April 2, 2012

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

SUBJECT: Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2013 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2013 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html under Ratebooks and Supporting Data. The statutory component of the regional benchmarks, transitional phase-in periods for the Affordable Care Act rates, qualifying counties, and each county's applicable percentage are also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2013 and the national Medicare fee-for-service growth percentage. These growth rates will be used to update the 2013 rates. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 2.80 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2010 are being posted on the above website.

Information on deductibles for MSA plans is included below.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2013 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). Attachment VII presents the final Call Letter. We received 114 submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 17, 2012. Eight of the comments were from advocacy groups, 22 were from associations, 5 were from members of the public, 1 was from a State, 1 was from a Congressman, 1 was from a Congressional Advisory Committee, 68 were from health plans and 8 were from consultants.

Attachment IV contains tables with the Part D benefit parameters; Attachment V contains details regarding the Part D benefit parameters; Attachment VI contains tables with the 2013 revised frailty, 2013 revised CMS-HCC, and Rx-HCC risk adjustment factors.

Key Change from the Advance Notice:

National MA Growth Percentage. Attachment I provides the final estimates of the National MA Growth Percentages (growth trends) and information on deductibles for MSA.

Part D Benefit Parameters. See Attachment IV for the 2013 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy. The Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries has been revised to $6,954.52 to incorporate a plan and beneficiary liability (of 52.5% and 47.5% respectively) in the coverage gap for dispensing and vaccine administration fees for applicable drugs used by non-low-income beneficiaries.

Proposals Adopted as Issued in the Advance Notice:

As in past years, policies proposed in the Advance Notice that are not modified or retracted in the Rate Announcement become effective in the upcoming payment year, as set forth in the Advance Notice. Clarifications in the Rate Announcement supersede materials in the Advance Notice.

Rebasing County Rates

We will rebase the FFS capitation rates for 2013.

MA Benchmark, Quality Bonus Payments and Rebate

The Affordable Care Act (ACA) established a new blended benchmark as the county MA rate effective in 2012. In the Advance Notice we announced the continued implementation of the methodology used to derive the new ACA blended benchmark county rates, how the qualifying bonus counties will be identified, and how transitional phase in periods are determined. The continued applicability of the star system is also announced.

IME Phase Out. For 2013, CMS will continue phasing out indirect medical education amounts from MA capitation rates.

ESRD State Rates. As announced in the Advance Notice, CMS will update various aspects of ESRD payment including updates to the ESRD State capitation rates.

Clinical Trials. We are continuing 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 National Coverage Determinations on clinical trials.

Location of Network Areas for PFFS Plans in Plan Year 2014. The list of network areas for plan year 2013 is available on the CMS website at http://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/index.html.

CMS-HCC Risk Adjustment Model. We will implement the updated CMS-HCC Risk adjustment model proposed in the Advance Notice. We have updated this model with more recent and complete data and new constraints to categories of diabetes, among other updates.

Adjustment for MA Coding Pattern Differences. We will implement an MA coding pattern difference adjustment of 3.41% for payment year 2013.

New Enrollee Risk Scores for Chronic SNPs. In the Advance Notice, we proposed an updated model which will be used to create the new enrollee risk score for new enrollees in chronic SNPs. This model is built upon the CMS-HCC model and must be updated when the CMS-HCC model is updated. We will implement this model as proposed.

Normalization Factors. The normalization factors for 2013 are:

CMS-HCC model used for MA plans is 1.028.
CMS-HCC model used for PACE organizations is 1.070.
CMS-HCC ESRD Functioning graft status is 1.070.
CMS-HCC ESRD dialysis model is 1.023.
RxHCC model is 1.034.

Frailty Adjustment. The frailty factors for PACE plans and FIDE SNP's are announced in Attachment VI. We proposed continuing the policy of paying frailty to FIDE SNPs with frailty levels similar to PACE as defined as all that are able to be surveyed for frailty that fall within the positive PACE range surveyed on a sample of 100 enrollees or more.

MSP Factors. The 2013 MSP factor for working aged and working disabled beneficiaries is 0.173.

Reduced Coinsurance for Applicable Beneficiaries in the Coverage Gap. In 2013, the 79% beneficiary coinsurance for non-applicable drugs and 47.5% beneficiary coinsurance for applicable drugs in the coverage gap represent an increase in plan liability and a reduction in beneficiary cost sharing. Therefore, we further specify that these increased plan liability amounts do not count towards TrOOP. We announced that Part D sponsors must account for this reduced cost sharing and increased plan liability when developing their Part D bids for contract year 2013.

Dispensing Fees and Vaccine Administration Fees for Applicable Drugs in the Coverage Gap. The coinsurance for applicable (brand) drugs in the coverage gap uses a definition of negotiated price that excludes the dispensing and administration fees. This issue affects both the amount beneficiaries pay at the point-of-sale and Part D sponsor liability for dispensing fees (and vaccine administration fees, if any) for applicable drugs in the coverage gap. In the Advance Notice, we set forth a four step approach for determining manufacturer, beneficiary, and plan sponsor liabilities for coverage gap claims clarifying this issue.

Clarification of Plan and Beneficiary Liabilities Related to the Negotiated Price. In order to ensure a level playing field, uniform treatment of beneficiary liability across all Part D plans, and consistency of benefit administration across all phases of the benefit, plan and beneficiary liability for each cost component of the negotiated price will be calculated proportional to plan and beneficiary liability for the entire negotiated price in all phases of the benefit (plus non-low-income beneficiary liability for dispensing and vaccine administration fees for brand drugs in the coverage gap). Cost components of the negotiated price include ingredient cost, sales tax, dispensing fee, vaccine administration fee, and any other cost component. This approach resolves any ambiguity if, for example, it is necessary to determine what portion of the sales tax was paid by the beneficiary and plan if the sales tax needs to be refunded.

Update of the Rx-HCC Model. We will update the Part D model to reflect more recent data and changes in coverage gap payments.

Payment Reconciliation The 2013 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2012.

Part D Benefit Parameters. Attachment IV provides the updated 2013 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

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Attachments

2013 ANNOUNCEMENT
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Attachment I. Final Estimate of the Increase in the National Per Capita MA Growth Percentages and the National Medicare Fee-for-Service Growth Percentage for 2013

The Table 1 below shows the National Per Capita MA Growth Percentages (NPCMAGP) for 2013. An adjustments of 5.19 percent for the combined aged and disabled is included in the NPCMAGP to account for corrections to prior years' estimates as required by section 1853(c)(6)(C). The combined aged and disabled increase is used in the development of the ratebook.

Table 1 - Increase in the National Per Capita MA Growth Percentages for 2013

	Prior Increases	Current Increases			NPCMAGP for 2013 With §1853(c)(6)(C) adjustment[1]
	2003 to 2012	2003 to 2012	2012 to 2013	2003 to 2013	
Aged+Disabled	40.84%	48.15%	-2.27%	44.78%	2.80%

[1]Current increases for 2003 to 2013 divided by the prior increases for 2003 to 2012.

The Affordable Care Act of 2010 requires the Medicare Advantage benchmark amounts be tied to a percentage of the county FFS amounts. There will be a transition to the percentage of FFS over a number of years. Table 2 below provides the increase in the FFS USPCC which will be used for the county FFS portion of the benchmark. The percentage increase in the FFS USPCC is shown as the current projected FFS USPCC for 2013 divided by projected FFS USPCC for 2012 as estimated in the 2012 Rate Announcement released on April 4, 2011.

Table 2 – Increase in the FFS USPCC Growth Percentage

	Aged + Disabled	Dialysis –only ESRD
Current projected 2013 FFS USPCC	$767.99	$7,218.90
Prior projected 2012 FFS USPCC	$743.54	$7,359.76
Percent increase	3.29%	-1.91%

Table 3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2012 and 2013. In addition, for 2013, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2013. These data were furnished by the Office of the Actuary.

Table 3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2012 and 2013

	2012	2013	Change	2013 non-ESRD
Part A Benefits	$40.92	$40.99	0.2%	$38.98
Part B Benefits[1]	$100.20	$103.95	3.7%	$96.31
Total Medicare	$141.12	$144.94	2.7%	$135.29

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2013 is $10,900.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentages. Attached is a table that compares the published United States Per Capita Costs (USPCC) with current estimates for 2003 to 2013. In addition, this table shows the current projections of the USPCCs through 2015. We are also providing an attached set of tables that summarizes many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2003 through 2015.

Previously, most of the tables in this attachment showed information for aged and disabled non-ESRD separately. Since the MA payment rates are now exclusively based on combined aged and disabled data, we are showing most information on a combined basis. The ESRD information presented is for the combined aged-ESRD, disabled-ESRD and ESRD only.

All of the information provided in this enclosure applies to the Medicare Part A and Part B programs. Caution should be employed in the use of this information. It is based upon nationwide averages, and local conditions can differ substantially from conditions nationwide.

None of the data presented here pertain to the Medicare prescription drug benefit.

Comparison of Current Estimates of the USPCC with Published Estimates – non-ESRD

Calendar Year	Part A			Part B			Part A & Part B		
	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio	Current Estimate	Published Estimate	Ratio
2003	$295.77	$282.50	0.955	$249.37	$229.47	0.920	$545.14	$511.97	0.939
2004	$313.80	$318.43	1.015	$273.97	$261.89	0.956	$587.77	$580.32	0.987
2005	$334.52	$339.49	1.015	$293.53	$280.58	0.956	$628.05	$620.07	0.987
2006	$344.97	$342.67	0.993	$314.44	$312.09	0.993	$659.41	$654.76	0.993
2007	$357.00	$362.06	1.014	$332.28	$335.47	1.010	$689.28	$697.53	1.012
2008	$373.70	$379.02	1.014	$352.89	$352.75	1.000	$726.59	$731.77	1.007
2009	$386.59	$408.50	1.057	$369.97	$357.89	0.967	$756.56	$766.39	1.013
2010	$388.01	$407.38	1.050	$378.78	$360.25	0.951	$766.79	$767.63	1.001
2011	$397.24	$407.38	1.026	$396.54	$360.25	0.908	$793.78	$767.63	0.967
2012	$396.48	$402.32	1.015	$411.14	$363.54	0.884	$807.62	$765.86	0.948
2013	$403.13	$403.13	1.000	$386.13	$386.13	1.000	$789.26	$789.26	1.000
2014	$409.12			$402.22			$811.34		
2015	$408.05			$417.23			$825.28		

Comparison of Current Estimates of the ESRD Dialysis-only FFS USPCC with Prior Estimates

Calendar Year	Part A+B		
	Current Estimate	Last Year's Estimate	Ratio
2009	N/A	$6,929.45	
2010	$6,834.14	$7,121.32	1.042
2011	$7,031.65	$7,284.10	1.036
2012	$7,229.84	$7,359.76	1.018
2013	$7,218.90		
2014	$7,676.79		
2015	$7,925.55		

Basis for ESRD Dialysis-only FFS USPCC Trend

Calendar Year	Part A+B		
	All ESRD Cumulative FFS Trend	Adjustment Factor for Dialysis-only	Adjusted Dialysis-only Cumulative Trend
2011	1.0196	1.0091	1.0289
2012	1.0386	1.0185	1.0579
2013	1.0283	1.0272	1.0563
2014	1.0828	1.0374	1.1233
2015	1.1069	1.0477	1.1597

Note: 2010 All ESRD FFS USPCC is $4,695.55

Summary of Key Projections under Present Law [1]

Part A

Year	Calendar Year CPI Percent Increase	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2003	2.2	3.0	3.5
2004	2.6	3.4	8.4
2005	3.5	3.3	8.8
2006	3.2	3.7	5.9
2007	2.9	3.4	6.1
2008	4.1	3.3	7.7
2009	−0.7	2.7	6.9
2010	2.1	−0.9	3.2
2011	3.7	−0.6	4.9
2012	2.0	−0.1	3.4
2013	1.9	3.2	5.7
2014	2.0	2.5	5.4
2015	2.1	2.7	2.7

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees	Residual[3]		
2003	1.4	4.5%	4.4%	6.8%
2004	1.8	5.9%	11.1%	9.8%
2005	1.5	3.2%	10.8%	7.0%
2006	0.2	4.6%	5.1%	6.1%
2007	0.0	3.5%	8.3%	4.3%
2008	0.5	3.3%	6.2%	4.8%
2009	1.1	1.4%	8.5%	3.8%
2010	1.3	1.6%	5.4%	2.2%
2011	0.9	5.1%	10.2%	4.5%
2012	0.0	3.4%	6.0%	3.2%
2013	−30.8	8.4%	6.0%	−6.6%
2014	1.4	2.8%	6.6%	4.9%
2015	1.3	3.1%	6.7%	4.4%

[1]Percent change over prior year.
[2]Percent change in charges per Aged Part B enrollee.
[3]Residual factors are factors other than price, including volume of services, intensity of services, and age/sex changes.

Medicare Enrollment Projections under Present Law (In Millions)

Non-ESRD Total

	Part A		Part B	
Calendar Year	Aged	Disabled	Aged	Disabled
2003	34.426	5.928	33.027	5.187
2004	34.837	6.247	33.282	5.458
2005	35.243	6.573	33.608	5.746
2006	35.779	6.851	33.960	5.985
2007	36.430	7.128	34.448	6.212
2008	37.358	7.320	35.121	6.404
2009	38.235	7.531	35.811	6.629
2010	39.068	7.760	36.491	6.894
2011	39.811	7.997	37.218	7.156
2012	41.291	8.501	38.510	7.521
2013	42.745	8.759	39.812	7.774
2014	44.147	8.998	41.050	7.977
2015	45.572	9.152	42.305	8.118

Non-ESRD Fee For Service

	Part A		Part B	
Calendar Year	Aged	Disabled	Aged	Disabled
2003	29.582	5.595	28.086	4.847
2004	29.934	5.895	28.288	5.100
2005	30.001	6.141	28.274	5.309
2006	29.350	6.108	27.447	5.236
2007	28.821	6.186	26.765	5.264
2008	28.593	6.199	26.282	5.277
2009	28.542	6.246	26.050	5.338
2010	28.881	6.383	26.236	5.511
2011	29.072	6.485	26.413	5.639
2012	29.606	6.808	26.748	5.823
2013	30.924	7.049	27.912	6.060
2014	32.956	7.383	29.780	6.357
2015	35.458	7.698	32.113	6.659

ESRD

	ESRD-Total		ESRD-Fee For Service	
Calendar Year	Total Part A	Total Part B	Total Part A	Total Part B
2003	0.382	0.370	0.361	0.348
2004	0.399	0.382	0.377	0.360
2005	0.416	0.398	0.394	0.375
2006	0.435	0.416	0.406	0.386
2007	0.453	0.432	0.417	0.396
2008	0.471	0.450	0.428	0.406
2009	0.490	0.468	0.438	0.416
2010	0.508	0.486	0.453	0.431
2011	0.527	0.505	0.469	0.447
2012	0.551	0.529	0.491	0.468
2013	0.572	0.550	0.511	0.488
2014	0.591	0.568	0.533	0.510
2015	0.607	0.584	0.555	0.532

Part A Projections under Present Law for non-ESRD (Aged+Disabled) [1]

Calendar Year	Inpatient Hospital Aged + Disabled	SNF Aged + Disabled	Home Health Aged + Disabled	Managed Care Aged + Disabled	Hospice: Total Reimbursement (in Millions) Aged + Disabled
2003	2,588.58	371.32	124.42	458.37	5,446
2004	2,709.46	414.47	134.05	501.31	6,491
2005	2,812.46	451.65	141.04	603.02	7,615
2006	2,758.66	476.27	141.48	758.13	8,899
2007	2,722.39	505.58	144.37	907.54	9,964
2008	2,711.44	537.99	151.57	1,079.18	10,842
2009	2,676.51	553.49	154.42	1,250.75	11,673
2010	2,666.78	575.76	156.90	1,253.05	12,445
2011	2,633.00	669.20	152.52	1,306.22	13,345
2012	2,601.98	631.15	149.63	1,369.53	14,309
2013	2,680.46	679.89	154.25	1,317.58	15,252
2014	2,794.65	735.79	160.56	1,212.44	16,327
2015	2,891.31	799.43	167.26	1,031.96	17,484

[1]Average reimbursement per enrollee on an incurred basis, except where noted.

Part B Projections under Present Law for non-ESRD (Aged+Disabled) [1]

Calendar Year	Physician Fee Schedule Aged + Disabled	Part B Hospital Aged + Disabled	Durable Medicare Equipment Aged + Disabled
2003	1240.44	365.14	197.17
2004	1367.32	419.28	196.45
2005	1404.39	478.18	195.32
2006	1403.33	498.05	196.84
2007	1381.41	527.56	194.70
2008	1380.97	555.56	199.92
2009	1391.15	598.93	183.02
2010	1435.01	629.30	185.17
2011	1508.93	692.42	182.07
2012	1516.11	726.20	192.57
2013	1116.05	782.44	191.45
2014	1206.75	867.35	195.64
2015	1318.25	970.86	214.50

Calendar Year	Carrier Lab Aged + Disabled	Other Carrier Aged + Disabled	Intermediary Lab Aged + Disabled
2003	74.78	333.74	75.25
2004	80.61	361.00	80.56
2005	82.56	363.88	84.26
2006	85.44	362.11	84.60
2007	91.42	367.23	84.48
2008	95.27	370.47	86.15
2009	102.90	389.64	90.62
2010	102.43	400.75	91.70
2011	103.73	421.56	97.57
2012	107.29	434.08	99.47
2013	110.35	457.89	101.02
2014	118.66	495.99	108.40
2015	128.46	532.62	117.18

Calendar Year	Other Intermediary Aged + Disabled	Home Health Aged + Disabled	Managed Care Aged + Disabled
2003	114.10	136.89	421.83
2004	119.70	156.61	471.86
2005	139.93	179.63	560.92
2006	142.25	203.12	770.83
2007	151.35	232.61	932.63
2008	158.39	252.75	1108.16
2009	173.19	277.68	1208.38
2010	173.28	280.64	1224.17
2011	180.29	272.48	1278.60
2012	193.59	268.69	1374.06
2013	177.87	277.22	1399.01
2014	196.37	288.94	1326.81
2015	218.00	301.17	1181.98

[1]Average reimbursement per enrollee on an incurred basis.

Claims Processing Costs as a Fraction of Benefits

Calendar Year	Part A	Part B
2003	0.001849	0.011194
2004	0.001676	0.010542
2005	0.001515	0.009540
2006	0.001245	0.007126
2007	0.000968	0.006067
2008	0.000944	0.006414
2009	0.000844	0.005455
2010	0.000773	0.005055
2011	0.000749	0.004396
2012	0.000749	0.004396
2013	0.000749	0.004396
2014	0.000749	0.004396
2015	0.000749	0.004396

Approximate Calculation of the USPCC, the National MA Growth Percentage for Combined (Aged+Disabled) Beneficiaries, and the FFS USPCC (Aged+Disabled)

The following procedure will approximate the actual calculation of the USPCCs from the underlying assumptions for the contract year for both Part A and Part B.

Part A:
The Part A USPCC can be approximated by using the assumptions in the tables titled "Part A Projections Under Present Law for non-ESRD (Aged+Disabled)" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part A Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts over all types of providers (excluding hospice). Next, multiply this amount by 1 plus the loading factor for administrative expenses from the "Claims Processing Costs" table. Then, divide by 12 to put this amount on a monthly basis.

Part B:
The Part B USPCC can be approximated by using the assumptions in the tables titled "Part B Projections under Present Law for non-ESRD (Aged+Disabled)" and "Claims Processing Costs as a Fraction of Benefits." Information in the "Part B Projections" table is presented on a calendar year per capita basis. First, add the per capita amounts over all types of providers. Next, multiply by 1 plus the loading factor for administrative expenses and divide by 12 to put this amount on a monthly basis.

The National Per Capita MA Growth Percentage:
The National Per Capita MA Growth Percentage for 2013 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2013 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2012.

The FFS USPCC:
The tables used to calculate the total USPCC can also be used to approximate the calculations of the FFS USPCC. The per capita data presented by type of provider in the projections tables for both Part A and B are based on total enrollment. To approximate the FFS USPCCs, first add the corresponding provider types under Part A and Part B separately. For the FFS calculations, do not include the managed care provider type. Next, rebase the sum of the per capita amounts for FFS enrollees, i.e. multiply the sum by total enrollees and divide by FFS enrollees. (The enrollment tables in this attachment now also include FFS enrollment). Then, multiply by 1 plus the loading factor for administrative expenses and divide by 12. The result will only be approximate because there is an additional adjustment to the FFS data which accounts for cost plan data which comes through the FFS data system. This cost plan data is in the total per capita amounts by type of provider, but is removed for the FFS calculations.

Attachment III. Responses to Public Comments

Section A. Estimate of the National Per Capita MA Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2013

Comment: Commenters requested more detail and documentation regarding how the growth percentage was calculated for the Advance Notice, including the basis for CMS' estimate. Commenters asked that CMS include information such as key assumptions underlying the estimate, information on revisions to prior year estimates as shown in Table I of the Advance Notice, and fee schedule and utilization trend assumptions by categories of service (as is typically shown in Attachment II of the Announcement). Commenters also requested that CMS place more documentation in the Advance Notice for future years to assist organizations in understanding the growth percentage.

Response: We will consider providing more detailed information in the Advance Notice to assist the public's understanding of the preliminary estimate of the growth percentage.

Comment: Commenters requested more details regarding the calculation of the FFS USPCC Growth Percentage to maintain consistency with the details provided for the National Per Capita MA Growth Percentage in the Advance Notice.

Response: Beginning with this Notice, we have added additional data in Attachment II regarding FFS enrollment and adjustments for cost plan data in the FFS sector. This information, along with other data in the Projections under Current Law tables, is sufficient to calculate the FFS USPCCs. We have added a discussion of how to use these data to calculate the FFS USPCC in the Approximate Calculation of the USPCC and the National MA Growth Percentage for Combined (Aged+Disabled) Beneficiaries section of Attachment II.

Comment: One commenter asserted that CMS has consistently understated the MA growth percentage in its annual announcements, on average by approximately 1.5 percentage points. The commenter believes there may be a bias in CMS' estimation methodologies that needs to be examined and adjusted for in the final 2012 rates and that it may not be driven by the SGR fix. The commenter is concerned that MA plans are being asked to defer a portion of their income.

Response: CMS's adjustments to prior year estimates include many cases of both positive and negative adjustments, suggesting that there is no bias in the initial estimates for any given year. There are often positive adjustments in the first year after the initial estimate is made, and the major reason for this trend is the consistent adjustment to the physician update factor which usually occurs after the MA rates have been announced. While there are other reasons for adjustments in the first year, the prominent adjustment is typically tied to an update to the physician fee schedule.

Comment: Several commenters contended that, given the fact that Congress, since 2003, has made adjustments to avoid reductions in physician payments under the SGR formula, it can be expected that Congress will again act legislatively to eliminate the reduction in payment for 2012 provided for under current law. These commenters accordingly requested that CMS include the impact of the expected SGR "fix" when calculating the national per capita MA growth percentage and prior year revision. Commenters recommended that CMS disclose the legislative and/or regulatory basis that requires it to ignore the consistent repeal of the SGR-legislated fee schedule reductions. One commenter noted that the policy is especially problematic for PFFS plans.

Response: CMS's consistent interpretation and longstanding practice has been to base the projected growth percentage on the law as it exists on the date of the announcement of the payment rate update. The statute requires that the growth percentage reflect the Secretary's estimate of the projected per capita rate of growth in expenditures "under this title." We believe that the best reading of this statutory language is that the growth percentage should be based on the provisions of "this title" (Title XVIII) as of the date that the rates are announced. As a result, every ratebook to date has been based on a USPCC increase estimated under the then current law. Changes to the Medicare statute are a fairly common occurrence. There have been a number of years where Medicare expenditures were expected to be reduced by pending legislative action. In those years, if we had anticipated the legislative changes in the projections, payments to Medicare Advantage plans would have been reduced. By following current law as the basis for the projection, any judgment regarding the likelihood or implications of unknown possible law changes is removed.

Comment: One commenter asked CMS to demonstrate how the year-over-year cost trends are reduced by a younger, baby boomer, Medicare population.

Response: The effects of the baby boomers are implicitly included in OACT's projections of future Medicare costs. OACT's main projection models include age-sex utilization adjustments for most types of service. As expected, these age-sex utilization adjustments are lowest for the younger aged population and generally increase by age. When combining the projected enrollment, the age-sex utilization adjustments and other assumptions affecting future costs, the projection models account for the baby-boomer effects.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: Commenters asked CMS to clarify its policy regarding the frequency with which we will rebase our rates. One commenter requested that CMS provide the overall impact of changes on health plans. Commenters stated that CMS should consider rebasing less frequently in order to maintain stability of the rates.

Response: Section 1853(c)(1)(D)(ii) requires CMS to rebase the county fee-for-service (FFS) rates, which form the basis of the specified amount, periodically, but not less than once every three years. When the rates are rebased, CMS updates its estimate of each county's FFS costs using more current FFS claims information. CMS will rebase the FFS rates for 2013. The new Affordable Care Act rate set under section 1853(n)(2) of the Act (specified amount) is based on FFS costs. Rebasing provides the most recent calculation of this cost and moves us closest to a FFS based rate. Rebasing also helps provide a smooth glide path toward the FFS rate, in that it limits the more radical changes that may occur with less frequent updates. We do not provide impact information in the Advance Notice because the data used to determine the county FFS costs are not available until the time of the Rate Announcement.

Comment: Commenters expressed concern over the transition for plans who were in double bonus counties in 2012 and who will no longer be in double bonus counties in 2013. A few commenters requested that CMS publish draft county FFS cost data in the Advance Notice to give plans an approximation of which counties will be eligible for double bonuses. One commenter suggested we use the same data that is used for the county quartile determination.

Response: The statute clearly provides for a transition to the blended benchmark (Section 1853(n)) and a transition for changes in the applicable percentage (Section 1853(n)(2)(D)). The statute is silent on transitions for changes in bonus county status. We interpret this to mean that the statute did not intend for a transition to occur for changes in bonus county status.

We do not use the same data for the qualifying county determination that is used for the county quartile determination, because the statute specifies that we use different data. For the county quartiles, 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. Determination of the qualifying county under section 1853(o)(3)(B)(iii) requires the use of expenditures for individuals enrolled under the original Medicare FFS program for the year. We do not provide double bonus county information in the Advance Notice because the data used to determine the county FFS costs are not available until the time of the Rate Announcement.

Comment: Several commenters expressed concerns that Puerto Rico rates are still artificially low because of special FFS payment provisions for Puerto Rico. Further, these commenters believe plans are disadvantaged in achieving a three-star or higher rating and because double bonus counties are not possible because Puerto Rico does not have urban floors, plans cannot receive relief through quality bonus payments. These commenters also stated that Puerto Rico rate calculation changes from 2012 should not be phased-in.

Response: CMS began a detailed analysis of FFS spending in Puerto Rico in the fall of 2010. The results of that analysis confirmed Medicare enrollment, cost, and use patterns in Puerto Rico are different than in the States. A far greater proportion of beneficiaries in Puerto Rico enroll in

Medicare Advantage plans and those who remain in FFS are much less likely to enroll in Part B. While most mainland beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in Puerto Rico must take affirmative action to opt-in to Part B coverage. In addition, Medicare FFS payment rates in Puerto Rico tend to be lower than on the mainland.

Given that beneficiaries who enroll in Medicare Advantage are enrolled in both Part A and Part B, we concluded the FFS rate calculation in Puerto Rico should be based exclusively on beneficiaries who are enrolled in both Part A and Part B. This refinement was included in the FFS rates that OACT calculated and was announced in the 2012 Rate Announcement published on April 4, 2011. As a result of this change, rates increased in Puerto Rico counties relative to what they would have been under the previous methodology.

Commenters noted that these changes will not be fully reflected in the FFS calculation for several years because the FFS rate calculations are based on a five-year-rolling average and subject to a data lag. Commenters requested that we allow these changes in FFS payment methodologies to impact MA rates sooner. As with other changes that affect the average geographic adjustment (AGA) calculation, and to limit significant annual fluctuations, either upward or downward, for 2013 we will continue to reflect the new approach for tabulating Puerto Rico FFS claims and enrollees in an additional year of FFS tabulations. The statute prescribes how FFS costs must be calculated at 1853(c)(1)(D) and how the benchmarks must be calculated at 1853(n). We believe the calculation of FFS rates is based on the FFS payment rules, which cannot be adjusted for calculating MA payment. Additionally, Section 1853(o)(3)(B) defines the parameters for identifying qualifying counties, and does not incorporate any exceptions.

We appreciate the concerns commenters have raised regarding Puerto Rico. However, we have thoroughly reviewed the methodology used to calculate FFS rates and believe the methodology, including the refinement described above, represents the best and most accurate estimate of FFS costs in Puerto Rico.

Comment: One commenter expressed concern over the disparity between transition schedules toward rates based on FFS for counties in Rhode Island.

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

transition schedules for the blended benchmark are clearly defined in Section 1853(n) of the Statute.

Comment: One commenter asked that CMS provide clarification that any new MA contract will continue to receive a weighted average of star ratings of the parent organization.

Response: As stated in the 2013 Advance Notice, 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 quality bonus payment (QBP) purposes for 2013. These contracts are treated as new MA contracts during the demonstration until the contract has enough data to calculate a star rating. For a parent organization that has had MA contract(s) with CMS in the previous three years, any new MA contract under that parent organization will receive a weighted average of the star ratings earned by the parent organization's existing MA contracts or MA contracts in the previous three years if there are no existing contracts in the current year.

Comment: One commenter requested that CMS provide tentative dates for the release of the final analysis of the QBP demonstration and the methodology that will be utilized for plan years after 2014. Another commenter requested that the demonstration be time limited, in order to encourage three-star plans to improve quality. Other commenters wrote in support of the QBP demonstration.

Response: The Quality Bonus Payment demonstration is a three-year demonstration that will end in 2014. The QBP demonstration seeks to test whether providing an alternate bonus structure further incents plans to achieve quality improvements and, as a result, leads to more rapid and larger year-to-year improvements in quality scores. To the extent that three-star plans improve their quality scores, and in turn their star ratings, under the demonstration, this quality improvement and subsequent movement from three to four stars will provide a natural transition to the statutory bonus structure after the completion of the demonstration. We plan to complete the demonstration evaluation in July 2015, after the conclusion of the demonstration.

Comment: One commenter requested a statement regarding Program of All-Inclusive Care for the Elderly (PACE) organizations' exclusion from the new blended benchmark being used as the MA County rate as provided under the statute.

Response: We welcome the opportunity to clarify this issue. The blended benchmarks will not be used as the MA county rates applied to the payment to PACE organizations. The PACE rates will be published in a separate ratebook.

Section C. Miscellaneous Part C

Comment: Many commenters asked for more information on sequestration under the Budget Control Act of 2011. Commenters stated that it has the potential to significantly impact MA and Part D payments.

Response: This is a government-wide topic that is not specific to MA and Part D plans. The Administration is urging Congress to enact balanced deficit reduction legislation that avoids sequestration, as proposed in the FY 2013 President's Budget. Sequestration guidance will be provided later as appropriate.

Comment: Two commenters asked that we provide guidance as soon as possible on the methodology that we will use to calculate the Medicare medical loss ratio (MLR), which will be implemented for 2014. One commenter asked CMS to consider the extensive administrative obligations for MA plans.

Response: CMS plans to release a Medicare MLR proposed rule for public comment in future months.

Section D. CMS-HCC Risk Adjustment Model

Comment: Many commenters expressed support for periodically recalibrating the current CMS-HCC model based on newer and more complete data to ensure that more recent coding and expenditure patterns are reflected in plan payments, as well as to increase the model's accuracy for payment. Several commenters also expressed appreciation for maintaining the current condition categories in the model for 2013, while one commenter expressed disappointment in not seeing dementia added to this model, and requested CMS reconsider its inclusion for 2013.

Response: We appreciate the support for implementing the proposed CMS-HCC model for 2013. We also appreciate the commenters' input regarding the diagnoses in the model. Our decision to recalibrate the current CMS-HCC model without adding or deleting any condition categories for 2013 was to increase the model's accuracy for payment, while also providing some continuity in payment methodology for MA organizations in 2013, given other changes that are taking place.

Comment: Several commenters asked specifically about the new constraint on the diabetes coefficients in the model, expressing concern regarding its potential impact on payment, stating that clinical distinctions of the disease should have a graduated reimbursement factor, and inquiring as to how these constraints increase the accuracy of the model. A few commenters expressly requested that CMS reconsider the constraints applied to the diabetes categories, while a few requested that CMS provide plan-specific payment impacts for changes to the model, and one requested an impact analysis on the plan benchmarks and rates from the model changes.

Response: As stated in the Advance Notice, constraints are implemented on HCCs for a number of reasons, including retaining the appropriate statistical relationship between the level of severity of HCCs, limiting variation where coding is new or otherwise does not well represent clinical experience, and where the sample size for specific HCCs does not result in a stable estimate. The constraint applied to the diabetes coefficients is in keeping with the articulated model development policies and principles. CMS estimates the aggregate impact of the 2013 CMS-HCC model to be approximately a positive 0.1% on the national average Medicare Advantage risk score. However, the 2013 model will have a differential effect across plans depending upon the make-up of plan-specific populations and, as a result, the impact of the new model on plans' risk scores can vary.

Comment: Several commenters inquired about CMS's indication that, as part of our ongoing process to identify and analyze ways to improve the model, we are exploring the incorporation of additional aspects of coding quality and completeness, and requested that CMS provide further details and insights on this topic. One commenter stated that the HCC system was designed to be a risk based model based on claims and diagnostic data, not a treatment based system.

Response: We appreciate the interest this topic generated, and the comments provided. CMS conducts comprehensive evaluations of its CMS-HCC model on a regular basis. Additionally, the Affordable Care Act requires a periodic evaluation of the CMS risk adjustment system used to account for medical expenditures and care coordination costs for specified subsets of beneficiaries. In the course of evaluating the CMS-HCC model, CMS is exploring the possibility of researching and examining additional aspects of coding quality and completeness to determine the most appropriate approach for potentially incorporating the results of such analyses into a future CMS-HCC model in order to increase payment accuracy.

Comment: A few commenters requested that when CMS considers changing the risk adjustment model structure by adding and/or deleting condition categories that CMS disclose this type of model change no less than six to nine months prior to the final Rate Notice so that organizations can make system changes.

Response: While we understand that Medicare Advantage Organizations (MAOs) need to make system changes, releasing recalibrated models prior to the release of the Advance Notice for a year would result in models with longer lags in the underlying data. While some data lags cannot be avoided, CMS wants to shorten the data lag as much as possible for the purposes of payment accuracy. The CMS-HCC model that we are implementing for 2013 uses 2008-2009 FFS data to produce the coefficients, and releasing the model any earlier would mean using even earlier years of data. Because the relative values of the model reflect the relationship between diagnosis and expenditures, using earlier years of data would incorporate less recent health care

utilization and treatment patterns into the models. We also note that CMS faces similar timelines for system changes as MAOs.

Comment: One commenter expressed concern about the accuracy of the risk adjustment model for full benefit duals who are under 65 and duals with advanced age, frailty, and/or advanced stages of illnesses, and inquired about how CMS is approaching the Affordable Care Act (ACA) language requiring further refinements of the underlying model. Several commenters also requested that CMS increase transparency regarding the model recalibration and development process by providing data and statistical outputs.

Response: Our model development process involves a thorough assessment of the ability of the CMS-HCC model to predict Medicare costs for not only all Medicare beneficiaries, but also for subpopulations of Medicare beneficiaries. We direct the commenter to the evaluation that we published with the 2012 Rate Announcement at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf, as it more thoroughly explains the processes through which the model is created, including the methodologies used to ascertain which HCCs are included within the model. The output of the regression model (the dollar coefficients) for the HCCs that are in the payment model can be obtained simply by multiplying the relative factors by the model denominator.

For information on how the risk adjustment model addresses frailty, please refer to Section 2 of the evaluation, where extensive research on the frailty model and potential methods for more effectively capturing these costs are summarized. For information on how the risk adjustment model performs in capturing the costs of individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, please refer to Section 3 of the evaluation and the extensive discussion of model performance over a wide range of diagnoses, combinations of diagnoses, and range of risk given a number of serious conditions. Finally, for discussion of an assessment of the ability of the risk adjustment model to capture the scale of morbidity among beneficiaries enrolled in C-SNPs, please refer to Section 4 of the evaluation. Please also refer to the following publication for more information on model development and performance: http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/Downloads/04summerpg119.pdf

Comment: One commenter inquired if CMS used the 13 newly "tagged" conditions in the chronic condition warehouse as announced on January 30th by the Medicare-Medicaid Coordination Office in the 2007 data used for the risk adjustment update, and if not, how CMS uses these conditions in the HCC model.

Response: The flags in the Chronic Condition Warehouse (CCW) are used for analytic purposes, and are derived using algorithms developed to best identify those beneficiaries who have a certain condition. Flags are derived from data found on claims, including ICD-9, CPT4, and

HCPCS codes, along with requirements relating to the type and number of encounters. The CMS-HCC model uses diagnoses as part of a model developed to predict Medicare costs. As such, we use diagnoses taken directly from claims or from MA reported data.

Section E. Adjustment for MA Coding Pattern Differences

Comment: One commenter suggested that CMS examine the General Accountability Office's (GAO) findings, published in the January 2012 report entitled "CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practice" and account for coding differences between Fee-for-Service Medicare and Medicare Advantage that may result in inaccurate risk score adjustments and overpayments to plans.

Response: CMS uses a different methodology than was used in GAO's analysis and, while we found their method informative, we believe that our methodology results in an accurate measure of the coding differential between FFS and MA. CMS continually develops its understanding of coding trends and makes an assessment for each payment year regarding the appropriate adjustment based on specific considerations of both coding trends and other market changes.

Comment: One commenter expressed support for CMS's decision to maintain the level of the 2012 adjustment for 2013, stating that doing so mitigates the significant adverse and disproportionate impact that that the ACA is having on Puerto Rico MA plan funding.

Response: We acknowledge the commenter's support for maintaining the current coding pattern adjustment.

Section F. New Enrollee Risk Scores for Chronic SNPs

Comment: A few commenters suggested that the new enrollee factor for chronic care Special Needs Plans (C-SNPs) should apply to all existing Medicare beneficiaries who are newly enrolling in a C-SNP instead of being applied only to those who are new to Medicare, while other commenters requested that a new enrollee factor be calculated for beneficiaries new to all SNPs and PACE organizations as well, not just C-SNPs.

Response: CMS interprets the current statutory requirement to only require the application of the C-SNP risk adjustment model to new Medicare beneficiaries. CMS is not planning to develop a set of risk scores for continuing Medicare enrollees who are new to C-SNPs. Under CMS's risk adjustment methodology, risk scores reflect prior year diagnoses and, given the strict rules about documenting reported diagnoses, CMS does not consider it appropriate that we impute prior year diagnoses for beneficiaries not new to Medicare. Many beneficiaries who are enrolled in MA plans develop conditions in the payment year that they did not have previously, and the risk model is designed to accurately predict risk across subgroups of beneficiaries, including groups

of high-risk beneficiaries. As documented in the evaluation published with the 2012 Rate Announcement, the current model works well within subgroups of risk, including high-risk groups such as those enrolled in C-SNPs. As we further documented in the published evaluation, there is evidence that C-SNP enrollees are not higher risk or more sick than similar FFS enrollees.

Additionally, CMS is not considering applying specially-tailored new enrollee risk scores to Dual SNP, Institutional SNP, or PACE enrollees. We believe that the new enrollee risk score is adequate for enrollees in these other types of plans. While the C-SNP new enrollee model appropriately reflects additional disease burden of beneficiaries with specific diseases enrolled in C-SNPs, the regular new enrollee risk score model captures the additional costs due to Medicaid, disabled, and institutional status.

Section G. Normalization Factors

Comment: A few commenters requested that CMS provide additional details regarding the methodology used to develop the 2013 normalization factors, and how CMS is accounting for the influx of baby boomers, and a likely demographic shift to a younger population in Medicare when developing both the 2013 normalization factors and future year normalization factors.

Response: The formula for calculating normalization factors used to adjust risk scores takes into account the following factors:

(1) The annual trend in risk scores, calculated over a rolling set of years; and (2) the number of years between the denominator year and the payment year.

Each year's normalization factor may change marginally due to updating the annual trend and, to a larger degree, as a result of any change in the gap between the denominator year and the payment year. When we calculate the normalization factor for the payment year, we use the most recent data available for the beneficiaries in the denominator, so as to reflect recent trends. We have decided to calculate an annual trend over five years of risk scores specifically to smooth this trend. No adjustments are made to the data based on expected enrollment or future trends in expenditures. Over time, changes in enrollment patterns, e.g., the influx of baby boomers into Medicare, will be reflected in the trend used to calculate the normalization factors.

The final 2013 CMS-HCC Part C model normalization factor is 1.028.

- The Part C normalization factor is used to normalize the following risk scores: Aged/disabled community, aged/disabled institutional, aged/disabled new enrollee, and C-SNP new enrollee.

- Population used to calculate annual trend: FFS beneficiaries.

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

2007: 0.945
2008: 0.956
2009: 0.972
2010: 0.986
2011: 1.000

The linear annual trend over these five years (2007-2011) is 0.0141. This annual trend is applied for the years between the denominator year (2011) and the payment year (2013) by taking it to the second power. The normalization factor is obtained as follows: $1.0141^2 = 1.028$.

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

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

2007: 0.991
2008: 0.994
2009: 1.000
2010: 1.006
2011: 1.013

The linear annual trend over these five years (2007-2011) is 0.0056. This annual trend is applied for the years between the denominator year (2009) and the payment year (2013) by taking it to the fourth power. The normalization factor is obtained as follows: $1.\ 0056^4 = 1.023$.

The final 2013 normalization factor for the Functioning Graft segment of the ESRD risk adjustment model, and the PACE risk adjustment model is 1.070.

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

2007: 0.966
2008: 0.977
2009: 1.000
2010: 1.016
2011: 1.032

The linear annual trend over these five years (2007-2011) is 0.0172. This annual trend is applied for the years between the denominator year (2009) and the payment year (2013) by taking it to the fourth power. The normalization factor is obtained as follows: $1.\ 0172^4 = 1.070$.

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

- The Part D normalization factor is used to normalize all Part D risk scores.
- Population used to calculate annual trend: PDP and MA enrollees

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

2006: 0.956
2007: 0.964
2008: 0.974
2009: 0.986
2010: 1.000

The linear annual trend over these five years (2006-2010) is 0.01105. This annual trend is applied for the years between the denominator year (2010) and the payment year (2013) by taking it to the third power. The normalization factor is obtained as follows: $1.01105^3 = 1.034$.

Section H. Frailty Adjustment

Comment: One commenter expressed appreciation for CMS's efforts to update the PACE frailty factors for 2013.

Response: We appreciate the support.

Comment: A few commenters were concerned by the terminology CMS used to describe how Fully Integrated Dual Eligible (FIDE) SNP frailty scores will be compared to PACE frailty scores for payment year 2013 in order to determine which FIDE SNPs will receive a frailty add-on to the risk scores of beneficiaries enrolled in the FIDE SNP, and indicated that those FIDE SNPs that that have a frailty score *equal to* or above, not just *above* the PACE threshold should qualify.

Response: We welcome the opportunity to clarify this policy. CMS agrees that for 2013, once the PACE range is established as described in the Advance Notice, those FIDE SNPs that have a frailty score equal to or greater than the minimum PACE score in the range will receive a frailty add-on to the risk scores of beneficiaries enrolled in their FIDE SNP. We further clarify that, as described in the Advance Notice, for 2013, low enrollment (30 or fewer respondents to the Health Outcome Survey (HOS)/Health Outcome Survey-Modified (HOS-M)) or new FIDE SNPs (those who were not eligible to participate in the 2012 HOS due to the length of time the plan was in operation) will not be eligible to receive a frailty score, and therefore will not receive a frailty add-on to their beneficiaries' risk scores.

Comment: A few commenters urged CMS to consider incorporating frailty adjusted payments into the overall risk adjustment system for MA plans, or at a minimum, to incorporate frailty adjusted payments into the risk adjustment methodology used by SNP plans. Several commenters also suggested that CMS develop individual level frailty scores instead of plan level scores so that all plans that have a beneficiary with a PACE level of frailty will receive a commensurate payment for those beneficiaries regardless of plan type. A few commenters also recommended implementing frailty in a budget neutral way so that healthier enrollees would receive a negative frailty adjustment.

Response: By law, CMS must use the same payment methodology for all MA plans, including Special Needs Plans (SNPs), except as explicitly provided for in statute. For example, Section 3205 of the Affordable Care Act permits CMS to make frailty-adjusted payments to only certain dual SNPs identified as FIDE SNPs. Thus, CMS cannot make frailty payments to any SNP that does not meet the Affordable Care Act criteria without implementing frailty payments program-wide. As discussed in further detail within the 2008 Advance Notice and the CMS-HCC model evaluation published with the 2012 Rate Announcement (which includes a discussion of frailty within Section 2), methodological concerns, along with improvements made to the CMS-HCC model, lead us to conclude that the application of frailty adjustment program-wide would not improve payment accuracy. Additionally, as activities of daily living (ADL) data are collected via survey for a subset of a plan's membership, it is not presently possible to pay frailty calculated at an individual level for all enrollees in a plan, and CMS continues to have concerns about the feasibility of collecting detailed beneficiary level data on frailty without causing undue burden on plans. Even if applied industry-wide at the individual beneficiary level, many enrollees would receive a negative frailty adjustment. Given this potential burden, and consistent with studies we have conducted on this topic, we believe that ADLs provide an adequate measure of frailty that can be obtained based on available survey data. Notwithstanding the foregoing, CMS will continue to explore ways to incorporate refinements to our frailty methodology.

Comment: A few commenters requested details regarding other methods for measuring frailty that have been explored by CMS and what limitations have been evidenced that have lead CMS to exclude them from the current methodology. A few commenters also suggested various other methods that CMS should consider to determine plan levels of frailty including, recognizing State assessments of frailty, standardizing SNP specific functional assessments to the same scale for this purpose, surveying only the nursing facility eligible enrollees in dual eligible Special Needs Plans (DSNPs) using the HOS-M, or incorporating Medicaid rate cells to determine institutional status for Medicare beneficiaries. One commenter urged CMS to undertake a comprehensive review of the most recent frailty literature and incorporate the findings into

CMS's next published evaluation of the Risk Adjustment System required under the Affordable Care Act.

Response: We appreciate these comments. CMS recognizes that frailty has many aspects and, as discussed in our responses to comments in the 2012 Rate Announcement and in the evaluation published therewith, CMS continues to evaluate alternative sources of data, including State level assessments, to determine frailty. However, CMS continues to believe that the HOS survey, because it can be sampled at the plan benefit package (PBP) level, presently provides our best estimate of a plan's frailty score. The differences in eligibility criteria by State for home and community based programs could make frailty comparison between FIDE SNPs and PACE difficult, and it would severely limit CMS's ability to calibrate a model that is statistically valid. As the commenters' recognized, State level assessments and SNP-specific functional assessments can vary from one State or plan to another, while the HOS is a uniform national survey, so CMS could not consider using State or SNP assessment tools until they are similarly standardized at a national level. Moreover, as mentioned above, CMS continues to have concerns about the feasibility of collecting detailed beneficiary level data on frailty without causing undue cost burdens on plans.

Comment: One commenter inquired as to why the FIDE SNP frailty factors are based on Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey data while CMS uses HOS data to calculate plan level frailty scores.

Response: CAHPS data, which we used to recalibrate the frailty factors, and HOS data, which we use to calculate frailty scores for payment, both collect ADL information via mail surveys with telephone follow-up. Because CMS calibrates the model on the FFS enrollees, we also need to collect ADL information from FFS enrollees. CMS collects this information from the FFS CAHPS survey. CMS collects ADL information from MA and PACE enrollees from the HOS and HOS-M. The ADL questions asked on the two surveys are similar.

Comment: One commenter expressed concerns regarding DSNPs that may be participating in the Financial Alignment Capitated Model demonstration, and urged CMS to establish the same payment levels for DSNPs participating in the demonstration regardless of whether they meet the FIDE SNP definition so that there are no disparate financial advantages.

Response: We appreciate the commenter's concern. Further guidance regarding the payment structure for plans participating in the Financial Alignment Capitated Model demonstration will be forthcoming.

Comment: A few commenters stated their beliefs that CMS's current methodology of comparing PACE organization frailty scores to a FIDE SNP plan population's frailty score is unfair, especially in areas where State enrollment policies require that DSNPs serve all beneficiaries,

regardless of setting rather than permitting them to carve out certain populations, while PACE programs are permitted to enroll only members that reside in the community but meet nursing home level of care criteria. These commenters suggested CMS change the current methodology by identifying subpopulations of beneficiaries enrolled in FIDE SNP plans and comparing those populations only to PACE populations to determine if they have a frailty score equal to or greater than the minimum PACE score in the range.

Response: The Affordable Care Act directs CMS to look at a FIDE SNP's level of frailty (i.e., plan-level frailty) in comparison to the PACE level of frailty. We believe that our policy is consistent with the statute. Additionally, because the HOS is developed based on a random sample of enrollees, allowing plans to select enrollees to be surveyed would violate the principle of randomization, which would mean that the frailty score could not be generalized to the entire plan. The frailty model is calibrated using a similar methodology of a randomized sample across the FFS population. Therefore, frailty factors reflect the proper weights for this survey approach to measuring frailty in a population.

Comment: One commenter requested that CMS clarify the current rules for defining the population of FIDE SNPs used to determine if the frailty level exceeds that of PACE plans and the range of members that are eligible to receive the frailty payment in the FIDE SNP.

Response: As stated above, the Affordable Care Act directs CMS to look at a FIDE SNP's level of frailty in comparison to PACE. The HOS survey is fielded at the plan benefit package level in order to be able to calculate a frailty score for any FIDE SNP that exists at a sub-contract level. CMS groups the data for each respondent into the following categories: 0 ADLs, 1-2 ADLs, 3-4 ADLs, and 5-6 ADLs. There are separate categories for Medicaid and non-Medicaid respondents.

As noted above, for 2013, low enrollment or new FIDE SNPs will not be eligible to receive a frailty score. Those FIDE SNPs that are determined to be eligible to receive a frailty score will receive a frailty add-on to those beneficiaries' risk scores within their plan that are community residing and at least 55 years old. As is the case with PACE enrollees, the frailty add-on is not applied to institutional beneficiaries. For more information on the frailty model, see http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/Downloads/04-05Winterpg1.pdf For more information on the Health Outcomes Survey, see http://www.hosonline.org/Content/Default.aspx.

Comment: A few commenters suggested that as a result of their model of care and high levels of care coordination, beneficiaries in their plans may not express difficulties with ADLs on telephone or mail surveys as these beneficiaries' experiences may not be reflective of their needs.

Response: The HOS survey has had considerable validation of its ability to accurately capture functional limitation and other health related characteristics. For example, see Journal of Ambulatory Care Management. 2008 Apr-Jun;31(2):161-77, "Patients' self-report of diseases in the Medicare Health Outcomes Survey based on comparisons with linked survey and medical data from the Veterans Health Administration,." Miller DR, Rogers WH, Kazis LE, Spiro A 3rd, Ren XS, Haffer SC**.** As such, CMS believes that the HOS survey continues to provide an accurate measurement of frailty because it collects data consistently between respondents and survey results can be compared across plans.

Section I. MSP Factor

Comment: One commenter asked us to clarify that the MSP factor of 0.173 is only for the aged and disabled population and that the ESRD factor remains unchanged.

Response: The MSP factor of 0.173 is for the aged, disabled and postgraft populations. The MSP factor for the ESRD dialysis and transplant population remains 0.189.

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

Comment: One commenter recommended specifying that coverage gap discounts count towards TrOOP, whereas plan liability does not count towards TrOOP.

Response: Plan liability amounts do not count towards TrOOP. In accordance with section 1860D-2(b)(4)(E) of the Social Security Act, manufacturer discount payments under the coverage gap discount program are treated as incurred costs for purposes of calculating the beneficiary's TrOOP.

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

Comment: Several commenters supported our clarification that dispensing and vaccine administration fee liabilities for applicable (brand) drugs are shared between sponsors and applicable (non-low-income) beneficiaries at 52.5% and 47.5%, respectively.

Response: We appreciate the support and believe this policy supports full closure of the coverage gap for non-low-income beneficiaries by year 2020.

Comment: Several commenters disagreed with our clarification of sponsor and non-low-income beneficiary liabilities for dispensing and vaccine administration fees for brand drugs in the coverage gap. They believe that sponsors and non-low-income beneficiaries should share them at 2.5% and 97.5%, respectively.

Response: Section 1860D-2(B)(2)(D)(i) explains how a non-low-income beneficiary's coinsurance for the ingredient cost and sales tax for brand drugs in the coverage gap is determined, but does not explain non-low-income beneficiary liability for dispensing and vaccine administration fees for brand drugs in the coverage gap. In order for non-low-income beneficiaries to achieve 25% cost sharing (or its actuarial equivalent) in the coverage gap for the defined standard benefit by 2020, they must share dispensing and vaccine administration fee liability with sponsors in a proportion commensurate with their coverage gap coinsurance. Thus, in 2013, non-low-income beneficiaries will be liable for 47.5% of dispensing and vaccine administration fees for brand drugs in the gap.

Comment: Some commenters stated that our clarification of non-low-income beneficiary liabilities for dispensing and vaccine administration fees for brand drugs in the coverage gap seems inconsistent with the preamble in the April 15, 2011 regulation, which says that the beneficiary is fully liable for any dispensing fees.

Response: Until 2013, non-low-income beneficiaries are fully liable for all brand drug expenditures in the gap (assuming no enhanced benefits), after the coverage gap discount is applied. Thus, until 2013, non-low-income beneficiaries are fully liable for the dispensing and vaccine administration fee for brand drugs in the gap (assuming no enhanced benefits) as the preamble language in the April 15, 2011 rule explains.

However, the preamble language in the April 15, 2011 rule must be limited to the 2012 plan year and does not address dispensing and vaccine fee liability once Part D plans begin increasing coverage in the gap starting in 2013. Although it is clear that the dispensing and vaccine administration fees still are not subject to the manufacturer discount and remain excluded from the definition of negotiated price in the coverage gap, we believe plan and beneficiary liabilities for these fees beginning in 2013 must be commensurate with the beneficiary coverage gap coinsurance in order to achieve 25% non-low-income beneficiary coinsurance in 2020. Therefore, non-low-income beneficiaries will be liable for 47.5% of dispensing and vaccine administration fees for brand drugs in the coverage gap in 2013 and Part D plans will be liable for the remaining 52.5% of these fees. Part D plan liability for these fees will continue to increase by the same percentage as the non-low-income beneficiary coverage gap coinsurance percentage decreases until 2020.

Comment: Several commenters were concerned that our clarification of non-low-income beneficiary liabilities for dispensing and vaccine administration fees for brand drugs in the coverage gap (47.5% in 2013) will lead to beneficiary confusion, as opposed to, for example, 97.5% in 2013.

Response: We disagree that this clarification will lead to beneficiary confusion. We believe it is more straightforward for a beneficiary to pay 47.5% cost sharing for the entire Part D brand drug

in the coverage gap, as opposed to 47.5% of the ingredient cost and sales tax plus 97.5% of the dispensing and vaccine administration fees.

Comment: One commenter recommended that CMS not require an explanation of beneficiary liability for dispensing and vaccine administration fees in the Explanation of Benefits.

Response: Consistent with current policy, CMS is not requiring that the Explanation of Benefits include an itemized explanation of non-low-income beneficiary liability for dispensing and vaccine administration fees for brand drugs in the coverage gap. Plan sponsors must accurately report dispensing and vaccine administration fees on prescription drug event records.

Comment: One commenter pointed out that the dispensing fee methodology for generic drugs is not identical to that of brand drugs.

Response: Although the methodology of calculating dispensing and vaccine administration fees in the coverage gap differs for brand drugs and generic drugs, the end result of the calculations is consistent. In 2013, beneficiaries will be liable for 79% of the ingredient cost, sales tax, and dispensing and vaccine administration fees for generic drugs in the coverage gap and will be liable for 47.5% of the ingredient cost, sales tax, and dispensing and vaccine administration fees for brand drugs in the coverage gap.

Comment: Several commenters requested additional explanation for claims that straddle the coverage gap phase of the Part D benefit ("straddle claims") relating to determining manufacturer, beneficiary, and plan sponsor liabilities for the negotiated price, as well as for dispensing and vaccine administration fees.

Response: The four step approach discussed in the 2013 Advance Notice will supersede previous policy guidance regarding dispensing and vaccine administration fees for claims that straddle the coverage gap phase of the Part D benefit for CY2013. As beneficiary liability for each cost component of the negotiated price is calculated proportional to beneficiary liability for the negotiated price in all phases of the benefit (plus non-low-income beneficiary liability for dispensing and vaccine administration fees for brand drugs in the coverage gap), we can now divide the dispensing and vaccine administration fees between the phases that a claim straddles. For example, if only half of a claim falls into the coverage gap, then we will apply the four step approach on half of the dispensing and vaccine administration fee. CMS will engage in discussions with industry regarding operational matters (e.g., PDE submissions) and implementation deadlines. Where appropriate, formal operational guidance will be forthcoming from that collaborative process.

Comment: Many commenters requested additional explanation for determining manufacturer, beneficiary, and plan sponsor liabilities for dispensing and vaccine administration fees in various

scenarios, such as: employer group waiver plans (EGWPs), basic alternative plans, and enhanced alternative plans.

Response: The four step approach proposed in the 2013 Advance Notice for determining manufacturer, beneficiary, and plan sponsor liabilities for dispensing and vaccine administration fees in the coverage gap applies to claims for Part D plans with no enhanced or supplemental benefits.

Beginning in 2013, the beneficiary liability for the dispensing fee (and vaccine administration fees, if any) is commensurate with the coinsurance percentage, (if coinsurance), or commensurate with the percentage of total Part D claim cost attributed to the after discount copayment for enhanced alternative plans (if copayment). Total Part D claim cost includes ingredient cost, sales tax and any dispensing and/or vaccine administration fees.

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

Comment: A couple commenters noted that the plan and beneficiary liabilities for dispensing and vaccine administration fees are different in the gap and outside the gap, and suggested that we use greater precision when we use the coverage gap definition of negotiated price versus the non-coverage gap definition.

Response: We agree that the two statutory definitions of negotiated price, one that includes dispensing fees (and by regulation, vaccine administration fees) in the coverage gap and another that excludes them in the coverage gap, necessitates greater precision of language. Thus, we revise our clarification of plan and beneficiary liabilities related to the negotiated price in the 2013 Advance Notice. The four step approach for determining manufacturer, beneficiary, and plan sponsor liabilities for dispensing and vaccine administration fees in the coverage gap for non-low-income beneficiaries also applies to the negotiated price of brand drugs in the coverage gap for non-low-income beneficiaries.

Comment: One commenter recommended that CMS not require plans to break down the plan and beneficiary liability for each component of the negotiated price, including for reporting prescription drug events (PDEs), because this level of detail is neither needed nor valuable. Moreover, the commenter recommends not explaining the calculations in the Explanation of Benefits.

Response: CMS is not requiring that the Explanation of Benefits include an explanation of beneficiary liability for each component of the negotiated price. The cost components of negotiated price (Ingredient Cost Paid, Dispensing Fee Paid, Total Amount Attributed to Sales Tax, and Vaccine Administration Fee) are already existing fields on each prescription drug event

record and will continue to capture gross drug costs. We do not expect to add corresponding fields to capture beneficiary liability for these amounts.

Comment: Many commenters requested additional explanation for determining manufacturer, beneficiary, and plan sponsor liabilities for negotiated price cost components in various scenarios, such as basic alternative plans and enhanced alternative plans.

Response: Beginning in 2013, the beneficiary liability for the cost components of the negotiated price is commensurate with the beneficiaries' coinsurance percentage applicable in each phase of the benefit (if coinsurance), or commensurate with the percentage of total Part D claim cost attributed to the copayment applicable in each phase of the benefit. Total Part D claim cost includes ingredient cost, sales tax and any dispensing and/or vaccine administration fees.

Comment: Several commenters asked for additional explanation around straddle claims for determining manufacturer, beneficiary, and plan sponsor liabilities for the cost components of the negotiated price.

Response: As mentioned in response to a comment within Section K above, since beneficiary liability for each cost component of the negotiated price is calculated proportional to beneficiary liability for the negotiated price in all phases of the benefit (plus non-low-income beneficiary liability for dispensing and vaccine administration fees for brand drugs in the coverage gap), we can now divide the cost components of the negotiated price between the phases a claim straddles. CMS will engage in discussions with industry regarding operational matters (e.g., PDE submissions) and implementation deadlines. Where appropriate, formal operational guidance will be forthcoming from that collaborative process.

Section M. Update of the Rx-HCC Model

Comment: One commenter asked if the denominator was adjusted for the 2013 gap coverage benefits for non-low income (non-LI) beneficiaries, similar to the way the numerator was adjusted.

Response: The denominator is created by taking a 2010 July cohort of Medicare beneficiaries and running their diagnoses through the newly-recalibrated model with dollar coefficients. The average of the beneficiaries' predicted values was used to denominate the model and create relative factors by dividing all the dollar coefficients by the average predicted costs for the denominator year. Since the model itself was calibrated using costs that were adjusted to reflect the 2013 gap adjustment, the denominator reflects the 2013 gap adjustment.

Comment: One commenter suggested that the denominator used be the average per capita expenditure from 2009 (adjusted to 2013 benefits) to align with the expenditure data used in the

model, and ensure the average RxHCC risk-score is 1.0. The previous recalibration (for CY 2010) used 2008 FFS data, 2009 PDE data, and 2009 average per capita costs as the denominator.

Response: The year of the denominator establishes the year in which the risk scores produced by a model, without additional normalization, average 1.0. CMS calculates a denominator in the most recent year possible to minimize the normalization factor. For example, if we had denominated the RxHCC model with a 2009 denominator, the average 2009 risk score would have been set to 1.0. For 2013, we would then have needed to apply a normalization factor to adjust for coding trends between 2009 and 2013 (for four years). By denominating the model in 2010, the average 2010 risk score is 1.0, and we then can apply a normalization factor that adjusts for three years of trend: 2010 through 2013. In 2011, we first implemented an RxHCC model that incorporated PDE data. The data years in the calibration for 2011 were 2007 (diagnoses) and 2008 (expenditures), and the denominator was 2008. In 2012, the non-Low Income segments of the RxHCC model were updated for the 2012 gap adjustment, and since we had to recalculate the denominator to reflect changes in plan liability, we updated it to 2009, even though the data years were still 2007 and 2008.

Comment: A couple commenters stated that the plan liability of 2.5% used for brand claims in the recalibration should be closer to 3% in order to account for the 52.5% plan liability for the dispensing and vaccine administration fees for non-low-income beneficiaries' brand drug use in the coverage gap. Thus, even after adjusting the denominator to reflect the higher plan liability for non-low-income members, the commenters believe that the resulting coefficients are likely too low for non-low income members and too high for low-income members, resulting in an understatement of costs for non-low-income members.

Response: While the plan liability for brand drugs in the gap will be higher than the 2.5% used in the calibration, the total plan liability will only be minimally affected, as the 52.5% plan liability for dispensing and vaccine administration fees applies only to brand drugs in the gap for non-low-income beneficiaries. Nonetheless, we will consider adding this level of detail to our recalibration of the model the next time we update it.

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

Comment: One commenter asked whether the Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries in the 2013 Advance Notice includes a 52.5% sponsor liability for dispensing and vaccine administration fees for brand drugs used by non-low-income beneficiaries in the coverage gap.

Response: We have revised the Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries to $6,954.52 to incorporate plan and beneficiary liability (of 52.5% and 47.5% respectively) in the coverage gap for dispensing and vaccine administration fees for brand drugs used by non-low-income beneficiaries.

Attachment IV. Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Part D Benefit Parameters

	2012	2013
Standard Benefit		
Deductible	$320	$325
Initial Coverage Limit	$2,930	$2,970
Out-of-Pocket Threshold	$4,700	$4,750
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,657.50	$6,733.75
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,730.39	$6,954.52
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) [category code 3]	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold (1)	$1.10	$1.15
Generic/Preferred Multi-Source Drug (5)	$3.30	$3.50
Other (5)	$0.00	$0.00
Above Out-of-Pocket Threshold		
Over 100% FPL [category code 1]		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,940 (individuals) or ≤ $10,410 (couples) (6) [category code 1]		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $11,570 (individual) or $23,120 (couple) [category code 4]		
Deductible	$65.00	$66.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.60	$2.65
Other	$6.50	$6.60
Retiree Drug Subsidy Amounts		
Cost Threshold	$320	$325
Cost Limit	$6,500	$6,600

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from $1.10 per generic or preferred drug that is a multi-source drug, and $3.30 for all other drugs in 2012[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 payment years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. Beginning with the 2009 payment year, the annual percentage increases are based on Part D program data. For the 2013 payment year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

[1] Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2012 value of $65.23.

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

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

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

The 2013 benefit parameters reflect the 2012 annual percentage trend as well as a revision to the prior estimates for prior years' annual percentage increases. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table III-1.

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

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

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

Table III-2. Annual Percentage Increase

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

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

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 payment year 2013, the September

2012 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2012 CPI based on the projected amount included in the President's FY2013 Budget. The September 2011 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for payment year 2013 is calculated as follows:

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

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

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

Table III-3. Cumulative Annual Percentage Increase in CPI

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

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

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

For 2013, the estimated total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $6,954.52. It is calculated as the ICL plus 100% beneficiary cost sharing divided by the weighted gap coinsurance factor. The factor is calculated assuming 100% beneficiary cost sharing in the deductible phase, 25% in the initial coverage phase and in the coverage gap, 79% for non-applicable (generic) drugs, 97.5% for the ingredient cost and sales tax for applicable (brand) drugs, and 47.5% for dispensing and vaccine administration fees for applicable (brand) drugs. For purposes of this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.88% of the gross covered brand drug costs used by non-low-income beneficiaries in the coverage gap. Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries is calculated as follows:

$$\text{ICL} + \frac{\text{100\% beneficiary Cost Sharing in the gap}}{\text{weighted gap coinsurance factor}} \text{ or } \$2{,}970 + \frac{\$3{,}763.75}{94.4593\%} = \$6{,}954.52$$

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

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

OOP threshold − OOP costs up to the ICL *or* $4,750 − $986.25 = $3,763.75

Weighted gap coinsurance factor is calculated as follows:

(Brand GDCB % for non-LIS × 97.06% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 79% cost sharing for non-applicable drugs)

or

(85.6% × 97.06%) + (14.4% × 79%) = 94.4593%

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to applicable (brand) drugs as reported on the 2011 PDEs.
- Gap cost sharing for applicable drugs is the cost sharing incurred by applicable beneficiaries for applicable (brand) drugs in the coverage gap, where

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

  or

  97.06% = [(99.12% × 97.5%) + (0.88% × 47.5%)]

- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries attributable to non-applicable (generic) drugs as reported on the 2011 PDEs.
- Gap cost sharing for non-applicable drugs is the coinsurance incurred by applicable beneficiaries for non-applicable (generic) drugs in the coverage gap.

V. Retiree Drug Subsidy Amounts

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

multiple of $50. The cost threshold and cost limit are defined as $310 and $6,300, respectively, for plans that end in 2011, and, as $320 and $6,500, respectively, for plans that end in 2012. For 2013, the cost threshold is $325 and the cost limit is $6,600.

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

Tables

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

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

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

Disease Coefficients	Description Label	Community Factors	Institutional Factors
HCC83	Angina Pectoris/Old Myocardial Infarction	0.170	0.331
HCC92	Specified Heart Arrhythmias	0.289	0.245
HCC95	Cerebral Hemorrhage	0.359	0.151
HCC96	Ischemic or Unspecified Stroke	0.265	0.151
HCC100	Hemiplegia/Hemiparesis	0.534	0.069
HCC101	Cerebral Palsy and Other Paralytic Syndromes[3]	0.131	-
HCC104	Vascular Disease with Complications	0.594	0.470
HCC105	Vascular Disease	0.302	0.138
HCC107	Cystic Fibrosis	0.385	0.378
HCC108	Chronic Obstructive Pulmonary Disease	0.340	0.378
HCC111	Aspiration and Specified Bacterial Pneumonias	0.734	0.605
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.206	0.197
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.236	0.440
HCC130	Dialysis Status	1.348	2.228
HCC131	Renal Failure	0.297	0.353
HCC132	Nephritis	0.116	0.353
HCC148	Decubitus Ulcer of Skin	1.165	0.517
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.476	0.291
HCC150	Extensive Third-Degree Burns[3]	1.246	-
HCC154	Severe Head Injury	0.580	0.060
HCC155	Major Head Injury[3]	0.171	-
HCC157	Vertebral Fractures without Spinal Cord Injury	0.467	0.154
HCC158	Hip Fracture/Dislocation[3]	0.435	-
HCC161	Traumatic Amputation	0.793	0.266
HCC164	Major Complications of Medical Care and Trauma	0.311	0.325
HCC174	Major Organ Transplant Status	1.084	0.925
HCC176	Artificial Openings for Feeding or Elimination	0.659	0.861
HCC177	Amputation Status, Lower Limb / Amputation Complications	0.793	0.266
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections[3]	0.597	-
D_HCC44	Disabled_Severe Hematological Disorders	1.340	0.633
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.383	0.284
D_HCC52	Disabled_Drug/Alcohol Dependence	0.105	0.284
D_HCC107	Disabled_Cystic Fibrosis[3]	2.556	-
Disease Interactions			
INT1	DM_CHF[2]	0.150	0.111
INT2	DM_CVD	0.150	0.051
INT3	CHF_COPD	0.278	0.248
INT4	COPD_CVD_CAD	0.233	0.118
INT5	RF_CHF[2,3]	0.262	-
INT6	RF_CHF_DM[2]	0.600	0.373

NOTES:

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

[2] Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms

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

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

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

The 2011 denominator of $9,004.65 used to calculate both the community and institutional factors is the national predicted average annual cost under the model.

DM is diabetes mellitus (HCCs 15-19).

CHF is congestive heart failure (HCC 80).

COPD is chronic obstructive pulmonary disease (HCC 108).

CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).

CAD is coronary artery disease (HCCs 81-83).

RF is renal failure (HCC 131).

SOURCE: RTI International analysis of 2008/2009 Medicare 100%FFS claims.

SOURCE: RTI International analysis of 2008/2009 Medicare 100% institutionalFFS claims.

Table 2. Disease Hierarchies for the CMS-HCC Model

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

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

Table 3. CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees

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

NOTES:

1. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
2. The 2011 denominator of $9,004.65 used to calculate the new enrollee factors is the national predicted average annual cost under the model.

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

Table 4. CMS-HCC Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)

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

NOTES:

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

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

Table 5. CMS RxHCC Model Relative Factors for Continuing Enrollees

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

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

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
RXHCC72	Spinal Cord Disorders	0.078	0.141	0.044	0.071	-
RXHCC74	Polyneuropathy	0.084	0.189	0.081	0.186	0.059
RXHCC75	Multiple Sclerosis	0.568	0.932	0.627	1.526	0.176
RXHCC76	Parkinson`s Disease	0.417	0.483	0.277	0.246	0.149
RXHCC78	Intractable Epilepsy	0.317	0.590	0.261	0.733	0.102
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.186	0.226	0.118	0.268	0.050
RXHCC80	Convulsions	0.093	0.101	0.069	0.180	0.022
RXHCC81	Migraine Headaches	0.127	0.228	0.121	0.186	0.112
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.082	0.144	0.107	0.158	0.090
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.251	0.429	0.271	0.392	0.112
RXHCC87	Congestive Heart Failure	0.163	0.074	0.224	0.097	0.095
RXHCC88	Hypertension	0.155	0.072	0.202	0.091	0.060
RXHCC89	Coronary Artery Disease	0.155	0.082	0.142	0.055	0.017
RXHCC93	Atrial Arrhythmias	0.055	0.045	0.015	-	-
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.069	0.009	0.054	-	-
RXHCC98	Spastic Hemiplegia	0.135	0.239	0.049	0.151	0.016
RXHCC100	Venous Thromboembolism	-	0.044	-	0.080	-
RXHCC101	Peripheral Vascular Disease	0.058	0.048	0.098	0.062	-
RXHCC103	Cystic Fibrosis	0.215	0.758	0.236	1.401	0.153
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.215	0.134	0.236	0.210	0.115
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.132	0.134	0.110	0.210	0.041
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	-	0.072	-	0.038	0.037
RXHCC111	Diabetic Retinopathy	0.106	0.077	0.085	0.044	0.040
RXHCC113	Open-Angle Glaucoma	0.164	0.124	0.177	0.142	0.117
RXHCC120	Kidney Transplant Status	0.268	0.246	0.346	0.506	0.346
RXHCC121	Dialysis Status	0.220	0.246	0.301	0.506	0.240
RXHCC122	Chronic Kidney Disease Stage 5	0.123	0.157	0.137	0.173	0.122
RXHCC123	Chronic Kidney Disease Stage 4	0.123	0.157	0.137	0.173	0.122
RXHCC124	Chronic Kidney Disease Stage 3	0.099	0.157	0.107	0.173	0.072
RXHCC125	Chronic Kidney Disease Stage 1, 2, or Unspecified	0.034	0.047	0.031	0.062	0.039
RXHCC126	Nephritis	0.034	0.020	0.031	0.062	0.018
RXHCC142	Chronic Ulcer of Skin, Except Pressure	0.040	0.066	0.025	0.053	-
RXHCC145	Pemphigus	0.108	0.172	0.181	0.263	-
RXHCC147	Psoriasis, Except with Arthropathy	0.106	0.158	0.198	0.292	0.131
RXHCC156	Narcolepsy and Cataplexy	0.269	0.419	0.356	0.516	0.091
RXHCC166	Lung Transplant Status	0.984	0.735	0.900	1.175	0.336
RXHCC167	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	0.482	0.269	0.436	0.399	0.149
RXHCC168	Pancreas Transplant Status	0.268	0.246	0.346	0.298	0.149
Non-Aged Disease Interactions						
NonAged_RXHCC1	HIV/AIDS	-	-	-	-	1.222
NonAged_RXHCC58	Schizophrenia	-	-	-	-	0.341
NonAged_RXHCC59	Bipolar Disorders	-	-	-	-	0.199
NonAged_RXHCC60	Major Depression	-	-	-	-	0.126
NonAged_RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.084
NonAged_RXHCC62	Depression	-	-	-	-	0.055
NonAged_RXHCC63	Anxiety Disorders	-	-	-	-	0.037
NonAged_RXHCC65	Autism	-	-	-	-	0.084

Disease Coefficients	Description Label	Community, Non-Low Income, Age>=65	Community, Non-Low Income, Age<65	Community, Low Income, Age>=65	Community, Low Income, Age<65	Institutional
NonAged_RXHCC75	Multiple Sclerosis	-	-	-	-	0.578
NonAged_RXHCC78	Intractable Epilepsy	-	-	-	-	0.032
NonAged_RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	-	-	-	-	-
NonAged_RXHCC80	Convulsions	-	-	-	-	-

Note:

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

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

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

Variable	Baseline – Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.465	0.907	-	-
35-44 Years	0.738	1.180	-	-
45-54 Years	1.012	1.454	-	-
55-59 Years	1.115	1.557	-	-
60-64 Years	1.166	1.608	-	-
65 Years	0.727	1.169	1.118	1.560
66 Years	0.738	1.180	0.889	1.331
67 Years	0.738	1.180	0.889	1.331
68 Years	0.738	1.180	0.889	1.331
69 Years	0.738	1.180	0.889	1.331
70-74 Years	0.715	1.157	0.715	1.157
75-79 Years	0.676	1.118	0.676	1.118
80-84 Years	0.668	1.110	0.668	1.110
85-89 Years	0.590	1.032	0.590	1.032
90-94 Years	0.590	1.032	0.590	1.032
95 Years or Over	0.590	1.032	0.590	1.032
Male				
0-34 Years	0.318	0.760	-	-
35-44 Years	0.565	1.007	-	-
45-54 Years	0.810	1.252	-	-
55-59 Years	0.916	1.358	-	-
60-64 Years	0.997	1.439	-	-
65 Years	0.769	1.211	1.002	1.444
66 Years	0.765	1.207	0.765	1.207
67 Years	0.765	1.207	0.765	1.207
68 Years	0.765	1.207	0.765	1.207
69 Years	0.765	1.207	0.765	1.207
70-74 Years	0.737	1.179	0.737	1.179
75-79 Years	0.666	1.108	0.666	1.108
80-84 Years	0.563	1.005	0.563	1.005
85-89 Years	0.505	0.947	0.505	0.947
90-94 Years	0.505	0.947	0.505	0.947
95 Years or Over	0.505	0.947	0.505	0.947

NOTES:

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

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

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

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

NOTES:

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

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

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

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

NOTES:

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

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

Table 9. Disease Hierarchies for the Revised RxHCC Model

DISEASE HIERARCHIES

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

Source: RTI International.

Attachment VII: 2013 Call Letter

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How to Use This Call Letter

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

Over the past year, CMS has committed its resources to improving the quality of plan choices for beneficiaries who elect to enroll in Medicare Advantage (MA) and prescription drug plans (PDP). As part of this effort, CMS recently issued a final rule that revised the Parts C and D regulations (CMS 4157-FC).

This Call letter implements certain requirements contained in the new final rule (4157-FC) that were not included in the draft Call Letter circulated for comment; we note that with the rulemaking process an opportunity has already been provided to comment on such requirements. We remind sponsoring organizations to continue to familiarize themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Advantage and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, Health Plan Management System (HPMS) data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

If you have questions concerning this Call Letter, please contact: Heather Rudo at Heather.Rudo@cms.hhs.gov (Part C issues) and Lisa Thorpe at Lisa.Thorpe@cms.hhs.gov (Part D issues).

Section 1 – Program updates

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

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
January 10, 2012	Release of the 2013 MAO/MA-PD/PDP/Service Area Expansion Applications.	✓	✓	✓
January 11 & 18, 2012	Industry training on 2013 Applications.	✓	✓	✓
February 21, 2012	2013 Applications are due to CMS.	✓	✓	✓
Late February 2012	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓		
March 1, 2012	CMS releases guidance concerning updates to Parent Organization designations in HPMS.	✓	✓	✓
March 2, 2012	Initial Submission deadline for risk adjustment data with dates of service January 1, 2011 through December 31, 2011.	✓		✓
March 15, 2012	Parent Organization Update requests from sponsors due to CMS (instructional memo to be released in February 2012).	✓	✓	
March 26, 2012	Release of the Health Plan Management System (HPMS) formulary submissions module.	✓	✓	
Late March/Early April 2012	CY 2013 Out-of-pocket cost (OOPC) estimates for each plan and an OOPC model in SAS will be made available to MAOs to download from the CMS website that will assist plans in meeting meaningful difference and MA total beneficiary cost requirements prior to bid submission.	✓	✓	
TBD	Conference call with industry to discuss the 2013 Call Letter.	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
Early April 2012	Information about renewal options for contract year 2013 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
April 2, 2012	2013 Final Call Letter released. Announce CY 2013 MA Capitation Rates and MA and Part D Payment Policies. *(Applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 6, 2012	Release of the 2013 Plan Benefit Package (PBP) online training module	✓	✓	✓
April 6, 2012	Release of the 2013 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓
April 11 – 12, 2012	Medicare Advantage and Part D Spring Conference.	✓	✓	
April 16, 2012	2013 Formulary Submissions due from all sponsors offering Part D (11:59 p.m. EDT). Transition Attestations due to CMS *(Part D sponsors only)*	✓	✓	
April 23, 2012	Release of the 2013 Medication Therapy Management (MTM) Program Submission Module in HPMS.		✓	
April/May 2012	CMS contacts Medicare Advantage Organizations (MAO) and PDPs with low enrollment plans.	✓	✓	✓
May 2012	Final ANOC/EOC, LIS rider, EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2013 will be available for all organizations.	✓	✓	
May 2012	Release of Medicare Marketing Guidelines for CY 2013.	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
May 2, 2012	CMS strongly encourages MA, MA-PD and PDP plans to notify us of its intention to non-renew a county(ies) for individuals, but continue the county(ies) for "800 series" EGWP members, convert to offering employer-only contracts, or reduce its service area at the contract level, by May 2, 2012. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓
May 7, 2012	2013 MTM Program submission deadline.		✓	
May 11, 2012	Release of the 2013 Bid Upload Functionality in HPMS	✓	✓	✓
Late-May/June 2012	CMS sends qualification determinations to applicants based on review of the 2013 applications for new contracts or service area expansions.	✓	✓	✓
June to Early September, 2012	CMS completes review and approval of 2013 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	
June 1, 2012	Release of the 2011 DIR Submission Module in HPMS.		✓	
June 4, 2012	Release of the 2013 Actuarial Certification Module in HPMS	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
June 4, 2012	Deadline for submission of CY 2013 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2013 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Voluntary Non-Renewal. Deadline for MA plans, MA-PD plans, PDPs and Medicare cost-based contractors and cost-based sponsors to submit a contract non-renewal, service area reduction notice to CMS for CY 2013. Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PD plan benefit package (i.e., Plan 01, Plan 02) for CY 2013.	✓	✓	✓
June 6, 2012	Sponsors may begin to upload agent/broker compensation information in HPMS.	✓	✓	✓
June 6, 2012	Release of the 2013 Marketing Module in HPMS.	✓	✓	✓
June 8, 2012	Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS.	✓	✓	
June 22, 2012	Release of the CY 2013 Summary of Benefits (SB) hard copy change request module in HPMS.	✓	✓	✓
Late June 2012	Non-Renewal. CMS sends an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓
June 30, 2012	Final date to submit CY 2012 marketing materials to ensure timely CMS review and approval. NOTE: Sponsors may continue to submit CY 2012 file and use materials as these may be filed in HPMS five calendar days prior to their use.	✓	✓	✓
Early July 2012	2013 Plan Finder pricing test submissions begin	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
July1, 2012	All Dual Eligible SNPs are required to have a contract with the State Medicaid Agency.	✓		
July 5, 2012	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.		✓	
July 30, 2012	2013 MTM Program Annual Review completed.		✓	
Late July 2012	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓
Late July/Early August 2012	CMS encourages cost-based plans to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Plan Finder" and the *Medicare & You* handbook. SBs must be submitted by this date to be assured of being included.			✓
Early August 2012	CMS releases the 2013 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, and the Medicare Advantage regional PPO benchmarks	✓	✓	✓
Early August 2012	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓
August 1, 2012	Plans are expected to submit model Low Income Subsidy (LIS) riders in HPMS.		✓	
August 1, 2012	CMS informs currently contracted organizations of its decision to not renew of a contract for 2013.	✓	✓	
August 23-27, 2012	First CY 2013 preview of the 2013 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	✓
August 29 – August 31, 2012	First CY 2013 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
Late August 2012	Contracting Materials submitted to CMS.	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
End of August/Early September 2012	Plan preview period of star ratings in HPMS.	✓	✓	
September 2012	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓
September 7, 2012	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2011 through June 30, 2012.	✓		✓
Mid-September 2012	All 2013 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓	✓	✓
September 11 - September14, 2012	Second CY 2013 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
September 16 – 30, 2012	CMS mails the 2013 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
September 30, 2012	CY 2013 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by September 30th. Plans have the option to include Pharmacy/Provider directories in this mailing. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies with the ANOC/EOC to ensure current member receipt by September 30th. CMS is in the process of finalizing an EOC member receipt date for FIDE SNPs. Additional guidance, including the member receipt date, will be released with the Medicare Marketing Guidelines. Note: With the exception of the ANOC/EOC, LIS Rider, directories, and abridged or comprehensive formularies, no additional materials may be sent prior October 1.	✓	✓	✓
October 1, 2012	Organizations may begin marketing their CY 2013 plan benefits. Note: Once an organization begins marketing CY 2013 plans, the organization must cease marketing CY 2012 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2012 materials upon request, conduct one-on-one sales appointments and process enrollment applications.	✓	✓	✓

2013*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
October 1, 2012	Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS. Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request any SB hard copy change.	✓	✓	✓
October 1, 2012	Tentative date for 2013 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
October 2, 2012	The final personalized beneficiary non-renewal notification letter must be received by PDPs, MA plan, MA-PD plans, and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2012.	✓	✓	✓
October 11, 2012	Plan ratings go live on medicare.gov.	✓	✓	
October 15, 2012	Part D sponsors must post PA and ST criteria on their websites for the 2013 contract year.		✓	
October 15, 2012	2013 Annual Coordinated Election Period begins. All organizations must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓	✓
November 9, 2012	Notices of Intent to Apply (NOIA) for CY 2014 due for MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	✓
Late November 2012	Display measures data are posted in HPMS for plan review.	✓	✓	✓
Late November 2012	2013 Readiness Assessment due to CMS	✓	✓	
November – December, 2012	CMS issues "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	✓

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

Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. Since this user fee reflects the annual funding for COB-related activities, user fees may vary (increasing or decreasing) yearly to reflect those needs.

Our projection of the incremental on-going costs of Part D COB activities indicates the user fee must be decreased to $1.17 per enrollee per year for contract year 2013. The 2013 COB user fee will be collected at a monthly rate of $0.13 for the first 9 months of the coverage year (for an annual rate of $0.0975 per enrollee per month) for a total user fee of $1.17 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2013 bids.

In 2012, we will implement a new process for the creation of the table of supplemental payer routing information used by the switch community to identify claims that are supplemental to Part D. Initially, the table will be a combination of the table currently created by the CMS COB contractor and a new table to be created by the Part D Transaction Facilitator based on the information in the Part D COB file. During 2012, we plan to refine this process, enabling us to move to exclusive use of the Transaction Facilitator table. We are also working to assist ADAPs and SPAPs by implementing a new procedure to address problems caused by the delays associated with no more than monthly processing of their eligibility data by the COB contractor. Under the new procedure, the Transaction Facilitator will reprocess ADAP and SPAP claims transactions once a week for four weeks then once monthly for 2 months when a Part D plan is not initially identified for an ADAP or SPAP member. These changes will improve the identification of claims supplemental to Part D and increase the volume of reporting (N) transactions to Part D sponsors to support accurate TrOOP calculation and the handling of refunds/recoveries resulting from retrospective claims adjustments.

We appreciate the comments we received concerning COB data and processes and will address these comments in the next update of the COB chapter of the Medicare Prescription Drug Benefit Manual.

Enhancements to the Plan Ratings

One of CMS's most important strategic goals is to increase the quality for Medicare, including Fee for Service (FFS) and private health and drug plans. In this effort we are increasing the level of accountability for the care provided by physicians, hospitals, and other providers. Consistent with efforts in the traditional fee-for-service Medicare program, Parts C and D sponsors are accountable for the care provided by physicians, hospitals, and other providers.

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

and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

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

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

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

2013 Plan Ratings

For the 2013 Plan Ratings, we are continuing to make enhancements to the current methodology to further align it with the Three-Part Aim. Below we describe the enhancements being considered for the 2013 Plan Ratings. Unless noted below, we do not anticipate changing the methodology from the 2012 Plan Ratings. The 2012 methodology can be found at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html under the 2012 Plan Ratings link. The star cut points for all measures and

case-mix coefficients for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Health Outcomes Survey (HOS) will be updated with the most current data available.

As announced in previous years, we will review on an annual basis the quality of the data across all measures, variation among plans, and the measures' accuracy and validity before making a final determination about inclusion of measures in the Plan Ratings. This review will occur once data are received in summer 2012. However, any Plan Ratings added for 2013 will be drawn from those discussed below to the extent not already in place for 2012.

New Measures

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

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

  Some of these are new questions for the Medicare Advantage CAHPS survey in 2012 and all of the questions were drawn from existing CAHPS surveys. Once the data are available after survey administration, we will construct a care coordination composite using factor analysis and determine its reliability prior to making a final decision about inclusion. We will ensure through the reliability analyses that we are capturing true differences in performance across contracts. We are working to develop and test additional care coordination measures for future years. The initial measure in the Plan Ratings focuses on physician activities, but we will expand this to capture other plan activities around care coordination as they are developed. Plans are responsible for the care provided by physicians contracted by their plan.

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

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

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

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

Changes to the Methodology of Current Measures

We are modifying the methodology for the following current measures:

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

- High-Risk Medication (HRM) measure (Part D). CMS will adopt modifications reflecting specification changes made by the Pharmacy Quality Alliance (PQA) or National Committee for Quality Assurance (NCQA) about the types of fills that may be excluded, as well as increase the number of HRM fills from one to two for the 2013 Plan Ratings. CMS is testing PQA and NCQA's revised specifications and medication list based on the American Geriatrics Society's (AGS) update to the Beers List, and will use them to evaluate either CY2012 or CY2013 PDE data, for the 2014 or 2015 Plan Ratings, respectively. Based on testing, CMS will notify sponsors when these revised

specifications become effective for future Plan Ratings. The revised specifications related to the AGS update will not be applied for CY2011 PDE data for the 2013 Plan Ratings. We will also evaluate the inclusion or exclusion of benzodiazepines and specified barbiturates in the measure calculation. Due to extensive specification changes, the previously established 4-star threshold will not be applied for the 2013 Plan Ratings. Instead, all of the star thresholds for this measure will be based on statistical analyses and relative ranking of plans' scores.

- Diabetes Treatment measure (Part D). CMS will test recently updated PQA specifications to include direct renin inhibitors. The updated measure will be defined as the percentage of Medicare Part D beneficiaries who were dispensed a medication for diabetes and a medication for hypertension who were receiving an angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), or direct renin inhibitor medication which are recommended for people with diabetes.

- Adherence (ADH) measures (Part D). Medication adherence continues to be a high priority, and CMS' publication of these three disease/drug class specific measures complement many CMS and HHS initiatives, including cardiovascular disease prevention. We will continue to use Proportion of Days Covered (PDC) as a proxy for beneficiaries' adherence to their prescribed medications. We will also continue to work with our quality measure development partners to examine appropriate methods of adjusting the PDC measure calculation for the 2013 Plan Ratings, to account for beneficiaries' inpatient stays (such as inpatient hospitals or skilled nursing facilities) in which their medication fills would not be included in PDE data. CMS will not incorporate additional disease/drug class measures for the 2013 Plan Ratings. Any other changes are expected to be minor. While this measure will continue to be based on PDE data, we will continue to improve beneficiary and pharmacist education and help maximize the claims submitted to sponsors and therefore included in drug event data.

- Plan Makes Timely Decisions about Appeals (Part C). This metric will now be defined as percent of appeals timely processed by the contract (numerator) compared to all the contract's appeals decided by the IRE (includes upheld, overturned, partially overturned and dismissed appeals) (denominator). This measure is calculated as: ([Number of Timely Appeals] / ([Appeals Upheld] + [Appeals Overturned] + [Appeals Partially Overturned] + [Appeals Dismissed]) * 100. The measure will include *all* Standard Coverage, Standard Claim, and Expedited appeals (including Dismissals) received by the IRE, regardless of the appellant. The calendar year 2011 data which will be used for the 2013 Plan Ratings included dismissed appeals. Such appeals include appeals requested by a beneficiary, appeals requested by a party on behalf of a beneficiary, and appeals requested by non-contract providers. Appeals may be requested by a beneficiary, by a party on

behalf of a beneficiary, or by non-contract providers. Withdrawn cases will be excluded from this measure. These are not significant changes from prior years.

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

- Enrollment Timeliness (Part C and D). This measure is defined as the percent of plan generated enrollment transactions submitted to CMS within 7 days of the application date. We are expanding this measure from PDPs and MA-PDs to include MA-only contracts. The data timeframe for this measure will be January 1, 2012 through May or June 2012, depending on availability of June data in time for the 2013 Plan Ratings, and the measure includes only enrollment transactions that happened during this timeframe. We will alert plans when data are available in HPMS to begin review of data accuracy.

- Beneficiary Access and Performance Problems (Part C and D). The methodology is being modified so the effectiveness score for contracts that received a full performance audit will be replaced with the percentage of elements passed out of all elements audited. We are exploring setting a minimum threshold of five audited elements in order to include audit results in the final calculation, and we will adjust the CAP reporting period from the current 14 months to the 12 months from 1/1 to 12/31 of a year. CMS is still using a risk-based strategy to identify contracts for performance audits in 2011, and this measure is scored for all contracts. There are no other changes to methodology.

Four Star Thresholds

Similar to 2012, we will continue to apply previously established thresholds for a 4-star rating, unless changes have been made to a measure's technical specifications. We will not pre-

determine other star rating cut points, as that would decrease our ability to maximize differences between stars or minimize differences within a star rating. As stated earlier, because of planned technical specification changes, previously set 4-star thresholds do not apply for measures with specification changes for the 2013 Plan Ratings. We are also reviewing the methodology to determine cut points and thresholds for Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. The current thresholds for all other measures can be found in the Technical Notes available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html under the 2012 Plan Ratings link.

Weighting Categories of Measures

We are keeping the same weighting categories used for the 2012 Plan Ratings, in which outcome and intermediate outcome measures were given 3 times the weight of process measures, while patient experience and access measures were given 1.5 times the weight of process measures. We are assigning new Plan Ratings measures a weight of "1" the first year, and then the weight in the second year would depend on the weighting category. We will continue to weight the HRM and Diabetes Treatment measures as intermediate outcome measures, as they had been in 2012 Plan Ratings. CMS had considered changing their weighting category to process measures. These measures, however, examine plans' influences on promoting safe and appropriate medications for beneficiaries over 65 years of age, and evidence-based prescribing for patients with diabetes and hypertension, which are outside the scope of simply measuring the delivery of health care. Re-categorizing these two important patient safety measures as process measures would actually contradict CMS' continuing efforts to recognize quality initiatives by Prescription Drug Plans. The following table lists the proposed 2013 Plan Ratings measures and their weighting categories.

Table VI-1 2013 Plan Ratings

Measure Name	2013 Proposed Weighting Category	2013 Proposed Weight
Breast Cancer Screening	Process Measure	1
Colorectal Cancer Screening	Process Measure	1
Cardiovascular Care – Cholesterol Screening	Process Measure	1
Diabetes Care – Cholesterol Screening	Process Measure	1
Glaucoma Testing	Process Measure	1
Annual Flu Vaccine	Process Measure	1
Improving or Maintaining Physical Health	Outcome Measure	3
Improving or Maintaining Mental Health	Outcome Measure	3
Monitoring Physical Activity	Process Measure	1
Adult BMI Assessment	Process Measure	1
Care for Older Adults – Medication Review	Process Measure	1

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

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

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

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

Display measures on cms.gov are not part of the Plan Ratings calculation. Instead, they may be measures that have been transitioned from the Plan Ratings, or they could be new measures that are being tested before inclusion into the Plan Ratings. Similar to the 2012 display page, plans will have the opportunity to review display measure methodologies and technical notes and preview their data prior to release on our website. Data on measures moved to the display page will continue to be collected and monitored, and poor scores on display measures are subject to compliance actions. CMS believes that the display measures, as well as other unmeasured aspects of quality, continue to be important for Part C and D plans.

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

performance. Also, if the focus on these two areas changes, CMS may consider adding them back into the Plan Ratings.

We are also considering the following measures for the 2013 display page, which will be finalized by fall 2012. Many of these measures use existing data already reported by sponsors in 2011 through the Part C and D reporting requirements and validated spring 2012, therefore, changes to these data cannot be made. CMS can make changes for future years with respect to reporting of these data, as well as modify methodologies once those data are available.

- Measures from the Hospital Inpatient Quality Reporting program (formerly known as Reporting Hospital Quality Data for Annual Payment Update) (Part C). (See http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1138900298473 for a list of measures.) Since plans are responsible for their contracted providers, we are exploring whether the individual-level hospital data can be associated with individual MA contracts. We are examining the quality of Health Insurance Claim Numbers (HICNs) available on the hospital-level data to determine the feasibility of linking the hospital data to contract numbers. We will then analyze the data to determine if we can create an MA contract-level measure of the hospital care that enrollees in each contract receive. As we develop the measure, we will consider rural and urban differences in access to hospitals.

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

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

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

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

- Medication Therapy Management (MTM) program measure (Part D), based on the Pharmacy Quality Alliance (PQA) approved measure, Completion Rate for Comprehensive Medication Review (CMR). This measures the percentage of MTM-eligible beneficiaries who received a CMR (annual interactive person-to-person or telehealth consultation with written summaries). It serves to promote the delivery of this required and valuable MTM service to Medicare Part D beneficiaries. We will calculate the 2013 display measure using 2011 beneficiary level plan-reported MTM data (collected as part of the Part D reporting requirements). The denominator will include Part D beneficiaries who were at least 18 years of age and were enrolled in the MTM program for at least 60 days. Only beneficiaries who meet CMS requirements in the reporting period will be included in the denominator. A minimum number of MTM-eligible beneficiaries will be required in order to calculate a contract's percentage for this measure. Since sponsors were not required to offer CMRs for long-term care (LTC) residents in 2011, MTM beneficiaries that are LTC residents will be excluded. The following beneficiaries will be included: Special Needs Plan (SNP), and low-income subsidy (LIS) beneficiaries. Also, beneficiaries who opt-out of the CMR or do not respond to offers for the CMR will not be excluded because doing so could mask barriers to access, patient dissatisfaction with the sponsors' MTM program, or ineffective methods of outreach. CMS will provide additional information about the rates and minimum number to calculate a contract's percentage during the plan preview period of the 2013 display measures. CMS will consider other MTM quality or outcomes measures when developed and endorsed through a public consensus process.

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

- Appeals Upheld (Part C and D). In response to requests to expand the current Plan Rating based on IRE data, we will investigate in the future creating a new Part C and D display measure based on plan-reported, validated redeterminations data. This display measure would be a separate measure of plans' performance from the current measures based on IRE data. The numerator will only include fully approved redeterminations.

As future specifications are developed, we will share them with plans. It is expected that all other 2012 display measures will continue to be shown on cms.gov. We are removing 'Appropriate implementation of Part D transition processes' as a possible display measure. We will use findings from CMS' monitoring program of Part D sponsors' transition programs primarily for compliance purposes.

Summary of Changes to the Methodology for 2013 Plan Ratings

As described above, we will be adding one or more of the above new measures to the 2013 Plan Ratings, including measures of care coordination and quality improvement. Two Part C measures (Pneumonia Vaccination and Access to Primary Care Doctor Visits) will be moved to the display page. We are maintaining the weights (3 for outcomes and intermediate outcomes, 1.5 for patient experience and access measures and 1 for process measures) assigned to each of the categories of measures that were used in the 2012 Plan Ratings.

2014 Plan Ratings

New Measures

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

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

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

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

- Medication Therapy Management (MTM) program measure (Part D). Release as a Plan Rating measure would follow production as a 2013 display measure.

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

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

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

All new measures would receive a weight of "1". We are proposing Evaluation of a contract's Chronic Care Improvement Program (CCIP) and Quality Improvement Project (QIP) (Part C) as a 2014 display measure.

Additional Methodological Enhancements for 2014

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

HEDIS 2013 Requirements

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

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

Low Enrollment Contracts

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

Timeline

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

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

In last year's call letter, CMS stated that we consider contracting organizations (i.e., MA organizations and PDP sponsors) with less than an "average" (or three-star) summary plan rating to be out of compliance with the requirements of the Part C or D programs. Consistent with last year, CMS does not believe it is in beneficiaries' best interest for CMS to continue to contract with organizations whose performance is consistently out of compliance with Medicare requirements. Contracting organizations should interpret a less than "average" (or three-star) summary rating on either their Part C or D performance to be a notice from CMS that they are to take corrective action to come into compliance with program requirements. CMS will continue a policy of issuing formal compliance notices each year to all sponsors that earned low ratings for that year.

In 2013, CMS will further the goals of facilitating beneficiary enrollment into higher quality plans by issuing notices to individuals enrolled in plans with less than three stars in three consecutive years, alerting them to the organization's low rating and offering an opportunity to contact CMS to request a special enrollment period (SEP) to move into a higher quality plan for 2013. These notices represent part of our ongoing effort to meet our obligation, as prudent purchasers on behalf of the Medicare program, to provide beneficiaries with information that will help them make a plan election that best meets their needs and represents the best value for the Medicare program.

CMS considers organizations that fail for three straight years to achieve at least a three-star summary rating on Part C or D to have ignored their obligation to meet program requirements and to be substantially out of compliance with their Medicare contracts over a significant period of time. In our view, such plans have demonstrated a serious lack of commitment to the programs and their enrollees. These organizations should expect CMS to apply closer scrutiny to

their operations and to issue notices to their plan members alerting them to the organization's low rating. They should also expect CMS to initiate action to terminate their contracts following: 1) our publication of the set of annual plan ratings that assigns the organization its third consecutive summary rating of less than three stars; and 2) our confirmation that the data used to calculate the star ratings reflect the sponsor's substantial non-compliance with Part C or Part D requirements. CMS would pursue such actions in a manner consistent with our existing statutory and regulatory Part C and D contract termination authority.

Section II. Part C

CY 2013 Bid Review

Portions of this guidance apply to section 1876 cost contractors, MA plans, including employer group plans, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs) and Institutional Special Needs Plans (I-SNPs). Employer group plans, D-SNPs, and cost contractors are excluded from our evaluation to identify duplicative plans, also referred to as the "meaningful difference" evaluation. Similarly, employer group plans also are not evaluated for low enrollment. Table VI-2 on page 25 of this final Call Letter shows criteria used in bid review and the plan types to which they apply. Note: We reserve the right to review employer plans for low enrollment and/or meaningful difference in future years.

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

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

The only changes to the cost sharing standards are:

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

We set the urgent care cost sharing standard equal to the emergency care standard, thereby allowing plans the flexibility to establish varying levels for both urgent care and emergency care in an attempt to encourage enrollees, when appropriate, to use urgent care services rather than emergency care services.

We did not propose to increase the MOOP or any of the service category cost sharing standards, other than a minimal increase to the SNF per diem for days 21 through 100, because our data and

actuarial analyses indicate that the standards established for CY 2012 continue to reflect appropriate levels estimated for CY 2013.

The minimum total OOPC difference used to evaluate meaningful difference between plans in a service area, currently set at $20.00 per member per month, will remain unchanged. The MOOP limits and the TBC change amount (approximately 10% or $36.00 per member per month) will remain the same as in CY 2012 and plans will be expected to satisfy the criteria in their initial bid submissions. To the extent that CMS increases the amount of the maximum Part B premium buy-down in the Bid Pricing Tool (BPT), we will provide a Part B premium adjustment for the difference between the maximum Part B premium buy-down for CY 2012 ($96.40) and the new amount for CY 2013. In addition, similar to last year, we intend to provide factors to plans through an HPMS posting in mid-April, **that adjust for payment rate, quality bonus changes and other technical adjustments for changes in the PBP software.** CMS reserves the right to further examine and request additional changes to a plan bid even if a plan's TBC is within the required amount, if we find it is in the best interest of the MA program. MOOP and service category cost sharing standards are shown in Tables VI-3 and VI-4 on pages 26 and 27 of this final Call Letter.

B. Plans With Low Enrollment

Before the end of May 2012, CMS will send each MAO a list of plans that have been in existence for three or more years but, as of April 2012, have fewer than 500 enrollees for non-SNP plans and 100 enrollees for SNP plans. The lists may not include plans with low enrollment that CMS determines are located in service areas that do not have a sufficient number of competing options of the same plan type.

Currently, we allow plans that have enrollment below our low enrollment thresholds for three years or more the flexibility to submit justifications for renewal. In the draft Call Letter, we indicated our intention to consider eliminating flexibility for plans with sustained very low enrollment, e.g., fewer than 25 enrollees over 3 or more years, due to our concern about the plans' operational viability and the quality of care they can provide.

We note that in addition to consideration of the plan's geographic location and other plan choices available in an area, we also consider justifications from MAOs that are offering a plan in an area because it is a CMS requirement to do so (e.g., in order for a an MAO to offer a MA–only plan in a service area, it also must offer a MA-PD plan in the same area). Thus, we will continue to consider the specific circumstances of plans with low enrollment, including plan type (e.g., C-SNP).

We intend to move forward to limit opportunities for renewal for plans with sustained (3 or more years) very low enrollment (fewer than 25 enrollees). Although such a plan may submit a

justification for renewal, we do not anticipate that we would allow a plan with sustained very low enrollment to renew, nor do we expect to consider many of the extenuating circumstances or other factors, e.g., type and number of other plans offered in the service area, as we have in previous years.

We corrected a clerical error that appeared in the draft Call Letter to reflect that cost contractors are not required to establish MOOP amounts and have added some additional information to Table VI-2, below. We added in-network $0 cost share preventive benefits to the table in order to clarify that plans, including employer groups and cost contract plans, are required to provide without cost sharing the same preventive benefits that are provided without cost sharing under original Medicare. This was finalized in our April 15, 2011 final rule (76 FR 21561) and is codified at 42 CFR §§417.454(d) and 422.100(k). Finally, we excluded dual-eligible SNPs from the column heading for non-employer plans to make clear that they are not included in that group of MA plans and added regulation citations to the footnotes.

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

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

Bid Review Criteria	Applies to Non-Employer Plans (Excluding Dual Eligible SNPs)	Applies to Non-Employer Dual Eligible SNPs	Applies to Cost Contractors	Applies to Employer Plans
Low Enrollment	Yes	Yes	No	No
Meaningful Difference	Yes	No	No	No
Total Beneficiary Cost	Yes	No	No	No
Maximum Out-of –Pocket (MOOP) Limits	Yes	Yes	No	Yes
PMPM Actuarial Equivalent Cost Sharing	Yes	Yes	Yes	Yes
Service Category Cost Sharing	Yes	Yes	Yes[1]	Yes
In-network $0 Cost Share Preventive Services	Yes	Yes	Yes[2]	Yes

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

[2] Requirement that all MA plans and 1876 cost contractors cover, without cost sharing, all in-network preventive services covered under original Medicare without cost sharing is codified at 42 CFR §§417.454(d) and 422.100(k).

Table VI-3 below displays the CY 2013 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to LPPOs and RPPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) will result in greater flexibility for individual service category cost sharing.

As codified at 42 CFR §§422.100(f)(4), (5) and (6), MA plans, including employer group plans and SNPs, must establish limits on enrollee out-of-pocket spending that do not exceed the annual maximum amounts set by CMS. MA plans may establish as a MOOP any amount within the ranges shown in the table. We chose to display the ranges of cost sharing within which plans may establish their MOOPs in order to illustrate that MOOP limits may be lower than the CMS-established maximum amounts and what MOOP amounts qualify as mandatory and voluntary MOOP limits.

Table VI-3. CY 2013 Voluntary and Mandatory MOOP Range Amounts By Plan Type

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

We are continuing our current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower voluntary MOOP limit than is available to plans that adopt a higher mandatory MOOP limit. Table VI-4 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans. CY 2013 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.

We note that, although it may be rare that a dual-eligible enrollee would be responsible for paying any cost sharing because the State Medicaid program is making those payments on

his/her behalf, all MA plans must track enrollees' actual out-of-pocket spending, if any, for covered services in order to be able to ensure that an enrollee does not spend more than the MOOP amount limit established by the plan. A dual-eligible enrollee may incur responsibility for the costs of care if the plan charges cost sharing for covered services and the enrollee loses his or her Medicaid eligibility.

Currently, SNPs have the flexibility to establish $0 as the MOOP amount, thereby guaranteeing that there is no cost sharing for plan enrollees. Otherwise, if the SNP does charge cost sharing for covered services, it must track enrollees' out-of-pocket spending and it is up to the plan to develop the process and vehicle for doing so.

Table VI-4. CY 2013 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient - 60 days	1a	N/A	$3,935
Inpatient - 10 days	1a	$2,231	$1,785
Inpatient - 6 days	1a	$2,016	$1,613
Mental Health Inpatient - 60 days	1b	$2,471	$1,977
Mental Health Inpatient - 15 days	1b	$1,796	$1,437
Skilled Nursing Facility – First 20 Days[1]	2a	$100/day	$50/day
Skilled Nursing Facility – Days 21 through 100[1]	2a	$150/day	$150/day
Emergency Care/Post Stabilization Care	4a	$65	$65
Urgently Needed Services	4b	$65	$65
Home Health	6a	20% or $30 copay	$0
Primary Care Physician	7a	$35 co-pay	$35 co-pay
Chiropractic Care	7b	$20 co-pay	$20 co-pay
Physician Specialist	7d	$50 co-pay	$50 co-pay
Psychiatric and Mental Health Specialty Services	7e and 7h	$40 co-pay	$40 co-pay
Therapeutic Radiological Services	8b	20% or $60 co-pay	20% or $60 co-pay
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10 co-pay
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10 co-pay
Renal Dialysis	12	20% or $30 co-pay	20% or $30 co-pay
Part B Drugs-Chemotherapy[2]	15	20% or $75 co-pay	20% or $75 co-pay
Part B Drugs-Other	15	20% or $50 co-pay	20% or $50 co-pay

1. MA plans may have cost sharing for the first 20 days of a SNF stay, consistent with cost sharing guidance. The per-day cost sharing for days 21 through 100 must not be greater than the Original Medicare SNF amount. Total cost sharing for the overall SNF benefit must be actuarially equivalent with Original Medicare.

2. Part B Drugs – Chemotherapy cost sharing displayed is for services provided on an outpatient basis and includes administration services.

Regarding our policy that allows cost sharing for the first 20 days of a covered SNF stay, we direct interested commenters to our discussion of this in the April 15, 2011 final rule (76 FR 21440 – 21442).

We wish to clarify that plans may charge coinsurance rather than copayments for cost sharing. Plans opting to charge a coinsurance amount for a service category for which Table VI-4 only shows a copayment, must ensure that the maximum coinsurance charged is not actuarially greater than the copayment amounts established by CMS. Thus, a plan with a mandatory MOOP may charge coinsurance for days 1-20 that will result in enrollee cost sharing that does not exceed $50/day.

Consistent with MA cost sharing policy (Chapter 4 of the MMCM), we establish the service category cost sharing standards relative to original Medicare benefit coverage. Chiropractors are not physician specialists and are considered by Medicare to be physicians for the purpose of payment only when furnishing appropriate covered manual manipulation of the spine to correct a subluxation that has resulted in a neuromusculoskeletal condition (42 CFR §410.21(b)).

PBP Notes Update for CY 2013

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

An appropriate note contains only information applicable to the service category in which the note section is located and provides relevant information that reviewers need for bid evaluation; it does not repeat the cost sharing information entered in the data entry field. Our efforts to limit the use and length of notes in the PBP focus entirely on eliminating duplicative and unnecessary notes. We continue to expect that the PBP notes fields will be used appropriately to provide the important explanatory information that cannot be entered into the PBP data entry fields but is needed to, for example, explain ranges of cost sharing or provide a description of a unique benefit.

For CY 2013, we have taken several steps to help plans present benefits without the need for extensive notes. Below, we clarify certain supplemental benefits in order to improve plans' understanding about services that are appropriately offered as supplemental benefits. We will

include additional, minor clarifications regarding a number of acceptable supplemental benefits in a future HPMS memo. We realize that notes are often used to support marketing material; therefore, we are coordinating our efforts with our marketing review staff to limit plans' use of notes to providing additional information and not as duplication, verbatim of the benefit descriptions.

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

In our final rule, CMS-4157, we allow plans to limit durable medical equipment (DME) by brand and manufacturer. More specifically, beginning in CY 2013, an MA plan may choose to cover only certain brands and manufacturers of DME as long as the plan meets specific requirements ensuring enrollees access to all necessary categories of DME.

Limiting DME based on brand/manufacturer works well with categories of DME whose items are essentially interchangeable. However, as addressed in several comments on the proposed rule, items in certain categories of DME are specifically tailored to individual needs and, consequently, require full or partial coverage.

In the final rule, we indicate that we will annually notify plans of categories of DME not subject to limitation based on brand/manufacturer. Generally, we intend to identify such categories of DME based on comments on the proposed rule, advice from CMS and DME MAC medical directors, and experience from the DMEPOS competitive bidding program and other Medicare programs. We will update the list as we consider new information that becomes available. If a category of DME may not be limited, then either: (1) MA plans must provide full coverage, i.e., furnish any DME brand and manufacturer in this category; (2) MA plans must provide partial coverage, i.e., the MA plans would be allowed to limit by brand and manufacturer, as long as certain subcategories of the DME are offered.

Based on comments on the proposed rule, and our discussions with CMS staff, we have identified the following five categories of DME that we recommend not be subject to full limitation based on brand/manufacturer for CY 2013:

1) Speech-Generating Devices: People who require speech generating devices frequently have other disabilities; the speech generating device is tailored to meet the individual needs. For example, a child with cerebral palsy (CP) could accidentally change a setting on the device. The device therefore needs to be sensitive to the movements of a child with CP. Another example includes a beneficiary with amyotrophic lateral sclerosis (ALS) who requires a device that allows the individual to rely only on eye movement to generate speech. Consequently, MA plans must furnish any speech-generating device purchased by an enrollee.

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

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

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

5) Diabetic supplies: During the comment period for the final rule, we received numerous comments indicating that large font and large button diabetic monitors are needed for visually impaired and arthritic enrollees. Therefore, we will be more specific, allowing plans to limit diabetic supplies by brand and manufacturer provided that both large-font monitors for the visually impaired and large-button monitors for individuals with arthritis are furnished.

Supplemental Benefits

As explained in our draft Call Letter, we were concerned that some MAOs and cost contractors were claiming "services" such as care coordination or case management as supplemental benefits in their CY 2012 bids when such services are inherent to the coordinated care plan model. Consequently, we determined there was a need for us to clarify that plans may not view such services (e.g., care coordination and case management) as a benefit(s) to be provided at their choice, and thereby, subject to change (or removal from the plan benefit package) each year.

To address MA and cost contract plans' misunderstanding and the resulting confusion among enrollees, we proposed to clarify our interpretations of what services are considered to be inherent in the "coordinated care" plan model that may not be offered as supplemental benefits and what types of services may be offered as supplemental benefits.

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

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

The terminology used across plans to refer to benefits and services varies greatly so that one plan's "case management" may be referred to by other plans as "disease management," "care coordination" or various other terms. In the draft Call Letter, we stated that it is our expectation that all beneficiaries enrolled in an MA coordinated care plan or cost contract will receive care coordination services that enhance the efficiency and effectiveness of the health care delivered under the plan. Furthermore, as we discussed at length, coordinated care plans that are SNPs are required to provide a higher level of care coordination and disease management as integral to the "special" care provided to their enrolled beneficiaries through the plan's development and CMS' approval of the SNP Model of Care (MOC) (42 CFR 422.152(g)).

We also described our concern about the number of MAOs that included "disease management" as a supplemental benefit in submitted bids for CY 2012 and our view that management of coordinated care plan enrollees' diseases is inherent in the care coordination that gives coordinated care plans their name. In addition, all MA plans are expressly required under the regulations to provide disease management to a target population under their Chronic Care Improvement Programs (CCIPs) (42 CFR 422.152(c)). However, because non-SNP MA plans do not have a MOC requirement, we believe that there are some services that could be included as supplemental benefits that go beyond the required disease management activities and programs. In an effort to increase the transparency of benefit design, we set forth a number of examples of activities and services that non-SNP MA plans could reasonably offer as "supplemental" benefits under an "enhanced disease management" program for CY 2013.

We presented examples of "enhanced" benefits that we would consider appropriate for inclusion as "supplemental" benefits for CY 2013. Our intent in providing the benefit descriptions was to help MAOs that offer coordinated care plans and cost contracts, to differentiate between: 1) plan activities that are presumed to be included in any coordinated care plan's delivery of benefits; 2) benefits covered under Medicare Parts A and B; and 3) enhancements to disease management-related activities that may be offered as supplemental benefits. We presented the benefits in the draft Call Letter as examples of acceptable supplemental benefits because, consistent with guidance in Chapter 4 of the Medicare Managed Care Manual, the services included: 1) are directly health related; 2) have value to the enrollee; 3) have costs beyond the administrative costs that a coordinated care plan would be expected to incur in coordinating the provision of MA plan and cost plan benefits; and 4) are not covered under original Medicare Part A or B.

We note that we did not propose to change our policy regarding our expectations for what types of activities and services may be included in a supplemental benefit. Our primary goal is to improve across-plan comparability and transparency for enrollees, while also streamlining our bid review process and ensuring that MA plans' enrollees know and are receiving the services described in the bid they are purchasing. We are finalizing our proposal to clarify the types of activities and services inherent to the coordinated care model as well as those that would be expected to be included in supplemental benefits. We continue to expect that MAOs will develop innovative plan benefit packages to effectively and efficiently provide services to enrollees.

Special Needs Plans (SNPs) and Model of Care (MOC)

In the draft Call Letter, we proposed to require SNPs to enter Enhanced Disease Management (EDM) and enrollee assessments into the PBP as supplemental benefits. As we discussed, SNPs must have the ability to address the needs of enrollees with "special needs" and therefore, must provide those activities and services identified in the SNP Model of Care (MOC).

In response to comments and after further consideration of program needs, we have determined that it may be unnecessarily disruptive to require SNPs to enter as supplemental benefits those activities and services already performed as required under their MOCs (42 CFR 422.152(g)). Our intention was to increase the transparency of benefits, not to require SNPs to develop new pricing methods, or to diminish SNPs' capacity to provide needed benefits and services to their vulnerable enrollee populations.

Therefore, we will not move forward with our proposed requirement that SNPs enter their higher levels of care coordination, enrollee assessment or disease management services in the PBP as supplemental benefits. Instead, SNPs should consider the costs associated with required MOC activities and services as part of the cost of being a SNP, and price them in their bid submissions as they have been.

We also would note that we encourage SNPs to continue to use their flexibility to offer supplemental benefits that are comprised of activities and services that are not required under their MOCs and that satisfy CMS' criteria as eligible supplemental benefits, as described above and in CMS guidance noted earlier.

Enhanced Disease Management

For non-SNP MA plans, we provide the following description of Enhanced Disease Management (EDM), which has been revised to reflect that case managers or other qualified health professionals may be responsible for the activities and services described in the first bulleted item below. Our intent is to ensure that the person is qualified and has the specialized knowledge and training the duties require.

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

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

- **Enrollees in the target group being assigned to qualified case managers or other qualified health professionals with specialized knowledge about the disease(s) who contact the enrollee to provide additional case management and monitoring services.** We believe that this should be an essential aspect of an effective EDM program and it is important for MAOs and cost contractors to understand the difference between the assignment of case managers for all enrollees and the assignment of a case manager with specialized knowledge about a specific individual enrollee's disease(s). The case manager, or other qualified health professional, assigned to the enrollee should work to ensure that the enrollee makes and keeps appointments necessary to receive appropriate care from physicians and other health care providers including obtaining preventive services. That assigned staff member should facilitate the enrollee's participation in both

standard disease management activities and supplemental EDM programs offered by the plan. The assigned case manager or other qualified plan staff should ensure that all scheduled monitoring of the enrollee takes place and that information is analyzed and communicated to all enrollees of the care team so that early signs of deterioration in the enrollee's condition are detected and action is taken to prevent further deterioration.

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

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

Although plans may describe an EDM benefit in marketing material in a manner that reflects the activities and services included in their benefit for PBP data entry purposes, the benefit would be entered with the title "Enhanced Disease Management" in an "Other" supplemental benefit field. This uniform benefit title streamlines CMS' bid review and enhances beneficiaries' ability to make comparisons across plan benefit packages. MAOs and cost contractors that submit PBPs may enter notes that describe services that are not included in the definition of the EDM benefit provided in this Call Letter. However, if the benefit is being offered as defined by CMS above, no note should be entered in the PBP notes field for EDM because it would be unnecessary and duplicative. During CY 2013 bid review, CMS will require removal of any extraneous or duplicative notes from the PBP. If no note is entered to describe a plan's EDM or other supplemental benefit, the signed PBP attestation will serve as verification that the benefit(s) offered is consistent with the CMS descriptions in this final Call Letter, Chapter 4 of the MMCM and/or other guidance for CY 2013, .

<u>$0 Cost Sharing Preventive Services</u>

Medicare covered $0 cost share preventive services and the frequency by which they are provided to beneficiaries is based on efficacy and clinical research. As such, we proposed in the draft Call Letter, to require that MA plans and cost contractors adhere to the schedule used under

Original Medicare for providing those preventive services, with two exceptions. We proposed to allow plans to offer additional sessions of smoking and tobacco cessation counseling and medical nutrition therapy as supplemental benefits, as described below. We specifically stated that none of the other $0 cost share preventive benefits, including screening Pap smear/pelvic exams, would be accepted as supplemental benefits for CY 2013. We explained that as Medicare Part B benefits, screening Pap tests and pelvic exams must be offered every two years as $0 cost share preventive services; otherwise, plans must cover only medically necessary Pap tests and pelvic exams.

1. Additional sessions of smoking and tobacco cessation counseling –

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

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

2. Medical Nutrition Therapy (MNT) –

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

   - Eligible supplemental benefit: Plans may offer additional hours of one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to all or a disease-defined group of its enrollees. Plans may offer additional hours of one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to enrollees with diabetes and renal disease or who have received a kidney transplant in the last three years in addition to the MNT services those enrollees are entitled to as a required Medicare Part A and B plan benefit.

Our proposed policy was based on sound clinical guidance and in no way restricts plans from providing medically necessary Pap smear/pelvic exams.

Our interests are in ensuring that beneficiaries receive high quality, effective health care services from their MA plans, and we are concerned that not adhering to the schedule for screening services adopted by Original Medicare is inconsistent with that goal. We are, however, sensitive to plans' hesitancy to withdraw those screening services without having time to educate enrollees about the reasons for doing so. Therefore, for CY 2013, we will allow plans to continue to offer annual screening Pap smear/pelvic exams as a supplemental benefit. We encourage plans to prepare for the probability that those annual screening services may not be allowed as supplemental benefits in future years.

Thus, for CY 2013, our final policy is to allow MAOs (including SNPs) and cost contractors to offer as supplemental benefits additional sessions of smoking and tobacco use cessation counseling and Medical Nutrition Therapy, as described above, and annual screening Pap smear/pelvic exams.

We would like to address comments about whether MA plans would be allowed to offer physical exams as supplemental benefits in CY 2013. Non-SNP MA plans and cost contractors may offer physical exams that would provide services not included in the required Annual Wellness Visits as supplemental benefits. The plans will be required to fully describe in the PBP notes for CMS review, the non-Medicare covered activities and services that will be included in the physical exam. As described earlier in this Call Letter, assessments of enrollees are inherent to the SNP's MOCs and thus, may not be offered as supplemental benefits by SNPs.

Web and Telecommunication Technologies

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

We have approved many web-based and telecommunication benefits, but continue to be concerned that these benefits preserve and complement an effective doctor-patient relationship and support quality health care. The following descriptions are intended to provide MAOs and cost contractors with information to support the development of acceptable supplemental benefits that use web and telecommunication technologies.

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

Telemonitoring services: MAOs and cost contractors may propose a supplemental benefit that provides in-home equipment and telecommunication technology to monitor enrollees with specific health conditions (e.g., hypertension or chronic heart failure). The benefit should be referred to as "Telemonitoring services" in the PBP and may not duplicate items or services provided under original Medicare (e.g., glucometers for diabetic beneficiaries). In addition, the supplemental benefit description should address the following issues: (a) telemonitoring services must supplement, rather than replace, face-to-face physician visits; (b) the enrollee must have had an initial physician visit to diagnose or confirm the diagnosis of the specific condition; (c) except in rare circumstances, the data must be collected/transmitted at least weekly, but may be required daily or more frequently, as appropriate for the particular disease; (d) the equipment provided to the enrollee must be disease-appropriate; (e) the enrollee must be trained on how to transmit the data properly; (f) health care professionals must monitor and take action, as needed, based on the collected/transmitted data; (g) the enrollee's physician must be included in the communication process; and (h) all devices must comply with applicable state and federal requirements. MAOs and cost contractors should include in notes a description of the monitoring services they propose to provide as supplemental benefits.

Web- and Telephone-Based Technologies: MAOs and cost contractors may propose a supplemental benefit in which the process of diagnosing and treating some conditions includes the enrollee answering a series of questions online and/or via telephone. We want to ensure that this type of service will not be used as a substitute for an effective, ongoing doctor-patient relationship, but rather, will be supportive of that relationship and of efficient delivery of needed care. Plans offering such a benefit should ensure that: (a) medical protocols are established and regularly updated based on relevant clinical guidelines and that prescribing and/or treatment recommendations are consistent with the State laws in the jurisdiction where the MAO operates and are within the provider's scope of practice; (b) when contacting the system, the enrollee is made aware that he or she is not required to use the system and can contact his/her plan provider directly, although perhaps at a later time; (c) the information provided by the enrolled

beneficiary during the web- or phone-based process is directed to his/her PCP or other plan provider specified by the enrollee and will become part of the medical record; and (d) a method and protocol for monitoring the use of the system by enrolled beneficiaries that will identify potential misuse and supplantation of appropriate PCP visits has been developed and is implemented for the contract year the benefit is offered. The MAO must provide CMS with this information upon request.

We wish to take this opportunity to clarify that a PPO may not use web- and telephone-based technologies services as described above to fulfill its requirement to provide out-of-network services and that email communication between an enrollee and his/her physician would not be acceptable as a supplemental benefit to the extent that such communication is an aspect of the Part B physician services MAOs are required to provide.

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

For purposes of PBP data entry, plans proposing this type of supplemental benefit must enter it in an "Other" supplemental benefit field and title it in the PBP as Web- and Telephone-Based Technologies to support CMS bid review and the ability for beneficiaries to make comparisons across plan benefit packages. Furthermore, MAOs and cost contractors must include in the PBP notes field a description of the web- and/or telephone-based services they propose to include in such supplemental benefits.

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

Health Education

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

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

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

We note that a health education supplemental benefit may not be used as an incentive program; rather, rewards and incentives are marketing tools covered under CMS Marketing Guidelines. However, consistent with our description of health education activities and services in the draft Call Letter, plans may develop health education services to address whatever health-related topics they identify as appropriate for their enrollee population and could certainly include as supplemental benefits programs that support and encourage enrollees to adopt healthier lifestyles.

Special Needs Plans (SNPs)

A. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans

In our final rule issued on April 2, 2012, we amended our regulations at 422.102(e) to allow certain dual eligible SNPs (D- SNPs) that meet high integration and performance standards to offer supplemental benefits beyond those that we currently permit for MA plans. In the preamble to that rule, we indicated that we would further describe the criteria that we would use to implement this proposed benefits flexibility in the final CY 2013 Call Letter. Below, we describe qualifying criteria—including qualifying standards and D-SNP contract design requirements—that we are applying to D-SNPs seeking this benefit flexibility. We also outline types and categories of benefits that we will allow D-SNPs to offer under this flexibility.

a) Contract Design Requirements for D-SNPs Participating in the Benefits Flexibility Initiative

We are limiting this benefit flexibility to D- SNPs that integrate Medicare and Medicaid benefits and services because we believe that these plans are best positioned to achieve the objective of keeping Medicare-Medicaid ("dual eligible") beneficiaries who are at risk of institutionalization

in the community. As a result of the comments we received supporting the application of this initiative to other types of SNPs that meet the needs of complex, high risk populations, this benefits flexibility initiative will be available to all highly integrated D-SNPs and will not be limited to FIDE SNPs as defined at § 422.2, as originally proposed. Below are contract design requirements that we will apply to D-SNPs in order to qualify for the benefits flexibility.

In order to meet the minimum contract requirements, for the purposes of qualifying for our new supplemental benefits flexibility in CY 2013, D-SNPs must:

- Be operational in CY 2013, and have operated in CY 2012;
- Facilitate access to all covered Medicare benefits and all Medicaid benefits covered in the State Medicaid plan;
- Have a current contract with a State Medicaid agency that includes capitated coverage of specified primary, acute, and long-term care benefits and services, to the extent that State policy permits the SNP to capitate these services;
- Coordinate delivery of covered Medicare and Medicaid primary, acute, and long-term care services throughout its entire service area; and
- Possess a valid contract arrangement with the State, as approved by CMS in accordance with the requirements at 42 CFR §422.107.

We will apply these contract design requirements at the individual SNP plan (i.e., plan benefit package) level for contracts with multiple SNP plan benefit packages. We will apply these requirements at the contract level for stand-alone SNP (i.e., SNP-only) contracts.

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

In addition to the contract design criteria above, in order to offer supplemental benefits under this initiative, a D-SNP must:

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

2) Either:

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

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

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

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

3) In addition, the D-SNP must not be a consistent poor performer, i.e., not be part of a contract with a score of 2 points or more on either the Part C or the Part D portion of the 2013 application cycle past performance review methodology.[6]

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

We do not intend for these additional Medicare supplemental benefits that are provided through this flexibility to replace State Medicaid or local benefits for enrollees that are eligible to receive identical Medicaid services. Rather, we seek to give D-SNPs flexibility to design their benefits in a way that adds value to the beneficiary by augmenting and/or bridging the gap between Medicare and Medicaid covered services. We believe that the additional supplemental benefits that are offered under this provision are most appropriate for individuals who need assistance with activities of daily living (ADLs). This may include, for example, eating, drinking, dressing, bathing, grooming, toileting, transferring, and mobility) or instrumental activities of daily living, (IADLs), e.g., transportation, grocery shopping, preparing food, financial management, and taking medication correctly. Furthermore, as written in our final rule, we are requiring D-SNPs to offer any new supplemental benefits they provide under this provision to the beneficiary at zero cost.

As a condition of offering these additional supplemental benefits, we are requiring qualified D-SNPs to attest, at the time of bid submission, that the additional supplemental benefit(s) that the SNP describes in their plan benefit package (PBP) do not inappropriately duplicate an existing service(s) that enrollees are eligible to receive under a waiver, the State Medicaid plan, Medicare Part A or B, or through the local jurisdiction in which they reside.

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

[6] The 2013 past performance methodology is described in our "2013 Application Cycle Past Performance Review Methodology Update" memo issued via the Health Plan Management System (HPMS) on December 2, 2011. The past performance methodology analyzes the performance of MA and Part D contracts in 11 distinct performance categories, assigning negative points to contracts with poor performance in each category. The analysis uses a 14-month look-back period; thus, for example, the 2013 application cycle analysis looks at performance from January 1, 2011 through February 28, 2012. While this analysis is done at the contract level, the results are rolled up to the legal entity level for purposes of denying applications based on past performance. We propose to use the contract-level results for purposes of the SNP quality formula.

CMS is also requiring D-SNPs that participate in this benefit flexibility initiative to submit a mandatory quality improvement project (QIP) on a topic that CMS will determine in consultation with stakeholders. D-SNPs would be able to choose this QIP topic from a list of broadly-defined topics designed to assess beneficiary outcomes (e.g., reduction of LTC utilization, preventing partial dual eligibles from declining to full-dual status) related to the provision of new supplemental benefits. CMS will consult with States and other stakeholders to develop these QIP topics, and will provide D-SNPs with additional operational details on this mandatory QIP submission in future guidance. As with any QIP, D-SNPs would have considerable latitude to develop the QIP so that it is tailored to the needs of their specific enrollee population.

Because this is a new flexibility rather than a new requirement for D-SNPs, D-SNPs may choose whether or not to include a supplemental benefit (or any combination of supplemental benefits) in their plan bids. For example, if a D-SNP's enrollees have access to a certain service through State or local coverage options, the D-SNP may choose not to include that service in its bid. Below, we set forth guidance on specific categories of supplemental benefits that we will permit D-SNPs to offer as part of the new benefits flexibility initiative.

Table VI-5. Supplemental Benefits for Consideration

Proposed Benefit Category	Benefit Description	Acceptable Means of Delivery	PBP description
Non-Skilled In-home Support Services	Non-skilled services and support services performed by a personal care attendant or by another individual that is providing these services consistent with State requirements in order to assist individuals with disabilities and/or chronic conditions with performing ADLs and IADLs as necessary to support recovery, to prevent decline following an acute illness, prevent exacerbation of a chronic condition, and/or to aid with functional limitations. This benefit category also includes non-medical transportation that assists in the performance of IADLs.	Services would be performed by individuals licensed by the State to provide personal care services, or in a manner that is otherwise consistent with State requirements.	Describe the criteria the plan intends to use (e.g., level of care need, ADL limitations, etc.) to determine which enrollees are eligible for personal care services.

Proposed Benefit Category	Benefit Description	Acceptable Means of Delivery	PBP description
In-Home Food Delivery	Meal delivery service (beyond the limited coverage described in Chapter 4, Section 30.5, of the Medicare Managed Care Manual (MMCM) for individuals who cannot prepare their own food (IADL limitation) due to functional limitations with ADLs or short-term functional disability, or for individuals who, based on a physician's recommendation, require nutritional supplementation following an acute illness or as a result of a chronic condition.	Meals would be provided consistent with plan policies for ensuring nutritional content (e.g., minimum recommended daily nutritional requirements)	Describe the Medicare meal benefit comprehensively, and clearly distinguish meal benefits for individuals who would already qualify under current meal benefit guidance from meal benefits under an expanded definition. Describe any limits imposed on meal benefits (e.g., duration, criteria for eligibility, number of meals/day).
Supports for Caregivers	Provision of respite care – either through a personal care attendant or provision of short-term institutional-based care – for beneficiary caregivers. Coverage may include benefits such as counseling and training courses (related to the provision of plan-covered benefits) for caregivers.	Specific caregiver support benefits must directly relate to the provision of plan-covered benefits.	Describe how benefits relate to plan-covered benefits, as well as any limitations (e.g., number of counseling/support sessions covered per year, number of hours/days of respite care covered per year and/or episode).

Proposed Benefit Category	Benefit Description	Acceptable Means of Delivery	PBP description
Home Assessments, Modifications, and Assistive Devices for Home Safety	Coverage of home safety/assistive devices, and home assessments and modifications beyond those permitted in Chapter 4, Section 30.3, of the MMCM. Coverage may include items/services such as rails in settings beyond the beneficiary's bathroom.	Home assessments would be performed by trained personnel (e.g., occupational therapists), or by persons with qualifications required by the State, if applicable.	Describe benefit comprehensively, and clearly distinguish safety assessments and devices already covered under Chapter 4 of the MMCM from additional benefits qualified SNPs could provide. Describe enrollee criteria for receiving these additional benefits (e.g., beneficiary at risk of falls, etc.)
Adult Day Care Services	Services such as recreational/ social activities, meals, assistance with ADLs/IADLs, education to support performance of ADLs/IADLs, physical maintenance/rehabilitation activities, and social work service.	Provided by staff whose qualifications and/or supervision meet State licensing requirements.	Describe the criteria imposed for receipt of adult day care services (e.g., prior authorization by a medical practitioner, institutional level of care requirement, etc.)

d) Notification of D-SNPs that qualify for supplemental benefit flexibility in CY 2013

CMS will review D-SNP contracts, past performance scores, and quality-based indicators to determine whether the a D-SNP qualifies to participate in this initiative based on the contract design and qualifying criteria outlined in the CY 2013 Final Call Letter. If CMS determines that a D-SNP meets the contract design and qualifying criteria, we will provide that D-SNP with written notification that confirms that it qualifies to offer the additional supplemental benefits.

In our CY 2013 draft Call Letter, we asked D-SNPs that wished to participate in this benefit flexibility initiative to notify us if they believed they would meet the requirements for the new flexibility. CMS will send these D-SNPs written notification that indicates whether or not they qualify to offer additional supplemental benefits in early April. CMS will also review other D-SNPs to determine whether they meet the requirements to participate in the benefit flexibility

initiative. We will notify these plans if they qualify to offer additional supplemental benefits no later than April 30th.

B. Marketing Flexibilities for Special Needs Plans

Through CMS' Medicare-Medicaid Coordination Alignment Initiative (see http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FederalRegisterNoticeforComment052011.pdf for more information), we have identified SNP marketing as an area in which different requirements in the Medicare and Medicaid programs may have created barriers to high quality, seamless, and cost-effective care for dual eligible beneficiaries. We are considering allowing integrated SNPs (those that provide access to all covered Medicare benefits and all Medicaid benefits covered in the State Medicaid plan; have a current, capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care benefits and services, where such coverage is consistent with State policy; coordinate delivery of covered Medicare and Medicaid primary, acute, and long-term care services throughout their entire service area; and possess a valid contract arrangement with the State, in accordance with CMS policy and the requirements at 42 CFR §422.107) to take advantage of certain marketing flexibilities starting in CY 2013. These flexibilities could include streamlining joint review processes and different requirements for standardized and other marketing materials for integrated SNPs than apply to other plan types. Any flexibility will still be subject to oversight and plans will be accountable for inappropriate practices.

In the draft Call Letter, we solicited comments on how we could streamline marketing requirements and review processes for integrated SNPs to provide more useful and integrated information to dual eligible beneficiaries as part of our broader effort to better align the Medicare and Medicaid programs. Commenters were generally supportive of the proposal to create streamlined marketing requirements and review processes for integrated SNPs. Some commenters requested that we consider extending this approach to any SNP providing Medicare and Medicaid benefits. Some commenters also recommended that a single entity review the materials. With respect to marketing guidelines, plans expressed concern about the change in the release date for the Evidence of Coverage (EOC) and requested that the flexibility to send the EOC by December 31 be retained to accommodate State Medicaid budget process. Other commenters urged CMS to ensure that streamlined materials are closely reviewed for accuracy and ease of comprehension and noted that D-SNP materials should be tailored to beneficiaries who are eligible for Medicare and Medicaid; specifically, that the materials clearly explain to what extent Medicaid coverage is available if service not covered by Medicare. We appreciate the constructive comments on streamlining marketing requirements and review processes for integrated SNPs to provide more useful information to dual eligible beneficiaries as part of the broader effort to better align the Medicare and Medicaid programs. We will take these comments

into consideration as we continue to develop this initiative for inclusion in the 2014 marketing guidelines.

C. State Role in Marketing Plan Sponsors' Products

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

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

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

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

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

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

Under current law, SNPs are only authorized through calendar year 2014. Should SNP authorization be extended into 2014, we would continue to raise the bar to ensure that high quality MOCs are submitted by the SNPs. For MOCs submitted for NCQA approval during CY 2013 for CY 2014, we will limit the number of cures offered for MOCs during the SNP approval

process. Only SNPs that have a failing score (less than 70 percent) for their initial MOC submission will have a cure opportunity to achieve a score within the passing range of 70-74 percent. **Regardless of the score following that cure, those SNPs will only receive a one-year approval**.

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

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

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

Table VI-6. MOC Proposed Review and Cure Process

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

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

E. All Dual Eligible SNPs Required to Contract with State Medicaid Agencies

Beginning in Contract Year 2013, all Medicare Advantage Organizations that offer Dual Eligible Special Needs Plans (D-SNPs) (existing, new and expanding) will be required to have contracts with the State Medicaid Agencies in the States in which they operate. D-SNPs that fail to secure a State Medicaid Agency contract will not be permitted to operate.

As in prior years, when completing the SNPs Proposal in HPMS during the February application period, in the appropriate area, SNPs may either submit the completed and signed contract for CY 2013 or describe the status of its negotiations with the State. MAOs were to upload contracts secured with the State Medicaid Agencies during the February 2012 application period only if they have been completed and ratified (i.e., signed indicating approval by both parties). In the absence of a ratified contract, SNPs should describe the status of their negotiations in the D-SNP State Medicaid Agency Contract Upload Document. The final submission date for the contracts for operation in CY 2013 is July 1, 2012. For more information, please refer to our HPMS memorandum of January 30, 2012, entitled, "Guidance for Submitting State Medicaid Agency Contracts." For additional information on State contracting requirements for D-SNPs, generally, please see section 40.5 of Chapter 16b of the Medicare Managed Care Manual.

In the draft Call Letter, we solicited comments on how to minimize disruption for beneficiaries who would need to be disenrolled by D-SNPs that are unable to secure a State contract. As noted above, D-SNPs will be required to secure a direct contract with their respective State Medicaid Agency or enter into a subcontracting arrangement that meets CMS' requirements (described in our HPMS memorandum of January 30, 2012) by July 1, 2012, in order to operate in the 2013 contract year. Thus, in the event that an MAO is not able to secure such a contract or subcontract for one or more of its D-SNPs, the MAO will have to terminate those D-SNPs in accordance with CMS' non-renewal instructions outlined in Section 140 of Chapter 4 of the Medicare Managed Care Manual. At this time, CMS expects that beneficiaries in these plans will be treated in the same way as other Medicare beneficiaries in non-renewing plans, and will be disenrolled to Original Medicare at the end of the year. These beneficiaries, by virtue of their dual eligible status, will have an ongoing special election period and thus can enroll in another MA plan (including a SNP plan) at anytime, and will be autoenrolled in a benchmark PDP effective January 1, 2013. CMS is committed to working closely with MAOs, beneficiary advocates, State Health Insurance Assistance Programs, and State Medicaid Agencies to increase beneficiaries' awareness of the transition and to minimize any disruption in care. (For more information about non-renewal processes and beneficiary notification requirements, please refer to our forthcoming guidance, to be released this summer, which will include additional information and model notices.)

F. Capitated Financial Alignment Demonstration

CMS issued initial guidance on key dates and plan selection processes, as well as other demonstration information, for organizations interested in offering demonstration plans in 2013 under the Capitated Financial Alignment Demonstration in a January 25, 2012 HPMS memorandum. This memorandum is available at http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FINALCMSCapitatedFinancialAlignmentModelplanguidance.pdf. CMS released additional guidance on key dates and plan selection processes in a March 29, 2012 HPMS memorandum that we expect to post to the Financial Alignment Demonstrations web page at http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html. As noted in the draft Call Letter, we encouraged organizations to carefully review our January 25, 2012 guidance and provide us with feedback on its contents. We considered those comments as we developed the March 29, 2012 guidance for interested organizations.

G. Fully Integrated Dual Eligible SNPs

Section 1853(a)(1)(B)(iv) of the Social Security Act authorizes CMS to make frailty payments to D-SNPs that are "fully integrated with capitated contracts with States for Medicaid benefits, including long-term care, and that have similar average levels of frailty . . . as the PACE program." In order for a SNP to be eligible to receive frailty payments pursuant to section 1853 of the Act, the SNP must: (1) satisfy the FIDE-SNP definition under 42 C.F.R. §422.2; and (2) have similar average levels of frailty as PACE organizations as described in the Advance Notice and Announcement for a year. The FIDE-SNP definition at 42 C.F.R. §422.2 requires the plan to have a contract with the state(s) in its service area specifying that the state(s) will pay the FIDE-SNP a capitation payment for primary, acute, and long-term care Medicaid benefits and services in exchange for the FIDE-SNP's provision of these benefits to its enrollees. In determining whether a D-SNP meets the FIDE-SNP definition, CMS will only allow Long Term Care benefit carve-outs or exclusions if the plan can demonstrate that it meets the following criteria:

(1) The plan must be at risk for substantially all of the services under the capitated rate; and
(2) The plan must be at risk for nursing facility services for at least six months (or one-hundred and eighty days) of the year; and
(3) The individual must not be disenrolled from the plan as a result of exhausting the service covered under the capitated rate; and

(4) The plan must remain responsible for managing all benefits, including any carved-out service benefits, notwithstanding the method of payment (e.g., fee-for-service, separate capitated rate) received by the plan.

Additionally, notwithstanding any benefit carve-outs permitted under such an arrangement, D-SNPs in states that currently require capitation of long term care benefits for a longer duration than this CMS minimum must maintain this level of capitation.

Private Fee-for-Service (PFFS) Plans

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

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

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

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

Regional Preferred Provider Organizations and Local Preferred Provider Organizations

A. RPPO and LPPO Deductible

The MA regulations at 42 CFR section 422.101(d)(1) establish requirements for regional PPO plans (RPPO) plans that choose to have a deductible. In our final rule, we finalized clarifications of the requirements for both RPPOs and local PPOs that elect to charge a deductible. In addition, in order to make rules for all PPO plans consistent, we extended the same deductible

requirements that currently apply to RPPOs to local PPO plans (FR 76 63057). The rules that apply to both local and RPPOs that choose to charge a deductible in CY 2013 are as follows:

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

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

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

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

Section 1876 Cost Plans

A. Supplemental Benefits for Section 1876 Cost Plans

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

B. Cost Plan Renewals and Service Area Reductions or Expansions

In accordance with the Affordable Care Act, beginning Contract Year (CY) 2013, cost plans will be non-renewed in service areas or portions of service areas in which at least two competing MA

local or two MA regional coordinated care plans that meet specified enrollment thresholds are available. Affected plans will be non-renewed for any portion of their service areas where there are at least two competing MA local or two MA regional coordinated care plans meeting specified enrollment thresholds for the entire previous year (i.e., CY 2012 for the initial cycle of non-renewals). The minimum enrollment thresholds are 5,000 enrollees for urban areas and 1,500 enrollees for non-urban areas. Cost contractors would not be able to operate in affected service areas in 2014. For purposes of plan renewal, the MA local and/or regional coordinated care plans must meet minimum enrollment requirements for the entire year prior to the non-renewal year in order to trigger mandatory cost-based plan non-renewal or service area reduction. However, for purposes of a cost plan's mid-year service area expansion, the MA plans must only meet minimum enrollment requirements as of the date of the proposed expansion.

We will provide affected cost plans CY 2012 data on MA plans in the service area that will be used to determine if cost plans will receive non-renewal notices for specified cost contract plans or portions of service areas for CY 2013 based on the MA plan "competition" provisions described above. (See 42 CFR §417.402 and 76 FR p. 21448 (April 15, 2011) for additional information on minimum enrollment and other requirements related to the cost plan competition provisions.)

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

C. Cost Plan Disclosure Requirements

In our final regulation, we extended Medicare Advantage and Part D prescription drug program disclosure requirements to cost contract plans. In previous rulemaking, we extended the MA and Part D marketing requirements to cost contract plans but inadvertently did not include the related, disclosure requirements. While we are extending the disclosure requirements specified in § 422.111 and §423.128 of the MA and Part D regulations, respectively, we want to clarify that cost contract plans will continue to follow their current schedules for delivering the Annual Notice of Change/Evidence of Coverage for receipt be enrollees. The receipt dates for the 2013 contract year are, therefore:

Cost (no Part D): December 1
Cost-PD: September 30, 2012

D. **Note**: please see the calendar, Section 1—Program Updates.

Section III. Part D

Preferred/Non-Preferred Network Pharmacies

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

Sponsors of plans that offer both preferred and non-preferred cost sharing should clearly designate their pharmacy contracts—including their standard terms and conditions available to any willing pharmacy—as either preferred or non-preferred Part D network contracts to improve transparency around these arrangements.

Collaboration between Pioneer and Medicare Shared Savings Program Accountable Care Organizations and Part D Sponsors to Enhance Pharmacy Care Coordination

Pioneer and potential Medicare Shared Savings Program Accountable Care Organizations (Medicare ACOs) and Part D Sponsors have indicated an interest in collaborating to enhance the coordination of pharmacy care for Medicare ACO beneficiaries. Similarly, CMS has an interest in sponsors of stand-alone prescription drug plans (PDPs) playing a greater role in managing the care of Medicare FFS beneficiaries and having greater accountability for overall health outcomes. We believe that Medicare ACOs provide a potential platform for such collaboration with Part D Sponsors and encourage these entities to form appropriate business arrangements that support improved pharmacy care coordination, provided such arrangements comply with all laws and regulations. We offer below collaboration principles for Medicare ACOs and Part D Sponsors that are considering forming such business arrangements.

Collaboration Principles

1. Focus the business arrangement on pharmacy care coordination and data sharing. CMS encourages Medicare ACOs and Part D Sponsors to establish mechanisms to improve the coordination of pharmacy care for Medicare ACO beneficiaries. Examples of pharmacy coordination approaches include establishing innovative approaches to increase formulary compliance (when clinically appropriate) and medication compliance; providing pharmacy counseling services; and implementing medication therapy management. Timely data will be essential to improved pharmacy care coordination. While Medicare ACOs will be provided by CMS with Part D prescription drug event data, it may be useful for both Medicare ACOs and Part D sponsors to share clinical data and pharmacy data with each other, provided that all beneficiary privacy and confidentiality rules and regulations, including HIPAA, and other applicable laws and regulations are followed.

   While CMS contemplates that the broad categories of arrangements listed above may provide viable approaches to Medicare ACO – Part D collaboration from a policy perspective, we stress that all Medicare ACOs should closely assess the structure of each arrangement with their counsel on a case-by-case basis to ensure legal compliance. All business arrangements between Part D Sponsors and Medicare ACOs must comply with the requirements of the participation agreement between the Medicare ACO and CMS and all applicable laws and regulations, including the fraud and abuse, Part D program, and other relevant laws and regulations. For instance, as only one example, any cash or cash equivalent contributions to beneficiaries for prescription drug cost-sharing or premium assistance must comply with existing fraud and abuse law and would not be covered by the patient incentives waiver applicable to Medicare ACOs. Part D sponsors must continue to meet all Part D requirements, including but not limited to offering plans subject to meaningful differences limitations, providing uniform formularies, benefits, and beneficiary protections, and ensuring there is no inappropriate drug cost shifting from Part B to Part D, such as shifts that increase beneficiary cost sharing.

2. Align financial arrangements with health outcomes and performance. As Medicare ACOs and Part D Sponsors contemplate terms for a business arrangement focused on pharmacy care coordination and data sharing, both parties might consider structuring the financial terms of the arrangement to reward party contributions to the achievement of better health outcomes, better health care, and lower per-capita expenditures for Medicare beneficiaries. Again, all business arrangements must comply with the requirements of the participation agreement between the Medicare ACO and CMS and all laws and regulations, including the fraud and abuse, Part D program, and other relevant laws and regulations.

3. Promote Competition. CMS encourages Medicare ACOs to promote competition in the marketplace to the extent possible, consistent with antitrust, fraud and abuse, and other laws.

Approach for Facilitating Collaboration between Medicare ACOs and Part D Sponsors

CMS encourages Medicare ACOs (that is, the Pioneer and Shared Savings Program ACOs) to consider finding Part D Sponsor partners through a Request for Proposals process and is willing to provide to Medicare ACOs upon request a list of Part D Sponsors currently offering plans in Medicare ACO markets, as well as to provide Medicare ACO staff contacts to those Part D sponsors. CMS has an interest in evaluating the collaboration between Medicare ACOs and Part D sponsors and the outcomes of such arrangements on meeting the goals of the Pioneer and Shared Savings Programs, and on the Part D program. We may exercise the right to review executed written agreements made between the ACO and Part D sponsor as a component of that evaluation. The evaluation results will be valuable in informing future improvements to Medicare programs.

Low Enrollment Plans (Stand-alone PDPs only)

Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options continue to be a concern to us. While we are particularly concerned about the smallest plans, we urge sponsors to consider withdrawing or consolidating any stand-alone plan with less than 1,000 enrollees on a voluntary basis. Sponsors are strongly encouraged to view data on plan enrollment at: www.cms.hhs.gov/MCRAdvPartDenrolData/ to determine if any of their plans meet this criterion. In April 2012, we will notify plans with less than 1,000 enrollees of available consolidation/withdrawal options. However, we will not be enforcing any specific criteria for CY 2013 except in respect to plans that were contacted last year about their low enrollment status and have not yet consolidated/withdrawn these plans consistent with their discussions with CMS. We reserve the right to require low enrollment plans to consolidate/withdraw in the future based on the marketplace at that time to ensure that all Part D plans offered in the marketplace are attractive to beneficiaries and not adding to their confusion in selecting a plan best suited to their prescription drug coverage needs.

Benefit Thresholds

Each year, in order to implement certain regulations, we set forth certain benefit parameters, which are based on updated data analysis, and therefore, are subject to change from year to year. Specifically, pursuant to § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered; and, pursuant to 42 CFR

423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. Since no changes have occurred in how we establish these parameters for CY 2013, nor in the applicable regulations, the benefit parameters for CY 2013 are set forth in Table VI-7 below. However, after reevaluating cost-sharing OOPC estimates using the CY2013 OOPC model, we have established minimum meaningful difference thresholds that differ from the draft Call Letter. The CY2013 OOPC model incorporates updated PBP and formulary data used for CY2013 bid submissions, as well as more precise brand and generic drug determinations for gap coverage cost-sharing estimates, which utilize Food and Drug Administration (FDA) data and are more in line with the way the Part D benefit is administered. Using the updated model, the minimum monthly cost-sharing OOPC difference between basic and enhanced plan offerings will remain relatively stable at $23. However, the minimum monthly cost-sharing OOPC difference between enhanced plan offerings will decrease to $12.

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

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

Table VI-7 Benefit Parameters

	Proposed CY2013 Threshold Values
Minimum Meaningful Differences(OOPC)[1]	
1st Enhanced Alternative Plan vs Basic Plan	$23
1st Enhanced Alternative Plan vs 2nd Enhanced Alternative Plan	$12
Maximum Pre-ICL and Additional Gap Coverage[2] Copay (INPh & INNPPh) - 3 or more tiers	INPh/INNPPh[3]
Preferred Generic/Generic Tier	$10
Non-Preferred Generic Tier	$33
Preferred Brand/Brand Tier	$45
Non-Preferred Brand Tier	$95
Injectable tier	$95
Maximum Pre-ICL Coinsurance (INPh &INNPPh) - 3 or more tiers	INPh/INNPPh[3]
Preferred Generic/Generic Tier	25%
Non-Preferred Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Maximum Additional Gap Coverage[2] Coinsurance (INPh &INNPPh) - 3 or more tiers	INPh/INNPPh[3]
Preferred Generic/Generic Tier	59%
Non-Preferred Generic Tier	59%
Preferred Brand/Brand Tier	69%
Non-Preferred Brand Tier	69%
Minimum Specialty Tier Eligibility	
1 month supply at in-network retail pharmacy	$600

[1]These thresholds are based on the 95th percentile of the CY2012 November Bid Data run through the CY2013 OOPC model which incorporates CY2013 PBP and Formulary Data, 2006/7 MCBS Data, and FDA Data for brand/generic determinations related to coverage gap cost-sharing estimates.

[2] We have provided background information in Appendix D regarding our analysis to determine how much additional coverage in the gap over the basic benefit would be considered to be substantially different. If additional gap coverage of a brand tier includes generic drugs, then the coinsurance maximum for generic drugs of 59% applies to all drugs on that tier. Injectable drug tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand tiers.

[3] These thresholds are based on the 95th percentile. They are subject to change based on an analysis of plans using the 95th percentile after CY 2013 bids are received. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary and for meaningful benefit offering tiers that have low or $0 cost-sharing (i.e., special needs plans targeting one or more specific conditions). Also please note that INPh means "In-network pharmacy"; INPPh means "In-network preferred pharmacy"; and INNPPh means in-network non-preferred pharmacy. **The INPPh cost-sharing amount submitted must be less than the INNPPh threshold in accordance with Section 50.9 of Chapter 5 of the Medicare Prescription Drug Benefit Manual.**

Plan Finder

We are committed to continuing to improve the Medicare Plan Finder (MPF) tool to give beneficiaries and caregivers the best possible drug cost estimate when comparing Part D plans. Currently, the MPF calculates costs for display on the MPF based on the unit cost of a drug times the quantity dispensed plus the dispensing fee. However, CMS is aware of scenarios where beneficiaries are actually paying a minimum or maximum price for a drug at the point of sale (POS) dependent upon contracted prices between the sponsor and a specific pharmacy for a given drug. Additionally, sponsors may have benefits that cover 30, 60, or 90-day fills at both retail and/or mail order In order to continue to provide beneficiaries with the best possible drug cost estimates to display on the MPF; we are developing enhancements for implementation on the MPF. The enhancements are:

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

For display purposes on the MPF, the floor price helps determine the starting point of the Co-pay/Co-insurance calculations, as well as provides the display value for the Full Price. If the "floor" price is greater than the calculated drug cost, the MPF will use the "floor" price as the starting price for the calculation. If the calculated drug cost is greater than the "floor" price, the MPF will use the calculated drug cost as its starting point. For example: Plan A has set a $3.00 "floor" price with Pharmacy Z. Plan A's unit cost for Drug A is $0.02 and Pharmacy Z's dispensing fee is $1.50. The cost of a 30 day supply of Drug A is $2.10 (($0.02*30) + $1.50). Since Plan A's "floor" price of $3 is higher than the calculated price, the starting point for the calculations will be the $3 "floor price" as shown below.

In this same example, if a plan's co-pay is $10, the beneficiary will pay the $3.00 floor price because the floor price is lower than the co-pay. However, if the plan's co-pay fell below $3.00 (for example, a $0 co-pay for selected generics), then the lesser than rule would apply, and the plan's co-pay would be displayed on the MPF.

Alternatively, in this same example, if a plan's co-insurance is 20%, the MPF would calculate the co-insurance based on the negotiated price ("floor" price of $3.00). Therefore, the MPF would display $0.60 (20% co-insurance * $3.00 floor price).

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

Provide a mechanism to submit and display pricing for 30, 60, or 90-day fills at both retail and mail order. CMS will utilize existing data from the plan benefit package (PBP) as well as new fields and new indicators that may be required on the CY 2013 Pricing Data Requirements to allow submission of 30-day and 60-day unit cost pricing for mail order and 60-day and 90-day unit cost pricing at retail. We also expect this enhancement to be implemented in September 2012 for the CY 2013 MPF display.

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

Limiting Online Enrollment through the Medicare Plan Finder (MPF)

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

In an effort to assist in guiding beneficiaries towards selecting higher performing plans, we will disable the MPF online enrollment function for Medicare health and prescription drug plans with the low-performing plan icon for CY2013 plan enrollments. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in geographical areas with limited plans) will be warned, via explanatory messaging of the plan's poorly rated performance, and directed to contact the plan directly to enroll.

Misuse of Five-Star Rating

The overall rating is defined as the highest level rating assigned to a contract by CMS. Plans that receive a 5-star rating as their highest level rating are referred to as "five-star contracts." It has come to our attention that certain sponsors are instead using their star rating in a lower category or measure to imply a higher overall plan rating for their marketing materials than is actually the case. For example, a plan which received a five-star rating in customer service promotes itself as a "five-star plan," when its overall plan rating is actually only two stars. We will scrutinize Parts C and D marketing materials to ensure they are not misleading in this manner. Sponsors must use their star ratings in marketing materials in a manner that does not mislead beneficiaries into enrolling in plans based on inaccurate information. If a lower category or measure rating is referenced in a plan's marketing materials, the plan's overall rating must also be prominently referenced. For example, "We are rated a five-star plan in customer service, but rated 3 stars overall." Additional guidance will be released with the Medicare Marketing Guidelines.

Complaint Tracking Module (CTM) Monitoring

For CY2013, we are planning to update the Evidence of Coverage (EOC) notice that is sent annually to beneficiaries to include a link to the online complaint form.

<u>Complaint Survey</u>

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

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

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

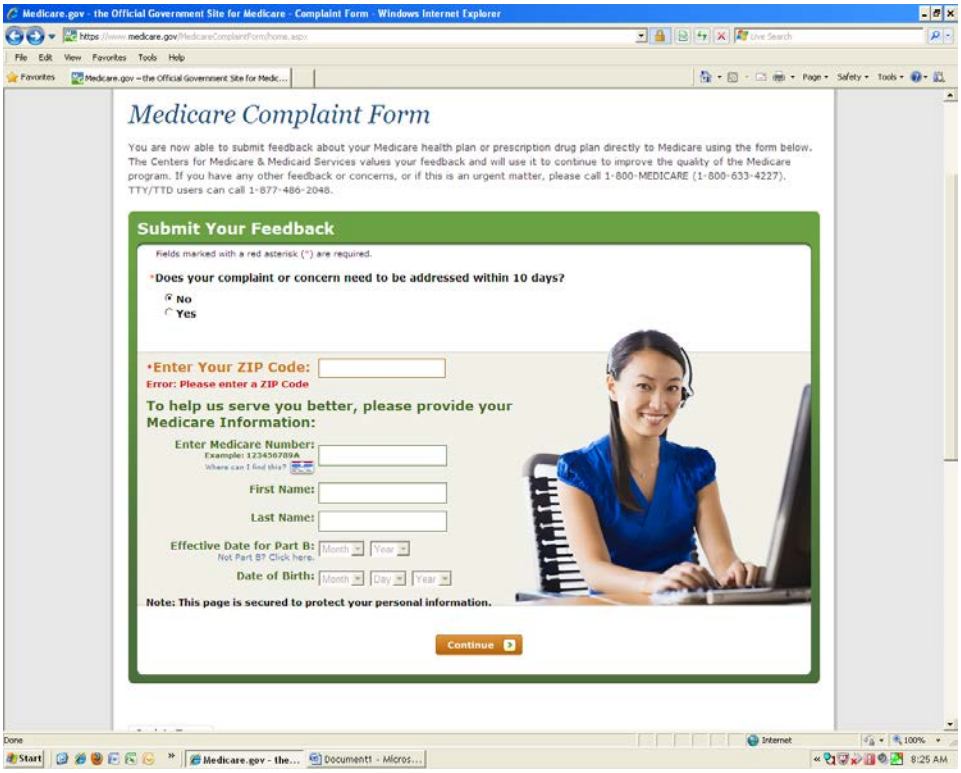
outcome of their complaint, indicating that the resolutions reached by plans were effective from the beneficiaries' perspective.

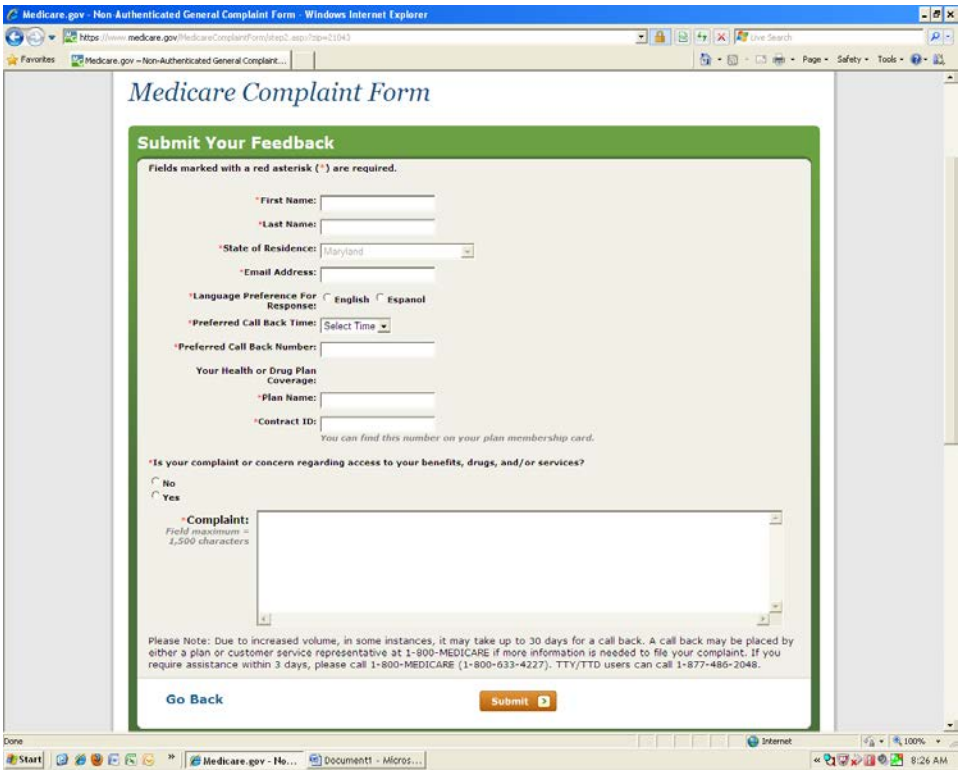
Based on these findings, we believe that obtaining beneficiaries' satisfaction with their plans complaint resolution process is an important patient protection. In 2012, a web-based version of this beneficiary survey will be made available via message notification after a beneficiary's complaint is closed.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

Medicare Online Complaint Form

Pursuant to Section 3311(b) of The Affordable Care Act, we implemented an electronic Medicare online complaint form. The online complaint form went live December 2010 and has been placed in three locations: 1) on the http://www.medicare.gov homepage; 2) on the Medicare Plan Finder homepage; and 3) on the Medicare Ombudsman homepage. As provided in 42 CFR 423.505(b)(22)(ii), MAOs and PDP sponsors are required to prominently display a link to this electronic complaint form on their websites.

Medicare Electronic Online Complaint Form:





Medication Therapy Management (MTM) Programs

We expected more Part D beneficiaries would be eligible for MTM following changes to the eligibility criteria requirements in 2010. However, the eligibility rate has remained at 10 to 13% since 2006. We are concerned that the Part D sponsors are restricting their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs and are required to be offered CMRs. We are conducting an analysis to examine the combinations of chronic diseases Part D plan sponsors require for targeted enrollment and prevalence in the Medicare population. We are also evaluating the extent to which MTM programs target populations with medication therapy issues and the programs' impact on clinical outcomes and costs. Changes to these eligibility requirements are being examined, and sponsors should optimize their targeting of beneficiaries who are most likely to benefit from access to MTM services. The CMS requirements for targeting beneficiaries for the MTM program are the floor, and not the ceiling. Therefore, sponsors may offer MTM program services to beneficiaries who do not meet the eligibility criteria per CMS' specifications.

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

Per Sec. 423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries is specified as costs for covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in §423.104(d)(5)(iv). Accordingly, the 2012 MTM program annual cost threshold is $3,100.20. The 2012 MTM program annual cost threshold is updated for 2013 using the annual percentage increase of 1.40%, as specified in the Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2013 MTM program annual cost threshold is $3,144.

In implementing Section 10328 of the Affordable Care Act, we consulted extensively with stakeholders to develop the standardized format for the action plan and summary that plan sponsors must provide to beneficiaries after their comprehensive medication review (CMR). A CMR is an interactive, person-to-person or telehealth medication review and consultation, including an individualized, written summary of the interactive consultation. The standardized format, instructions for implementation, and frequently asked questions will be posted on the CMS MTM web page (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html) no later than April 2012. The implementation

instructions include document, page, and field specifications; delivery requirements; additional guidance; and a completed sample. Part D sponsors must begin using the standardized format no later than January 1, 2013.

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

- Targeted beneficiaries are auto-enrolled when they meet the eligibility criteria, so sponsors should not wait for program acceptance (such as a returned enrollment mailing or affirmation via the phone) from the beneficiary to offer the required minimum MTM services (including interventions for both beneficiaries and prescribers, an annual CMR with written summaries in the standardized format, and quarterly targeted medication reviews with follow-up interventions when necessary).
- The provision of the action plan and written summary in our standardized format requires certain minimum service levels for the CMR, such as discussion of the beneficiary's concerns with their drug therapy, collection of the purpose and instructions for using their medications, review of a beneficiary's medications including prescription, non-prescription drugs and supplements to aid in assessing medication therapy, and engaging beneficiaries in management of their drug therapy.
- Sponsors should offer to provide a CMR to newly targeted beneficiaries (i.e. beneficiaries not enrolled in the sponsors' MTM program during the previous contract year) as soon as possible after enrollment into the MTM program, but no later than 60 days after being enrolled in the MTM program. For MTM enrollees who were enrolled in the MTM program during the previous contract year and continue to meet the criteria for the current contract year, sponsors should offer the CMR within one year of the last CMR offer.
- Sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries so they are able to receive MTM services and a CMR versus only reaching out via passive offers. Sponsors may increase beneficiary engagement by providing telephonic outreach after mailed outreach.

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

Beneficiary Awareness

We are committed to increasing beneficiaries' awareness about MTM programs, and sponsors are encouraged to promote the value of MTM services to beneficiaries. Information about MTM programs was included in the 2012 *Medicare & You Handbook*, and we will continue to enhance the information provided. Medicare beneficiaries are now able to view 2012 MTM program eligibility information through a link on the Medicare Plan Finder (MPF). We are exploring other ways to integrate this information into the MPF in a user-friendly manner to help beneficiaries differentiate between available plan offerings. Sponsors should ensure that their customer service representatives and staff are familiar with the plans' MTM program. Starting in 2013, sponsors will be required to have information on their website about their MTM program. Customer service and the website should provide at a minimum: the plan's MTM eligibility requirements, who to contact for more information, and a high level summary of services offered as part of the MTM program. Part D sponsors are also encouraged to post a blank Personal Medication List from the CMR standardized format on their website or provide information to beneficiaries about how to obtain a blank copy.

MTM Program Submissions

Annually, sponsors must submit an MTM program description to us for review and approval through the Health Plan Management System (HPMS) MTM Program Submission Module. Some Part D sponsors have informed us that they offer MTM services to beneficiaries beyond those who meet the required CMS targeting requirements. This is permitted, but lack of information on these beneficiaries affects our analysis of MTM program outcomes and structuring of control groups for study. In the 2013 Part D reporting requirements and the MTM Program Submission Module for 2013, we will begin to capture information about programs and beneficiaries identified as being eligible for MTM, whether based on our specifications or other plan-specific targeting criteria. The reported beneficiaries must receive MTM services that meet or exceed CMS' MTM program requirements. Additional details on the 2013 Part D reporting requirements, including the proposed data elements for capturing MTM enrollee level information, will be provided during the associated PRA public comment periods and OMB clearance process. We will provide 2013 submission guidance before the end of April 2012.

Improving Drug Utilization Review Controls in Part D

Introduction

Part D sponsors are, and have been, responsible for establishing reasonable and appropriate drug utilization management programs that assist in preventing overutilization of prescribed medications. Through discussions with the industry, CMS has determined that sponsors need to employ more effective concurrent and retrospective drug utilization review (DUR) programs to

address overutilization of medications in order to protect beneficiaries, to comply with drug utilization management (DUM) requirements at 42 CFR §423.153 et seq. and to reduce fraud, waste and abuse in the Part D program. While stakeholders need not wait for our input, we would be amenable to working with them to achieve consensus on consistent metrics to identify overutilization of medications, particularly opioid analgesics ("opioids"), but the health and safety of Medicare beneficiaries cannot wait for such consensus. Part D sponsors either already have, or should have, the existing expertise to address significant patterns of overutilization, and we are setting forth in this section how sponsors can use that expertise in ways some may not have thought permissible, have not previously considered, or have not implemented adequately.

We believe that, for many sponsors, several improvements to formulary management processes are necessary to curb overutilization. We are delineating specific, but sufficiently flexible, features such as a minimum standard for compliance for CY 2013. In particular, while we expect to see Improved Use of Concurrent Claim Edits (Safety Controls at POS) and Improved Use of Formulary Utilization Management Designs (QLs at POS), as described in detail below, applied to all medications to ensure dispensing at safe dosages, we expect to see Improved Retrospective DUR Programming and Case Management, also described in detail below, applied at a minimum to opioids in CY 2013. If these levels of DUR do not prove effective at establishing medical necessity, which we believe would be a rare occurrence, the sponsor may implement beneficiary-level POS edits under certain conditions.

As a matter of general clarification, the improvements we describe below do not change our existing policy on QLs, prior authorizations, step therapy and protected class drugs, and are in fact intended as improvements to formulary management processes that we expect sponsors to implement. We will provide further guidance to sponsors as needed and appropriate on the implementation of these improvements, and we remind sponsors that we will be monitoring their performance in appropriately implementing these improvements.

We are also outlining how sponsors may share beneficiary-level data about overutilization under HIPAA when a beneficiary changes plans. Further, we emphasize sponsors' ability to make referrals to the appropriate agencies when they suspect fraudulent activity in accordance with the policy set forth in Chapter 9 of the Medicare Prescription Drug Benefit Manual.

Finally, CMS is committing to undertaking a communication and educational campaign about medication overutilization, particularly opioids, for physicians and pharmacies in the fall of 2012 to support sponsors' strengthened efforts to address this issue in the Part D program. To encourage further dialogue between CMS and Part D sponsors about overutilization, we will also be offering a session on overutilization at the Medicare Advantage and Part D Spring Conference in April 2012, during which illustrative examples will be presented and reviewed, and we encourage sponsors to have representatives attend.

Background

A recent Government Accountability Office (GAO) report highlighted evidence that effective concurrent DUR has not been fully implemented across the Part D program (GAO-11-699 September 2011 http://www.gao.gov/new.items/d11699.pdf). This report summarized findings of egregious overutilization of medications by Part D beneficiaries who were obtaining medications from a minimum of five different prescribers and a maximum of fifty prescribers, with the vast majority of beneficiaries receiving medications from between five and ten providers. The medications most often identified as being potentially overprescribed were those opioid products containing hydrocodone followed distantly by oxycodone containing products. Therefore, we are focusing on addressing overutilization of opioids beginning CY 2013.

Overview of Improvements to Formulary Management Processes

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

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

Sponsors are in a unique position to identify potential medication overutilization and engage the involved prescribers. Sponsors are a central data collection point for beneficiary medication dispensing events, which may be generated from multiple providers and pharmacies, who may be unaware that a beneficiary is receiving the same drug (or therapeutic equivalent) simultaneously from different providers and pharmacies.

An adequate system to assist in preventing overutilization of prescribed medications, including opioids, includes several levels of improved formulary management. We have termed the first level "Improved Use of Concurrent Claim Safety Edits (Safety Controls at POS)." We believe that if safety edits, such as "therapeutic duplication," "maximum dose exceeded," and "refill too soon," had been appropriately implemented, and not routinely overridden, much of the egregious overutilization noted in the GAO report described above would have been averted. In addition to these POS edits, sponsors should apply safety edits that minimize the risk of overutilization of individual medications contained in combination products, such as opioid products containing acetaminophen ("APAP"), which does have maximum dosing limits when the ingredient APAP is considered across all unique combination products. The second level is "Improved Use of Formulary Utilization Management Designs (QLs at POS)," such as quantity limits (QLs) applied to medications that do not have a clear maximum dose, such as opioids that do not contain APAP, or QLs applied below the Food and Drug Administration ("FDA") labeled maximum dose. The third level is "Improved Retrospective DUR Programming and Case Management" to identify patterns that suggest drug overutilization based on number of prescribers and doses, patterns of prescribing, and cumulative dosing, and then employment of clinical case management intervention strategies.

We discuss each level in detail below, using opioids as the example. However, as noted above, we expect to see the improvements outlined in Level One and Two applied to all medications for CY 2013, and Level Three applied to opioids. As also noted above, it should be clear in reviewing these levels that we will continue to approve QLs and other required formulary and DUM submissions as per our current policy described in the applicable Part D manuals. Finally, we will develop monitoring protocols to ensure sponsors are implementing effective but appropriate controls against overutilization. Sponsors that establish inappropriate controls may be subject to a compliance action.

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

Part D sponsors, through the appropriate use of concurrent DUR systems, have the ability to substantially improve patient safety by facilitating a reduction in the incidence of inappropriate overutilization. As long as they are consistent with FDA labeling, the safety edits described in this level can be implemented without submission to or approval by us (e.g., edits that prevent the dispensing of a drug when the labeling clearly identifies the dispensing as unsafe). Therefore, all drugs (including the six protected classes and controlled substances) should be subject to DUR safety controls at POS, such as early refill edits, therapeutic duplication edits (i.e., patient receiving same drug or drug within the same class two days prior), and dose limitations at or above the maximum dose (as described in the Food and Drug Administration (FDA) approved label for most drug products and addressed again in more detail in Level Two (A) below).

Further, these safety controls at POS should not be suppressed during beneficiaries' transition periods. Based on their experience with the use of these edits, sponsors should use their discretion in implementing such edits as soft edits, or pharmacy messaging only, or hard edits, such as those requiring an authorization to resolve the edit.

However, based on the comments submitted in response to our September memo, it is evident that not all sponsors are fully utilizing available concurrent DUR tools. For example, while opioid analgesics do not always have a clearly defined approved maximum daily dose, those products that contain acetaminophen (APAP) do. Thus, we would expect all sponsors to consider the APAP content of opioid analgesics and implement edits in their systems that prevent the dispensing of unsafe daily doses of APAP (greater than 4gm/day as recommended by the FDA). Yet, comments on the September memo indicated that some sponsors believe our existing formulary guidance restricts their ability to implement such safety edits. Consequently, we are taking this opportunity to clarify that we consider safety edits to prevent dispensing of unsafe dosing of drugs to be part of the concurrent DUR requirements for all Part D drugs. Also, while POS edits provide a broad first level of beneficiary safety, more sophisticated levels of formulary management need to be employed by Part D sponsors to prevent overutilization, as discussed in further detail below.

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

A) QLs/ At or Above FDA Maximum Dose

For ease of reference (by consolidating our review of QLs in relation to FDA maximum doses in one place in this Call Letter), we are repeating the guidance just above on QLs at or above the FDA maximum dose here. So again, Part D sponsors are permitted to apply QLs at or above the FDA maximum approved dosing to covered Part D drugs, including drugs within a protected class, in order to promote safe use (by not allowing dosages beyond maximum dose or unsafe dosages) and to decrease fraud, waste and abuse. Again, QLs at or above the FDA labeled maximum daily dose do not have to be included as part of the HPMS formulary submission and do not require our approval, even if they are implemented as hard edits. We note that 42 CFR §423.120(b)(2)(vi)(B) permits exceptions to the protected classes requirement for "utilization management processes that limit the quantity of drugs due to safety."

B) QLs/No FDA Maximum Dose

Part D sponsors may also apply QLs to drugs, as appropriate, for which there is no clearly defined maximum dose in the approved labeling, such as most opioid analgesics, to ensure safety, promote cost-effectiveness through dose optimization, and to decrease fraud, waste and abuse. When developing QLs in such cases, sponsors' Pharmacy and Therapeutic (P&T) committees should consider existing best practices to control overutilization through formulary

management and document their conclusions. Sponsors are reminded that QLs where there is no FDA labeled maximum daily dose must be included as part of the HPMS formulary submission and are subject to our approval. Again exceptions to the protected classes requirement are permitted for utilization management processes that limit the quantity of drugs due to safety.

C) QLs/Below FDA Maximum Dose

Finally, Part D sponsors may apply QLs, as appropriate, below the FDA maximum approved dosing to promote cost-effectiveness through dose optimization, and to decrease fraud, waste and abuse, if the approved maximum dose is accessible on the plan formulary. An example of dose optimization would be to promote the use of one 80mg controlled release (CR) tablet rather than two 40mg CR tablets to achieve an 80mg CR tablet dose through QL restrictions on the 40mg CR tablets. Sponsors are reminded that QLs below the FDA labeled maximum daily dose also must be included as part of the HPMS formulary submission and are subject to our approval. In addition, this example would only be permitted so long as the 80mg CR tablet is also on formulary; however, it would not be permitted for protected class drugs unless such QLs are due to safety.

Level Three: Improved Retrospective DUR Programming and Case Management

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

For CY 2013, for those sponsors who are not already employing this type of approach, or are not doing so with respect to opioids, we expect these sponsors to implement this level to address opioid overutilization, at a minimum. This will allow these sponsors to gain experience in using this approach while addressing the most commonly overutilized medications according the GAO

report. Although we recognize that some beneficiaries may require high doses of opioids for appropriate indications to maintain analgesia, these medications may pose significant safety hazards to beneficiaries when overprescribed and not appropriately monitored.

Indeed, we recognize that the opioid class of medication presents many challenges for sponsors to ensure beneficiary safety and prevent fraud, waste and abuse. The application of current utilization management tools, such as safety controls at POS and QLs, may not be as effective in identifying overutilization of opioids when compared to other classes of medications. For instance, therapeutic duplication safety edit software at POS may not be currently programmed to the level of sophistication to prevent overutilization for opioids, and edits are often soft edits overridden at the pharmacy. These POS edits may not distinguish between drugs within a therapeutic class, or may be overly sensitive and identify regimens that are commonly used for pain management. Challenges such as concurrent use of long-acting with short-acting products, titration of dose, switching agents within the class, and new prescriptions written monthly for Schedule II drugs (often by different doctors) highlight the need for sponsors to implement effective retrospective DUR programs to identify beneficiaries who are at risk for overutilization of these medications.

In light of this, sponsors should have DUR programming (that is, retrospective report-generation criteria as opposed to POS claim edits) that identifies patterns which suggest that the identified patients may be at risk of overutilization, so that these cases may be further analyzed clinically for possible fraud, waste and abuse. Moreover, beneficiaries receiving multiple products, from multiple providers, dispensed from multiple pharmacies, may be at risk for harm and overutilization. Other examples are beneficiaries for whom a sponsor has authorized quantities in excess of the normal QL set by the sponsor, or beneficiaries for whom soft edits are consistently overridden, could trigger a referral for retrospective review/case management.

CMS conducted an informal survey of five Part D sponsors that demonstrated the limits of current utilization edits for beneficiaries receiving controlled substances and the need for retrospective DUR programs to identify patients at risk which have case management and prescriber communication as included features. The following example illustrates a case where retrospective DUR could identify possible overutilization that would not be identified through use of normal utilization management tools and POS safety edits:

> A beneficiary is receiving care from thirteen different physicians over the course of one year. Nine of these providers are writing for controlled substances. The patient is receiving methadone 30mg/day from one provider routinely each month, while receiving oxycodone SR 80mg three tablets/day routinely each month from a second provider. It is conceivable that they are each unaware the patient is on both of these Schedule II controlled substances. In addition, the patient is receiving #90 hydrocodone 10mg/APAP 650mg each month from a

third provider with five refills while receiving #90 hydrocodone 7.5mg/APAP 750mg also with five refills within one week from a fourth provider. In total, the patient appears to be taking 4.2 gm of APAP per day (which is over the FDA maximum recommended dose due to risk of hepatic toxicity).

We note several observations about this case:

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

Using variables such as those outlined above, Part D sponsors should create and monitor Part D utilization reports to identify patterns of apparent duplicative drug use over sustained periods of time and/or across multiple drug products.

When warranted by review of the retrospective DUR programmed reports and the beneficiaries' medication histories, clinical staff, such as case managers, should communicate with prescribers and beneficiaries to ascertain medical necessity. This clinician-to-clinician communication should include information about the existence of multiple prescribers and the beneficiary's total opioid utilization, as well as elicit any complicating factors, as necessary and appropriate features of such communication.

We expect that merely sharing information about multiple prescribers and the beneficiary's total opioid utilization by sponsors with the prescribers involved in most cases will result in

adjustments to future opioid medication regimens that are mutually agreeable to the prescribers and the sponsor. However, if necessary, more involved discussions around the beneficiaries' medical conditions and opioid prescriptions should occur. Our expectation is that these discussions will result in clinical decision-making about the appropriate level of opioid utilization for the beneficiary. Results of case management may confirm that the current level of opioids is medically necessary, or in some cases, that a lower level or no opioids, are warranted. In the latter cases, our expectation is that all, or some prescribers involved in the health care of the beneficiary, will agree to alter their level of prescribing going forward to achieve the medically necessary level and will be made aware of any beneficiary-level edits to be put in place to ensure this level.

We would expect the bases for the opioid overutilization thresholds or patterns that trigger reports to be documented by the P&T committee. Indeed, our expectation is that the opioid overutilization review program will be reviewed and have documented approval by the P&T committee. In addition to the clinical thresholds and prescription patterns established for triggering retrospective reports to identify beneficiaries that need further evaluation, expected components of the program would be a written policy and procedure that addresses (for beneficiaries who were further evaluated):

1) the required clinical contents of the case file, such as the threshold or pattern triggering the review, as well as the beneficiary medication history;

2) communication with prescribers and beneficiaries, such as the credentials of personnel conducting the communication, the number of attempts at communication to be made; and the documentation required of the communication;

3) the results of the communication with prescribers and beneficiaries, such as any case management plan that is mutually agreed to and the documentation required;

4) in the case of non-responsive prescribers, any action taken by the sponsors, such as beneficiary-level claim edits and the documentation required;

5) copies of the written notices issued to the beneficiary and prescriber(s) informing them of a pending beneficiary-level claim edit to be implemented. (We note that CMS will develop model notices for pending beneficiary-level claim edits, and that sponsors can expect us to ask for the case file when we receive a complaint).

Some sponsors have stated that this level of review and monitoring will be resource-intensive. However, as we have indicated above, the improved overutilization reviews are meant to complement existing, sound DUM and DUR. As such, we expect sponsors to implement programs in a manner that eliminates the need to review borderline cases of inappropriate opioid

overutilization. More effective implementation of concurrent DUM, as described above, should minimize the incidence of cases that will need to be reviewed at this more resource-intensive level, as we noted that comments on the September memo demonstrate that many sponsors are not currently applying tools, such as QLs and safety edits as effectively as they could be.

In response to the September memo, we also received comments suggesting that prescribers are currently non-responsive to retrospective DUR requests, and that this non-responsiveness and the sponsors' lack of authority over providers would reduce the impact of overutilization review activities. Therefore, under this process, to the extent that a Part D sponsor has identified a bona fide safety concern about a beneficiary's opioid utilization triggered through thresholds or patterns established in an overutilization review program, the sponsor may move forward with an overutilization protocol; provided, the sponsor has made reasonable efforts to contact the prescriber and beneficiary in accordance with the policy and procedure of the program and has taken complicating factors of which it is aware into account. More specifically, in the event that a beneficiary's prescription drug claims for opioid analgesics cannot be established as medically necessary for the level of prescribing from the information or documentation received from prescribers, if any, during case management, the sponsor may implement beneficiary-level edits at POS at all network pharmacies that will result in the rejection of claims, or rejection of quantities in excess of plan established limits of opioid analgesics, for the beneficiary. We would expect the sponsor to notify the prescriber(s) and beneficiary in writing that the rejections will begin after a reasonable period of time. In other words, if despite multiple attempts, a sponsor has been unable to work with prescribers to adjust prescribing to a safe level of dosing, the sponsor may prevent the dispensing of unsafe level of drugs. However, we note again that proper implementation of the several improvements to formulary management processes described above will significantly limit the cases requiring such edits.

We received comments from the draft Call Letter asking us to confirm that case management can address physician or pharmacy "shopping" by restricting the beneficiary to selected physicians and pharmacies, but we are not certain exactly what the commenters meant. To clarify our expectation, while the end result of a case management approach may be that prescriptions from certain prescribers who do not communicate with the sponsor may be denied, and the beneficiary is unable to fill them at any pharmacy, this is not the same thing as the sponsor restricting (or "locking-in") the beneficiary to certain providers in advance. If prescribers respond to sponsor outreach to discuss beneficiary case management, again, we expect clinician-to-clinician consultations to arrive at appropriate prescribing patterns going forward. Part D sponsors should limit denial of drug claims only to those prescribed by providers who do not work with the sponsor to assess the appropriate level of dosing.

As stated in the September memo, any such denials would be subject to routine exceptions and appeals processes. Furthermore, we would not expect the Improved Retrospective DUR

Programming and Case Management Level to be implemented in a manner that pharmacy providers are put at financial risk (i.e., sponsors would not retroactively recoup prescriptions for prescribers who determined that a particular prescription is no longer medically necessary). Rather, we envision the process described here to be a going-forward collaborative effort between sponsors and prescribers to improve patient safety and reduce fraud, waste and abuse, and not to consist of reviewing past claims for retroactive recoupment unless there is credible evidence of a pharmacy's participation in fraud related to opioid misuse.

Data Sharing Between Sponsors

Some organizations also expressed concerns that once they have implemented these edits for a beneficiary, the beneficiary could disenroll from their plan and enroll in another organization's plan and re-engage in overutilization of medications. They suggested that we should restrict the enrollment rights of dually-eligible beneficiaries who were identified through overutilization efforts. Section 1860D-1(b)(3)(D) of the Act permits LIS beneficiaries access to special election periods, and we will review our guidance in this area.

In the meantime, however, we are making clear that for CY 2013, a sponsor could share the record and actions generated by overutilization review, e.g., the record from the retrospective DUR review/case management, as well as beneficiary-specific POS edits, with the successor sponsor. That is, if a Part D sponsor implemented POS edits for a beneficiary based on retrospective review, and that beneficiary then voluntarily disenrolled and enrolled in another plan, the initial sponsor may share this information with the subsequent sponsor, who may immediately implement similar beneficiary-level edits if the new sponsor is satisfied that the documentation supports such edits. Again, however, we expect that proper implementation of the improvements described above should minimize the instances requiring such transfers of information. Nevertheless, when such transfers of information on specific beneficiaries are warranted, we expect Part D sponsors to promptly coordinate them. With respect to such transfers, we will welcome additional comments, as well as those already received, on how best to trigger and/or securely exchange this information and will take these under consideration for further guidance. However, in the absence of established automated processes, we expect sponsors to facilitate manual processes when necessary to convey their documented case files. In cases where such transfers result in the imposition of beneficiary-level edits for a beneficiary that has changed plans, denials by the subsequent sponsor would also be subject to routine exceptions and appeals processes.

It is our view that HIPAA permits such data sharing between sponsors. For example, subject to the "minimum necessary" requirements at 45 CFR §164.502(b), a covered entity is permitted under 45 CFR §164.506(c)(3) to disclose protected health information (PHI) to another covered entity for the payment activities of the entity that receives the information. The definition of

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

In addition, subject to the "minimum necessary" requirements at 45 CFR §164.502(b), if a subsequent sponsor were interested in obtaining information from the initial sponsor in advance of receiving a first prescription request for payment processing, it could do so under a fraud and abuse program (a kind of "health care operation" in HIPAA parlance) for new enrollees that seeks to identify beneficiaries for whom added oversight of prescriptions is needed. We note that this kind of program would be in keeping with sponsors' obligations to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse pursuant to 42 C.F.R. § 423.504(b)(4)(vi)(H) so long as the three requirements for a health care operations "fraud and abuse" disclosure under 45 CFR 164.506(c)(4) were met. However, such a program is not necessarily a part of a comprehensive fraud, waste, and abuse plan.

Thus, as we have described above, there are several avenues by which HIPAA may permit an initial sponsor to share a beneficiary's PHI with a subsequent sponsor. However, we would encourage sponsors to seek guidance from their own legal counsel to determine whether the specific facts, or any other applicable legal considerations, such as state privacy provisions, may place further limits on their options for sharing information for these purposes.

Reporting Suspected Fraudulent Activity

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

Summary

In order to more effectively address overutilization in CY 2013, we are delineating several improvements to formulary management processes that should be employed by Part D sponsors to comply with the drug utilization management (DUM) requirements at 42 CFR §423.153 et seq. Specifically, we would consider implementation of these levels by a sponsor to be a minimum standard for compliance with 42 CFR §423.153 with respect to overutilization of opioids beginning CY 2013. Should these levels of DUR not prove effective at establishing medical necessity, which we believe would be a rare instance, the sponsor may implement beneficiary-level POS restrictions under certain conditions. We are also clarifying that sponsors

may share beneficiary-level data about overutilization when a beneficiary changes plans. Finally, sponsors are cautioned that we will be monitoring the use of these tools to ensure that they are appropriately implemented.

Section IV. Cost Contractor Enrollment Mechanisms

Allowing Cost contractors to use the Employer Group Enrollment Mechanism

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

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

In the draft call letter we indicated that the group enrollment mechanism would be allowable in 2013. However, in response to a comment we received that urged us to allow this option immediately, we have determined that cost plans will have the option of implementing this provision upon release of the update to Chapter 17-D (Medicare Cost Plan Enrollment and Disenrollment Instructions) later this year. This manual update will provide further guidance on the group enrollment mechanism and will detail the requirements cost plans must meet in order to use this mechanism.

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

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

In response to a request from a commenter, we are clarifying that it is the overall star rating on the Medicare Plan Finder that applies for the purpose of this SEP.

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

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

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

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

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

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

Although many of the renewal options outlined in this guidance are permissible despite year-to-year changes in benefits, premiums, and cost-sharing, we urge organizations and sponsors to maintain comparable benefits across contract years to the greatest extent possible in order to

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

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.

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

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

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

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

Each renewal and non-renewal option outlined in the Medicare Managed Care Manual and Appendix B-2 includes, where applicable, instructions or deadlines for requesting particular renewal options that organizations and sponsors cannot themselves effectuate in the HPMS Plan Crosswalk. Organizations and sponsors will *not* be able to make changes to their HPMS Plan Crosswalks once bids are submitted to CMS on June 4, 2012. After that point, CMS will only make changes to organizations' and sponsors' HPMS Plan Crosswalks under exceptional circumstances.

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

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

Appendix A-1 – Contract Year 2013 Guidance for Prescription Drug Plan PBP Renewals and Non-Renewals

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

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

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) of its intent to non-renew one or more plans under a contract by the first Monday in June[9] pursuant to 42 CFR §423.507(a)(2)(i). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with regulatory requirements, CMS' PDP Eligibility, Enrollment, and Disenrollment Guidance, Chapter 3 of the Prescription Drug Benefit Manual and annual summer CMS non-renewal and service area reduction guidance.)

Each renewal/non-renewal option available to PDP sponsors for CY 2013 is outlined in Appendix B-2 and summarized below. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

1. New Plan Added

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries

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

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

2. Renewal Plan

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

3. Consolidated Renewal Plan

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

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

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

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

We will not, however, permit consolidation of two existing PBPs into a single renewal PBP through the HPMS Plan Crosswalk when it involves a change from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental

premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

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

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

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

Current enrollees will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions to MARx for those current enrollees. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to MARx for those new enrollees. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

5. Terminated Plan (Non-Renewal)

A PDP sponsor may elect to terminate a current PBP for the following contract year and must notify CMS in writing (by sending an email to nonrenewals@cms.hhs.gov) by June 4, 2012.[10] In this situation, the sponsor will not submit disenrollment transactions to MARx for affected enrollees. When a sponsor terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. To the extent that a current enrollee of a terminated PBP elects to enroll in another plan offered by the current or another PDP sponsor – or, alternatively, elects to enroll in an MA plan – he/she must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to MARx so that those individuals are enrolled. Enrollees of terminated PBPs will be sent a model termination notice that includes notification of a special election period, as well as information about alternative options. For more information about non-renewal processes and beneficiary notification requirements, refer to our forthcoming guidance, to be released this summer, providing non-renewal and service area reduction guidance and model notices.

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

6. Consolidated Plans under a Parent Organization

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

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

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

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added	A PDP sponsor creates a new PBP.	**HPMS Plan Crosswalk Definition:** A new plan added for 2013 that is not linked to a 2012 plan. **HPMS Plan Crosswalk Designation:** New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
2	Renewal Plan	A PDP sponsor continues to offer a CY 2012 PBP in CY 2013. **The same PBP ID number must be retained** in order for all current enrollees to remain in the same PBP in CY 2013.	**HPMS Plan Crosswalk Definition:** A 2013 plan that links to a 2012 plan and retains all of its plan service area from 2012. The 2013 plan must retain the same plan ID as the 2012 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan	**The renewal PBP ID must remain the same** so that current enrollees will remain in the same PBP ID. The PBP sponsor **does not** submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2013. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan	A PDP sponsor combines two or more PBPs offered in CY 2012 into a single renewal PBP for CY 2013. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2013 after consolidation. When a PDP sponsor combines an enhanced PBP with a basic PBP, the HPMS crosswalk only allows a crosswalk to a consolidated PBP that offers a basic benefit design.	**HPMS Plan Crosswalk Definition:** Two or more 2012 plans that consolidate into one 2013 plan. The 2013 plan ID must be the same as one of the consolidating 2012 plan IDs. **HPMS Plan Crosswalk Designation:** Consolidated Renewal Plan	**The PDP sponsor's designated renewal PBP ID must remain the same** so that CMS can consolidate current enrollees into the designated renewal PBP ID. The PDP sponsor **does not** submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2013.	Current enrollees are sent a standard ANOC.

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
4	Renewal Plan with an SAE (**applicable only to employer/ union group waiver plans**)	A PDP sponsor continues to offer an 800 series CY 2012 prescription drug PBP in CY 2013 and expands it s EGWP service area to include additional regions. **The PDP sponsor must retain the same PBP ID number** in order for all current enrollees to remain in the same PBP in CY 2013.	**HPMS Plan Crosswalk Definition:** A 2013 800-series plan that links to a 2012 800-series plan and retains all of its plan service area from 2012, but also adds one or more new regions. The 2013 plan must retain the same plan ID as the 2012 plan. **HPMS Plan Crosswalk Designation:** Renewal Plan with an SAE	**The renewal PBP ID must remain the same** so that current enrollees in the current service area will remain in the same PBP ID. The PDP sponsor does not submit enrollment transaction for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2013. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.
5	Terminated Plan (Non-Renewal)	A PDP sponsor terminated the offering of a 2012 PBP.	**HPMS Plan Crosswalk Definition:** A 2012 plan that is no longer offered in 2013. **HPMS Plan Crosswalk Designation:** Terminated Plan	The PDP sponsor does not submit disenrollment transactions. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization **must submit enrollment transactions** to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.

	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
6	Consolidated Plans across Contracts under the Same Parent Organization	A parent organization combines two or more whole PBPs under different contracts (the contracts may be the same legal entity or represent different legal entities) as a result of a merger, acquisition, or novation. A PDP sponsor cannot complete this renewal option in the HPMS Plan Crosswalk.	**Exceptions Crosswalk Request:** Sponsors must submit an exceptions request to CMS, which will complete the crosswalk on behalf of the sponsor **HPMS Plan Crosswalk Designation:** The plan being crosswalked must be marked as a terminated plan in the HPMS crosswalk. The remaining 2013 plan must be active and contain the applicable service area from the terminated plan being crosswalked.	PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. CMS will effectuate this renewal option and HPMS will record the consolidation of one or more whole PBPs. The PDP sponsor **does not** submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment election for current enrollees to remain enrolled in the renewal PBP in 2013. New enrollees must complete enrollment request.	Current enrollees are sent a special notice (based on the CMS model in Appendix C) along with a standard ANOC.

Appendix B – CMS Model Notice

Contract Year 2013 Guidance for PDP PBP Renewal Option 6 Special Disenrollment Notice

<Insert Date>

IMPORTANT NOTICE: Your Medicare Prescription Drug Coverage Is Changing

Dear <member name>,

<Organization name> will no longer offer <terminating plan name> after December 31, 2012. To make sure you continue to have the same level of Medicare Prescription Drug coverage, **you'll be enrolled in our <receiving plan name> starting < January 1, 2013>.**

Your new plan coverage starts January 1

<Organization name> has approval from Medicare to transfer your enrollment into our <receiving plan name> for 2013. Medicare approved this transfer because the prescription drug benefits in <receiving plan name> are similar to the prescription drug benefits you've been getting in <terminating plan name>. See the attached information about this new plan.

Here's what to do next

If you do nothing, you'll be a member of <receiving plan name> starting <January 1, 2013>. After reviewing your ANOC/EOC, if you have questions about your prescription drug benefits or how this new plan works, including what your costs will be or which pharmacies you can use call <receiving plan name> at <receiving plan phone number>. You should use this letter as proof of coverage under <receiving plan name> until you get your membership card.

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

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

If you don't want to be in <receiving plan name> in 2013, you have the right to choose another Medicare Prescription Drug Plan **anytime between <xxxxx date> and <xxxxx date>.** Your new coverage will start on January 1, 2013.

Here are your options for Medicare Prescription Drug coverage:

Option 1: If you do nothing, you'll get prescription drug coverage from <receiving plan> starting <January 1, 2013>.

Option 2: You can join another Medicare Prescription Drug Plan. Joining a new plan will automatically disenroll you from <receiving plan name>. You should compare the plans available in your area. You can call the plans to get more information about their rules and coverage and find a plan that best meets your needs.

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

Other information you need to know:

If you qualify for Extra Help (the low-income subsidy) for 2013, you have the right to change plans at any time.

If you have an employer or union group health plan, VA benefits, or TRICARE for Life, call your insurer or benefits administrator to find out how to join a new plan**.**
If you get help from the Medicaid program, contact <State Medicaid Agency and phone number> to learn how joining a new plan affects your Medicaid coverage.

Get help and more information about your options

If you need more information about your changing coverage, please call us at <Phone Number> <Days & Hours>. TTY users should call <insert number >. Tell the customer service representative you got this notice.

To join another Medicare Prescription Drug Plan, you should compare available plans and join one that meets your needs. You should find out which plans cover the prescriptions you take. For help comparing plans and joining a plan that works for you, visit http://www.medicare.gov, or call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You can also call your State Health Insurance Assistance Program for free personalized counseling at <SHIP phone number>.

To see if your state has a program for people with limited income and resources, call your State Medical Assistance Office at <State Medical Assistance Office Number>. You may be able to get help paying Medicare premiums, deductibles and coinsurance. TTY users should call <State Medical Assistance Office> at <TTY Number>.

Sincerely,
<CEO or other official of PDP organization>

[Insert Federal contracting statement.]

[Insert Material ID number] [insert **CMS Approved** *followed by mm/dd/yyyy]*

["Model Beneficiary Notice for CMS Approved Crosswalk Situations"- (material submission code # 2054).]

Appendix C

Additional Gap Coverage

Consistent with our bid submission requirements provided at 42 CFR 423.265, a Part D sponsor's bid submission must reflect differences in benefit packages or plan costs that we determine to represent substantial differences relative to a sponsor's other bid submissions. In 2013, the standard drug benefit will provide 21% of generic drug and 2.5% of brand drug coverage in the gap. We expect that the additional gap coverage of drugs offered by plans will reflect meaningful enhancements over the standard prescription drug benefit.

To determine how much additional cost-sharing coverage in the coverage gap over the basic benefit would be recognized as substantially different, we considered the amount of additional coverage provided by the Part D sponsors in their plan benefit packages for CY 2012. Based on this analysis, we are setting the maximum copay cost-sharing thresholds at the pre-ICL thresholds values set for CY 2013 (see also Benefit Parameters Table VI-7 above). Similar to the pre-ICL cost-sharing analysis, we completed an analysis of the additional gap coverage copay cost-sharing associated with the 95 percentile across all initially submitted bids consisting of three or more tiers. Table VI-8 below shows the results of the threshold analysis of the CY 2012 bid submissions, as well as the 2013 copay thresholds. Note that in all cases, the 95th percentile was at or below the established pre-ICL thresholds.

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

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

[1] Please note that INPh means "In-network pharmacy"; INPPh means "In-network preferred pharmacy"; and INNPPh means in-network non-preferred pharmacy.

With respect to coinsurance cost-sharing, we found that the 95th percentile of plans offering coverage in the gap had cost-sharing levels for generics and brands at a maximum level of 69% coinsurance. Therefore, we are setting the maximum coinsurance threshold for generics drugs at a beneficiary cost-sharing of 59%, which provides a benefit that is approximately two times the standard benefit of 21% for CY 2013. This is consistent with our approach last year. With respect to brand drugs, for which the standard benefit is 2.5% for CY 2013, we will maintain last year's threshold and require that the plan's benefit has beneficiary cost-sharing during the coverage gap that is equal to or less than 69% coinsurance. Table XZ below shows the results of the threshold analysis of the CY 2012 bid submissions, as well as the 2013 coinsurance thresholds.

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

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

[1] Please note that INPh means "In-network pharmacy"; INPPh means "In-network preferred pharmacy"; and INNPPh means in-network non-preferred pharmacy.

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