDs as the renewal plan ID for the following contract year.

Current eligible enrollees are not required to make an enrollment election to remain enrolled in the consolidated renewal PBP, and the MAO will not submit enrollment transactions to MARx for those current eligible enrollees. However, the MAO must submit disenrollment transactions for current enrollees who are no longer eligible for the renewing D-SNP's designation, pursuant to instructions CMS will release later this year.

Current eligible enrollees of the consolidated PBP (including newly transitioned enrollees) must receive an ANOC. Current enrollees whose enrollment is terminated because they are no longer eligible for the new State contracted D-SNP's designation must be sent a disenrollment notice that includes notification of plan options, a special election period, and, if appropriate, Medigap

guaranteed issue rights. (CMS anticipates providing a model for this special disenrollment notice in the final Call Letter,)

# 11. MAO with a Renewing D-SNP that Also Creates a New Medicaid Subset D-SNP and Transitions Eligible Enrollees into the New Medicaid Subset D-SNP

An MAO that renews a current D-SNP that retains the same service area for CY 2012 and also creates a new Medicaid subset D-SNP PBP for the following contract year may transition the subset of current enrollees who are eligible for the new Medicaid subset into the new Medicaid subset D-SNP PBP and may retain current enrollees who are not eligible for the new Medicaid subset D-SNP in the renewing D-SNP. The renewing plan must retain the same PBP ID number as in the previous contract year. MAOs that meet the criteria for this renewal option must complete and submit a request to Sara Silver at sara.silver@cms.hhs.gov by June 6, 2011. She will coordinate the review of the request and, if approved, the MAO will be permitted to submit enrollment transactions to transition eligible current enrollees into the new Medicaid subset D-SNP. To request the exception, organizations must indicate in the subject line of the email "HPMS Medicaid Subset MARx enrollment exception for <Organization Name>" and include the following information in the request:

2011 Contract	2011	2011 Plan ID	2012 Contract	2012	2012 Plan ID
Number	Contract		Number	Contract	of New
	Name			Name	Medicaid
					Subset D-
					SNP

Current enrollees not eligible for the new Medicaid subset D-SNP are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees not eligible for the new Medicaid subset D-SNP. The MAO must submit enrollment transactions for current enrollees eligible for the new Medicaid subset D-SNP in order to enroll them in the new Medicaid subset D-SNP pursuant to instructions that CMS will release later this year. New enrollees in either the renewing or new Medicaid subset D-SNP must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees.

Current enrollees not eligible for the new Medicaid subset D-SNP and who remain in the renewal D-SNP PBP must receive a standard ANOC. Current enrollees transitioned to the new Medicaid subset D-SNP must also receive a standard ANOC.

# 12. Renewing D-SNP in a Multi-State Service Area with a SAR to Accommodate State Contracting Efforts in Portions of that Service Area

As MAOs make efforts to comply with State contracting requirements for CY 2013, we are aware that the nature of negotiations with States may particularly impact MAOs with D-SNPs that operate across State lines. CMS will therefore allow a narrow renewal exception described below.

An MAO that renews a current D-SNP PBP operating in a multi-State service area (a service area that covers counties in more than one state) may reduce the service area of the current contract year's PBP to accommodate State contracting in portions of the service area. The MAO may then transition enrollees in the reduced area, who are thus no longer eligible for the renewed D-SNP PBP, into a new or renewal SNP service area in the following contract year.

The renewing plan must retain the same PBP ID number as in the previous contract year so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. MAOs cannot complete this renewal option in the HPMS Plan Crosswalk. An MAO that meets the criteria for this renewal option must complete and submit a request to Sara Silver at <u>sara.silver@cms.hhs.gov</u> by June 6, 2011. She will coordinate the review of the request and, if approved, the MAO will be permitted to submit enrollment transactions to transition eligible current enrollees into a new or renewal D-SNP. To request the exception, organizations must indicate in the subject line of the email "HPMS Renewing D-SNP in a Multi-State Service Area with a SAR enrollment exception for <Organization Name>" and include the following information in the request:

2011 Contract	2011	2011 Plan ID	2012 Contract	2012	2012 SNP
Number	Contract		Number	Contract	Plan ID of
	Name			Name	New or
					Renewal Plan

Current enrollees who remain eligible for the renewing D-SNP PBP are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to MARx for these current enrollees. The MAO must submit enrollment transactions for current enrollees being transitioned to a new or renewal D-SNP in order to enroll them in the new or renewal SNP pursuant to instructions that CMS will release later this year. New enrollees in any of the plans affected by this transition must complete enrollment requests, and the MAO will submit enrollment transactions to MARx for those new enrollees.

Current enrollees who remain in the renewal D-SNP PBP must receive a standard ANOC.

Current enrollees transitioned to a new or renewal D-SNP must also receive a standard ANOC.

#### 13. Renewing SNP with Ineligible or "Disproportionate Share" Members

As provided under MIPPA and section 3205(c) of the Affordable Care Act, SNPs may only enroll individuals who meet the plan's specific eligibility criteria; they may no longer enroll and serve a "disproportionate share" of individuals who do not meet the targeted criteria or condition. Also pursuant to MIPPA, chronic care SNPs (C-SNPs) may only enroll and serve individuals with certain chronic conditions, as specified by CMS.

Many SNPs currently include members: (1) who enrolled prior to January 1, 2010 under the previous "disproportionate share" policy option (i.e., the members did not meet the special needs criteria at the time of enrollment); or (2) who were enrolled in a C-SNP as of January 1, 2010, but no longer met the special needs criteria as of that date. In both of these circumstances, rather than require the MAO offering these SNPs to involuntarily disenroll these members as of December 31, 2009 because they no longer met the SNP's targeted criteria, CMS required the MAOs to allow these individuals to continue to be enrolled through CY 2011. However, effective CY 2012, SNPs that include members who enrolled under the two circumstances described above will be required to disenroll those individuals if they do not request enrollment in a different plan prior to January 1, 2012. MAOs will not be permitted to transition these current enrollees into other non-SNP MA plans offered by the organization. However, MAOs must retain any of these enrollees whose circumstances change and who attain special needs status prior to CY 2012.

In order to facilitate this process, in our January 11, 2010 HPMS memorandum, we required MAOs offering SNPs to provide their account managers with information regarding the total number of non-special needs individuals enrolled in these SNPs as of January 1, 2010. A similar process should be followed this year and more details will be provided in an upcoming HPMS memorandum. This accounting will assist MAOs with notifying and disenrolling these individuals for CY 2012. Once they have identified these members, MAOs must notify each individual on or before October 1, 2011, that he/she will be disenrolled effective January 1, 2012, and will need to enroll in another plan prior to that date if he/she wants MA coverage for CY 2012.

The MAO must submit disenrollment transactions to MARx for those individuals who do not meet the plan's specific eligibility criteria, pursuant to instructions that CMS will release this year. The MAO will send a disenrollment notice that includes notification of plan options, a special election period, and, if appropriate, Medigap guaranteed issue rights.

Refer to the renewal plan guidance provided in this memorandum for the notification requirements for current SNP enrollees who are not among the non-special needs individuals described above and will remain enrolled in the plan for 2012.

Enrollees whose enrollment is terminated because they lose their special needs status in 2011 must be sent a termination notice that includes notification of plan options, a special election period, and, if appropriate, Medigap guaranteed issue rights.<sup>9</sup>

#### II. Section 1876 Cost Contract Renewal and Non-Renewal Guidance

In general, the MA renewal and non-renewal guidance above applies to section 1876 cost contracts that submit PBPs.

A section 1876 cost contract may not, like MA plans, offer separate PBPs. Instead, a cost contract may offer supplemental benefits as separate collections of benefits under its contract for purposes of Medicare Plan Finder and Medicare & You. Because such benefit collections are not considered separate PBPs, a cost contract, unlike an MA plan, is not considered to have terminated a PBP. In the HPMS plan crosswalk, cost contracts are required to consolidate any collection of benefits that have been marked as "terminated" with another collection of benefits. Thus, instead of disenrolling the individual as in the transactions identified in the MA renewal and non-renewal guidance above, the cost contract must send an ANOC to enrollees specifying the benefit changes and notifying the beneficiary that he or she will remain enrolled in the cost contract's A and B-only package (with or without Part D depending on the individual's original election), or, if the enrollee so chooses, may receive one of the cost contract's other benefit packages.

<sup>&</sup>lt;sup>9</sup> Plans should note that the notification policy in this paragraph applies to those SNP enrollees who lost special needs status in 2011 *not* to disproportionate share enrollees who were not eligible for the SNP as of January 1, 2010.

## Appendix A-2 – Contract Year 2012 Guidance for Medicare Advantage and Medicare Advantage Prescription Drug Plan Renewals

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	<b>Beneficiary Notifications</b>
1	New Plan (PBP) Added.	An MAO creates a new plan benefit package (PBP)	HPMS Plan Crosswalk Definition: A new plan added for 2012 that is not linked to a 2011 plan HPMS Plan Crosswalk Designation:	The MAO must submit enrollment transactions for 2012.	New enrollees must complete an enrollment request.	None
2	Renewal Plan.	An MAO continues to offer a CY 2011 MA PBP in CY 2012 and retains all of the same service area. <b>The same</b> <b>PBP ID number must be</b> <b>retained</b> in order for all current enrollees to remain in the same MA PBP in CY 2012	New Plan HPMS Plan Crosswalk Definition: A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 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 MAO <b>does not</b> submit enrollment transactions for current enrollees.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan.	An MAO combines one or more whole MA PBPs of the same type offered in CY 2011 into a single renewal PBP so that all current enrollees in combined PBP are offered the same benefits in CY 2012 The MAO must designate which of the renewal PBP IDs will be retained in CY 2012 after consolidation. CMS will not allow for consolidations across contracts (with limited exceptions for some renewal options, as described elsewhere in this guidance). Only whole PBPs may be consolidated; a CY 2011 PBP may not be split among different PBPs in CY 2012 Note: If an MAO reduces a service area when consolidating PBP, it must follow the rules for a renewal plan with SAR described elsewhere in this guidance.	Method HPMS Plan Crosswalk Definition: One or more 2011 plans that consolidate into one 2012 plan. The 2012 plan ID must be the same as one of the consolidating 2011 plan IDs HPMS Plan Crosswalk Designation: Consolidated Renewal Plan.	Activities The MAO's designated renewal PBP ID must remain the same so that CMS can consolidate enrollees into the designated renewal PBP ID in CMS systems The MAO does not submit enrollment transactions for current enrollees. The MAO may have to submit 4Rx data for individuals whose PBP number changed	Procedures         No enrollment         request is         required for         current enrollees         to remain         enrolled in the         renewal PBP in         2012         New enrollees         must complete         enrollment         request.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
4	Renewal Plan with an	This option is available to	HPMS Plan Crosswalk	The renewal PBP ID	No enrollment	Current enrollees are sent
	SAE.	local MA Plans only. An	Definition:	must remain the same	request is	a standard ANOC.
		MAO continues to offer a	A 2012 plan that links to a	so that current enrollees	required for	
		CY 2011 local MA PBP in	2011 plan and retains all of	in the remaining in the	current enrollees	
		CY 2012 and retains all of	its plan service area from	service area will remain	to remain	
		the same PBP service area,	2011, but also adds one or	in the same PBP ID	enrolled in the	
		but also adds one or more	more new counties. The		renewal PBP in	
		new service areas. The	2012 plan must retain the	The MAO does not	2012	
		same PBP ID number must	same plan ID as the 2011	submit enrollment		
		be retained in order for all	plan	transactions for current	New enrollees	
		current enrollees to remain		2011 enrollees. The	must complete	
		in the same MA PBP in CY	HPMS Plan Crosswalk	MAO submits	enrollment	
		2012	Designation:	enrollment transactions	request.	
			Renewal Plan with an SAE.	for new enrollees.		
			Note: If the 2012 plan has			
			both an SAE and a SAR,			
			the plan must be renewed			
			as a renewal plan with a			
			SAR			

Activity	Guidelines	<b>Renewal Effectuation</b>	Systems Enrollment	Enrollment	Beneficiary Notifications
-		Method	Activities	Procedures	_
Renewal Plan with a SAR and no other MA options available	This option is available to local MA plans only. An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAO The MAO may offer the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR § 422.74(b)(3)(ii)) Note: One renewal plan with a SAR may have counties that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply	Method HPMS Plan Crosswalk Definition: A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan HPMS Plan Crosswalk Designation: Renewal Plan with a SAR. Note: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR	Activities The MAO must submit disenrollment transactions for individuals residing in the reduced portion of the service area for whom it does not collect an enrollment request The MAO does not submit enrollment transactions for current enrollees in the renewal portion of the service area.	Procedures Enrollees impacted by the SAR need to complete an enrollment request if the MAO offers the option of continued enrollment (see 42 CFR § 422.74(b) (3) (ii))	The MAO sends a termination notice to current enrollees in the reduced service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide affected enrollees additional information, within or following the termination notice, about the option to remain enrolled in the plan if the MAO elects to offer enrollment to enrollees in the reduced portion of the service area Current enrollees in the renewal portion of the service area receive the standard ANOC
	Renewal Plan with a SAR and no other MA options	Renewal Plan with a SAR and no other MA options availableThis option is available to local MA plans only. An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAOThe MAO may offer the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR § 422.74(b)(3)(ii))Note: One renewal plan with a SAR may have counties that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided	MethodRenewal Plan with a SAR and no other MA optionsThis option is available to local MA plans only. An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAOHPMS Plan Crosswalk Definition: A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan.The MAO may offer the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR § 422.74(b)(3)(ii))Note: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided in 5a (i.e., the guidance provided in 5a and other counties in the SAR that should follow the guidance provided in 5a and other counties in the SAR that should follow the guidance provided in 5a (i.e., the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided in 5a and 5b may both applyMethod HPMS Plan Crosswalk Designation: Renewal Plan with a SAR.	MethodActivitiesRenewal Plan with a SAR and no other MA options availableThis option is available to local MA plans only. An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAOHPMS Plan Crosswalk Definition: a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 planThe MAO must submit disenrollment transactions for individuals residing in the reduced portion of the service area for whom it does not collect an enrollment requestThe MAO may offer the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR § 422.74(b)(3)(ij))HPMS Plan Crosswalk Designation: Renewal Plan with a SAR.The MAO does not submit enrollment transactions for current enrollees in the renewal as a renewal plan with a SARNote: One renewal plan with a SAR may have counties that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided in 5a, and other counties in the san and 5b may both applyHethod	Renewal Plan with a SAR and no other MA options availableThis option is available to Iocal MA plans only. An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAOHethol Plan Crosswalk Definition: A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must the 2011 planThe MAO must submit disenrollment transactions for undividuals residing in the reduced portion or any other MAOProceduresThe MAO may offer the option to individuals in the reduced portion of the service area for CY 2012 to enroll in its remaining PBP if no other MA plans are available (see 42 CFR § 422.74(b)(3)(ii))MethodActivitiesProceduresNote: If the 2012 plan must be renewed as a renewal plan with a SARNote: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SARThe MAO does not continued enrollment transactions for current enrollees in the renewal portion of the service area.The MAO does not continued enrollment transactions for current enrollees in the renewal portion of the service area.The MAO does not continued enrollment transactions for current enrollees in the renewal portion of the service area.The MAO does not continued enrollment transactions for current enrollees in the renewal portion of the service area.The MAO does not continued enrollment transactions for current enrollees in the renewal portion of the service area.The MAO does not continued enrollees in the renewal portion of the serv

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
56	Renewal Plan with a SAR when the MAO will offer another PBP in the reduced portion of the service area	This option is available to local MA plans only. An MAO reduces the service area of a CY 2011 MA PBP and the reduced service area is part of a new or renewal PBP offered by that MAO in 2012 The MAO may market to enrollees in the reduced service area any other PBP offered in the reduced service area for CY 2012. Affected enrollees who elect to enroll in another MA plan offered in the reduced service area must submit an enrollment request Note: One renewal plan with a SAR may have counties that should follow the guidance provided in 5a and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply to a single plan).	<ul> <li>HPMS Plan Crosswalk Definition:</li> <li>A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan</li> <li>HPMS Plan Crosswalk Designation: Renewal Plan with a SAR.</li> <li>Note: If the 2012 plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR.</li> </ul>	The MAO <b>must</b> <b>submit transactions to</b> <b>disenroll individuals</b> residing in the reduced portion of the service area The MAO submits enrollment transactions to enroll beneficiaries who have requested enrollment in other PBP offered in the reduced service area	Enrollees impacted by the SAR need to complete enrollment requests if they elect to enroll in another PBP (plan) in the same organization or a different MA plan.	The MAO sends a termination notice to current enrollees in the reduced portion of the service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide additional information, within or following the termination notice, including instructions on how to complete an enrollment request to switch to another PBP offered by the same organization Current enrollees in the renewal portion of the service area receive the standard ANOC.
6	Terminated Plan (Non- Renewal).	An MAO terminates the offering of a CY 2011 PBP	<ul> <li>HPMS Plan Crosswalk</li> <li>Definition:</li> <li>A 2011 plan that is no longer offered in 2012</li> <li>HPMS Plan Crosswalk</li> <li>Designation:</li> <li>Terminated Plan</li> </ul>	The MAO <b>does not</b> submit disenrollment transactions. If the terminated enrollee elects to enroll in another MA plan with the same or any other MAO, that organization <b>must submit</b> <b>enrollment</b> <b>transactions</b> to enroll the beneficiary.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even in the same organization.	Terminated enrollees are sent a termination notice that includes notification of SEP and guaranteed issue Medigap rights.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
7a	Non-network PFFS plan transitioning to a partial network PFFS plan.	For PFFS only: An MAO consolidates one or more CY 2011 non-network PFFS PBPs into a single new or renewing CY 2012 partial PFFS PBP under a separate contract held by the <u>same</u> legal entity. Only consolidation of whole PBPs is allowed under this option; PBPs may not be split.	Exceptions Renewal Request: Organizations cannot complete this transition via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS staff, who will complete the transition on behalf of the organization HPMS Plan Crosswalk Designation: The non-network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk. The 2012 partial network plan must be active and contain the applicable service area from the terminated plan being renewed.	HPMS will record the consolidation of one or more whole PBPs. The MAO <b>does not</b> submit enrollment transactions for current enrollees MAOs may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment request	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	<b>Beneficiary Notifications</b>
7b.	Some counties of a non- network PFFS plan transitioning to a partial network PFFS plan.	For PFFS only: For the counties in the 2011 non- network PFFS PBP that will remain non-network, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance For current enrollees residing in the counties in the 2011 non-network PFFS PBP that will be consolidated into a single new or renewing partial network PBP under a separate contract held by the <u>same</u> legal entity, the MAO must submit enrollment transactions.	Exceptions Crosswalk Request: . Organizations cannot complete the transition of current enrollees to the partial network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS. If approved, the MAO will be permitted to submit enrollment transactions HPMS Plan Crosswalk Definition: A 2012 non-network plan that links to a 2011 non- network plan and only retains the available non- network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan HPMS Plan Crosswalk Designation: Renewal Plan with a SAR	The MAO <b>must</b> submit enrollment transactions to transition current enrollees to the new or renewing partial network PBP under a separate contract held by the same legal entity For current enrollees that remain in the renewed non-network PFFS plan, the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
8a.	Non-network PFFS plan transitioning to a full network PFFS plan.	For PFFS only: An MAO consolidates one or more whole CY 2011 non-network PFFS PBPs into a single new or renewing CY 2012 full network PFFS PBP under a separate contract held by the <u>same</u> legal entity. Under this option, only consolidation of whole PBPs is allowed; PBPs may not be split.	Exceptions Crosswalk Request: Organizations cannot complete this transition via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS staff, who will complete the transition on behalf of the organization HPMS Plan Crosswalk Designation: The non-network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk The 2012 full network plan must be active and contain the applicable service area from the terminated plan being transitioned.	HPMS will record the consolidation of one or more whole PBPs. The MAO <b>does not</b> submit enrollment transactions for current enrollees MAOs may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
8b.	Some counties of a non- network PFFS plan transitioning to a full network PFFS plan.	For PFFS only: For the counties in the 2011 non- network PFFS PBP that will remain non-network, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance For current enrollees residing in the counties in the 2011 non-network PFFS PBP that will be consolidated into a single new or renewing full network PBP under a separate contract held by the <u>same</u> legal entity, the MAO must submit enrollment transactions.	<ul> <li>Exceptions Crosswalk</li> <li>Request:</li> <li>Organizations cannot</li> <li>complete the transition of</li> <li>current enrollees to the full</li> <li>network PFFS plan via the</li> <li>HPMS Plan Crosswalk.</li> <li>Organizations must submit</li> <li>an exceptions request to</li> <li>CMS. If approved, the</li> <li>MAO will be permitted to</li> <li>submit enrollment</li> <li>transactions.</li> <li>HPMS Plan Crosswalk</li> <li>Definition:</li> <li>A 2012 non-network plan</li> <li>that links to a 2011 non-</li> <li>network plan and only</li> <li>retains the available non-</li> <li>network counties in its plan</li> <li>service area. The 2012 plan</li> <li>must retain the same plan</li> <li>ID as the 2011 plan</li> <li>HPMS Plan Crosswalk</li> <li>Designation:</li> <li>Renewal Plan with a SAR.</li> </ul>	The MAO <b>must</b> submit enrollment transactions to transition current enrollees to the new or renewing full network PBP under a separate contract held by the same legal entity For current enrollees that remain in the renewed non-network PFFS plan the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
9a	Partial network PFFS plan transitioning to a full network PFFS plan.	For PFFS only: An MAO consolidates one or more CY 2011 partial network PFFS PBPs into a single new or renewing CY 2012 full network PFFS PBP under a separate contract held by the <u>same</u> legal entity. Only consolidation of whole PBPs is allowed; PBPs may not be split.	Exceptions Renewal Request: Organizations cannot complete this transition via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS staff, who will complete the transition on behalf of the organization HPMS Plan Crosswalk Designation: The partial network plan being transitioned must be marked as a terminated plan in the HPMS Plan Crosswalk The 2012 full network plan must be active and contain the applicable service area from the terminated plan being transitioned	HPMS will record the consolidation of one or more whole PBPs. The MAO <b>does not</b> submit enrollment transactions for current enrollees MAOs may need to submit updated 4RX data for enrollees affected by the consolidation, as applicable.	No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
9b.	Some counties of a partial PFFS plan transitioning to a full network PFFS plan.	For PFFS only: For the counties in the 2011 partial network PFFS PBP that will remain partial, the MAO must follow the rules for a renewal plan with SAR described elsewhere in this guidance For current enrollees residing in the counties in the 2011 partial network PFFS PBP that will be consolidated into a single new or renewing full network PBP under a separate contract held by the <u>same</u> legal entity, the MAO must submit enrollment transactions.	Exceptions Crosswalk Request: Organizations cannot complete the transition of current enrollees to the full network PFFS plan via the HPMS Plan Crosswalk. Organizations must submit an exceptions request to CMS. If approved, the MAO will be permitted to submit enrollment transactions HPMS Plan Crosswalk Definition: A 2012 partial network plan that links to a 2011 partial network plan and only retains the available partial network counties in its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan. HPMS Plan Crosswalk Designation: Renewal Plan with a SAR.	The MAO <b>must</b> submit enrollment transactions to transition current enrollees to the new or renewing full network PBP under a separate contract held by the same legal entity For current enrollees that remain in the renewed partial- network PFFS plan the MAO does not submit enrollment transactions.	No enrollment request is required for current enrollees New enrollees must complete enrollment requests.	Current enrollees are sent a standard ANOC.
10a.	Renewal D-SNP PBP with no State contract that converts to a different D- SNP designation and a State contract such that the same CY 2011 D-SNP PBP with no State contract still exists, but has a State contract and a different title for CY 2012	<b>For D-SNPs only</b> : An MAO offering a CY 2011 D- SNP PBP with no State contract that renews and has converted to a different D- SNP type for CY 2012.	<ul> <li>HPMS Plan Crosswalk</li> <li>Definition:</li> <li>A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan.</li> <li>HPMS Plan Crosswalk</li> <li>Designation:</li> <li>Renewal Plan</li> </ul>	The MAO does not send enrollment transactions for current enrollees who will remain enrolled in the 2012 renewal PBP The MAO submits disenrollment transactions for current enrollees who are ineligible for the renewing D-SNP.	No enrollment request is required for current enrollees who are eligible to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment requests.	Current enrollees eligible to remain enrolled in the renewal plan receive a standard ANOC The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are disenrolled, which will convey SEP and, if appropriate, guaranteed issue Medigap rights.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
10Ь.	D-SNP with no State contract consolidating with a D-SNP with a State contract, so that, effectively, an entire D- SNP is transferred into another D-SNP with a state contract and the D-SNP without a State contract no longer exists	For D-SNPs only: An MAO offering a CY 2011 D- SNP PBP with no State contract may consolidate with a CY 2012 D-SNP, offered under the same contract, which has a contract with the State.	HPMS Plan Crosswalk Definition: Two or more whole 2011 D-SNP plans (PBPs) that consolidate into one 2012 plan. The 2012 plan ID must be D-SNP with the state contract.HPMS Plan Crosswalk Designation: Consolidated Renewal Plan.	The MAO does not send enrollment transactions for current enrollees who will remain enrolled in the 2012 PBP The MAO must submit disenrollment transactions for current enrollees who are ineligible for the renewal PBP.	No enrollment request is required for current eligible enrollees to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment requests.	Current enrollees eligible to remain enrolled in the renewal plan receive a standard ANOC The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are disenrolled, which will convey SEP and, if appropriate, guaranteed issue Medigap rights.
11.	Renewing D-SNPs that also creates new Medicaid subset D-SNP and transitions eligible enrollees into the new Medicaid subset D-SNP	For D-SNPs only: An MAO renewing a D-SNP plan for 2012 and also creating a new Medicaid subset D-SNP for 2012. A subset of current enrollees under the renewing D-SNP is eligible to be enrolled in the new Medicaid subset D-SNP. The organization must submit enrollment transactions to move the eligible D-SNP enrollees into the new Medicaid subset D-SNP	<ul> <li>Exceptions Crosswalk</li> <li>Request:</li> <li>Organizations must submit an exceptions request to CMS to transition eligible enrollees into the new Medicaid subset D-SNP</li> <li>HPMS Plan Crosswalk</li> <li>Definition:</li> <li>A 2012 D-SNP that links to a 2011 D-SNP and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan</li> <li>In addition, a new Medicaid Subset plan is added for 2012 that is not linked to a 2011 plan</li> <li>HPMS Plan Crosswalk</li> <li>Designation: Renewal Plan (renewing D- SNP designation) AND</li> <li>New Plan (new Medicaid Subset D-SNP designation).</li> </ul>	The renewal PBP ID must remain the same so that the HPMS Plan Crosswalk will indicate that beneficiaries remain in the same PBP ID The MAO <b>must</b> submit enrollment transactions to transition eligible current enrollees into the new Medicaid subset D-SNP Individual enrollees not transitioned by the submission of enrollment transactions will remain enrolled in the renewing PBP	No enrollment requests: required for current enrollees to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment request.	Current enrollees transitioned to the renewal plan receive a standard ANOC. Current enrollees who are transitioned to the new Medicaid subset PBP receive a standard ANOC.

	Activity	Guidelines	Renewal Effectuation Method	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
12.	Renewing D-SNP in a multi-state service area with a SAR to accommodate State contracting efforts in portions of that service area	For D-SNPs only: An MAO reduces the service area of a CY 2011 D-SNP PBP to accommodate State contracting efforts in a multi-State service area. Current enrollees in the reduced portion of the service area are transitioned to one or more new or renewing CY 2012 D-SNP PBPs. The organization must submit enrollment transactions to move current enrollees in the reduced portion of the CY 2011 D- SNP PBP into the new or renewing CY 2012 D-SNP PBPs.	<ul> <li>Exceptions Crosswalk</li> <li>Request:</li> <li>Organizations must submit an exceptions request to CMS to disenroll individuals residing in the reduced portion of the service area and to enroll those individuals in more than one PBP.</li> <li>HPMS Plan Crosswalk</li> <li>Designation:</li> <li>A 2012 plan that links to a 2011 plan and only retains a portion of its plan service area. The 2012 plan must retain the same plan ID as the 2011 plan</li> <li>In addition, a new plan is added for 2012 that is not linked to a 2011 plan, or a 2011 plan is renewed in 2012</li> <li>HPMS Plan Crosswalk</li> <li>Designation: Renewal Plan with a SAR AND New Plan OR Renewal Plan</li> </ul>	The renewal PBP ID must remain the same so that the HPMS Plan Crosswalk will indicate that beneficiaries remain in the same PBP ID . The MAO must submit enrollment transactions to transition current enrollees in the reduced portion of the service area into a new or renewing D-SNP Individual enrollees not transitioned by the submission of enrollment transactions will remain enrolled in the renewing PBP.	No enrollment request is required for current enrollees in the remaining portion of the service area to remain enrolled in the renewal PBP in CY 2012. New enrollees must complete enrollment request.	Current enrollees in the renewal portion of the service area receive the standard ANOC Current enrollees in the reduced portion of the service area who are transitioned to a new or renewal D-SNP PBP receive the standard ANOC.

	Activity	Guidelines	<b>Renewal Effectuation</b>	Systems Enrollment	Enrollment	Beneficiary Notifications
			Method	Activities	Procedures	
13.	Renewing SNP with ineligible, or "disproportionate share," enrollees.	<b>For D-SNPs only</b> : An MAO renewing a SNP that includes a subset of current enrollees who do not meet the eligibility criteria for enrollment in the SNP ("disproportionate share" enrollees or enrollees affected by change in scope of C-SNP).	<ul> <li>HPMS Plan Crosswalk</li> <li>Definition:</li> <li>A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan.</li> <li>HPMS Plan Crosswalk</li> <li>Designation:</li> <li>Renewal Plan</li> </ul>	The MAO does not send enrollment transactions for current enrollees who meet the SNP eligibility criteria for enrollment and will remain enrolled in the 2012 PBP Plans must submit disenrollment transactions for current enrollees who do not meet the eligibility criteria for enrollment in the SNP.	No enrollment request is required for enrollees eligible to remain enrolled in the renewal PBP in 2012 New enrollees must complete enrollment requests.	Enrollees who remain eligible for the renewing plan receive a standard ANOC The MAO sends a CMS model disenrollment notice to ineligible current enrollees who are disenrolled, which will convey SEP and, if appropriate, guaranteed issue Medigap rights.

### Appendix B-1: CY 2012 PDP PBP Renewal and Non-Renewal Guidance

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 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: <u>http://www.cms.hhs.gov/</u> <u>PrescriptionDrugCovContra/04\_RxContracting\_ApplicationGuidance.asp#TopOfPage</u>.

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 drugbenefitimpl@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June<sup>10</sup> 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 CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2012 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

<sup>&</sup>lt;sup>10</sup> CY 2012 bids are due no later than June 6, 2011

offering the PBP must submit enrollment transactions to MARx. No beneficiary notice is required in this case beyond receipt of the Evidence of Coverage (EOC), and other documents as required by current CMS guidance, following enrollment.

### 2. Renewal Plan

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

### 3. Consolidated Renewal Plan

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

- (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. 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. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming HPMS memorandum providing non-renewal and service area reduction guidance and model notices, to be released this summer.

#### 6. Consolidated Plans under a Parent Organization

For purposes of ensuring compliance with transition requirements following an acquisition or merger under our significant differences policy, or to make plan transitions following a novation, CMS may elect to combine two or more entire PBPs offered under different contracts (the contracts may be offered by the same legal entity or represent different legal entities). PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. A PDP sponsor must complete and submit a request to Sara Silver at <u>sara.silver@cms.hhs.gov</u> by June 6, 2011.

She will coordinate the review of the request and, if approved, complete the renewal on behalf of the requesting PBP. To request the exception, organizations must include in the subject line of the email "HPMS PDP Plan Consolidation across contracts for <Organization Name>" and include the following information in the request:

2011 Contract	2011	2011 Plan	2012 Contract	2012	2012 Plan	Reason for
Number	Contract	ID	Number	Contract	ID	Request
	Name			Name		(Merger,
						Acquisition,
						Novation)

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. (CMS anticipates providing a model for this special notice in the final Call Letter)

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added	PDP sponsor creates a new PBP.	HPMS Plan Crosswalk Definition: A new plan added for 2012 that is not linked to a 2011 plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
			HPMS Plan Crosswalk Designation: New Plan			
2	Renewal Plan	A PDP sponsor continues to offer a CY 2011 PBP in CY 2012. <b>The same PBP ID</b> <b>number must be retained</b> in order for all current enrollees to remain in the same PBP in CY 2012.	<ul> <li>HPMS Plan Crosswalk</li> <li>Definition:</li> <li>A 2012 plan that links to a 2011 plan and retains all of its plan service area from 2011. The 2012 plan must retain the same plan ID as the 2011 plan</li> <li>HPMS Plan Crosswalk</li> <li>Designation: Renewal Plan</li> </ul>	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 2012 New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

## Appendix B-2 – Contract Year 2012 Guidance for Prescription Drug Plan Renewals

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment	Enrollment	Beneficiary
				Activities	Procedures	Notifications
3	Consolidated Renewal Plan	A PDP sponsor combines two or more PBPs offered in CY 2011 into a single renewal PBP for CY 2012. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2012 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.	<ul> <li>HPMS Plan Crosswalk Definition: Two or more 2011 plans that consolidate into one 2012 plan. The 2012 plan ID must be the same as one of the consolidating 2011 plan IDs</li> <li>HPMS Plan Crosswalk Designation: Consolidated Renewal Plan</li> </ul>	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 2012.	Current enrollees are sent a standard ANOC.
4	Renewal Plan with an SAE ( <b>applicable only</b> to employer/union group waiver plans)	A PDP sponsor continues to offer an 800 series CY 2011 prescription drug PBP in CY 2012 and expands it s EGWP service area to include additional regions. <b>The PDP</b> <b>sponsor must retain the same</b> <b>PBP ID number</b> in order for all current enrollees to remain in the same PBP in CY 2012.	HPMS Plan Crosswalk Definition: A 2012 800-series plan that links to a 2011 800- series plan and retains all of its plan service area from 2011, but also adds one or more new regions. The 2012 plan must retain the same plan ID as the 2011 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 2012. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment	Enrollment	Beneficiary
	-			Activities	Procedures	Notifications
5	Terminated Plan	A PDP sponsor terminated the	HPMS Plan Crosswalk	The PDP sponsor	Terminated	Terminated enrollees
	(Non-Renewal)	offering of a 2011 PBP.	Definition:	does not submit	enrollees must	are sent a CMS model
		_	A 2011 plan that is no	disenrollment	complete an	termination notice
			longer offered in 2012.	transactions	enrollment	including SEP
					request if they	information and receive
			HPMS Plan Crosswalk	If the terminated	choose to	a written description of
			Designation:	enrollee elects to	enroll in	options for obtaining
			Terminated Plan	enroll in another PBP	another PBP,	prescription drug
				with the same or	even a PBP	coverage in the service
				another PDP sponsor	offered by the	area.
				or MAO, the	same PDP	
				enrolling PDP	sponsor.	
				sponsor or		
				organization must		
				submit enrollment		
				transactions to		
				enroll the terminated		
				enrollees.		

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment	Enrollment	Beneficiary
				Activities	Procedures	Notifications
6	Consolidated	A parent organization combines	Exceptions Crosswalk	PDP sponsors cannot	No enrollment	Current enrollees are
	Plans across	two or more whole PBPs under	<b>Request:</b> Sponsors	complete this renewal	election for	sent a special notice
	Contracts under	different contracts (the	cannot complete this	option in the HPMS	current	(based on a model CMS
	the Same Parent	contracts may be the same legal	crosswalk via the HPMS	Plan Crosswalk.	enrollees to	will provide) along with
	Organization	entity or represent different	crosswalk. Sponsors	CMS will effectuate	remain	a standard ANOC.
		legal entities) as a result of a	must submit an	this renewal option	enrolled in the	
		merger, acquisition, or	exceptions request to	and HPMS will	renewal PBP	
		novation. A PDP sponsor	CMS, which will	record the	in 2012	
		cannot complete this renewal	complete the crosswalk	consolidation of one		
		option in the HPMS Plan	on behalf of the sponsor.	or more whole PBPs.	New enrollees	
		Crosswalk.		The PDP sponsor	must complete	
			HPMS Plan Crosswalk	does not submit	enrollment	
			Designation:	enrollment	request.	
			The plan being	transactions for		
			crosswalked must be	current enrollees		
			marked as a terminated			
			plan in the HPMS	Sponsors may need to		
			crosswalk	submit updated 4RX		
				data for enrollees		
			The remaining 2012 plan	affected by the		
			must be active and	consolidation.		
			contain the applicable			
			service area from the			
			terminated plan being			
			crosswalked.			