April 1, 2013

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

SUBJECT: Announcement of Calendar Year (CY) 2014 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 2014 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2014 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 Percentage for 2014 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2014. These growth rates will be used to calculate the 2014 capitation 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 2.96 percent, and the final estimate of the increase in the FFS Growth Percentage is 3.53 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 Percentage.

The basis for the Growth Percentage for 2014 has been changed to incorporate an assumption that Congress will act to prevent the scheduled 25-percent reduction in Medicare physician payment rates from occurring. The Office of the Actuary has been directed by the Secretary to use this assumption, on the grounds that it is a more reasonable expectation than the reduction required under the statutory "sustainable growth rate" (SGR) formula. Although the Office of the Actuary agrees that Congress is very likely to override the physician fee reduction, the assumption conflicts with the Office's professional judgment that, as in all past years, the determination should be based on current law, not an assumed alternative.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita FFS expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2011 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2014 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice). Attachment IV contains the changes in the payment methodology for Medicare Part D for CY 2014. Attachment V contains tables with the Part D benefit parameters; Attachment VI

contains details regarding the Part D benefit parameters; Attachment VII contains tables with the 2014 CMS-HCC and RxHCC risk adjustment models.

Attachment VIII presents the final Call Letter. We received many submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 15, 2013. Comments were received from professional organizations, MA and Part D sponsors, advocacy groups, the pharmaceutical industry, pharmacy benefit managers, pharmacies, and concerned citizens.

Key Changes from the Advance Notice:

Growth Percentages: Attachment I provides the final estimates of the National MA Growth Percentage and the FFS Growth Percentage and information on deductibles for MSAs.

Calculation of FFS Rates: In 2014, we will begin transitioning to a methodology in which the historical claims data are adjusted to reflect the most current hospital wage index and physician geographic practice cost index. More information on this methodology change is provided in Attachment III, Section C. For CY 2014, the blend between the repriced and non-repriced AGAs will be done based on a 50-50 split.

CMS-HCC Risk Adjustment Model: We will implement the updated, clinically revised CMS-HCC risk adjustment model proposed in the Advance Notice with the following differences: (1) we will not adjust the denominator and (2) we will blend the risk scores calculated using this model with the risk scores calculated using the 2013 CMS-HCC model, weighting the risk scores from the 2013 CMS-HCC model by 25 percent and the risk scores from the 2014 CMS-HCC model by 75 percent. We include in this Announcement the final version of the updated, clinically revised model, including community, institutional, new enrollee, and C-SNP new enrollee segments. The relative factors for 2013 CMS-HCC model can be found in the 2013 Announcement.

PACE Model: We will continue to use the same risk adjustment model for PACE payments that we have used in 2012 and 2013.

Normalization Factor for the CMS-HCC Model: Because the normalized risk scores from the 2014 and 2013 CMS-HCC models will be blended, there are two normalization factors for 2014. They are:

- 2013 CMS-HCC model: 1.041.
- 2014 CMS-HCC model: 1.026.

Normalization Factor for the PACE Model: The final normalization factor for the PACE model is 1.085.

Normalization Factor for the RxHCC Model: The final normalization factor for the RxHCC model is 1.030.

Frailty Adjustment: The 2014 frailty factors for PACE organizations are the same frailty factors posted in the 2013 Advance Notice. There are two sets of FIDE SNP frailty factors for 2014; we will calculate frailty scores using the frailty factors associated with the 2014 CMS-HCC model and using the frailty factors associated with the 2013 CMS-HCC model. The FIDE SNP frailty factors associated with the 2014 CMS-HCC model are finalized in this Announcement. The FIDE SNP frailty factors associated with the 2013 CMS-HCC model are posted in the 2013 Advance Notice. CMS will separately calculate frailty scores for FIDE SNPs using each set of factors and blend the two frailty scores in the same manner as the 2014 risk scores. These blended frailty scores will be used both to determine a FIDE SNP's eligibility for frailty payments and, if eligibility is met, for payment.

MA Enrollee Risk Assessments: In response to comments received on the proposed policy for MA Enrollee Risk Assessments, CMS is delaying the collection of "flags" for these assessments until 2014 dates of service. We will propose and finalize a policy on the extent to which diagnoses from 2014 Enrollee Risk Assessments will be used to calculate risk scores for payment year 2015 in the 2015 Advance Notice and Rate Announcement.

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. Clarifications in the Rate Announcement supersede materials in the Advance Notice.

Rebasing County Rates: We will rebase the FFS capitation rates for 2014, using historical claims data for 2007 through 2011.

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, along with the QBP demonstration. This Announcement finalizes these proposals.

IME Phase Out: For 2014, CMS will continue phasing out indirect medical education amounts from MA capitation rates.

Clinical Trials: We are continuing the policy of paying on a FFS 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 2015: The list of network areas for plan year 2015 is available on the CMS website at http://www.cms.gov/PrivateFeeforServicePlans/, under PFFS Plan Network Requirements.

Adjustment for MA Coding Pattern Differences: We will implement an MA coding pattern difference adjustment of 4.91 percent for payment year 2014.

Normalization Factors for ESRD models: The normalization factors for the ESRD models for 2014 are:

- CMS-HCC ESRD Functioning graft status: 1.085
- CMS-HCC ESRD dialysis model: 1.039

Update of the RxHCC Model: We will update the Part D model to reflect more recent data and changes in plan liability in the coverage gap.

Payment Reconciliation: The 2014 risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2013.

Part D Benefit Parameters: Attachment V provides the updated 2014 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

/ s /
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/ s /
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Attachments

2014 ANNOUNCEMENT

Attachment I. Final Estimate of the Increase in the National Per Capita MA Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for 2014

The Table I-1 below shows the National Per Capita MA Growth Percentages (NPCMAGP) for 2014. An adjustment of 0.77 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 I-1 - Increase in the National Per Capita MA Growth Percentages for 2014

	Prior Increases	Current Increases			
	2003 to 2013	2003 to 2013	2013 to 2014	2003 to 2014	NPCMAGP for 2014 With §1853(c)(6)(C) adjustment[1]
Aged+Disabled	44.78%	45.90%	2.17%	49.06%	2.96%

[1]Current increases for 2003-2014 divided by the prior increases for 2003 to 2014.

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 I-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 2014 divided by projected FFS USPCC for 2013 as estimated in the 2013 Rate Announcement released on April 2, 2012.

Table I-2 – Increase in the FFS USPCC Growth Percentage for CY 2014

	Aged + Disabled	Dialysis –only ESRD
Current projected 2014 FFS USPCC	$795.11	$7,063.55
Prior projected 2013 FFS USPCC	$767.99	$7,218.90
Percent increase	3.53%	−2.15%

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2013 and 2014. In addition, for 2014, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2014. These data were furnished by the Office of the Actuary.

Table I-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2013 and 2014

	2013	2014	Change	2014 non-ESRD
Part A Benefits	$40.99	$39.13	−4.5%	$37.23
Part B Benefits[1]	$103.95	$114.99	10.6%	$107.05
Total Medicare	$144.94	$154.12	6.3%	$144.28

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2014 is $11,200.

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 last year's estimate of United States Per Capita Costs (USPCC) with current estimates for 2003 to 2015. In addition, this table shows the current projections of the USPCCs through 2016. We are also providing an attached set of tables that summarize many of the key Medicare assumptions used in the calculation of the USPCCs. Most of the tables include information for the years 2003 through 2016.

Most of the tables in this attachment present combined aged and disabled non-ESRD data. 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 & Previous Estimates of the Total USPCC – non-ESRD

Calendar Year	Part A Current Estimate	Part A Last Year's Estimate	Part B Current Estimate	Part B Last Year's Estimate	Part A & Part B Current Estimate	Part A & Part B Last Year's Estimate	Ratio
2003	$295.77	$295.77	$249.37	$249.37	$545.14	$545.14	1.000
2004	$313.80	$313.80	$273.97	$273.97	$587.77	$587.77	1.000
2005	$334.52	$334.52	$293.53	$293.53	$628.05	$628.05	1.000
2006	$344.97	$344.97	$314.44	$314.44	$659.41	$659.41	1.000
2007	$355.59	$357.00	$332.26	$332.28	$687.85	$689.28	0.998
2008	$373.36	$373.70	$352.68	$352.89	$726.04	$726.59	0.999
2009	$385.74	$386.59	$369.93	$369.97	$755.67	$756.56	0.999
2010	$385.58	$388.01	$378.57	$378.78	$764.15	$766.79	0.997
2011	$390.04	$397.24	$388.44	$396.54	$778.48	$793.78	0.981
2012	$382.67	$396.48	$398.54	$411.14	$781.21	$807.62	0.967
2013	$386.10	$403.13	$409.27	$386.13	$795.37	$789.26	1.008
2014	$382.36	$409.12	$430.24	$402.22	$812.60	$811.34	1.002
2015	$383.54	$408.05	$442.62	$417.23	$826.16	$825.28	1.001
2016	$396.10		$457.28		$853.38		

Comparison of Current & Previous Estimates of the FFS USPCC – non-ESRD

Calendar Year	Part A Current Estimate	Part A Last Year's Estimate	Part B Current Estimate	Part B Last Year's Estimate	Part A & Part B Current Estimate	Part A & Part B Last Year's Estimate	Ratio
2010	$373.21	$376.48	$377.18	$377.51	$750.39	$753.99	0.995
2011	$373.94	$387.64	$387.71	$400.83	$761.65	$788.47	0.966
2012	$363.60	$381.50	$398.83	$416.29	$762.43	$797.79	0.956
2013	$371.79	$393.22	$409.18	$374.77	$780.97	$767.99	1.017
2014	$375.59	$401.47	$419.52	$393.00	$795.11	$794.47	1.001
2015	$380.58	$404.14	$436.60	$411.93	$817.18	$816.07	1.001
2016	$393.40		$451.66		$845.06		

Comparison of Current & Previous Estimates of the ESRD Dialysis-only FFS USPCC

Calendar Year	Part A+B Current Estimate	Part A+B Last Year's Estimate	Ratio
2010	$6,834.14	$6,834.14	1.000
2011	$6,770.39	$7,031.65	0.963
2012	$6,834.71	$7,229.84	0.945
2013	$7,039.85	$7,218.90	0.975
2014	$7.063.55	$7,676.79	0.920
2015	$7,324.21	$7,925.55	0.924
2016	$7,945.05		

Basis for ESRD Dialysis-only FFS USPCC Trend

	Part A+B		
Calendar Year	All ESRD Cumulative FFS Trend	Adjustment Factor for Dialysis-only	Adjusted Dialysis-only Cumulative Trend
2012	1.0032	1.0063	1.0095
2013	1.0268	1.0126	1.0398
2014	1.0240	1.0188	1.0433
2015	1.0546	1.0258	1.0818
2016	1.1353	1.0336	1.1735

Note: 2011 All ESRD FFS USPCC is $4,721.87

Summary of Key Projections

Part A[1]

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%	5.8%
2008	4.1%	2.7%	8.0%
2009	-0.7%	2.7%	6.8%
2010	2.1%	1.9%	3.1%
2011	3.6%	-0.6%	4.0%
2012	2.1%	-0.1%	1.7%
2013	1.8%	2.8%	4.4%
2014	2.2%	0.5%	2.9%
2015	2.4%	3.3%	3.0%
2016	2.5%	3.5%	6.3%

Part B[2]

	Physician Fee Schedule			
Calendar Year	Fees	Residual[3]	Part B Hospital	Total
2003	1.4%	4.5%	4.4%	6.8%
2004	3.8%	5.9%	11.1%	9.8%
2005	2.1%	3.2%	10.8%	7.0%
2006	0.2%	4.6%	5.1%	6.1%
2007	-1.4%	3.5%	8.3%	4.3%
2008	0.4%	3.3%	6.3%	4.8%
2009	1.6%	1.4%	8.7%	3.8%
2010	2.5%	1.4%	5.0%	2.2%
2011	0.9%	2.4%	8.1%	2.6%
2012	-1.0%	1.1%	8.0%	2.1%
2013	-0.1%	0.4%	6.2%	1.9%
2014	-0.5%	2.4%	7.1%	3.9%
2015	0.0%	1.9%	7.7%	3.2%
2016	0.0%	1.7%	7.9%	4.1%

[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 (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	36.429	7.128	34.448	6.212
2008	37.358	7.320	35.121	6.404
2009	38.235	7.531	35.811	6.628
2010	39.068	7.788	36.494	6.900
2011	39.912	8.091	37.202	7.201
2012	41.511	8.245	38.499	7.386
2013	42.887	8.489	39.874	7.567
2014	44.333	8.694	41.151	7.750
2015	45.799	8.880	42.437	7.912
2016	47.308	9.017	43.764	8.036

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	28.820	6.186	26.765	5.264
2008	28.593	6.199	26.282	5.277
2009	28.542	6.245	26.050	5.337
2010	28.880	6.411	26.238	5.518
2011	29.172	6.578	26.395	5.684
2012	29.785	6.526	26.698	5.663
2013	30.112	6.575	27.024	5.648
2014	30.934	6.687	27.672	5.738
2015	32.507	6.887	29.067	5.915
2016	34.387	7.081	30.763	6.096

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	0.433	0.417	0.397
2008	0.471	0.450	0.428	0.406
2009	0.491	0.469	0.439	0.417
2010	0.510	0.488	0.456	0.433
2011	0.526	0.503	0.468	0.445
2012	0.543	0.521	0.481	0.458
2013	0.563	0.540	0.495	0.472
2014	0.581	0.558	0.510	0.487
2015	0.597	0.575	0.527	0.504
2016	0.613	0.590	0.544	0.521

Part A Projections for non-ESRD (Aged+Disabled)

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	5,733
2004	2,709.46	414.47	134.05	501.31	6,832
2005	2,812.46	451.65	141.04	603.02	8,016
2006	2,758.66	476.27	141.48	758.13	9,368
2007	2,707.07	504.64	143.91	907.34	10,518
2008	2,709.78	537.92	151.56	1,076.78	11,413
2009	2,668.41	553.23	154.33	1,248.97	12,290
2010	2,644.78	569.94	155.77	1,252.94	13,088
2011	2,609.93	616.09	143.85	1,304.69	13,983
2012	2,520.54	556.19	137.25	1,372.72	14,980
2013	2,515.37	566.40	136.97	1,409.18	15,922
2014	2,506.32	587.40	137.57	1,351.82	17,066
2015	2,559.11	623.57	141.18	1,273.94	18,396
2016	2,695.91	670.07	145.22	1,238.50	19,878

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

Part B Projections for non-ESRD (Aged+Disabled)

Calendar Year	Physician Fee Schedule Aged + Disabled	Part B Hospital Aged + Disabled	Durable Medical Equipment Aged + Disabled
2003	1,240.44	365.14	197.17
2004	1,367.32	419.28	196.45
2005	1,404.39	478.18	195.32
2006	1,403.33	498.05	196.84
2007	1,381.42	527.57	194.70
2008	1,381.06	555.82	199.92
2009	1,390.63	600.72	183.34
2010	1,433.17	627.58	184.44
2011	1,461.81	675.97	176.27
2012	1,427.55	719.81	178.48
2013	1,407.02	752.00	164.73
2014	1,417.28	805.28	157.18
2015	1,474.17	887.80	165.33
2016	1,534.03	983.60	160.20

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	370.48	85.89
2009	102.89	389.40	90.70
2010	102.23	400.25	91.44
2011	102.44	412.51	95.43
2012	109.47	412.53	97.50
2013	109.01	416.91	95.81
2014	113.01	431.70	99.08
2015	120.12	450.71	105.16
2016	130.68	473.55	114.33

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	932.32
2008	158.34	252.75	1,105.68
2009	167.68	283.19	1,206.55
2010	170.06	286.46	1,224.39
2011	169.59	269.65	1,277.21
2012	176.50	257.98	1,381.70
2013	186.86	257.14	1,500.29
2014	166.32	258.66	1,691.78
2015	179.49	265.75	1,639.62
2016	195.02	273.53	1,598.44

Average reimbursement per enrollee on an incurred basis.

2014 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service Type	Current Estimate	Last Year's Estimate	Ratio
Part A			
Inpatient Hospital	2,506.32	2,794.65	0.897
SNF	587.40	735.79	0.798
Home Health	137.57	160.56	0.857
Managed Care	1,351.82	1,212.44	1.115
Part B			
Physician Fee Schedule	1,417.28	1,206.75	1.174
Part B Hospital	805.28	867.35	0.928
Durable Medical Equipment	157.18	195.64	0.803
Carrier Lab	113.01	118.66	0.952
Other Carrier	431.70	495.99	0.870
Intermediary Lab	99.08	108.40	0.914
Other Intermediary	166.32	196.37	0.847
Home Health	258.66	288.94	0.895
Managed Care	1,691.78	1,326.81	1.275

* 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
2016	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 2014 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2014 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2013.

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. Final Estimate of the National Per Capita Growth Percentage and the Fee-for-Service (FFS) Growth Percentage for Calendar Year 2014

Comment: As has been the case with respect to comments on the Advance Notice for a number of years, numerous commenters requested that, when calculating the growth percentage estimates, CMS should assume that there will be a "fix" to the physician payment rates produced by the Sustainable Growth Rate (SGR) formula in 2014 as there has been for the last eleven years. Specifically, commenters requested that CMS assume a zero percent update to avoid subjecting MA plans to a reduction in rates based on an estimate of Medicare spending growth that is lower than it would turn out to be if a fix is enacted. Commenters argued that Sections 1853(c)(6) and 1876(a)(4) require CMS to develop "estimates" of the projected growth rate in Medicare expenditures and applicable county-specific FFS costs that serve as the basis for MA rates and that the statute permits the agency to rely on the best available information on what is actually expected to happen in making such estimates. Commenters contended that these statutory provisions grant CMS a significant degree of flexibility in determining how to calculate estimated rates for MA payments and, therefore, would permit CMS to assume that an "SGR fix" will be enacted. Many commenters argued that if CMS projects county rates reflecting an SGR impact that is not likely to occur, CMS would be setting MA rates at a level lower than the Congress intended.

Response: The Social Security Act requires that the national MA growth percentage reflect the Secretary's estimate of the projected per capita rate of growth in expenditures "under this title" (title XVIII). CMS historically has responded to comments urging CMS to assume an SGR fix by indicating that we interpreted the use of the phrase "under this title" to mean that the estimate was to be based on the provisions of title XVIII as in effect on the date that the rates are announced. Given the increasing number of years in a row for which Congress has enacted an SGR fix after the MA rates for the upcoming year have been released in April, CMS now agrees with the commenters that it would be more reasonable to instead interpret the phrase "under this title" as a general reference to the nature of the expenditures, namely expenditures from the Part A and Part B trust funds, rather than necessarily interpreting the phrase to incorporate current provisions of law into CMS's best estimate of the extent to which Medicare expenditures are actually expected to change.

Accordingly, we are accepting the commenters' recommendation that we change our interpretation of how we calculate the estimate of projected per capita rate of growth under this title under 1853(c)(6)(A) from an estimate of what *would occur* to the physician fee schedule for the following year under current law to a best estimate of what CMS believes *actually will* occur to the physician fee schedule for the following year based on recent history, and we are revising the growth rate to assume a zero percent change for the physician fee schedule for 2014. We made this change to reflect the fact that Congress has annually changed the law every year since

2003 such that the projected SGR cut does not occur. We believe it is more reasonable to base the estimate of projected growth in Medicare expenditures on the assumption that a fix will occur than it would be to base the estimate on current law. Therefore, we have calculated the final MA Growth Percentage and the FFS Growth Percentage based on the assumption of a zero percent change for the physician fee schedule for 2014. Details on the growth percentages are contained in Attachment I.

Comment: Many commenters requested that CMS release underlying data and assumptions used by CMS in the development of the preliminary estimates of the MA growth percentage and FFS Growth Percentage. One commenter requested that CMS provide as much data as possible by March 8 and additional data as quickly as possible thereafter. This commenter argued that the data are critical to MA organizations' planning and bid development activities.

Response: We have added additional detail on our methodology in Attachment II of the Rate Announcement. We will consider providing more detailed information in the Advance Notices for future years to assist the public's understanding of the preliminary estimates of the growth percentages. In addition, we will consider adding a discussion of our recent trend work to actuarial user group calls.

Comment: We also received a comment that OACT should not wait until the final Rate Announcement to release details on the costs of health care services by line item and wanted CMS to distribute data on how the different components of Medicare spending are changing in the latest forecast of the 2004 to 2014 USPCCs. This commenter recommended that OACT provide similar detail on the USPCCs that it provides in the Rate Announcement for the historical years and the upcoming contract year.

Response: In response to requests for further detail, we have provided in Attachment II, tables that can be used to crosswalk information from the Advance Notice. In particular, we are providing a table that compares the previous and current estimate of the USPCC, and shows the percent changes between these estimates. We have also provided an additional table that compares, for 2014, the previous and current estimates of the USPCC by Medicare type of service. These tables supplement the tables routinely published in the Rate Announcement. We are evaluating the tables used in the Advance Notice and will consider changes in these tables for 2015 to better complement the final rate notice tables. Details of the final growth percentage are included in Attachments I and II of the Rate Announcement. Shortly after release of this Rate Announcement, CMS will provide additional detailed data to the public on the CMS web site at (http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/). We will announce this release during our actuarial user group calls.

Comment: One commenter noted that CMS assumes that recent low Medicare medical cost trends will continue through 2014. This commenter asked CMS to consider a more moderate forecast of Medicare medical costs, including an element of reversion to long-term mean on

2013 and 2014 trends. A few commenters noted that the trend factors reflected in CMS' estimates are not consistent with plans' experiences or market conditions. Other commenters stated that there is no evidence that stronger economic growth will not lead to a rebound in health care spending, and they did not believe that OACT should assume that the low USPCC trends for 2010-2012 will continue beyond these three years when historically there has never been such an extended period for low growth rates in the USPCCs.

Response: CMS believes that, based on the evidence from Medicare data, spending has slowed in the Medicare program compared to historical levels. Our forecast is based on historical trend, anticipated economic factors, and changes in Medicare laws and regulations. It is expected that some of the factors contributing to plan cost and utilization changes will be different than FFS Medicare.

Comment: Commenters stated that CMS' estimated growth rate for CY14 of -2.3 percent is far lower than actual medical cost trends and over five percentage points lower than the growth rate for CY2013 (+2.8%). A few plan commenters stated that their data suggested that medical costs for their Medicare members grew by about 5 percent in 2012.

Response: The preliminary estimate of the MA Growth Percentage for CY14 of -2.3 percent is comprised of a prior period adjustment of -3.9 percent and 2013-2014 projected growth of 1.6 percent. Most of the prior period adjustment was attributable to the lower actual Medicare trends for 2011 and 2012. Specifically, in the 2013 rate announcement, the total USPCC trend from 2010 through 2012 was estimated to be 5.3 percent. This two-year trend has been revised down to 2.3 percent in calculating the preliminary growth percentage. We note that MA plan bids increased by 1.8 percent during this two-year period, which suggests that the average cost trends that MA plans experienced from 2010 to 2012 are in line with the revised 2.3 percent trend in FFS Medicare. It is also worth noting that changes mandated by the American Taxpayer Relief Act of 2012 (ATRA) reduced the preliminary 2013-2014 growth percentage by 1.1 percent.

Comment: One commenter recommended that CMS recalculate the growth percentages so that the geographic areas of the country that have done a poor job of controlling costs are not rewarded for unsustainable behavior, while areas that have done a good job controlling costs are required to make even more cuts to benefits.

Response: The growth percentages treat all areas equally in an effort to pay, as the statute requires, based on the expected costs to Medicare.

Comment: Some commenters stated that the estimated reduction in the MA growth percentage is derived as the result of the application of a statutorily-required formula, not due to a change in policy. These commenters noted that the reduction is unsurprising because Medicare costs overall have grown more slowly than expected in recent years.

Response: We appreciate the comment and concur that the growth of Medicare spending has slowed.

Comment: Several commenters had concerns about the magnitude of changes proposed in the Advance Notice and the impact to Medicare beneficiaries and plans. Commenters contended that the payment reductions described in the Notice were unanticipated and will lead to significantly higher MA premiums or significantly reduced benefits or both. Some commenters argued that these cuts would lead to MA plans exiting the market. One commenter argued that chronically ill patients would experience higher cost increases than the average beneficiary. Some commenters felt that cutting funding to MA plans would not be in line with the nation's move away from a FFS model toward a more coordinated and integrated system. Some providers noted that the reductions to MA contained in the Advance Notice would seriously threaten their ability to provide innovative, high quality care to beneficiaries. We also received comments that the cuts would lead to market contraction, less competition, and ultimately less access for beneficiaries.

Response: As we stated in the Advance Notice, we recognize that plans face several payment changes that present challenges for plans. We also share the commenters' concern on reducing plan choices and increasing costs for beneficiaries. At the same time, we have seen increased enrollment and stable benefits within the MA program, and note that this strong enrollment growth has happened during a time when payment rates are transitioning to be more aligned with FFS Medicare rates. We have not always seen a reduction in benefits in areas that have had declines in payment rates.

However, to address concerns with the variety of payment changes for MA, we have modified some of our proposed payment policies for 2014. As discussed above, we have updated the MA capitation rates with growth percentages that assume an SGR fix, which we believe will result in a more accurate estimate of what FFS expenditures will be in 2014. In addition, we are phasing in changes to the risk adjustment model (shown in Section D) by blending risk scores under the 2013 and 2014 CMS-HCC models, as well as changes to the AGA methodology (shown in Section C).

Comment: One commenter urged that CMS stop MA cuts from happening. This commenter suggested that if CMS plans to proceed with the MA cuts, they recommend that CMS establish annual maximum allowed benchmark payment reduction thresholds at a county level in order to minimize member disruption and program volatility. The commenter encouraged CMS to consider all possible bases for such an approach, including the potential use of demonstration authority under sections 402 or 1115A of the Social Security Act.

Response: We do not agree that a demonstration would be appropriate as suggested by the commenter, as it is not clear what would be tested under such a demonstration.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: A number of commenters asked that CMS not rebase the rates for 2014. These commenters noted that CMS has rebased in each of the last two years and the statute does not require CMS to rebase in 2014. Furthermore, these commenters noted that rebasing creates additional uncertainty for plans, and some asked that CMS not rebase the rates until 2016. One commenter noted that rebasing each year is too frequent.

Response: Section 1853(c)(1)(D)(ii) requires CMS to rebase the county FFS rates, which form the basis of the ACA specified amount, periodically, but not less than once every three years. The new ACA rate set under section 1853(n)(2) of the Act (specified amount) is based on FFS costs. In some counties, MA rates are based entirely on FFS rates as of 2013.

Rebasing means that CMS is basing the FFS-based components of MA rates on the most recent historical claims costs from the FFS program. Frequent rebasing also helps provide a smooth transition toward the ACA requirement that100 percent of MA rates will be based on FFS costs, in that it limits the more significant changes that may occur with less frequent updates.

Comment: Some commenters suggested that if a county qualifies for double bonus status in 2013 that CMS should allow for a two year policy transition if a county loses its double bonus status in 2014.

Response: We do not believe this transition policy would be consistent with the description of double bonus counties in the statute, in which the determination is made on an annual basis based on the county's relationship to the FFS USPCC. The other two criteria that determine a double bonus county status – the MA penetration rate as of December 2009 and the county's status as previously being an urban floor county – do not change.

Comment: One commenter asked CMS to confirm that the 2014 FFS spending used in the qualifying county determination will be consistent with implementation of the proposed new AGA methodology.

Response: Yes, the 2014 FFS spending is used to determine the qualifying county determination. Section 1853(o)(3)(B) of the Social Security Act defines a qualifying county as a county that meets the following three criteria: 1) has an MA capitation rate that, in 2004, was based on the amount specified in subsection (c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000; 2) as of December 2009, had at least 25 percent of beneficiaries residing in the county enrolled in an MA plan; and 3) has an average FFS county spending for 2014 that is less than the national average FFS spending for 2014.

Comment: One commenter asked us to clarify the star rating that will be assigned for new contracts in new parent organizations for QBP purposes, and wanted to confirm if the 2014 bonus for new organizations would be 3.5 percent.

Response: We define a new MA plan as an MA contract offered by a parent organization that has not had another MA contract in the previous three years. A new contract under a new parent organization will be assigned a star rating of 3.5 stars. Thus, the appropriate quality bonus payment (QBP) for new plans in contract year 2014 is 3.5 percent. 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 asked that CMS continue to publish a preliminary list of the county quartiles with the Advance Notice each time the prior year's FFS rates are rebased, as it is helpful for the plan to understand its potential benchmark levels for the coming year.

Response: CMS will consider making this file available next year. However, we would note that the county level FFS data needed to rank the counties into quartiles for 2015 will be included in the 2014 ratebook calculation file.

Comment: We received a number of comments expressing concern about the MA payment rates in Puerto Rico. Some of these commenters expressed concerns that Puerto Rico rates are artificially low because of special Medicare FFS payment provisions for Puerto Rico. These commenters also urged that refinements CMS has made to the AGA calculation for Puerto Rico, which began to be phased-in starting in 2012, be fully implemented in 2014.

Response: CMS began a detailed analysis of FFS spending in Puerto Rico in the fall of 2010. The results of that analysis confirm that Medicare enrollment, cost, and use patterns in Puerto Rico are different than on the mainland. A far greater proportion of beneficiaries in Puerto Rico enroll in MA 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 MA are all by law enrolled in both Part A and Part B, we concluded that, beginning with payment year 2012, the FFS rate calculation in Puerto Rico used to determine MA rates should be based exclusively on beneficiaries who are enrolled in both Part A and Part B. We have applied this refinement to historical FFS data for 2009 and 2010 for payment years 2012 and 2013. Due to the unique circumstances of Puerto Rico, we will fully implement this change for payment year 2014. As a result of this change, rates in Puerto Rico counties are higher relative to what they would have been under the methodology proposed in the Advance Notice. Due to the technical challenges of making this correction, the rates published with this Rate Notice will not include this change. We will publish revised rates for Puerto Rico to reflect this change before the end of April.

Clinical Trials

Comment: We received one comment from a commenter that erroneously believed that MA enrollees were not eligible to participate in cancer clinical trials. Specifically, this commenter believes that as the clinical trial policy currently stands, individuals in MA plans would be required to relinquish their MA coverage and revert to standard FFS Medicare if they wish to participate in a clinical trial.

Response: MA plan members are free to participate in any certified clinical trial that any other (FFS) Medicare beneficiary can participate in. MA beneficiaries are not required to relinquish their MA coverage if they wish to participate in a clinical trial. If an MAO conducts its own clinical trial, the MA can explain the benefits of participating in the MAO sponsored clinical trial. But, an MAO may not require pre-authorization for a non-plan-sponsored clinical trial, nor may it create impediments to a plan member's use of a non-plan clinical trial, even if the MAO believes it is sponsoring a clinical trial of similar nature. MA plans must cover all Medicare services including qualified clinical trials. Finally, effective for CY 2011 and subsequent years, as finalized in the 2011 Rate Announcement, our policy is that MA plans are required to reimburse beneficiaries' for cost sharing incurred for clinical trial services that exceeds the MA plans' in-network cost sharing for the same category of service, and members' clinical trial cost sharing must count towards their in-network out-of-pocket maximum.

Section C. Calculation of Fee for Service Rates

Comment: We received a number of comments asking for more detailed, county level information on the repricing of claims data proposed in the Advance Notice. These commenters expressed concern that they could not adequately comment on the proposed changes without these impacts. In addition, these commenters suggested that CMS delay implementation of the repricing of claims until more information is made available on the potential impacts of the repricing.

Response: We are publishing with the final Rate Announcement files that contain the wage indices in each claim year (*i.e.*, 2007-2011), and the wage indices for 2013, by county. We will consider publishing additional data with the Advance Notice in future years that can help stakeholders understand the potential impacts of proposed changes in the Advance Notice.

Comment: One commenter asked whether OACT is proposing to use an SGR update of over -30 percent to price the historical 2007 to 2011 physician claims, or will they use the 2013 SGR update of 0 percent. This commenter stated that there will be a major difference depending on which assumption OACT uses. Using current law's 2014 SGR update would truly distort historical physician claims, and would significantly distort the Part B costs of counties, particularly counties with a higher proportion of Part B costs.

Response: The repricing of claims adjusts the historical physician claims for the ratio of the 2013 geographic practice cost index to the geographic practice cost index in effect at the time. The historical claims already include the effect of physician fee fixes enacted for each year; there is no SGR adjustment to the AGAs.

Comment: One commenter noted that hospice claims should be carved out of the Puerto Rico rates by using national hospice FFS rates. This commenter noted that hospice costs are higher in Puerto Rico than in the mainland due to inappropriate use or billing of hospice care in Puerto Rico.

Response: The MA program does not pay for hospice claims, and for this reason, hospice claims are excluded from FFS data used to determine annual MA capitation rates. We believe that the current methodology accurately removes these claims from the FFS rates. Please see the Advance Notice and final Rate Announcement for 2012 for more detail on this methodology.

Comment: We received several comments in support of repricing the historical FFS claims.

Response: We appreciate the support for this approach.

Comment: One commenter asked that CMS limit the effect of repricing to no more than plus or minus 2 percent.

Response: We believe that this approach would result in FFS rates that would not accurately represent the expected FFS costs for a plan; furthermore this approach would potentially underpay in some counties and overpay in others. Finally, we do not believe this approach would be consistent with the statute.

Comment: Several commenters asked that CMS not adopt the proposal to re-price historical FFS claims data used to determine MA rates, in light of the uncertainty about the impacts and the potential for market disruption. One commenter suggested that CMS use an average of the previous two to three years of wage indices instead of only the previous year's wage index. Others asked that CMS consider phasing in the changes over time in order to mitigate the impacts.

Response: We recognize that the potential exists for disparate geographic impacts, and we also appreciate the concern that plans be given more time to adjust to potential changes in county rates. At the same time, we believe that repricing the claims provides for more accurate county level FFS rates. As such, we will be phasing in the changes over a two year period. For 2014, the repriced AGAs will be blended with non-repriced AGAs on a 50/50 basis (e.g., 50 percent repriced AGA and 50 percent non-repriced AGAs). Both sets of AGAs are included with the ratebook files posted on the CMS website. For 2015, we anticipate that the AGAs will be repriced and that no blending will occur.

However, we are not finalizing our proposal to recalculate home health claims to account for the outlier payment policy that went into effect in 2010. While the impact of the outlier payment policy will be reflected in home health claims in two of the five years in the AGA (2010 and 2011), we will not adjust claims in 2007 through 2009 to reflect the outlier policy.

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

Comment: Many commenters prefer delaying implementation of the CMS-HCC risk adjustment model, phasing in implementation of an updated model over time, and/or seeking additional industry input before implementing an updated model. Several commenters noted that CMS has the discretion to update risk adjustment models and that we should not update a model in a year when MA organizations are facing other negative adjustments. Commenters cited concerns in a number of areas, including: decrease in risk scores and payments, insufficient time to determine impacts, negative impacts on MA organizations, particularly those with high numbers of beneficiaries with chronic health conditions, and operational and administrative burdens. Some commenters requested more information and clarification of the transition plan to an updated model. Some commenters support improvements to the model that provide for more accurately capturing the risk of MA beneficiaries.

Response: We are finalizing the proposed model generally, but to mitigate the changes in risk scores faced by individual MA organizations, for 2014 we will blend the risk scores calculated using the 2014 CMS-HCC model with risk scores calculated using the 2013 CMS-HCC model, each appropriately normalized, weighting the normalized risk scores from the 2013 model by 25 percent and the normalized risk scores from the clinically revised model by 75 percent. These risk scores from the 2013 and 2014 CMS-HCC models will include the risk scores calculated from the community, institutional, new enrollee, and C-SNP new enrollee segments of the model and will be used in Part C payment for aged/disabled beneficiaries enrolled in MA plans. Given that we will blend risk scores under the 2013 and 2014 CMS-HCC models, no reduction to the model denominator will be made instead, we will use the unadjusted model denominator of $9,276.26. For PACE organizations, we will continue using the PACE model we have used in 2012 and 2013.

Comment: A number of commenters believe that the proposed changes in the risk adjustment model were intended for the sole purpose of addressing the difference in health care condition coding between MA and original FFS.

Response: CMS balanced several goals when updating the CMS-HCC model for the MA program. One significant goal of the revised model was to conduct a fresh model build in order to clinically revise the model. Though CMS annually maps new ICD-9 codes into the existing HCCs, the base groupings in the CMS-HCC model are still based on ICD-9 codes from the late 1990s. CMS has not conducted a fresh model build since the model was created. Thus, a key feature of the proposed restructuring of the condition categories proposed for CY 2014 was

achieved by taking into account ICD-9 codes that have been created in the decade since the original model was created. We also considered whether the condition categories predict expenditures, whether the diagnostic classifications measure disease burden, and whether diagnosis codes subject to discretionary or inappropriate coding should be excluded.

Comment: A few commenters asked that CMS wait until we have MA diagnoses that would support the clinical revision.

Response: The main purpose of the clinical revision was to rebuild the HCCs to reflect the changes in ICD-9 codes since the late 1990s, when the current HCCs were created. The HCCs are clusters of diagnoses that have similar clinical and cost implications. As with all costs in the model, including those used in a regular recalibration, the source of costs is FFS. However, the determination of clinical similarity is made based on input of a panel of clinical experts.

Changes to HCCs in the Model

Comment: One commenter believed that changes in HCC numbers could present challenges in maintaining which historical HCCs map to current ones.

Response: CMS understands the system changes that need to be undertaken to accommodate the changes in the numbering of the HCCs, since we will need to make system changes as well. Because the 2014 CMS-HCC model revises the groupings of the HCCs, some HCCs in the previous model have been split, while some have been newly formulated. Because we want the HCCs to be in a logical order, we undertook a renumbering of the HCCs, so that like categories are numbered close together. Given the restructuring of the HCCs, we did not think it was possible to retain all of the previous HCCs' numberings.

Comment: Some commenters contended that, by focusing risk adjustment changes on diagnoses that are reported at higher rates by MA organizations than by FFS providers, these changes penalize beneficiaries who benefit from disease and care management programs targeted to address their needs and plan efforts to identify the diagnoses important to their care.

Response: CMS understands the clinical value of disease and care management programs in targeting conditions early and preventing or slowing the progression of disease, improving the health of beneficiaries, and potentially saving health care costs. The goal of risk adjusted payments is to pay accurately using the appropriate relative risk for a beneficiary. Therefore, a key objective when we develop a risk adjustment model is to measure risk in the best way possible. As long as we have a model based on FFS costs and diagnoses patterns, differences in MA coding, relative to FFS coding patterns, results in relative risk that is measured incorrectly. Specifically, when MA plans report more diagnoses than FFS providers, risk scores are overstated. We do note that when specified HCCs are removed from the model, the model is recalibrated and the same costs are predicted with the new set of HCCs. The relative factors for

conditions that are comorbid with the excluded HCC may increase, as may the various demographic factors.

Comment: Some commenters asked that certain lower-level kidney HCCs be included in the 2014 CMS-HCC model. These include: Chronic Kidney Disease (CKD) stage 3; CKD stages 1-2 or unspecified; unspecified renal failure; and/or nephritis.

Response: CMS understands the clinical significance of these conditions and the importance of appropriately managing patients to slow the progression of kidney disease. However, we are also concerned that MA organizations code the renal-related conditions much more often than in FFS. Compared to the 2013 CMS-HCC model, there is increased granularity in the renal-related HCCs in the 2014 CMS-HCC model. Since the most aggressive treatment occurs for CKD stages 4 and 5, we decided to include these higher level CKD stages in the 2014 CMS-HCC model.

We decided to exclude CKD stages 1-2 or unspecified, unspecified renal failure, and nephritis since these conditions are relatively mild and non-specific. We also decided to exclude CKD stage 3 because of the clinical variability in this stage, which leads to greater variability in diagnosing and coding. MA plans have a greater incentive than FFS to conduct routine eGFR test on a patient in order to pick up a lab finding that might qualify for staging. The stage is easily computed from the creatinine level as part of a panel of blood tests. Treatment itself in stage 3 would usually be with prescription drugs, frequently for other symptoms, such as high blood pressure. We note that if nephritis or unspecified renal failure is associated with deteriorating renal function, then it will likely be captured in the higher level CKD codes, particularly for those that have nephritis over a long period of time. Unspecified renal failure is a vague diagnosis that could cover a wide range of failure and the stage should be determined.

Although some kidney-related diagnoses are not in the 2014 CMS-HCC model, the model still predicts beneficiaries' total costs, including costs associated with these conditions. For example, beneficiaries with kidney disease may also experience associated cardiac comorbidities. Costs associated with cardiac conditions are captured by the cardiac HCCs, which are higher than they would be if these lower-level kidney conditions were in the model. To the extent that drug costs are incurred by beneficiaries with any level of CKD, these are captured by the RxHCC model, which includes these lower-level kidney HCCs.

Comment: One commenter would like for certain diagnoses that were in the 2013 CMS-HCC model to be retained in the 2014 CMS-HCC model. These diagnoses include: history of myocardial infarction, hypoxia, and/or celiac disease.

Response: While all diagnoses with ICD-9 codes are mapped to a condition category, not all condition categories are included in the model used in payment. The decision to include a condition category in the model is made after balancing several considerations, including each category's ability to predict costs for Medicare Parts A and B benefits, whether the diagnostic

classifications measure disease burden, and whether diagnosis codes that are subject to discretionary or inappropriate coding should be excluded. The model also focuses on conditions that require active treatment and not those that could be the result of testing or screening an entire population. For these reasons, history of myocardial infarction and hypoxia are not in the 2014 CMS-HCC model; however, some of the costs associated with history of myocardial infarction and hypoxia are captured by the heart and lung HCCs in the 2014 CMS-HCC model and the RxHCC model. Celiac disease is not strongly predictive of Medicare costs and treated mainly by control of components of a person's diet.

Comment: Many commenters recommended that an HCC for dementia be included in the proposed risk adjustment model. They expressed concern that not recognizing dementia in the model will disproportionally affect payment rates for the sickest beneficiaries, which runs counter to the express purpose of risk adjustment. Several commenters noted that the proposed model failed to recognize the growing prevalence of dementia in the Medicare population. Other commenters emphasized the particular impact on SNPs, especially FIDE SNPs and I-SNPs, due to the failure to account for dementia-related costs. Finally, commenters felt that the CMS' explanation not to include dementia was inadequate, and they were unclear how CMS could conclude that a dementia diagnosis is not predictive of resource use and costs.

Response: CMS understands that the treatment of dementia can be costly and that including dementia in the model would potentially increase the risk scores of beneficiaries who have been diagnosed with dementia. Our concern focuses on the diagnosis and coding of dementia, and the broad clinical definitions that have been developed in order to identify the disease. We fully support these efforts to identify and treat dementia. We are concerned, however, that the broad clinical definition of dementia may result in dementia being coded at greater levels in MA, relative to FFS, such that payment will be inaccurate. In addition, many of the costs directly associated with dementia are not Medicare Part A and B costs.

Comment: We received several comments regarding diabetes in the 2014 CMS-HCC model. Specifically, one commenter thought that the proposed diabetes HCC groupings would disproportionately affect payment rates for the neediest beneficiaries, whereas another commenter found the average risk scores for their diabetic population would be unchanged. Two commenters noted that the 2014 CMS-HCC model has two fewer diabetes interactions as compared with the 2013 CMS-HCC model, one of whom asked whether we expected the average diabetic risk score to decrease.

Response: Plans with a non-random distribution in their patient population may experience varying risk scores impacts; the actual change in risk score of any beneficiary with diabetes will depend on the totality of their risk profile, including their demographic factors and other diagnoses. When developing the 2014 CMS-HCC model, we found that the empirical strength of the two diabetes-related interactions that were in the 2013 CMS-HCC model were not strong enough to retain. However, beneficiaries that have the individual elements of an interaction term

will still receive credit for those individual conditions in the risk scores for their enrollees with diabetes.

Comment: One commenter observed that the relative factor for a continuing community enrollee with HIV/AIDS has fallen considerably from the 2009 to the 2013 and 2014 CMS-HCC models.

Response: Drug therapy and early detection for HIV/AIDS has improved markedly in recent years. As more recent underlying data was used to develop the 2013 and 2014 CMS-HCC models, the relative factors reflect these changes. Specifically, for the 2009 model used in 2009-2012, diagnoses from 2004 were used to predict costs in 2005. For the 2013 CMS-HCC model, 2008 diagnoses were used to predict 2009 costs.

Comment: A number of commenters emphasized that PACE organizations have limited ability to respond to reductions in payments from CMS; several commenters also mentioned the 2 percent payment cut due to sequestration. Commenters stated that PACE organizations cannot modify benefits and cannot make up reductions in payments by increasing beneficiaries' premiums or cost sharing. Many commenters thus requested that for 2014, CMS retain the current CMS-HCC risk adjustment model that has been used to risk adjust payments to PACE organizations in 2012 and 2013. Commenters were concerned that the model proposed in the Advance Notice deletes the HCCs for dementia, noting that almost half of PACE enrollees have a dementia diagnosis and require more careful monitoring to ensure compliance with their care plans and more services overall than those without dementia. Some commenters were also concerned about the removal of HCCs related to chronic kidney disease, of which there is a high prevalence among PACE members, and felt that the proposed elimination of HCCs related to this condition would lead to an under prediction of PACE costs.

Response: We have reviewed the comments requesting that CMS apply the same risk adjustment model for the PACE program in 2014 as used for 2012 and 2013, and in response to the arguments made in these comments, have determined that we will not implement the model proposed in the Advance Notice for PACE organizations. For 2014, for the PACE program, we will retain the current model used for 2013 PACE payments. (This model is described in the 2012 Rate Announcement, Tables 9 through 11).

New enrollee segments

Comment: One commenter asked whether the CMS-HCC relative factors for new enrollees with ages below 65 were displayed in the correct column in Table 2 of the 2014 Advance Notice.

Response: New enrollees who are currently below age 65 and who are first entitled to Medicare by disability are indicated in the "non-originally disabled" column. The originally disabled category distinguishes beneficiaries who are currently age 65 or over, but were first entitled to Medicare before age 65 due to disability.

New enrollee Risk Scores for Chronic SNPs

Comment: Several commenters requested that CMS develop a New Enrollee Risk Score Model not only for C-SNPS but for all types of SNPs, including FIDE SNPs and I-SNPs, arguing that the rationale for the creation of New Enrollee risk scores for C-SNPs would apply to other types of SNPs. One commenter emphasized that the SNPs not eligible for the C-SNP new enrollee factor or the frailty adjustment (applicable to qualifying FIDE SNPs) experience higher costs due to uncompensated risk and higher administrative costs for multiple mandates from Congress (such as the costs of implementing Model of Care rules, additional quality reporting, and NCQA approval for licensure). A number of commenters stated that CMS should develop a new enrollee risk factor methodology for the PACE program that reflects the high acuity of PACE organizations' enrollees, who must meet their states' eligibility criteria for nursing home level of care. As a result, the average risk for a new PACE enrollee is substantially higher than that of the average MA enrollee.

Response: Chronic SNP enrollees must, as a condition of enrollment, have specific conditions; thus, we previously determined that the average new enrollee risk score used for all other MA plans was likely to understate these beneficiaries' risk. CMS is not considering applying similar new enrollee risk scores to dual SNPs, including FIDE SNPs, or to PACE organizations because we believe that dual SNPs' new enrollee risk scores are adequate to address aggregate risk faced by these plans.

The new enrollee segment of the CMS-HCC model is used in Part C payment for beneficiaries enrolled in MA plans or PACE organizations who do not have adequate diagnoses to calculate a risk score. Operationally, we identify these beneficiaries as those who do not have 12 months of Part B in the data collection period, and the vast majority of new enrollees are new to Medicare. The new enrollee segment of the CMS-HCC model comprises demographic factors: age, sex, Medicaid status, and originally disabled status. Since the main new enrollee risk score model captures the additional costs due to Medicaid status, we believe that it is appropriate for paying for new enrollees across plan type.

Phase in of 2014 CMS-HCC Model

Comment: Several commenters asked how the 2.5 percent adjustment to the denominator affected the model. Some asked how we knew it was an appropriate adjustment amount or how it differed from the MA coding adjustment factor. Several commenters requested that CMS implement the new model in a budget neutral fashion at the plan level, instead of at the industry level.

Response: In response to these comments, for 2014 we will transition to the new model by blending the risk scores calculated using the 2013 CMS-HCC model and the 2014 CMS-HCC model. With this transition, we will not be adjusting the denominator of the 2014 CMS-HCC

model. This approach to calculating 2014 risk scores will minimize the impact on individual risk scores and on plan average risk scores.

Section E. MA Enrollee Risk Assessments

Comment: Many commenters either opposed the policy to require a subsequent submission of a diagnosis to receive payment or requested that CMS delay implementation until after data are collected, analyzed, and the policy proposal is commented on by MA plans.

Response: As noted above, CMS is delaying the collection of "flags" for these assessments until 2014 dates of service. Risk adjusted payments for 2014 will not be affected by this policy. We will propose and finalize a policy on the extent to which diagnoses from 2014 Enrollee Risk Assessments will be used to calculate risk scores for payment year 2015 in the 2015 Advance Notice and Rate Announcement.

Comment: Many commenters raised concerns with how CMS defines a "Medicare Advantage Enrollee Risk Assessment." Some questioned the link between the MA Enrollee Risk Assessment and the Health Risk Assessment required as part of an Annual Wellness Visit.

Response: CMS recognizes that the term risk assessment is used to describe a variety of different encounters between providers and beneficiaries. We acknowledge that a more detailed definition will need to be provided for the purposes of data collection and risk adjustment. CMS will provide this guidance prior to the start of data collection.

Comment: A few commenters raised a concern that requiring treatment for payment conflicts with CMS' HCC risk adjustment methodology and that to exclude diagnoses not associated with treatment in calculating risk adjustment is inconsistent with how risk adjustment coefficients are calculated. A couple of other commenters suggested that if diagnoses captured from the MA Enrollee Risk Assessment were excluded, CMS would need to recalibrate the model based on FFS data that also excludes diagnoses from FFS risk assessments. While some other commenters indicated that not all chronic conditions require active treatment but should be captured to treat enrollees holistically.

Response: We appreciate these comments and will take them into consideration as we develop the proposed policy for 2015 and future years.

Comment: Several commenters raised concerns that implementing this policy will result in fewer risk assessments being completed and will negatively impact care to beneficiaries.

Response: CMS continues to strongly encourage these assessments to identify health conditions and to further promote the development of treatment plans and follow-up care for Medicare beneficiaries. CMS does not believe that any requirement to flag these assessments should negatively affect Medicare beneficiaries. However, CMS remains concerned that, while these

risk assessments can be valuable, they may sometimes be used as a vehicle to maximize MA revenue without follow-up care or treatment being provided to the beneficiary by the plan.

Comment: From a data perspective, a few commenters contended that submitting a subsequent encounter would be costly and administratively burdensome. Some commenters requested additional guidance on how CMS is planning to operationally "flag" diagnosis codes in the risk adjustment data submitted to CMS. A few commenters raised concerns with requiring a flag for diagnoses with 2013 dates of service, stating it would be burdensome to do so soon and requested a delay.

Response: As noted above, CMS is delaying the collection of "flags" for these assessments until 2014 dates of service to provide more lead time and allow for more planning. At this time it should be noted that, CMS is only asking that plans flag the encounters for 2014 dates of service, and is not requiring data filtering. CMS will release operational guidance as to how these assessments will be flagged prior to the start date.

Comment: A few commenters shared CMS' concern that data obtained from MA Enrollee Risk Assessments should not be used for the sole purpose of collecting diagnoses for risk adjustment. They agree it should be used to identify the needs of the patient and ensure appropriate treatment or intervention is provided.

Response: CMS appreciates the support.

Section F. Adjustment for MA Coding Pattern Differences

Comment: A number of commenters argued that the changes to the risk adjustment model to address coding intensity are duplicative of the MA coding adjustment factor.

Response: We understand that different model versions may affect the coding difference trend differently and, when CMS determines the MA coding adjustment factor, we take into account the version of the model that will be in use during the payment year. Because we make determinations regarding the appropriate level of the MA coding adjustment by taking into account the impact on coding of the risk model, the model adjustments made to address coding does not duplicate the MA coding adjustment factor applied to the risk scores.

Comment: One commenter believed that the coding adjustment factor applied to PACE organizations is inconsistent with PACE coding over time. This commenter stated that coding for beneficiaries staying in the PACE program increased by approximately the same increase as in the FFS program and significantly less than the increase in the MA program. The application of a coding adjustment factor to PACE, based on coding changes in the MA program, results in a reduction in risk scores, and consequently payment, that this commenter did not believe would be supported by PACE's coding experience over time.

Response: CMS applies the MA coding adjustment by developing a uniform adjustment factor. Similar in approach to the normalization factor, the goal is to set the average risk score to the correct level by adjusting for trends in the overall market.

Comment: One commenter questioned the appropriateness of modifying new member risk scores by the MA coding adjustment factor because these members have no MA coding that would differ from FFS coding that would necessitate an adjustment.

Response: MA coding adjustment is a methodological adjustment to risk scores to ensure payment accuracy given differential coding patterns in MA and FFS. The coding adjustment factor is calculated using data collected over a defined set of consecutive years from a cohort of beneficiaries continuously enrolled in MA or continuously enrolled in FFS over the entire collection period, otherwise known as the 'stayer cohort'. The coding adjustment factor also accounts for varying lengths in enrollment in MA. For operational purposes, we apply the coding adjustment factor to all MA risk scores, but adjust the factor by the percentage of stayers in the year prior to the payment year. By making this downward adjustment to the factor, we take into account that MA plans cannot affect the coding of these new members.

Section G. Normalization Factors

G1. Normalization for the CMS-HCC Model (aged/disabled beneficiaries enrolled in MA plans)

For 2014, CMS is blending the risk scores from the 2013 CMS-HCC model with the risk scores from the 2014 CMS-HCC model to calculate the risk scores used for payment. Therefore, two normalization factors, *i.e.*, one normalization factor for the 2013 CMS-HCC model and one normalization factor for the 2014 CMS-HCC model, will be calculated to adjust the risk scores using each respective model. The normalized risk scores will then be blended for payment purposes with the risk scores from the 2014 model weighted at 75 percent and the risk scores from the 2013 model weighted at 25 percent.

The final normalization factor for the 2013 CMS-HCC model is 1.041 and for the 2014 CMS-HCC model is 1.026.

- 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:

Year	2013 CMS-HCC Model	2014 CMS-HCC Model
2008	0.959	0.947
2009	0.975	0.963
2010	0.990	0.979
2011	1.000	0.988
2012	1.015	1.000

The linear annual trend over these five years (2008-2012) using the 2013 CMS-HCC model is 0.0135 and using the 2014 CMS-HCC model is 0.0130. These annual trends are applied for the years between the denominator years and the 2014 payment year. For the 2014 CMS-HCC model, we will account for the trend between the 2012 denominator year and 2014 payment year by taking it to the second power. For the 2013 CMS-HCC model, we will account for the trend between the 2011 denominator year and 2014 payment year by taking that annual trend to the third power. The normalization factors are obtained as follows:

2013 CMS-HCC model $1.0135^3 = 1.041$

2014 CMS-HCC model $1.0130^2 = 1.026$

G2. Normalization Factor for the Rx Hierarchical Condition Category (RxHCC) Model

Due to a technical revision, the final 2014 normalization factor for the RxHCC model is 1.030.

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

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

Year	Current RxHCC Model
2007	0.964
2008	0.970
2009	0.981
2010	0.995
2011	1.000

The linear annual trend over these five years (2007-2011) is 0.010. This annual trend is applied for the years between the denominator year (2011) and the payment year (2014) by taking it to the third power. The normalization factor is obtained as follows: $1.010^3 = 1.030$.

Comment: Four commenters requested CMS to downwardly adjust the normalization factor to account for lower projected FFS costs and trends and changes in risk scores in the FFS population due to the influx of baby boomers. One commenter requested that CMS compare consistency of its calculations of normalization and projections of the national per capita growth rate, and to consider using a method more sensitive to changes in the FFS cost trends in

calculating the normalization factors. One commenter recommended a phase-in of the normalization reduction.

Response: The calculation of the normalization factors is based on the annual trend in risk scores over a defined set of consecutive years, and the number of years between the denominator year (when the 1.0 average risk score is determined) and the payment year. We incorporate a rolling five years of risk scores specifically to smooth the annual trend. Changes in trends due to fluctuations in FFS costs or enrollment will be reflected over time in future calculations of normalization factors. No adjustment will be made to the normalization factor calculation for projected costs and enrollment.

Comment: One commenter asked for a separate normalization factor for PACE.

Response: Normalization factors are calculated annually for each model to create an average 1.0 risk score in the payment year. Since we will continue to use the risk adjustment model used in 2012 and 2013 for PACE, we will continue to have separate normalization factor for PACE.

Section G. Frailty Adjustment

The 2014 frailty factors for PACE organizations are the same frailty factors posted in the 2013 Advance Notice. There are two sets of FIDE SNP frailty factors for 2014; we will calculate frailty scores using the frailty factors associated with the 2014 CMS-HCC model and using the frailty factors associated with the 2013 CMS-HCC model. The FIDE SNP frailty factors associated with the 2014 CMS-HCC model are finalized in this Announcement. The FIDE SNP frailty factors associated with the 2013 CMS-HCC model are posted in the 2013 Advance Notice. CMS will separately calculate frailty scores for FIDE SNPs using each set of factors and blend the two frailty scores in the same manner as the 2014 risk scores. These blended frailty scores will be used both to determine a FIDE SNP's eligibility for frailty payments and, if eligibility is met, for payment.

Comment: One commenter supports frailty as part of Medicare payment.

Response: We appreciate the support.

Comment: Four commenters recommended that CMS consider the application of frailty program wide and at the beneficiary level.

Response: CMS has explored ways of capturing frailty by all MA plans and found challenges with a number of approaches (see the "Evaluation of the CMS-HCC Risk Adjustment Model," published March 2011, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf). The CMS-HCC model is intended to accurately pay plans with average risk profiles, unlike PACE organizations and qualifying FIDE SNPs that have higher than average risk profiles and are

eligible to receive frailty payments. Additionally, the application of a frailty adjustment to all MA plans would need to be done on a budget neutral basis with consideration to the fact that some enrollees would have a negative adjustment. Also, frailty adjustments are calculated using survey data submitted by PACE organizations and FIDE SNPs (from a subset of their enrollees), and, therefore, are calculated at the contract level for PACE organizations and at the plan level for FIDE SNPs.

Comment: Two commenters suggested that CMS apply the same survey consistently to programs for frailty score determination.

Response: We appreciate this suggestion and are evaluating it.

Comment: One commenter asked about the timing of the publication of 2014 frailty adjustment and inclusion in the MMR.

Response: The PACE frailty factors that we will use in 2014 are published in the 2013 Advance Notice. The FIDE SNP frailty factors associated with the 2013 CMS-HCC model are published in the 2013 Advance Notice; the frailty factors associated with the 2014 CMS-HCC model are published below. Frailty scores will be calculated using each model, and then these two scores will be blended for 2014 payment in the same manner as the 2014 risk scores. The 2014 PACE and FIDE SNP specific frailty scores will be calculated in late 2013 and will be made available in HPMS.

Recalibrated FIDE SNP Frailty Factors Associated with the 2014 CMS-HCC Model

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

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

Comment: Commenters noted they will be submitting comments on the medical loss ratio requirements through the notice and comment process and urged us to finalize the regulation as soon as possible.

Response: Proposed regulation CMS-4173 on the medical loss ratio requirements went on display on February 15, 2013 in the Federal Register. CMS appreciates the desire of plans to have final guidance on the medical loss ratio requirement. Comments on the proposed rule are due no later than April 16th, and we intend to publish a final medical loss ratio regulation as soon as possible thereafter.

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

Comment: Commenters stated their support for A1(a), which maintains the current policy of placing the dispensing fee and vaccine administration fee outside of the coverage gap phase to the greatest extent possible on straddle claims. Commenters also stated their support for A1(b), in which the dispensing fee and vaccine administration fee liability for beneficiaries will be commensurate with the coinsurance percentage. If the beneficiary pays a copay, the beneficiary liability for the dispensing fee and vaccine administration fee will be commensurate with the percentage of the total Part D claim cost attributed to the before-discount copay. Two commenters reported typos in the TrOOP Accumulators in the examples. Some commenters requested additional examples to ensure consistent application of the proposed methods.

Response: The values presented in the example TrOOP Accumulators were accurate. Additional language has been added to this document to clarify the TrOOP eligible fields and the TrOOP accumulator amounts in those examples to facilitate better understanding. CMS will provide additional examples of the adopted policies in forthcoming operational guidance.

Comment: The majority of commenters were in support of option A2(a), in which each cost component of the negotiated price, with the exception of dispensing fee and vaccine administration fees that would be subject to the coverage gap straddle claim policy proposed in section A1(a), will be calculated proportional to beneficiary and plan liability for the entire negotiated price in all phases of the benefit. Some commenters felt that option A2(b) would be too complex for beneficiaries to understand and would be too complex to implement. Some commenters asked if there would be a requirement to start reporting the negotiated price on a PDE by phase for each component. Some commenters requested additional examples to ensure consistent application of the proposed method.

Response: CMS will not require PDE reporting of the negotiated price by benefit phase for each component. The specific purpose of these examples was to provide an extra level of detail to explain how this policy applies so that plans can determine the correct cost that is used for PDE reporting. Our PDE reporting requirements are not changed by this policy; rather, this policy will clarify the payment liability. None of the examples were intended to serve as specific operational submission guidance. Such guidance would be beyond the scope of this policy document. CMS will provide additional examples of the adopted policy in forthcoming operational guidance.

Comment: Commenters were in support of the option in A3 where sponsors will report negative Patient Liability Reduction due to Other Payer (PLRO) amount in situations in which the other health insurance (OHI) coverage results in increased beneficiary liability. Commenters felt that the PDE should reflect what the beneficiary pays at point of sale. Some commenters were concerned about adopting the policy for low income eligible beneficiaries. Some commenters

requested additional PDE information to the example provided. Other commenters requested additional examples to ensure consistent application of the proposed method.

Response: As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR §423.322). Ideally, a PDE based on information available at point of sale (POS) can comply with the reporting requirements necessary for accurate payment. However, in certain cases new information (*e.g.*, PLRO not known at POS) can alter one or more PDE payment fields that subsequently affect reconciled Part D payments. The PDE should reflect the appropriate incurred costs. Accordingly, we are adopting a policy that plan sponsors should report negative PLRO, where applicable, for all beneficiaries in all plan types. Moreover, while it has been assumed that OHI generally provides benefits in the form of reduced cost sharing, CMS has a policy interest in studying the actual impact. We are aware of certain situations where OHI results in the beneficiary paying higher cost sharing for certain dispensing events. The PDE will allow CMS to evaluate the extent to which secondary payers may be diminishing the value of the Part D benefit. Additional PDE information has been added to the existing example in this document. CMS will provide additional examples of the adopted policy in forthcoming operational guidance.

Comment: Two commenters agreed with eliminating operational EA mapping Rule 4, which was proposed in A4. One commenter indicated that beneficiaries will pay 12.5 percent more in the coverage gap for brand drugs as a result of this policy change.

Response: EA mapping Rule 4 has been an operational instruction for certain PDE submissions in enhanced alternative plans. From data analysis over time and discussions with industry, CMS now believes that operational EA mapping Rule 4 is both overly burdensome and could potentially lead to inaccuracies in reconciled payments. Thus, the purpose of eliminating the operational EA mapping Rule 4 is to both simplify the PDE reporting process and to ensure accurate reconciled Part D payments.

CMS acknowledges that, in rare instances, the beneficiary may pay more for brand drugs on tiers that are excluded from supplemental coverage in the gap by changing this PDE reporting instruction. However, if EA mapping Rule 4 remained, similar impacts would exist in certain situations.

For CY2014, if operational EA mapping Rule 4 remains, the plan would map 15 percent of applicable drug cost to CPP while defined standard plans would report 2.5 percent of applicable drug costs as CPP in CY2014. For CY2014, if a beneficiary is in the coverage gap, where operational EA mapping Rule 4 would have applied, and the EA plan does not offer supplemental coverage on a brand drug, the beneficiary will pay 12.5 percent more in the coverage gap (*i.e.*, the difference between CPP operational EA mapping Rule 4 amount of 15 percent and the operational EA mapping Rule 3 amount of 2.5 percent) but if the EA plan offers

supplemental coverage, the 12.5 percent would continue to be plan liability but would be reported as Non Covered Plan Paid (NPP) amount.

As the coverage gap phase continues to close with increased sponsor cost sharing in the coverage gap, the Covered D Plan Paid (CPP) amount in the coverage gap for applicable drugs will increase to 25 percent in CY2020 for Defined Standard plans. If operational EA mapping Rule 4 were to remain in place in 2020, EA plans would map 15 percent of applicable drug cost to CPP while defined standard plans would report 25 percent of applicable drug costs as CPP in CY2020. If we continued to use the operational EA mapping Rule 4, in CY2020, the beneficiary would pay 10 percent more for a brand drug that is on a tier that is not part of the EA plan's supplemental coverage in the gap compared to a beneficiary in a defined standard plan in the coverage gap (*i.e.*, the difference between the operational EA mapping Rule 3 CPP amount of 25 percent and the operational EA mapping Rule 4 amount of 15 percent).

The beneficiary impact of eliminating operational EA mapping Rule 4 will be limited to drugs in which the EA plan does not offer supplemental coverage in the gap and this impact will go away in 2018 for brand drugs when the CPP amount in the coverage gap is 15 percent for defined standard plans, which is equivalent to the current operational EA mapping Rule 4 amount of 15 percent. When there is supplemental coverage in the gap, the elimination of operational EA mapping Rule 4 will shift plan liability from CPP to NPP beginning in CY2014 and ending in CY2018 when CPP is 15 percent in the coverage gap.

The elimination of operational EA mapping Rule 4 does not change existing payment policy; it makes certain that payments are more accurate through reporting that is more consistent with existing payment policy, reduces administrative burden on sponsors, and reduces beneficiary cost sharing in the long term as sponsors continue to increase coverage in the coverage gap phase. In addition, because the costs in operational EA mapping rule 4 are not allowable risk corridor costs as defined under §1860D-15 (e)(1)(B) of the Social Security Act we will eliminate operational EA mapping Rule 4 effective with benefit year 2014.

Section J. Update of the RxHCC Model

Comment: Three commenters did not support updating the RxHCC risk adjustment model because it is not required by statute, would result in administrative costs, and would have a negative effect on payments.

Response: The RxHCC risk model predicts plan liability under the Part D benefit. As the coverage gap closes, plan liability in the gap increases each year until the coverage gap is effectively closed for applicable beneficiaries by contract year 2020. Therefore, for the reasons stated in the Advance Notice, we are recalibrating the RxHCC model yearly as the gap closes to reflect the increasing plan liability in the gap for applicable beneficiaries.

Comment: One commenter inquired about inclusion of generics on the market since 2011 in the RxHCC model.

Response: The RxHCC model was recalibrated for 2014 using 2010 diagnoses and PDE expenditures submitted with 2011 dates of service, since 2012 expenditures are not yet fully reported.

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

Comment: One commenter asked about plan liability in the coverage gap for 2014.

Response: In 2014, plan liability in the coverage gap for non-applicable (generic) drugs increases by 7 percent and remains the same for applicable (brand) drugs. The Affordable Care Act, as enacted in section 3301 and amended by section 1101 of HCERA, phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Medicare Part D benefit by reducing beneficiary coinsurance for drugs in the gap for applicable beneficiaries. This reduction in cost sharing began in CY 2011 and continues through CY 2020, ultimately resulting in 75 percent cost sharing for applicable drugs, prior to the application of any manufacturer discounts, and 25 percent cost sharing for other covered Part D drugs (non-applicable drugs). Applicable drugs are defined at section 1860D-14A(g)(2) of the statute and are generally brand covered Part D drugs that are either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic, licensed under section 351 of the Public Health Service Act (BLA). Non-applicable drugs are covered Part D drugs that do not meet the definition of an applicable drug (*i.e.*, generic drugs). The reductions in cost sharing, in conjunction with the coverage gap discount program, will serve to effectively close the Medicare Part D benefit coverage gap for non-LIS beneficiaries by CY 2020.

In 2014, the coinsurance under basic prescription drug coverage for certain beneficiaries is further reduced from 2013 for non-applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit. The coinsurance charged to eligible beneficiaries will be equal to 72 percent. Also in 2014, the coinsurance under basic prescription drug coverage for certain beneficiaries for applicable covered Part D drugs purchased during the coverage gap phase of the Part D benefit will stay the same as in 2013 and will be equal to 47.5 percent of the negotiated price.

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

The 72 percent coinsurance for non-applicable drugs and 47.5 percent coinsurance for applicable drugs in the coverage gap represent an increase in plan liability and a reduction in beneficiary cost sharing. Therefore, we further specify that these increased plan liability amounts do not count towards TrOOP. Part D sponsors must account for the reductions in cost sharing and increased plan liability when developing their Part D bids for payment year 2014.

Comment: We received several comments in support of the Part D benefit parameters decreasing, for the most part, from the prior year.

Response: We appreciate the support.

Comment: One commenter noted that a couple of the parameters are going up and encouraged us to communicate this to plans and pharmacies to avoid beneficiary confusion.

Response: We will take this suggestion into consideration.

Comment: One commenter suggested that the annual percentage trend of -2.76 percent may be too low due to CMS underestimating drug costs during August 2012-July 2013, which used PDE data incurred from August to December 2012 and was projected through July 2013.

Response: As 2013 PDE data will not be finalized until after the payment year, we used PDE data submitted in 2012 for projecting January 2013 through July 2013 drug costs. Because PDE data are the best source for actual Part D drug costs, the -2.76 percent annual percentage trend for July 2013 is the most accurate estimate we can provide at this time.

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

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

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

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

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

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

A4. Enhanced Alternative Plan Mapping Rules.

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

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

CMS is adopting the following policies beginning with CY2014:

a) Coverage Gap Straddle Claims

Applicable to all Part D plans

The dispensing and vaccine administration fees will be included in the negotiated price to the greatest extent possible. In effect, this policy will maintain the current policy that the dispensing/vaccine administration fee for any coverage gap straddle claim is included in the

portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold to the greatest extent possible. We believe this is the most beneficiary friendly approach that ensures uniform treatment of beneficiary liability across all Part D plans and the accurate calculation of the coverage gap discount amount.

The following two examples demonstrate how this proposed policy would be implemented for PDE reporting. The examples use benefit year 2013 parameters.

Example 1 – Defined Standard Benefit

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

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

Distribution of Drug Cost across benefit phases

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

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

1. **Determine the costs that fall in the Coverage Gap:** $30.00
2. **Determine Discount Eligible Cost:** $30.00

3. **Calculate Gap Discount:** $30.00 × 50% = $15.00. The Gap Discount amount is TrOOP eligible.
4. **Determine Beneficiary cost sharing in the Coverage Gap:** $30.00 × 47.5% = $14.25. The Patient pay amount is TrOOP eligible. The TrOOP amount in the Coverage Gap Phase is $29.25 ($15.00 in Reported Gap Discount plus $14.25 in Patient Pay amount).
5. **Calculate Covered Portion of Plan Paid Cost sharing:** $30.00 × 2.5% = $.75

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

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

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

In preparation for the next claim, the TGCDC Accumulator will be $7,126.52 ($6,924.52 + $202.00) and the TrOOP Accumulator will be $4,750 ($4,720.75 + $15.00 Reported Gap Discount + $14.25 Patient Pay Amount in the Coverage Gap phase).

Example 2 – EA Benefit

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

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

Distribution of Drug Cost across benefit phases

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

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

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

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

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

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

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

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

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

In preparation for the next claim, the TGCDC Accumulator will be $6,902.00($6,700.00 + $202.00) and the TrOOP Accumulator will be $4,750 ($4,720.00 + $15.00 Reported Gap Discount + $15.00 Patient Pay Amount in the Coverage Gap Phase).

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

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

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

This approach to applicable drug coverage gap claims under EA plans aligns with our shared responsibility approach on applicable drug coverage gap claims under basic benefits that is needed to correctly implement 1860D-2(b)(2)(D) of the Social Security Act. Moreover, it is consistent with the proportional plan and beneficiary liability for other negotiated price cost components discussed in Section A2 of Attachment IV and, therefore, will help ensure uniform treatment of beneficiary liability across all Part D plans.

The following example demonstrates how this policy will be implemented for PDE reporting for EA plans with supplemental coverage in the gap. The example uses benefit year 2013 parameters.

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

PDE Fields	Claim Total
Total Gross Covered Drug Cost Accumulator	$3,000.00
True Out of Pocket Accumulator	$1,110.00
Beginning Benefit Phase	G
Ending Benefit Phase	G
Pricing Exception Code	<blank>
Non-Standard Format Code	<blank>

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

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

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

7. **Determine beneficiary liability for dispensing fee and vaccine administration fee within the coverage gap phase:**

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

The table below shows the PDE fields for this example. The patient pay amount is the sum of the beneficiary's portion of the discount eligible cost ($30.00) and the beneficiary's portion of the dispensing fee ($0.60).

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

In preparation for the next claim, the TGCDC Accumulator will be $3,202.00 ($3,000.00 + $202.00) and the TrOOP Accumulator will be $1,170.60 ($1,110.00 + $30.00 Reported Gap Discount + $30.60 Patient Pay Amount)

Additional examples of both policies will be provided in forthcoming guidance.

A2. Beneficiary and Plan Negotiated Price Cost Component Liability

Applicable to all Part D plans

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

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

However, if a claim straddles benefit phases, we are adopting the following policy for determining beneficiary and plan's negotiated price cost component liability:

a) Implement the policy proposed in the Advance Notice for CY 2013 and adopted in the Final Rate Notice for CY 2013 that each cost component of the negotiated price, except for dispensing and vaccine administration fees that will be subject to the coverage gap straddle claim policy in section A1(a) of Attachment IV, be calculated proportional to beneficiary and plan liability for the entire negotiated price in all phases of the benefit. Under this policy, a

plan can either apply programming logic that calculates the proportional liability of each cost component in each phase or alternatively calculate the proportional liability based upon the aggregate beneficiary/plan liability for the claim. Either methodology will take into account the differing proportional liability in each phase of the benefit and will ensure that the plan can consistently determine individual negotiated price cost component liability when necessary. Note that this policy would not change the existing straddle claim rules described in current PDE guidance (April 26, 2007 HPMS memorandum titled, "A Q and A that addresses claims straddling co-payment benefit phases" and rules and examples provided in the 2011 PDE Participant Guide).

The following example demonstrates how this policy will be implemented for PDE reporting. The example uses benefit year 2013 parameters.

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

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

Distribution of Drug Cost across benefit phases

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

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

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

   Determine CPP and NPP in the Coverage Gap phase:

   CPP is 2.5 percent of the ingredient cost and sales tax
   2.5% × $100.00 = $2.50
   The dispensing fee is not included in the coverage gap.
   NPP is $100.00 − ($15.00 + $15.00 + $2.50) = $67.50.
   Determine CPP and NPP for cost falling outside of the Coverage Gap phase:
   The plan amount is the lesser of 95 percent of the drug cost in the catastrophic phase or Drug cost in the catastrophic phase - $6.60. In this example, the CPP in the catastrophic phase is $95.40.
   NPP in the catastrophic phase is $0.00.
7. **Determine beneficiary liability for dispensing fee and vaccine administration fee:** In this example, the dispensing fee is in the catastrophic phase and will be considered when determining beneficiary liability for cost falling outside of the Coverage Gap.
8. **Determine beneficiary liability for cost falling outside of the Coverage Gap:** In the catastrophic phase, the beneficiary pays the greater of $6.60 or 5 percent of the drug cost in the catastrophic phase. In this example, the beneficiary pays $6.60.

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

In preparation for the next claim, the TGCDC Accumulator will be $6,902.00 ($6,700.00 + $202.00) and the TrOOP Accumulator will be $4,750 ($4,720.00 + $15.00 Reported Gap Discount + $15.00 Patient Pay Amount in the Coverage Gap).

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

Applicable to all Part D plans

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

We believe the PDE should reflect actual point-of-sale incurred costs, and we need to know whether EGWP sponsors are providing creditable coverage and to what extent secondary payers are diminishing the value of the Part D benefit; therefore, we are adopting the following policy when OHI results in beneficiary cost sharing that is greater than it would be under the Part D plan benefit for an individual market basic or EA plan, or that is greater than it would be under the defined standard benefit for an EGWP:

If the OHI increases the amount the patient pays at the pharmacy then the Patient Pay Amount on the PDE reflects what the patient pays at POS and PLRO is negative. CMS has always interpreted that beneficiary payments for covered Part D drugs are TrOOP eligible; therefore, the amount reported in the Patient Pay Amount field counts toward TrOOP.

For example, the beneficiary purchases a $100.00 drug in the initial coverage phase. The beneficiary has a $30.00 copay with their OHI. In the defined standard benefit, the beneficiary would pay $25.00 and the plan would pay $75.00. PLRO is determined by taking the patient pay amount under the defined standard benefit and subtracting the patient pay amount under the OHI. In this example, the PLRO is -$5.00 ($25.00- $30.00). The Patient Pay Amount on the PDE would be $30.00.

PDE Fields	Patient Pay Amount	CPP	PLRO
	$30.00	$75.00	-$5.00

The Patient Pay amount field is TrOOP eligible; therefore, $30.00 is the TrOOP amount for this PDE.

If the beneficiary is LICS then the Part D sponsor will take the following steps to populate the PDE:

1. Determine beneficiary cost sharing.
2. Determine LICS based upon the patient pay compared to the LICS co-pay amount.
3. Determine PLRO based upon the OHI using the existing formula for determining PLRO.

If PLRO is negative, the negative PLRO offsets the LICS amount. In such instances, by having cost sharing in excess of the standard benefit, even though the coverage as a whole is required to be actuarially equivalent to or better than defined standard, the sponsor is electing to forego LICS because the sponsor did not subsidize the LIS beneficiary's cost sharing amount by charging the lower LIS copay amount.

The following two examples will illustrate the steps outlined above.

A low income beneficiary purchases a brand drug in the initial coverage phase. The low income beneficiary is a category two low income beneficiary in which the co-pay for a brand drug is $3.50. The cost of the drug is $100.00. In the initial coverage phase, a non-low income beneficiary would pay $25.00 for this drug.

Example 1: Under the OHI benefit, the beneficiary pays $40.00.

Step 1: In a defined standard benefit the beneficiary would pay $25.00.

Step 2: The LICS amount is the difference between the non-low income beneficiary amount ($25.00) and the category two co-pay amount ($3.50), which is $21.50.

Step 3: The beneficiary has OHI in which the co-pay is $40.00. To determine PLRO, the OHI patient pay amount ($40.00) is subtracted from the original patient pay amount ($3.50). The PLRO amount is −$36.50.

The negative PLRO will completely offset the LICS amount and LICS is adjusted to zero. PLRO is then adjusted using the following calculation: LICS + PLRO. In this example, PLRO will be $21.50 + - $36.50 = - $15.00.

PDE fields	Patient Pay Amount	CPP	PLRO	LICS
	$40.00	$75.00	-$15.00	$0.00

Patient pay ($40.00) and LICS ($0.00) are TrOOP eligible fields; therefore, the TrOOP amount for this PDE is $40.00.

Example 2: Under the OHI, the beneficiary pays $20.00.

Step 1: In a defined standard benefit the beneficiary would pay $25.00.

Step 2: The LICS amount is the difference between the non-low income beneficiary amount ($25.00) and the category two co-pay amount ($3.50), which is $21.50.

Step 3: The beneficiary has OHI in which the co-pay is $20.00. To determine PLRO, the OHI patient pay amount ($20.00) is subtracted from the original patient pay amount ($3.50). The PLRO amount is −$16.50.

The negative PLRO offsets a portion of the LICS amount. The updated LICS amount is calculated as $21.50 - $16.50 = $5.00. PLRO is zero.

PDE fields	Patient Pay Amount	CPP	PLRO	LICS
	$20.00	$75.00	$0.00	$5.00

Additional PDE examples will be provided in forthcoming guidance.

A4. Enhanced Alternative Plan Mapping Rule 4

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

As a result of the Affordable Care Act changes to the Defined Standard Benefit that began closing the coverage gap for non-applicable drugs in 2011 and begins closing the coverage gap for applicable drugs in 2013, CMS has been asked if EA Mapping Rule 4 will change. CMS is eliminating EA Mapping Rule 4 beginning in CY2014. EA sponsors are already being paid for the additional 15 percent through supplemental beneficiary premiums and more importantly, YTD Gross Covered Drug costs greater than the estimated total covered Part D spending at the OOP threshold when TrOOP is less than or equal to the OOP threshold are not allowable risk corridor costs under §1860D-15(e)(1)(B) of the Social Security Act. Therefore, we will no longer credit the additional amount as CPP so that our operational guidance for PDE reporting more accurately aligns with existing payment policy. EA plans will always use EA Mapping Rule 3 to map to the basic Part D benefit when a beneficiary has drug spend above the initial coverage limit but TrOOP is less than or equal to the OOP threshold.

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

Annual Percentage Increases

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

Part D Benefit Parameters

	2013	2014
Standard Benefit		
Deductible	$325	$310
Initial Coverage Limit	$2,970	$2,850
Out-of-Pocket Threshold	$4,750	$4,550
Total Covered Part D Spend at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,733.75	$6,455.00
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,954.52	$6,690.77
Minimum Cost sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries [category code 3]	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) [category code 3]	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL [category code 2]		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (2)	$1.15	$1.20
Other (2)	$3.50	$3.60
Above Out-of-Pocket Threshold	$0.00	$0.00
Over 100% FPL (category code 1)		
Up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		
Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $8,580 (individuals) or ≤ $13,620 (couples) (6)[category code 1]		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00

	2013	2014
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,300 (individual) or $26,580 (couples)(6)(category code 4)		
Deductible	$66.00	$63.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.65	$2.55
Other	$6.60	$6.35
Retiree Drug Subsidy Amounts		
Cost Threshold	$325	$310
Cost Limit	$6,600	$6,350

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.
(2) For beneficiaries who are not considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are not eligible for the coverage gap program, this is the amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.
(3) For beneficiaries who are considered an "applicable beneficiary" as defined at section 1860D-14A(g)(1) and are eligible for the coverage gap discount program, this is the estimated average amount of total drug spending required to reach the out-of-pocket threshold in the defined standard benefit. Enhanced alternative plans must use this value when mapping enhanced alternative plans to the defined standard benefit for the purpose of calculating covered plan paid amounts (CPP) reported on prescription drug event (PDE) records.
(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (couple) was not receiving home and community-based services qualify for zero cost sharing as of January 1, 2013, as specified by the Secretary.
(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2013 values of $66.14, $1.16, and $3.49, respectively.
(6) The actual amount of resources allowable will be updated for contract year 2014.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100 percent of the Federal poverty line. These copayments are increased from $1.15 per generic or preferred drug that is a multi-source drug, and $3.50 for all other drugs in 2013[2], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

Section C. Calculation Methodology

Annual Percentage Increase

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

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[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 2013 value of $66.14.

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

Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2014 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

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

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

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

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

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

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

Table IV-2. Annual Percentage Increase

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

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

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

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

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

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

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

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

Table IV-3. Cumulative Annual Percentage Increase in CPI

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

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

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

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

0.26 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 52.5 percent reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.13 percent to 97.37 percent in cost sharing for applicable (brand) drugs in the coverage gap.

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

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

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

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

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

Weighted gap coinsurance factor is calculated as follows:

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

or

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

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

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

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

  or

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

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

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

Section E. Retiree Drug Subsidy Amounts

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

Attachment VII. CMS-HCC and RxHCC Risk Adjustment Factors

Table 1. 2014 CMS-HCC Model Relative Factors for Community and Institutional Beneficiaries

Variable		Community	Institutional
Female			
0-34 Years		0.197	1.169
35-44 Years		0.205	0.949
45-54 Years		0.263	0.915
55-59 Years		0.326	0.981
60-64 Years		0.392	0.986
65-69 Years		0.288	1.237
70-74 Years		0.348	1.145
75-79 Years		0.437	1.033
80-84 Years		0.539	0.922
85-89 Years		0.677	0.836
90-94 Years		0.815	0.705
95 Years or Over		0.840	0.533
Male			
0-34 Years		0.121	1.162
35-44 Years		0.124	0.894
45-54 Years		0.181	0.910
55-59 Years		0.269	0.951
60-64 Years		0.311	1.081
65-69 Years		0.288	1.388
70-74 Years		0.356	1.431
75-79 Years		0.442	1.391
80-84 Years		0.543	1.327
85-89 Years		0.683	1.252
90-94 Years		0.848	1.076
95 Years or Over		1.028	0.948
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid_Female_Aged		0.151	0.067
Medicaid_Female_Disabled		0.085	0.067
Medicaid_Male_Aged		0.177	0.067
Medicaid_Male_Disabled		0.086	0.067
Originally Disabled_Female		0.239	0.013
Originally Disabled_Male		0.163	0.013
Disease Coefficients	**Description Label**		
HCC1	HIV/AIDS	0.470	1.904
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.535	0.575
HCC6	Opportunistic Infections	0.440	0.344
HCC8	Metastatic Cancer and Acute Leukemia	2.484	1.203
HCC9	Lung and Other Severe Cancers	0.973	0.674
HCC10	Lymphoma and Other Cancers	0.672	0.412
HCC11	Colorectal, Bladder, and Other Cancers	0.317	0.296
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.154	0.198
HCC17	Diabetes with Acute Complications	0.368	0.474
HCC18	Diabetes with Chronic Complications	0.368	0.474
HCC19	Diabetes without Complication	0.118	0.182
HCC21	Protein-Calorie Malnutrition	0.713	0.399
HCC22	Morbid Obesity	0.365	0.579

Variable		Community	Institutional
HCC23	Other Significant Endocrine and Metabolic Disorders	0.245	0.282
HCC27	End-Stage Liver Disease	0.923	1.083
HCC28	Cirrhosis of Liver	0.399	0.351
HCC29	Chronic Hepatitis	0.251	0.351
HCC33	Intestinal Obstruction/Perforation	0.310	0.384
HCC34	Chronic Pancreatitis	0.286	0.095
HCC35	Inflammatory Bowel Disease	0.302	0.318
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.498	0.340
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.374	0.351
HCC46	Severe Hematological Disorders	1.136	0.794
HCC47	Disorders of Immunity	0.521	0.519
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.252	0.164
HCC54	Drug/Alcohol Psychosis	0.420	0.053
HCC55	Drug/Alcohol Dependence	0.420	0.053
HCC57	Schizophrenia	0.490	0.311
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.330	0.311
HCC70	Quadriplegia	1.234	0.650
HCC71	Paraplegia	1.052	0.539
HCC72	Spinal Cord Disorders/Injuries	0.509	0.280
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.958	0.367
HCC74	Cerebral Palsy	0.045	-
HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	0.408	0.300
HCC76	Muscular Dystrophy	0.565	0.215
HCC77	Multiple Sclerosis	0.556	-
HCC78	Parkinson's and Huntington's Diseases	0.691	0.173
HCC79	Seizure Disorders and Convulsions	0.284	0.144
HCC80	Coma, Brain Compression/Anoxic Damage	0.570	0.104
HCC82	Respirator Dependence/Tracheostomy Status	1.520	1.769
HCC83	Respiratory Arrest	0.802	1.169
HCC84	Cardio-Respiratory Failure and Shock	0.329	0.442
HCC85	Congestive Heart Failure	0.368	0.229
HCC86	Acute Myocardial Infarction	0.275	0.515
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.258	0.515
HCC88	Angina Pectoris	0.141	0.474
HCC96	Specified Heart Arrhythmias	0.295	0.262
HCC99	Cerebral Hemorrhage	0.339	0.216
HCC100	Ischemic or Unspecified Stroke	0.317	0.216
HCC103	Hemiplegia/Hemiparesis	0.581	0.061
HCC104	Monoplegia, Other Paralytic Syndromes	0.396	0.061
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.413	0.886
HCC107	Vascular Disease with Complications	0.410	0.301
HCC108	Vascular Disease	0.299	0.107
HCC110	Cystic Fibrosis	0.417	0.364
HCC111	Chronic Obstructive Pulmonary Disease	0.346	0.364

Variable		Community	Institutional
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.274	0.260
HCC114	Aspiration and Specified Bacterial Pneumonias	0.672	0.285
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.200	0.285
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.203	0.433
HCC124	Exudative Macular Degeneration	0.335	0.166
HCC134	Dialysis Status	0.476	0.509
HCC135	Acute Renal Failure	0.476	0.509
HCC136	Chronic Kidney Disease (Stage 5)	0.224	0.509
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.224	0.294
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.488	1.050
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.338	0.435
HCC161	Chronic Ulcer of Skin, Except Pressure	0.536	0.311
HCC162	Severe Skin Burn or Condition	0.411	0.327
HCC166	Severe Head Injury	0.570	0.104
HCC167	Major Head Injury	0.163	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.497	0.228
HCC170	Hip Fracture/Dislocation	0.446	-
HCC173	Traumatic Amputations and Complications	0.265	0.122
HCC176	Complications of Specified Implanted Device or Graft	0.566	0.522
HCC186	Major Organ Transplant or Replacement Status	0.891	0.515
HCC188	Artificial Openings for Feeding or Elimination	0.651	0.594
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.779	0.468
Disease Interactions			
CANCER_IMMUNE	Cancer*Immune Disorders	0.947	-
CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	0.259	0.221
CHF_RENAL	Congestive Heart Failure*Renal Disease	0.317	-
COPD_CARD_RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	0.456	0.506
DIABETES_CHF	Diabetes*Congestive Heart Failure	0.182	0.189
SEPSIS_CARD_RESP_FAIL	Sepsis*Cardiorespiratory Failure	0.214	-
ARTIF_OPENINGS_ PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	-	0.282
ASP_SPEC_BACT_PNEUM_ PRES_ULCER	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	-	0.495
COPD_ASP_SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	-	0.319
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	-	0.212
SCHIZOPHRENIA_COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	-	0.389
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	-	0.452

Variable		Community	Institutional
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	-	0.553
SEPSIS_ASP_SPEC_ BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	-	0.339
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	-	0.522
Disabled/Disease Interactions			
DISABLED_HCC6	Disabled, Opportunistic Infections	0.451	-
DISABLED_HCC34	Disabled, Chronic Pancreatitis	0.548	-
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	-	0.383
DISABLED_HCC46	Disabled, Severe Hematological Disorders	1.347	-
DISABLED_HCC54	Disabled, Drug/Alcohol Psychosis	0.331	-
DISABLED_HCC55	Disabled, Drug/Alcohol Dependence	-	-
DISABLED_HCC77	Disabled, Multiple Sclerosis	-	0.407
DISABLED_HCC85	Disabled, Congestive Heart Failure	-	0.441
DISABLED_HCC110	Disabled, Cystic Fibrosis	2.415	-
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	-	0.430
DISABLED_HCC176	Disabled, Complications of Specified Implanted Device or Graft	0.503	-
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer	-	0.270

Notes:

1. The denominator is $9,276.26.
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Sepsis = HCC 2.
   Opportunistic Infections = HCC 6.
   Cancer = HCCs 8-12.
   Diabetes = HCCs 17, 18, 19.
   Bone/Joint/Muscle Infections/Necrosis = HCC 39.
   Immune Disorders = HCC 47.
   Schizophrenia = HCC 57.
   Multiple Sclerosis = HCC 77.
   Seizure Disorders and Convulsions = HCC 79.
   Cardiorespiratory Failure = HCCs 82-84.
   Congestive Heart Failure = HCC 85.
   Chronic Obstructive Pulmonary Disease = HCCs 110-111.
   Aspiration and Specified Bacterial Pneumonias = HCC 114.
   Renal Disease = HCCs 134-137.
   Pressure Ulcer = HCCs 157-158. HCCs 159-160 are no longer included in the pressure ulcer interaction terms.
   Chronic Ulcer of Skin, except Pressure = HCC 161.
   Artificial Openings for Feeding or Elimination = HCC 188.

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

Table 2. 2014 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	0.677	0.912	-	-
35-44 Years	0.827	1.092	-	-
45-54 Years	0.908	1.252	-	-
55-59 Years	0.971	1.323	-	-
60-64 Years	1.123	1.434	-	-
65 Years	0.510	1.031	1.169	1.491
66 Years	0.504	0.980	1.228	1.642
67 Years	0.535	0.980	1.228	1.642
68 Years	0.570	0.980	1.228	1.642
69 Years	0.627	0.980	1.228	2.118
70-74 Years	0.673	0.984	1.228	2.118
75-79 Years	0.857	1.159	1.228	2.118
80-84 Years	0.972	1.434	1.228	2.118
85-89 Years	1.237	1.617	1.228	2.118
90-94 Years	1.237	1.617	1.228	2.118
95 Years or Over	1.237	1.617	1.228	2.118
Male				
0-34 Years	0.422	0.773	-	-
35-44 Years	0.610	1.024	-	-
45-54 Years	0.796	1.288	-	-
55-59 Years	0.845	1.467	-	-
60-64 Years	0.884	1.536	-	-
65 Years	0.515	1.163	0.873	1.601
66 Years	0.522	1.058	0.934	1.601
67 Years	0.581	1.208	0.934	2.164
68 Years	0.647	1.208	1.244	2.164
69 Years	0.679	1.208	1.244	2.164
70-74 Years	0.783	1.208	1.244	2.164
75-79 Years	1.036	1.388	1.244	2.164
80-84 Years	1.303	1.743	1.244	2.164
85-89 Years	1.507	1.891	1.244	2.164
90-94 Years	1.507	1.891	1.244	2.164
95 Years or Over	1.507	1.891	1.244	2.164

Notes:

1. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
2. The denominator is $9,276.26.

Table 3. 2014 CMS-HCC Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.383	1.433	-	-
35-44 Years	1.383	1.433	-	-
45-54 Years	1.383	1.788	-	-
55-59 Years	1.485	1.889	-	-
60-64 Years	1.582	1.950	-	-
65 Years	0.927	1.497	1.672	2.103
66 Years	0.927	1.497	1.672	2.103
67 Years	0.998	1.547	1.675	2.124
68 Years	0.998	1.547	1.675	2.124
69 Years	0.998	1.547	1.675	2.124
70-74 Years	1.173	1.686	1.859	2.346
75-79 Years	1.395	1.876	1.970	2.464
80-84 Years	1.589	2.065	2.252	2.642
85-89 Years	1.813	2.309	2.252	2.642
90-94 Years	1.813	2.309	2.252	2.642
95 Years or Over	1.813	2.309	2.252	2.642
Male				
0-34 Years	1.314	1.326	-	-
35-44 Years	1.314	1.326	-	-
45-54 Years	1.380	1.740	-	-
55-59 Years	1.495	1.910	-	-
60-64 Years	1.526	1.922	-	-
65 Years	0.957	1.617	1.604	2.116
66 Years	0.957	1.617	1.604	2.116
67 Years	1.010	1.651	1.653	2.189
68 Years	1.010	1.651	1.653	2.189
69 Years	1.010	1.651	1.653	2.189
70-74 Years	1.220	1.872	1.827	2.344
75-79 Years	1.431	1.962	1.939	2.547
80-84 Years	1.677	2.186	2.181	2.547
85-89 Years	1.936	2.439	2.181	2.547
90-94 Years	1.936	2.439	2.181	2.547
95 Years or Over	1.936	2.439	2.181	2.547

Notes:

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

Source: RTI analysis of 2010-2011 Medicare C-SNP community continuing enrollees.

Table 4. Disease Hierarchies for the 2014 CMS-HCC Model

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

How Payments are Made with a Disease Hierarchy -- EXAMPLE: If a beneficiary triggers Disease Groups 135 (Acute Renal Failure) and 136 (Chronic Kidney Disease (Stage 5)), then DG 136 will be dropped. In other words, payment will always be associated with the HCC in column 1, if a HCC in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on HCC 135 rather than HCC 136.

Table 5. Comparison of 2013 and 2014 CMS-HCC Risk Adjustment Model HCCs

2013 CMS-HCC Model (with 70 HCCs)		2014 CMS-HCC Model (with 79 HCCs)		
HCC	**Description**	**HCC**	**Description**	**Category Short Name**
HCC1	HIV/AIDS	HCC1	HIV/AIDS	Infection
HCC2	Septicemia/Shock	HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	
HCC5	Opportunistic Infections	HCC6	Opportunistic Infections	
HCC7	Metastatic Cancer and Acute Leukemia	HCC8	Metastatic Cancer and Acute Leukemia	Neoplasm
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	HCC9	Lung and Other Severe Cancers	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	HCC10	Lymphoma and Other Cancers	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	HCC11	Colorectal, Bladder, and Other Cancers	
		HCC12	Breast, Prostate, and Other Cancers and Tumors	
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	HCC17	Diabetes with Acute Complications	Diabetes
HCC16	Diabetes with Neurologic or Other Specified Manifestation	HCC18	Diabetes with Chronic Complications	
HCC17	Diabetes with Acute Complications	HCC19	Diabetes without Complication	
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation			
HCC19	Diabetes without Complication			
HCC21	Protein-Calorie Malnutrition	HCC21	Protein-Calorie Malnutrition	Metabolic
		HCC22	Morbid Obesity	
		HCC23	Other Significant Endocrine and Metabolic Disorders	
HCC25	End-Stage Liver Disease	HCC27	End-Stage Liver Disease	Liver
HCC26	Cirrhosis of Liver	HCC28	Cirrhosis of Liver	
HCC27	Chronic Hepatitis	HCC29	Chronic Hepatitis	
HCC31	Intestinal Obstruction/Perforation	HCC33	Intestinal Obstruction/Perforation	Gastrointestinal
HCC32	Pancreatic Disease	HCC34	Chronic Pancreatitis	
HCC33	Inflammatory Bowel Disease	HCC35	Inflammatory Bowel Disease	
HCC37	Bone/Joint/Muscle Infections/Necrosis	HCC39	Bone/Joint/Muscle Infections/Necrosis	Musculoskeletal
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	

2013 CMS-HCC Model (with 70 HCCs)		2014 CMS-HCC Model (with 79 HCCs)		
HCC	**Description**	**HCC**	**Description**	**Category Short Name**
HCC44	Severe Hematological Disorders	HCC46	Severe Hematological Disorders	Blood
HCC45	Disorders of Immunity	HCC47	Disorders of Immunity	
		HCC48	Coagulation Defects and Other Specified Hematological Disorders	
HCC51	Drug/Alcohol Psychosis	HCC54	Drug/Alcohol Psychosis	Substance Abuse
HCC52	Drug/Alcohol Dependence	HCC55	Drug/Alcohol Dependence	
HCC54	Schizophrenia	HCC57	Schizophrenia	Psychiatric
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	HCC58	Major Depressive, Bipolar, and Paranoid Disorders	
HCC67	Quadriplegia, Other Extensive Paralysis	HCC70	Quadriplegia	Spinal
HCC68	Paraplegia	HCC71	Paraplegia	
HCC69	Spinal Cord Disorders/Injuries	HCC72	Spinal Cord Disorders/Injuries	
HCC70	Muscular Dystrophy	HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	Neurological
HCC71	Polyneuropathy	HCC74	Cerebral Palsy	
HCC72	Multiple Sclerosis	HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	
HCC73	Parkinson's and Huntington's Diseases	HCC76	Muscular Dystrophy	
HCC74	Seizure Disorders and Convulsions	HCC77	Multiple Sclerosis	
HCC75	Coma, Brain Compression/Anoxic Damage	HCC78	Parkinson's and Huntington's Diseases	
		HCC79	Seizure Disorders and Convulsions	
		HCC80	Coma, Brain Compression/Anoxic Damage	
HCC77	Respirator Dependence/Tracheostomy Status	HCC82	Respirator Dependence/Tracheostomy Status	Arrest
HCC78	Respiratory Arrest	HCC83	Respiratory Arrest	
HCC79	Cardio-Respiratory Failure and Shock	HCC84	Cardio-Respiratory Failure and Shock	
HCC80	Congestive Heart Failure	HCC85	Congestive Heart Failure	Heart
HCC81	Acute Myocardial Infarction	HCC86	Acute Myocardial Infarction	
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	
HCC83	Angina Pectoris/Old Myocardial Infraction	HCC88	Angina Pectoris	
HCC92	Specified Heart Arrhythmias	HCC96	Specified Heart Arrhythmias	

2013 CMS-HCC Model (with 70 HCCs)		2014 CMS-HCC Model (with 79 HCCs)		
HCC	**Description**	**HCC**	**Description**	**Category Short Name**
HCC95	Cerebral Hemorrhage	HCC99	Cerebral Hemorrhage	Cerebrovascular Disease
HCC96	Ischemic or Unspecified Stroke	HCC100	Ischemic or Unspecified Stroke	
HCC100	Hemiplegia/Hemiparesis	HCC103	Hemiplegia/Hemiparesis	
HCC101	Cerebral Palsy and Other Paralytic Syndromes	HCC104	Monoplegia, Other Paralytic Syndromes	
HCC104	Vascular Disease with Complications	HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	Vascular
HCC105	Vascular Disease	HCC107	Vascular Disease with Complications	
		HCC108	Vascular Disease	
HCC107	Cystic Fibrosis	HCC110	Cystic Fibrosis	Lung
HCC108	Chronic Obstructive Pulmonary Disease	HCC111	Chronic Obstructive Pulmonary Disease	
HCC111	Aspiration and Specified Bacterial Pneumonias	HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	HCC114	Aspiration and Specified Bacterial Pneumonias	
		HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	Eye
		HCC124	Exudative Macular Degeneration	
HCC130	Dialysis Status	HCC134	Dialysis Status	Kidney
HCC131	Renal Failure	HCC135	Acute Renal Failure	
HCC132	Nephritis	HCC136	Chronic Kidney Disease (Stage 5)	
HCC148	Decubitus Ulcer of Skin	HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	Skin
HCC149	Chronic Ulcer of Skin, Except Decubitus	HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	
HCC150	Extensive Third-Degree Burns	HCC161	Chronic Ulcer of Skin, Except Pressure	
		HCC162	Severe Skin Burn or Condition	
HCC154	Severe Head Injury	HCC166	Severe Head Injury	Injury
HCC155	Major Head Injury	HCC167	Major Head Injury	
HCC157	Vertebral Fractures w/o Spinal Cord Injury	HCC169	Vertebral Fractures without Spinal Cord Injury	
HCC158	Hip Fracture/Dislocation	HCC170	Hip Fracture/Dislocation	
HCC161	Traumatic Amputation	HCC173	Traumatic Amputations and Complications	
HCC164	Major Complications of Medical Care and Trauma	HCC176	Complications of Specified Implanted Device or Graft	Complications
HCC174	Major Organ Transplant Status	HCC186	Major Organ Transplant or Replacement Status	Transplant

2013 CMS-HCC Model (with 70 HCCs)		2014 CMS-HCC Model (with 79 HCCs)		
HCC	**Description**	**HCC**	**Description**	**Category Short Name**
HCC176	Artificial Openings for Feeding or Elimination	HCC188	Artificial Openings for Feeding or Elimination	Openings
HCC177	Amputation Status, Lower Limb/Amputation Complications	HCC189	Amputation Status, Lower Limb/Amputation Complications	Amputation
Community Model Interactions				
D_HCC5	Disabled_Opportunistic Infections	D_HCC6	Disabled, Opportunistic Infections	**Disabled/ Disease Interactions**
D_HCC44	Disabled_Severe Hematological Disorders	D_HCC34	Disabled, Chronic Pancreatitis	
D_HCC51	Disabled_Drug/Alcohol Psychosis	D_HCC46	Disabled, Severe Hematological Disorders	
D_HCC52	Disabled_Drug/Alcohol Dependence	D_HCC54	Disabled, Drug/Alcohol Psychosis	
D_HCC107	Disabled_Cystic Fibrosis	D_HCC55	Disabled, Drug/Alcohol Dependence	
		D_HCC110	Disabled, Cystic Fibrosis	
		D_HCC176	Disabled, Complications of Specified Implanted Device or Graft	
INT1	DM_CHF	SEPSIS_CARD_ RESP_FAIL	Sepsis*Cardiorespiratory Failure	**Disease Interactions**
INT2	DM_CVD	CANCER_ IMMUNE	Cancer*Immune Disorders	
INT3	CHF_COPD	DIABETES_CHF	Diabetes*Congestive Heart Failure	
INT4	COPD_CVD_CAD	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	
INT5	RF_CHF	CHF_RENAL	Congestive Heart Failure*Renal Disease	
INT6	RF_CHF_DM	COPD_CARD_ RESP_FAIL	Chronic Obstructive Pulmonary Disease*Cardiorespiratory Failure	
Institutional Model Interactions				
D_HCC5	Disabled_Opportunistic Infections	D_HCC85	Disabled, Congestive Heart Failure	**Disabled/ Disease Interactions**
D_HCC44	Disabled_Severe Hematological Disorders	D_PRESSURE_ ULCER	Disabled, Pressure Ulcer	
D_HCC51	Disabled_Drug/Alcohol Psychosis	D_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	
D_HCC52	Disabled_Drug/Alcohol Dependence	D_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	
D_HCC107	Disabled_Cystic Fibrosis	D_HCC77	Disabled, Multiple Sclerosis	
		D_HCC6	Disabled, Opportunistic Infections	

2013 CMS-HCC Model (with 70 HCCs)		2014 CMS-HCC Model (with 79 HCCs)		
HCC	**Description**	**HCC**	**Description**	**Category Short Name**
DM_CHF1	Diabetes_Congestive Heart Failure	CHF_COPD	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease	**Disease Interactions**
DM_CVD_	Diabetes_Cerebrovascular Disease	COPD_CARD_ RESP_FAIL	Chronic Obstructive Pulmonary Disease *Cardiorespiratory Failure	
CHF_COPD	Congestive Heart Failure_Chronic Obstructive Pulmonary Disease	SEPSIS_ PRESSURE_ ULCER	Sepsis*Pressure Ulcer	
COPD_CVD_ CAD_	Chronic Obstructive Pulmonary Disease_Cerebrovascular Disease_Coronary Artery Disease	SEPSIS_ARTIF_ OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	
RF_CHF1	Renal Failure_Congestive Heart Failure	ART_OPENINGS_ PRESSURE_ ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	
RF_CHF_DM	Renal Failure_Congestive Heart Failure_Diabetes	DIABETES_CHF	Diabetes*Congestive Heart Failure	
		COPD_ASP_ SPEC_ BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	
		ASP_SPEC_ BACT_PNEUN PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	
		SEPSIS_ASP_ SPEC_BACT_ PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	
		SCHIZOPHRENIA _COPD	Schizophrenia*Chronic Obstructive Pulmonary Disease	
		SCHIZOPHRENIA _CHF	Schizophrenia*Congestive Heart Failure	
		SCHIZOPHRENIA _SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	

Source: RTI International.

Table 6. RxHCC Model Relative Factors for Continuing Enrollees

Continuing Enrollee (CE) RxHCC Model Segments

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

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC11	Prostate and Other Cancers and Tumors	0.011	0.021	0.072	0.030	0.026
RXHCC14	Diabetes with Complications	0.276	0.211	0.344	0.341	0.289
RXHCC15	Diabetes without Complication	0.184	0.151	0.255	0.261	0.204
RXHCC18	Diabetes Insipidus and Other Endocrine and Metabolic Disorders	0.402	1.012	0.358	0.815	0.115
RXHCC19	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.056	0.074	0.021	0.065	0.066
RXHCC20	Thyroid Disorders	0.046	0.093	0.056	0.110	0.047
RXHCC21	Morbid Obesity	0.045	-	0.038	0.026	0.094
RXHCC23	Disorders of Lipoid Metabolism	0.101	0.097	0.150	0.181	0.078
RXHCC25	Chronic Viral Hepatitis	0.138	0.171	0.285	0.190	0.016
RXHCC30	Chronic Pancreatitis	0.113	0.061	0.055	0.065	0.041
RXHCC31	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.060	0.056	0.055	0.065	0.041
RXHCC32	Inflammatory Bowel Disease	0.289	0.216	0.210	0.397	0.122
RXHCC33	Esophageal Reflux and Other Disorders of Esophagus	0.088	0.074	0.136	0.151	0.069
RXHCC38	Aseptic Necrosis of Bone	0.063	0.115	0.061	0.196	0.122
RXHCC40	Psoriatic Arthropathy	0.338	0.460	0.736	1.252	0.558
RXHCC41	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.161	0.210	0.222	0.420	0.103
RXHCC42	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.133	0.210	0.165	0.255	0.101
RXHCC45	Osteoporosis, Vertebral and Pathological Fractures	0.042	0.126	0.121	0.156	-
RXHCC47	Sickle Cell Anemia	0.111	0.244	0.043	0.614	0.320
RXHCC48	Myelodysplastic Syndromes, Except High-Grade	0.259	0.389	0.316	0.321	0.343
RXHCC49	Immune Disorders	0.183	0.211	0.198	0.226	0.148
RXHCC50	Aplastic Anemia and Other Significant Blood Disorders	0.030	0.027	0.025	0.087	0.025
RXHCC54	Alzheimer`s Disease	0.453	0.229	0.245	0.151	-
RXHCC55	Dementia, Except Alzheimer`s Disease	0.232	0.127	0.100	0.020	-
RXHCC58	Schizophrenia	0.341	0.429	0.551	0.861	0.341
RXHCC59	Bipolar Disorders	0.301	0.310	0.355	0.564	0.291
RXHCC60	Major Depression	0.254	0.275	0.316	0.401	0.237
RXHCC61	Specified Anxiety, Personality, and Behavior Disorders	0.156	0.183	0.181	0.384	0.163
RXHCC62	Depression	0.118	0.142	0.122	0.215	0.134
RXHCC63	Anxiety Disorders	0.041	0.080	0.083	0.176	0.110
RXHCC65	Autism	0.156	0.260	0.406	0.509	0.163

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
RXHCC66	Profound or Severe Mental Retardation/Developmental Disability	0.062	0.260	0.403	0.325	-
RXHCC67	Moderate Mental Retardation/Developmental Disability	0.022	0.100	0.271	0.231	-
RXHCC68	Mild or Unspecified Mental Retardation/Developmental Disability	0.022	0.018	0.134	0.097	-
RXHCC71	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.187	0.266	0.175	0.404	0.052
RXHCC72	Spinal Cord Disorders	0.058	0.112	0.046	0.050	-
RXHCC74	Polyneuropathy	0.083	0.167	0.084	0.154	0.079
RXHCC75	Multiple Sclerosis	0.858	1.384	0.837	2.004	0.327
RXHCC76	Parkinson`s Disease	0.378	0.442	0.240	0.224	0.154
RXHCC78	Intractable Epilepsy	0.196	0.408	0.161	0.632	0.033
RXHCC79	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.108	0.094	0.054	0.172	-
RXHCC80	Convulsions	0.049	0.053	0.040	0.121	-
RXHCC81	Migraine Headaches	0.096	0.167	0.122	0.126	0.102
RXHCC83	Trigeminal and Postherpetic Neuralgia	0.073	0.143	0.103	0.130	0.110
RXHCC86	Pulmonary Hypertension and Other Pulmonary Heart Disease	0.248	0.513	0.303	0.458	0.128
RXHCC87	Congestive Heart Failure	0.152	0.081	0.257	0.116	0.127
RXHCC88	Hypertension	0.143	0.067	0.244	0.113	0.076
RXHCC89	Coronary Artery Disease	0.180	0.097	0.169	0.066	0.031
RXHCC93	Atrial Arrhythmias	0.069	0.039	0.017	-	0.021
RXHCC97	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.078	0.017	0.058	-	-
RXHCC98	Spastic Hemiplegia	0.159	0.187	0.070	0.133	0.035
RXHCC100	Venous Thromboembolism	-	0.035	-	0.088	0.022
RXHCC101	Peripheral Vascular Disease	0.054	0.051	0.102	0.060	-
RXHCC103	Cystic Fibrosis	0.237	1.285	0.272	1.778	0.163
RXHCC104	Chronic Obstructive Pulmonary Disease and Asthma	0.237	0.135	0.272	0.230	0.163
RXHCC105	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.127	0.135	0.108	0.230	0.038
RXHCC106	Gram-Negative/Staphylococcus Pneumonia and Other Lung Infections	-	0.011	-	-	0.020
RXHCC111	Diabetic Retinopathy	0.124	0.074	0.104	0.071	0.074
RXHCC113	Open-Angle Glaucoma	0.189	0.153	0.232	0.188	0.179
RXHCC120	Kidney Transplant Status	0.191	0.191	0.254	0.271	0.192
RXHCC121	Dialysis Status	0.131	0.196	0.240	0.522	0.203

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

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

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

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

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

Notes:

1. The Part D Denominator used to calculate relative factors is $1,182.35. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

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

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

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

Notes:

1. The Part D Denominator used to calculate relative factors is $1,182.35. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

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

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

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

Notes:

1. The Part D Denominator used to calculate relative factors is $1,182.35. This Part D Denominator is based on the combined PDP and MA-PD populations.

2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).

3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

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

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

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

Source: RTI International.

Attachment VIII. 2014 Call Letter

2014 Announcement
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Attachment VIII: Call Letter 2014

How to Use This Call Letter

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

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

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

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

Section I – Parts C and D

Annual Calendar

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

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

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
April 2013	Conference call with industry to discuss the 2014 Call Letter.	✓	✓	✓
April 2013	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	
April 1, 2013	2014 Final Call Letter released. Announce CY 2014 MA Capitation Rates and MA and Part D Payment Policies. *(Applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 3, 2013	Industry training on CY 2014 Formulary Submission	✓	✓	
April 5, 2013	Release of the 2014 Plan Benefit Package (PBP) online training module	✓	✓	✓
April 5, 2013	Release of the 2014 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓
April 22, 2013	Release of the 2014 Medication Therapy Management (MTM) Program Submission Module in HPMS.		✓	
May, 2013	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2013 will be available for all organizations.	✓	✓	
Early May, 2013	D-SNPs that applied to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications	✓		
May 2, 2013	CMS strongly encourages MA, MA-PD and PDP plans to notify us of its intention to non-renew a county (ies) for individuals, but continue the county (ies) for "800 series" EGWP members, convert to offering employer-only contracts, or reduce its service area at the contract level, by May 2, 2013. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓
May 6, 2013	2014 MTM Program submission deadline.		✓	
May 6, 2013	Medicare Advantage and Part D Spring Conference	✓	✓	
May 10, 2013	Release of the 2014 Bid Upload Functionality in HPMS	✓	✓	✓
May 13, 2013	Release of Health Plan System (HPMS) Formulary Submission Module	✓	✓	

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
May 31, 2013	2014 Formulary Submissions due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Transition Attestations due to CMS PA/ST Attestations due to CMS P&T Attestations due to CMS	✓	✓	
Late May/Early June, 2013	Release of the 2014 Medicare Marketing Guidelines in HPMS (Chapter 3 of the Medicare Managed Care Manual/Chapter 2 of the Prescription Drug Benefit Manual)	✓	✓	✓
Late May/June, 2013	CMS sends qualification determinations to applicants based on review of the 2014 applications for new contracts or service area expansions.	✓	✓	
Late May/June to Early September, 2013	CMS completes review and approval of 2014 bid data. Submit attestations, contracts, and final actuarial certifications.	✓	✓	✓
May 31, 2013	Release of the 2012 DIR Submission Module in HPMS.	✓	✓	
May 31, 2013	Plans / Part D Sponsors may begin to upload agent/broker compensation information in HPMS.	✓	✓	✓
May 31, 2013	Release of the 2014 Marketing Module in HPMS. Note: Plans / Part D Sponsors may begin to submit 2014 marketing materials.	✓	✓	✓
June 3, 2013	Deadline for submission of CY 2014 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans, "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2014 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for MA plans, MA-PD plans, PDPs and Medicare cost-based contractors and cost-based sponsors to submit a contract non-renewal, service area reduction notice to CMS for CY 2014. Deadline also applies to an MAO that intends to terminate a current MA and/or MA-PD plan benefit package (i.e., Plan 01, Plan 02) for CY 2014.	✓	✓	✓
June 7, 2013	Deadline for submitting Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, and Home Infusion file through HPMS.	✓	✓	✓
June 7, 2013	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)*	✓	✓	
June 24, 2013	Release of the CY 2014 Summary of Benefits (SB) hard copy change request module in HPMS.	✓	✓	

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
Late June, 2013	CMS sends an acknowledgement letter to all MA, MA-PD, PDP and Medicare cost-based plans that are non-renewing or reducing their service area.	✓	✓	✓
June 30, 2013	Final date to submit CY 2013 marketing materials to ensure timely CMS review and approval. NOTE: Plans/Part D Sponsors may continue to submit CY 2013 file and use materials as these may be filed in HPMS five calendar days prior to their use.	✓	✓	✓
Early July, 2013	2014 Plan Finder pricing test submissions begin	✓	✓	✓
July 1, 2013	Deadline for Dual Eligible SNPs to have uploaded their required State Medicaid Agency Contract and Contract Matrix to HPMS	✓	✓	✓
July 1, 2013	Deadline for Dual Eligible SNPs requesting to be reviewed as Fully Integrated Dual Eligible SNPs to submit their FIDE SNP Matrix to HPMS.	✓		
July 5, 2013	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓		
July 31, 2013	2014 MTM Program Annual Review completed.		✓	
Mid-Late July, 2013	CY 2014 Limited Formulary Update Window	✓	✓	
Late July, 2013	Submission deadline for agent/broker compensation information via HPMS.		✓	
Late July/Early August, 2013	CMS encourages cost-based plans to submit their summary of benefits (SBs) by this date so that materials can be reviewed and approved prior to the publishing of "Medicare Plan Finder" and the *Medicare & You* handbook. SBs must be submitted by this date to be assured of being included.	✓	✓	✓
Early August, 2013	CMS releases the 2014 Part D national average monthly bid amount, the Medicare Part D base beneficiary premium, the Part D regional low-income premium subsidy amounts, the Medicare Advantage regional PPO benchmarks, and the de minimis amount.	✓	✓	✓
Early August, 2013	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓
August 1, 2013	Plans are expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓
August 1, 2013	CMS informs currently contracted organizations of its decision to not renew a contract for 2014.	✓	✓	✓

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
August 22-26, 2013	First CY 2014 preview of the 2014 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	
August 28 – August 30, 2013	First CY 2014 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
Late August 2013	Contracting Materials submitted to CMS.	✓	✓	✓
End of August/Early September 2013	Plan preview periods of Star Ratings in HPMS.	✓	✓	✓
September 6, 2013	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2012 through June 30, 2013.	✓	✓	
Mid-September 2013	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓
Mid- September 2013	All 2014 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓		✓
September 10 - September13, 2013	Second CY 2014 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
September 16 – 30, 2013	CMS mails the 2014 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓
September 30, 2013	CY 2014 standardized, combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) is due to current members of all MA plans, MA-PD plans, PDPs and cost-based plans offering Part D. MA and MA-PD plans must ensure current members receive the combined ANOC/EOC by September 30. Plans have the option to include Pharmacy/Provider directories in this mailing. All plans offering Part D must mail their LIS riders and abridged or comprehensive formularies with the ANOC/EOC to ensure current member receipt by September 30. Note: With the exception of the ANOC/EOC, LIS Rider, directories, and abridged or comprehensive formularies, no additional materials may be sent prior October 1.	✓	✓	✓
Late September, 2013	D-SNPs that requested review for Fully Integrated Dual Eligible (FIDE) Special Needs Plan (SNP) determination notified as to whether they meet required qualifications.	✓		
Early October, 2013	Release of the online CY 2014 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs)	✓	✓	✓

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D Sponsors**	**Cost**
October 1, 2013	Organizations may begin marketing their CY 2014 plan benefits. Note: Once an organization begins marketing CY 2014 plans, the organization must cease marketing CY 2013 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2013 materials upon request, conduct one-on-one sales appointments and process enrollment applications.	✓	✓	✓
October 1, 2013	Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request a plan correction to the plan benefit package (PBP) via HPMS. Deadline for Part D sponsors, cost-based, MA and MA-PD organizations to request any SB hard copy change.	✓	✓	✓
October 1, 2013	Tentative date for 2014 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
October 2, 2013	The final personalized beneficiary non-renewal notification letter must be received by PDPs, MA plan, MA-PD plans, and cost-based plan enrollees. PDPs, MA plans, MA-PD plans, and Medicare cost-based organizations may not market to beneficiaries of non-renewing plans until after October 2, 2013.	✓	✓	✓
October 8, 2013	Star Ratings go live on medicare.gov on or around October 8, 2013.	✓	✓	✓
October 15, 2013	Part D sponsors must post PA and ST criteria on their websites for the 2014 contract year.	✓	✓	
October 15, 2013	2014 Annual Election Period begins. All organizations/sponsors must hold open enrollment (for EGWPs, see Chapter 2 of the Medicare Managed Care Manual, Section 30.1).	✓	✓	
November 9, 2013	Notices of Intent to Apply (NOIA) for CY 2015 due for MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	
Late November, 2013	Display measures data are posted in HPMS for plan preview.	✓	✓	✓
Late November, 2013	2014 Readiness Assessment due to CMS	✓	✓	✓
November – December, 2013	CMS issues "close out" information and instructions to MA plans, MA-PD plans, PDPs, and cost-based plans that are non-renewing or reducing service areas.	✓	✓	
December 1, 2013	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.	✓	✓	✓

2014*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D Sponsors also apply to MA and cost-based plans offering a Part D benefit.		*Part C	*Part D Sponsors	Cost
December 1, 2013	Cost-based plans must publish notice of non-renewal.			✓
December 7, 2013	End of the Annual Election Period.	✓	✓	
Mid- December, 2013	Display measures data on CMS.GOV updated.	✓	✓	✓
2014				
January 1, 2014	Plan Benefit Period Begins	✓	✓	✓
January 1 – February 14, 2014	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓		
Early January 2014	Release of CY 2015 MAO/MA-PD/PDP/SAE/EGWP applications.	✓	✓	
Mid-January, 2014	Industry training on CY 2015 applications.	✓	✓	✓
January 31, 2014	Final Submission deadline for risk adjustment data with dates of service January 1, 2012 through December 31, 2012.	✓	✓	✓
Late February 2014	Applications due for CY 2015.	✓	✓	✓
March 7, 2014	Initial Submission deadline for risk adjustment data with dates of service January 1, 2013 through December 31, 2013	✓	✓	✓
September 5, 2014	Initial Submission deadline for risk adjustment data with dates of service from July 1, 2013 through June 30, 2014	✓	✓	✓

Plan Corrections

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

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

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

Incomplete Bid Submissions

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

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

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

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

The Health Plan Management System (HPMS) Bid Upload functionality, made available each May, allows all organizations to submit each required component of their bids well in advance of the deadline and reporting tools track those components which were successfully submitted and which are still outstanding. Given the resources available to organizations to monitor and verify the status of bid submissions, CMS expects that all components of a bid will be submitted successfully and accurately by the submission deadline.

All organizations are expected to contact CMS about any technical upload or validation errors well in advance of the bid submission deadline. CMS may give consideration to late submissions in rare situations if the late submission is the result of a technical issue beyond the Organization's control. All organizations should ensure that appropriate personnel are available

both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that are preventing the bid from proceeding to desk review.

Formulary Submission Deadline

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

The decision to change the CY 2014 formulary submission window and deadline was made after consideration was given to the valuable feedback CMS received from Part D plan sponsors with respect to the proposed changes. We have evaluated the impact of the formulary submission deadline date change with respect to Formulary Reference File (FRF) release dates, formulary submission windows, and the Part D out-of-pocket cost (OOPC) analyses. CMS released the first CY 2014 FRF in March 2013. The March FRF release will be used in the production of the OOPC model tool, scheduled to be released in April 2013, in order to assist plan sponsors in meeting meaningful difference and MA total beneficiary cost requirements prior to bid submission. Sponsors should note that the OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below.

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

CMS notes that there will be a change in the current formulary submission process beginning for CY 2014, as follows: while CMS will continue to offer a summer formulary update, formulary changes during this particular update submission will be limited to: 1) the addition of drugs that are new to the summer release of the FRF (historically posted in July); and 2) the submission of negative changes on brand drugs, only if the equivalent generic is added to the summer FRF and corresponding formulary file. Thus, plan sponsors need to carefully consider any newly added drugs on the May release of the FRF 2014, since additional limitations will be imposed on the summer formulary update window, as noted in the December 19, 2012 HPMS Memo entitled "CY 2014 Formulary Submission Deadline."

Star Ratings Changes

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

In November 2012, CMS sent out a Request for Comments to Part C and D sponsors, stakeholders, and advocates that described CMS' proposed methodology for the 2014 Star Ratings and beyond for Medicare Advantage (MA) and Prescription Drug Plans (PDP). The purpose of this comment period was to provide plans and advocates with additional notice of the methodology so that CMS could identify any needed changes in advance of the Call Letter. We received approximately 80 comment letters. We incorporated this feedback in developing the enhancements proposed in the draft Call Letter. Based on the feedback received, we are making changes to methodologies on current measures, but we are not introducing new measures for 2014. Appendix 5 contains a summary of the comments received on the draft Call Letter and CMS' response. As announced in previous years, we will annually review the quality of the data across all measures, variation among contracts, and the measures' accuracy and validity before making a final determination about inclusion of measures in the Star Ratings.

Changes to the Methodology of Current Measures

CMS is modifying the methodology for the following measures:

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

- *Quality Improvement (Part C and D).* CMS' methodology currently includes a hold harmless provision for contracts with overall ratings of 4 or more stars that would have their overall rating decreased with the addition of the improvement measure(s). CMS is modifying the methodology so contracts are also held harmless if their individual measure stars are 5 stars in the two years being evaluated for improvement. That is, if a contract receives 5 stars in an individual measure for the two years being measured, and demonstrates a statistically significant decline (at the 0.05 significance level) on the eligible measure, then this measure will not be included in the contract's improvement

measure calculation. Contracts must have data for at least half of the eligible measures used to calculate the improvement score to be eligible for the improvement measure. Measures that are held harmless as described here will be included in the count of eligible measures used to determine eligibility for the measure. Improvement scores of 0 (equivalent to no net change on the eligible measures included in the improvement calculation) will receive 3 stars when assigning the star ratings for the improvement measure.

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

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

  - The original PQA HRM list (i.e. the one used for the 2013 Star Ratings) will continue to be applied to calculate the HRM measure for the 2014 Star Ratings using 2012 Prescription Drug Event (PDE) data.
  - The updated PQA HRM list, based on the AGS recommendations to the Beer's List, will be applied to calculate the HRM measure for the 2015 Star Ratings using 2013 PDE data.
  - Since CMS began using the updated PQA HRM medication list to calculate the 2012 HRM rates provided to contracts via the Patient Safety Analysis Website in August 2012, CMS will redesign the reports to also include 2012 HRM rates

using the original PQA HRM list. The timing for the revised reports is still being determined. We also anticipate releasing 2013 reports by May of 2013.

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

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

- *Rounding of measure data.* CMS will round measure data and cut points used for CMS' Star Ratings (including Part D Patient Safety measures) to whole numbers, in order to avoid small differences in decimal values that result in differences in performance ratings, except for the following measures: Part C and D Complaints about the Health and Drug Plan measures, Health and Drug Plan Quality Improvement measures, and Part D Appeals Auto-Forward. For the measures rounded to whole numbers, we will use standard rounding rules where raw measure scores that end in less than 0.50 are rounded

down and raw measure scores that end in 0.50 or more are rounded up. The Complaints measures are rounded to two decimal points, the Improvement measures are rounded to three decimal points and Part D Appeals Auto-forward is rounded to one decimal point. The rounding discussed here does not apply to the overall and summary ratings.

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

Four Star Thresholds

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

In the draft Call Letter, CMS proposed additional pre-set 4-star thresholds for measures that have been part of the Star Ratings for at least two years based on the historical data. We are delaying the setting of any new pre-set 4-star thresholds for the 2014 Star Ratings based on feedback received from sponsors on the changes to the overall rating methodology. CMS is concerned that pre-setting 4-star thresholds could contribute to potential misclassification. We are not establishing any new pre-set 4-star thresholds for the 2014 Star Ratings while we complete a more comprehensive analysis of the impact of the pre-set 4-star thresholds.

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

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

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

Table 1: Revised Pre-set Thresholds for 2015 Star Ratings

Measure	**2015 4-star Threshold**
Cardiovascular Care- Cholesterol Screening	≥ 87%
Controlling Blood Pressure	≥ 65%
Diabetes Treatment	MA-PDs ≥ 87%; PDPs ≥ 84%
Medication Adherence for Diabetes Medications	MA-PDs ≥ 78%; PDPs ≥ 79%
Medication Adherence for Hypertension (RAS antagonists)	MA-PDs ≥ 79%; PDPs ≥ 81%
Medication Adherence for Cholesterol (Statins)	MA-PDs ≥ 74%; PDPs ≥ 76%

Changes in the Calculation of the Overall Rating and the Part C and D Summary Ratings
In constructing Star Ratings for public reporting and the Quality Bonus Payment (QBP) program, a key concern is the possibility of generating Star Ratings that do not reflect a contract's "true" performance. This possibility is called the risk of "misclassifying" a contract (e.g., scoring a "true" 4-star contract as a 3-star contract). Additionally, beginning with the 2015 Star Ratings, CMS intends to propose the inclusion of low-enrollment contracts in the Star Rating program. The change discussed here becomes more critical in 2015 since the risk of performance misclassification for all contracts increases when including low-enrollment contracts. To address this issue, CMS has been evaluating several analytic strategies in order to determine an approach to mitigate the risk of misclassification. There were a number of comments to the draft Call Letter on the proposed change to the calculation of the overall rating and Part C and D summary ratings, including requests for additional clarifications and a delay in implementation.

Currently, the plans' overall/summary ratings are calculated by averaging the individual measures' stars rather than the underlying scores that plans achieve on each of the measures. By using the average of the individual measure stars, we lose information about the actual performance on the individual measures. In the draft Call Letter, CMS had proposed a new method for computing the overall/summary ratings that would have averaged the underlying measures' scores. The new method would improve the correspondence between a plan's true

performance in measures and its overall/summary stars by directly averaging the unrounded underlying individual measure scores. By avoiding "rounding" of performance, CMS' proposal would improve the precision of the calculation of plans' overall ratings and avoid potential misclassification of plans.

As we have looked at issues around the precision of the overall rating calculations, CMS is concerned that the pre-set 4-star thresholds may also be contributing to the issue. CMS has decided to delay implementing modifications to the calculation of the overall/summary ratings until additional research can be done. Thus, the same methodology used in prior years to calculate the overall/summary ratings will be used for the 2014 Star Ratings. If we intend to change the overall rating methodology in future years, we will give advance notice to plans on the proposed methodology. We hope to present the results of our additional research to plans this summer. We will also help plans understand the impact of the proposed changes by calculating what their revised overall rating would be under a new methodology as part of an HPMS preview.

Low Performer Icon

CMS currently assigns the Low Performer Icon (LPI) to contracts receiving less than 3 stars for their Part C or Part D summary ratings for the last 3 consecutive years. Concerns have been raised by stakeholders over this definition, specifically that an MA-PD contract under the current definition may switch back and forth from poor performance in Part C to poor performance in Part D from year to year and these contracts will not receive the LPI for poor performance. For example, under the current methodology, a contract can avoid being assigned the LPI if they previously had three years of low performance (2.5 stars or lower) on Part C but raised it to 3 stars in the current year, although they may have one or more years of low performance on Part D. In order to avoid providing potentially misleading information to beneficiaries, as well as creating inequality in CMS' monitoring and outreach activities for LPI contracts, starting with the 2014 Star Ratings CMS will assign the LPI to any MA-PD contract receiving 2.5 stars or lower for any combination of their Part C or their Part D summary ratings for three consecutive years. Contracts are responsible for providing adequate care and services across both Part C and D. This change will encourage consistent improvement in the quality of care across all of the Part C and D measures for MA-PD contracts.

Weighting Categories of Measures

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

Table 2: Part C Measure Weights

Measure Name	Weighting Category	Part C Summary	MA-PD Overall
Breast Cancer Screening	Process Measure	1	1
Colorectal Cancer Screening	Process Measure	1	1
Cardiovascular Care – Cholesterol Screening	Process Measure	1	1
Diabetes Care – Cholesterol Screening	Process Measure	1	1
Glaucoma Testing	Process Measure	1	1
Annual Flu Vaccine	Process Measure	1	1
Improving or Maintaining Physical Health	Outcome Measure	3	3
Improving or Maintaining Mental Health	Outcome Measure	3	3
Monitoring Physical Activity	Process Measure	1	1
Adult BMI Assessment	Process Measure	1	1
Care for Older Adults – Medication Review	Process Measure	1	1
Care for Older Adults – Functional Status Assessment	Process Measure	1	1
Care for Older Adults – Pain Screening	Process Measure	1	1
Osteoporosis Management in Women who had a Fracture	Process Measure	1	1
Diabetes Care – Eye Exam	Process Measure	1	1
Diabetes Care – Kidney Disease Monitoring	Process Measure	1	1
Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	3
Diabetes Care – Cholesterol Controlled	Intermediate Outcome Measure	3	3
Controlling Blood Pressure	Intermediate Outcome Measure	3	3
Rheumatoid Arthritis Management	Process Measure	1	1
Improving Bladder Control	Process Measure	1	1
Reducing the Risk of Falling	Process Measure	1	1
Plan All-Cause Readmissions	Outcome Measure	3	3
Getting Needed Care	Patients' Experience and Complaints Measure	1.5	1.5
Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	1.5
Customer Service	Patients' Experience and Complaints Measure	1.5	1.5
Overall Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	1.5
Overall Rating of Plan	Patients' Experience and Complaints Measure	1.5	1.5

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

Table 3: Part D Measure Weights

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

Integrity of Star Ratings

The data used for CMS' Star Ratings must be accurate and reliable. CMS has taken several steps in the past years to protect the integrity of the data; however we continue to guard against new vulnerabilities when inaccurate or biased data are included. CMS' policy is to reduce a contract's measure rating to 1 star if it is identified that biased or erroneous data have been submitted by the plan or identified by CMS. This would include cases where CMS finds plans' mishandling of data, inappropriate processing or implementation of incorrect practices have resulted in biased or erroneous data. Examples would include, but are not limited to: a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract's failure to adhere to Plan Finder data requirements; a contract's errors in processing coverage determinations and exceptions; compliance actions taken against the contract due to errors in operational areas that would directly impact the data reported or processed for specific measures; and a contract's failure to pass data validation directly related to data reported for specific measures.

Disaster Implications

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

As announced by CMS in the December 10, 2012 HPMS memorandum, affected plans were to contact CMS through the Part C and D Star Ratings mailboxes if they believed their operations and/or clinical care experienced major issues as a result of the storm that would impact their Star Ratings measures. Plans that contacted CMS about storm-related issues related to Star Ratings measures are providing detailed information about the zip codes impacted, the specific relief being requested and justification for why the relief is warranted. In responding to issues raised by some comments on the draft Call Letter, we consider this type of information essential to help establish standard procedures for accommodating effects of future disasters. We ask that in the future, plans impacted by other disasters contact the PartCRatings@cms.hhs.gov and/or PartDmetrics@cms.hhs.gov so that CMS can evaluate each contract's unique circumstances on a case-by-case basis.

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

Display measures on http://www.cms.gov are not part of the Star Ratings. These may be measures that have been transitioned from the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed for informational purposes only.

CMS will give advance notice if we are moving display measures to the Star Ratings. Similar to the 2013 display page, plans have the opportunity to preview their data on the display measures prior to release on CMS' website. Data on measures moved to the display page will continue to be collected and monitored, and poor scores on display measures are subject to compliance actions by CMS.

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

We plan to introduce the following measures to the 2014 display page in preparation for them potentially being included as new 2015 Star Rating measures:

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

- *Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (Part C).* We are considering adding the percentage of adult members with a new episode of alcohol or other drug (AOD) dependence who received: 1) Initiation of AOD Treatment—the percentage of members who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis; 2) Engagement of AOD Treatment—the percentage of members who initiated treatment and who had two or more additional services with a diagnosis of AOD within 30 days of the initiation visit. See HEDIS 2012 Technical Specifications, Volume 2 for more information about data specifications. The measure used would focus on the 18 years old and above. Analysis of submitted data suggests that there is little missing data for this measure.

- *HEDIS Scores for Low Enrollment Contracts (Part C).* As a precursor to including low enrollment contracts in the 2015 Star Ratings, CMS will publish HEDIS scores for low

enrollment contracts as part of the 2014 display page. Contracts with less than 1,000 enrollees are first submitting HEDIS data to CMS in the summer of 2013. These data will be analyzed and presented on the display page prior to these data becoming part of the Star Ratings in 2015.

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

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

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

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

  LTC beneficiaries are excluded from this measure calculation using the plan-reported LTC enrollment element, in which plans indicate for each beneficiary eligible for MTM if the beneficiary was a LTC resident for the entire time they were enrolled in MTM during the reporting period. CMS has conducted additional testing and has concerns about the accurate exclusion of MTM program enrollees based on plan-reported LTC status. CMS' initial attempts to validate the plan-reported LTC status of MTM program

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

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

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

- *Drug-Drug Interactions Measure (Part D).* This measure is adapted from the PQA Drug-Drug Interactions measure. It is defined as the percent of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or subsequent to

the initial prescription. The PQA reviewed and updated the list of drug-drug interactions. We propose to continue to use the current PQA DDI measure list for the 2014 Display Measure (using 2012 PDE data) and to test and implement the updated PQA DDI measure list for the 2015 Display Measure (using 2013 PDE data). The changes made to the DDI list include:

- Delete the DDIs - carbamazepine and propoxyphene; tamoxifen and SSRIs; warfarin and cimetidine; warfarin and fibrates (fenofibrate, fenofibric acid, gemfibrozil).
- Add the DDIs - carbamazepine and clarithromycin, erythromycin and telithromycin.

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

Forecasting to 2015 and Beyond

Potential new measures we are considering for 2015 include:

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

Changes to Measure Specifications or Calculations

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

- NCQA's public comment period has recently ended and they are in the process of reviewing the comments received. NCQA will make final recommendations to the Committee for Performance Measurement for final approval of any changes. Updated specifications will be available by July 2013 as part of volume 2 of the HEDIS 2014 Technical Specifications. *HOS Calculations.* The Star Ratings incorporate health outcome measures from the Health Outcomes Survey (HOS). CMS is exploring alternative scoring approaches such as a model that combines multiple health dimensions into a score from 0 to 1, where 0 represents death and 1 represents optimum functioning. Work is underway to assess reliability and validity of the model. CMS will provide plans with additional details on this model as they become available in the fall of 2013. If the additional work proves successful, CMS would consider adding the measure derived from this model to the 2015 display page and potentially to Star Ratings in subsequent years.

Measures for Informational Purposes Only

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

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

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

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

Additional measures under consideration for the future include:

- *CAHPS – Health Information Technology – EHR measures*. There are many local, regional, and national initiatives to accelerate the adoption of electronic health records that will result in changes in terms of how care is delivered. Given this significant change in the healthcare delivery system, it is important to assess the use of electronic health records from the perspective of patients. CMS is considering adding a small set of questions to the CAHPS survey to obtain information on the use of electronic health

records from the patient perspective. CMS is currently exploring modifying for the health plan setting a subset of questions that have previously been developed for the Clinician & Group CAHPS Survey that focus on:

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

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

Plan/Sponsor Continuity of Operations (COOP)

In the draft 2014 Advance notice / Call Letter, we indicated that we were considering developing regulations that would establish COOP requirements for MA organizations and Part D sponsors. These standards would help ensure the continuity of essential functions, operational areas, and critical IT support systems, and ultimately, continued access to coverage and care for beneficiaries in the event of an emergency, such as Hurricane Sandy last year. We requested comments from MA organizations and Part D sponsors on what minimum requirements should be established, and specifically, what key operations must be available or be recoverable in the immediate aftermath of an event.

We received a number of comments from stakeholders on issues we should consider if we decide to proceed with rulemaking. We thank the commenters for their feedback and insights.

Revisions to Good Cause Processes

In the draft Call Letter, we indicated CMS was considering making changes to the good cause process, which allows reinstatement into a MA or Part D plan when an individual is disenrolled for failure to pay premiums or the Part D income-related monthly adjustment amount (Part D IRMAA), but is determined to have good cause. Specifically, we stated that we were exploring expanding the plans' role in the process to include accepting the initial requests for reinstatement by former plan members and gathering information prior to submitting the requests to CMS. These changes would build upon operational improvements already implemented based on feedback from plans during the first year of this policy implementation, help streamline the process and possibly lessen the number of good cause requests in CTM inappropriately directed

to plans for resolution. We requested comments from MA organizations and Part D sponsors on ways CMS might improve the process to receive and review good cause requests for reinstatement.

We received a number of comments from stakeholders on issues we should consider if we decide to proceed with rulemaking or guidance changes. We thank the commenters for their feedback and insights.

Year 7 Agent/Broker Compensation Guidance

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

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

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

Capitated Financial Alignment Demonstrations

In the draft 2014 Advance Notice/Call Letter we discussed certain aspects relating to the Capitated Financial Alignment Demonstration, including auto and facilitated assignment, enrollment, marketing, and coordination with annual reassignment of low income beneficiaries. The language remains unchanged and is reiterated below.

We thank the commenters for their feedback. Throughout the development of the Capitated Financial Alignment Demonstration, we have worked with numerous stakeholders, including

beneficiary advocacy groups and States, and considered beneficiary protection a top priority. We will continue to work with the stakeholders involved to provide beneficiaries with clear, concise information about their options.

Annual Low Income Beneficiary Reassignment

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

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

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

Passive Enrollment of the Newly Dually Eligible

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

Enrollment

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

Marketing

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

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

Section II – Part C

Benefit Flexibility for Certain Special Needs Plans

Regulations at 42 CFR §422.102(e) allow dual eligible special needs plans (D-SNPs) that meet a high standard of integration and minimum performance and quality-based standards to offer supplemental benefits beyond those currently permitted for MA plans. Below, we remind MA plans of those qualifying criteria for CY2014. Additional information, including the qualifying criteria listed below and the list of applicable benefits may also be found in the updated Medicare Managed Care Manual Chapter 16b – Special Needs Plans that will be issued in early Spring 2013.

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

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

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

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

(b) Qualifying Standards for Benefits Flexibility Eligibility

The D-SNP must:

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

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

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

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

As indicated in the draft Call Letter, D-SNPs that believe they met the qualifying criteria set forth above, and that wished to offer additional supplemental benefits were required to notify us of their intent by March 4, 2013. Technical questions regarding specific eligibility determinations will be addressed individually for those plans that indicated their intent to offer supplemental benefits. We will review those requests and notify each applicable plan about whether or not it will be eligible to offer additional benefits in early May 2013. Qualified D-SNPs would include their specific proposed benefits as a part of their PBPs during bid submission, and we will approve D-SNPs' specific new supplemental benefits, as appropriate.

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

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

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

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

For CY 2014, D-SNPs that wish to be reviewed as a Fully Integrated Dual Eligible (FIDE) Special Needs Plan (SNP) must have attested that they would like to be reviewed as a FIDE SNP in HPMS by February 21, 2013. Those D-SNPs that requested to be reviewed for FIDE SNP qualification must upload a completed FIDE SNP Contract Review Matrix (found in the CY 2014 SNP Proposal) in HPMS by July 1, 2013. Plans should use this matrix to identify where each FIDE SNP element is met within their State Medicaid Agency Contract (SMAC). The matrix will be used to assist CMS in reviewing the SMAC to determine whether a D-SNP qualifies as a FIDE-SNP under 42 CFR §422.2, i.e., that the D-SNP: 1) provides dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization; 2) has a capitated contract with a State Medicaid Agency that includes coverage of specified primary, acute, and long term care benefits and services consistent with State policy; 3) coordinates the delivery of covered Medicare and Medicaid health and long term care services using aligned care management and specialty care network methods for high-risk beneficiaries: and 4) employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, enrollment, communications, grievance and appeals, and quality improvement. CMS will issue its determination electronically to the D-SNPs that wish to be reviewed as FIDE SNPs in late September 2013. Medicare Advantage Organizations Offering D-SNPs that have questions about FIDE qualification should send them to snp_mail@cms.hhs.gov.

Supplemental Benefits Guidance

Pap Smear /Pelvic Exam

As stated in our CY 2014 draft Call Letter, MAOs will be required to adhere to the Medicare Part B benefits schedule, and will not be allowed to offer the $0 cost sharing preventive services, screening Pap smears and screening pelvic exams annually as supplemental benefits. 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. That schedule calls for covered $0 cost sharing screening Pap smears and screening pelvic exams once every 24 months for women not at high risk for developing cervical or vaginal cancer. For beneficiaries who are

at high risk of developing cervical or vaginal cancer or are of childbearing age with an abnormal Pap smear within the previous 3 years, the screenings are covered annually. As for all Medicare Part B benefits, plans must cover all medically necessary pap smears and pelvic exams.

Thus, beginning CY 2014, we will adopt the Original Medicare schedule for $0 cost share preventive screening Pap smears and pelvic exams and will not allow plans to offer those services as supplemental benefits.

We received comments asking whether employer MA plans could receive a waiver to continue offering annual screening pap smears and pelvic exams. While an MAO may request an employer group waiver for this requirement, CMS would not expect to approve the waiver at this time given our policy to adopt the Original Medicare schedule for the screening services and thus, creating consistent coverage across all Medicare beneficiaries.

CMS is also taking this opportunity to clarify that MAOs and section 1876 cost contractors may continue to offer additional sessions of smoking and tobacco cessation counseling and non-Medicare covered medical nutrition therapy as supplemental benefits as described in the Medicare Managed Care Manual, Chapter 4.

Rewards and Incentives Programs for Medicare Advantage Organizations

In the draft Call Letter, CMS expressed an interest in exploring how our existing rewards and incentive policy and guidelines may be expanded further to promote innovative programs to improve health outcomes and lower healthcare costs. In order to fully consider whether, and how, we could expand current Part C rewards and incentives policy, we asked for information from Medicare Advantage Organizations regarding the experience and impact of rewards and incentives programs currently offered in the commercial market.

CMS is continuing to evaluate possible options for expanding its current rewards and incentives program guidance and expects to issue further guidance soon, for the 2014 contract year. In developing such guidance, we will certainly consider concerns raised by some commenters that rewards programs could discriminate against the disabled, frail elderly, and minority beneficiaries. We will also examine ways to ensure that those types of rewards and incentives permitted are likely to lead to meaningful and sustained changes in health behaviors and outcomes.

Provider / Beneficiary "Shared Decision Making"

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

condition, services and procedures, and the options available for treatment. Research suggests shared decision-making is especially helpful when there is no clear "best" treatment option for an individual.

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

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

CMS is interested in facilitating shared decision-making as a feature of MA plans through the identification of current programs or unique approaches that have demonstrated effectiveness. In the draft Call Letter, we asked MAOs to share proposals or descriptions of their current shared decision-making programs that may help CMS establish standards for such approaches. Responses to our solicitation supported our efforts to encourage shared decision-making programs. We will consider the comments we received, and may issue guidance on shared-decision making in the Part C program in the future.

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

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

Nevertheless, an MA organization may not require enrollees to engage in this practice in order to force the enrollee to obtain drug coverage under Medicare Part D when coverage would otherwise be available under Medicare Part B. In other words, the decision to forgo Part B coverage for Part D coverage of a drug that would ordinarily be covered under Part B when furnished at a physician's office out of the physician's own stock rests entirely with the enrollee (and their physician) and such decision may not be mandated or influenced by the MA organization. This does not affect the MA organization's ability to contractually require its network physicians to obtain Part B drugs from specified suppliers that bill the MA organization directly as long as such arrangements do not result in coverage being shifted from Part B to Part D (see Chapter 6, Appendix C of the Medicare Prescription Drug Benefit Manual "Part B

Covered Drugs in the Context of a Professional Service"). Please note this guidance applies to all MA and Cost Plans offering Part D Coverage.

Plans with Low Enrollment

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

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

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

Overview of CY 2014 Benefits Bid Review

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

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

Table 1. Plan Types and Applicable Bid Review Criteria

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

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

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

Meaningful Difference (Duplicative Plan Offerings)

MAOs offering more than one plan in a given service area must ensure that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs. For CY 2014, CMS will use plan-specific per member per month (PMPM) out-of-pocket cost (OOPC) estimates to identify meaningful differences among the same plan types.

OOPC estimates are based on a nationally representative cohort of more than 12,000 Medicare beneficiaries represented in the 2008 and 2009 Medicare Current Beneficiary Survey data and are used to provide estimated plan cost information to beneficiaries on Medicare Plan Finder. Estimated out-of-pocket costs for each plan benefit package are calculated on the basis of utilization patterns for the MCBS cohort. The calculation includes Parts A, B, and D services and certain mandatory supplemental benefits, but not optional supplemental benefits. The plan's current enrollment and risk scores will not affect the OOPC calculation. The CY 2014 OOPC model incorporates updated PBP and formulary data, as well as more precise brand and generic drug cost sharing estimates for gap coverage, which utilize Food and Drug Administration data.

All documentation and instructions associated with running the OOPC model are posted on the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html

As explained in our draft Call Letter, CMS proposed to combine HMO and HMO-POS as one plan type for evaluating meaningful difference. A reasonable business case can be made that HMO-POS plans are very similar to HMO plans in those instances where few benefits are offered on an out-of-network basis. Hence, with minimal benefits offered out-of-network, beneficiaries may be unable to differentiate the value between two plans in making their MA selection.

We received comments describing potential alternative solutions and how delaying implementation of this change may be advantageous to beneficiaries. After further consideration, we have determined that HMO and HMO POS will remain two separate plan types for purposes of the CY 2014 meaningful difference review. CMS will analyze the CY 2014 bids to establish a minimum POS out-of-network benefit requirement for purposes of next year's (CY 2015) meaningful difference evaluation. For example, at a minimum an HMO-POS may be required to cover all Parts A and B services out-of-network in order to be considered meaningfully different from an HMO plan.

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

1. The MAO's non-SNP plan offerings will be separated into five plan type groups on a county basis: (1) HMO; (2) HMO POS; (3) Local PPO; (4) Regional PPO; and (5) PFFS.

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

3. Plans within each plan type group will be further divided into MA-only and MA-PD sub-groups for evaluation. That is, the presence or absence of a Part D benefit is considered a meaningful difference.

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

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

CMS expects MAOs to submit CY 2014 plan bids that meet the meaningful difference requirements, but will not prescribe how the MAOs should redesign benefit packages to achieve the differences. Furthermore, CMS may choose not to allow MAOs to revise their bid submissions if a plan's initial bid does not comply with meaningful difference requirements because MAOs have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission. CMS will not approve plan bids that do not meet these requirements. MAOs must follow the CY 2014 renewal/non-renewal guidance in the final Call Letter to determine if their plans may be consolidated with other plans.

Total Beneficiary Cost (TBC)

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

In the draft Call Letter, we proposed to reduce the allowed TBC change amount from $36.00 per member per month (PMPM) to $30.00 PMPM for CY 2014 bids. We received numerous comments from Medicare Advantage Organizations describing potential challenges complying with the TBC requirement, given the number of payment-related changes and the new health insurance providers fee. In past years, CMS has incorporated adjustments in the TBC calculation for payment rate and quality bonus changes, along with other technical adjustments for changes in the PBP software. Consistent with that policy, we will refine the adjustment factor for CY 2014 to also account for changes in the coding intensity adjustment. In addition, we are establishing the TBC threshold at $34.00 PMPM for CY 2014 to provide some flexibility in navigating other changes that will occur in CY 2014. Thus, a plan experiencing a net increase in benchmark, bonus payment, and/or coding intensity impact will have an effective TBC change amount below the $34.00 per member per month (PMPM) requirement. Conversely, a plan experiencing a net decrease in benchmark, bonus payment, and/or coding intensity impact will have an effective TBC change amount above the $34.00 PMPM requirement.

In response to comments, we remind MAOs that the Office of the Actuary extends flexibility on margin requirements so that MAOs can meet the TBC requirement. CMS will provide detailed operational guidance via an HPMS memo and will post TBC adjustment factors in HPMS, both in mid-April.

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

Maximum Out of Pocket (MOOP) Limits

Table 2 below displays the CY 2014 mandatory and voluntary MOOP amount and the combined (catastrophic) MOOP amount limits applicable to LPPOs and RPPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing.

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

Table 2. CY 2014 Voluntary and Mandatory MOOP Range Amounts By Plan Type

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

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

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

Whether in the aggregate, or on a service-specific basis, excess cost sharing is identified by comparing two values found in Worksheet 4 of the Bid Pricing Tool (BPT). Specifically, a plan's PMPM cost sharing for Medicare covered services (BPT Worksheet 4, Section IIA, column l) is compared to Original Medicare actuarially equivalent cost sharing (BPT Worksheet 4, Section IIA, column n). For inpatient facility and SNF services, the AE Original Medicare cost sharing values, unlike plan cost sharing values, do not include Part B cost sharing; therefore, an adjustment factor is applied to these AE Original Medicare values to incorporate Part B cost sharing and to make the comparison valid.

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

Table 3. Illustrative Comparison of Service-Level Actuarial Equivalent Costs to Identify Excessive Cost Sharing

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

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

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

MAO plans have asked whether an enrollee's dollar contribution toward its MA plan's annual MOOP is transferable when the enrollee makes a mid-year election of another MA plan of the same type offered by the MAO. Starting in contract year 2014, when an enrollee moves from one MA plan type (i.e., HMO, PPO, PFFS, SNP) to another MA plan *of the same* type offered under the same contract (i.e., H# or R#) in the same contract year, his/her accrued contribution toward the annual MOOP limit will count toward the annual MOOP in his/her new MA plan.

CMS will consider expanding the transferability of the MOOP contribution to include all MA plans of the same type offered by the same MAO in the future.

Service Category Cost Sharing Requirements

As stated in the draft Call Letter, 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 4 below summarizes the standards and cost sharing amounts by MOOP type (e.g., mandatory or voluntary) for local and regional MA plans. CY 2014 bids must reflect enrollee cost sharing for in-network services that is not greater than the amounts displayed below. For LPPOs and RPPOs, these standards will be applied only to in-network services. All standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles.

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

- Inpatient and home health requirements have been updated to reflect estimated changes in Original Medicare costs for 2014.

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

- Partial Hospitalization cost sharing has been added as a requirement for 2014.

Table 4. CY 2014 In-Network Service Category Cost Sharing Requirements

Cost Sharing Limits			
Service Category	**PBP Section B data entry field**	**Voluntary MOOP**	**Mandatory MOOP**
Inpatient - 60 days	1a	N/A	$3,973
Inpatient - 10 days	1a	$2,310	$1,848
Inpatient - 6 days	1a	$2,098	$1,678
Mental Health Inpatient - 60 days	1b	$2,475	$1,980
Mental Health Inpatient - 15 days	1b	$1,854	$1,483
Skilled Nursing Facility – First 20 Days[1]	2a	$50/day	$25/day
Skilled Nursing Facility – Days 21 through 100[2]	2a	$152/day	$152/day
Emergency Care/Post Stabilization Care	4a	$65	$65
Urgently Needed Services	4b	$65	$65
Partial Hospitalization	5	$55/day	$55/day
Home Health	6a	20% or $35	$0
Primary Care Physician	7a	$35	$35
Chiropractic Care	7b	$20	$20
Physician Specialist	7d	$50	$50
Psychiatric and Mental Health Specialty Services	7e and 7h	$40	$40
Therapeutic Radiological Services	8b	20% or $60	20% or $60
DME-Equipment	11a	N/A	20%
DME-Prosthetics	11b	N/A	20%
DME-Medical Supplies	11b	N/A	20%
DME-Diabetes Monitoring Supplies	11c	N/A	20% or $10
DME-Diabetic Shoes or Inserts	11c	N/A	20% or $10
Renal Dialysis	12	20% or $30	20% or $30
Part B Drugs-Chemotherapy[3]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

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

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

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

In response to comments, we wish to clarify that MAOs have the option to charge either coinsurance or a copayment for most service category benefits. For example, based on the cost sharing requirements indicated above for Part B Drugs – Chemotherapy, a plan can choose to either assign a 20% coinsurance or $75 copayment to that particular benefit. In addition, the cost sharing requirement for Partial Hospitalization may not exceed $55 per day regardless of whether the plan offers a mandatory or voluntary MOOP. The validation rule in the PBP had not been updated at the time of beta testing and will be corrected.

We also received comments regarding the cost sharing requirement for SNF being lowered during the first 20 days to enhance beneficiary protection. MA plans are required to meet the Per Member Per Month Actuarial Equivalence requirement for the overall SNF benefit, which encompasses days 1-100. The cost sharing requirement for SNF is separated into two periods to reflect Original Medicare: days 1 to 20 and days 21 to 100. Although Original Medicare has no cost sharing during the first 20 days, MA plans may charge some cost sharing during the first 20 days as defined annually by CMS. If a plan exercises the option to have cost sharing during the first 20 days, it will have to offset those charges by setting the cost sharing amounts for days 21-100 at less than $152 per day in order to satisfy the Per Member Per Month Actuarial Equivalence requirement.

Part C Optional Supplemental Benefits

As stated in the draft Call Letter, CMS will review non-employer bid submissions to ensure that beneficiaries electing optional supplemental benefits are receiving reasonable value. MAOs must ensure that the total value of all optional supplemental benefits offered to non-employer plans under each contract comply with the following requirements: (a) margin is no greater than 15% and (b) retention, defined as margin plus administrative expenses, is no greater than 30%.

In response to comments, we understand that some supplemental benefits are contracted on a multi-year basis, but the plan bids submitted each year are evaluated based on that particular plan year. CMS would like to clarify this is not a new policy; we have been evaluating optional supplemental benefits for the past few years and work with plans on a case-by-case basis to address their specific issues. CMS is taking this opportunity to be more transparent on how plans will be evaluated for CY 2014.

Part C Crosswalks: Segmentation

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

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

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

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

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

The following four categories of DME may be subject to partial limitation based on brand or manufacturer. Partial limitation means that plans may limit coverage based on brand or manufacturer, provided that the plan covers all items in the subcategories below:

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

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

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

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

Cost Plan Competition Requirements

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

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

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

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

Expanding use of the Blue Button® Initiative

In the draft Call Letter, CMS indicated our interest in expanding use of the Blue Button® Initiative among Medicare Advantage Organizations, which allows Medicare beneficiaries to download personal health information to a printer, computer, memory, or mobile device in the Blue Button® format(s) and share that information with their health care team and care providers. We recommended that MAOs add the Blue Button® icon and functionality to existing or new plan portals or websites, thereby providing beneficiaries with one-click secure access to download and/or print their health information. We further clarify that CMS is only recommending MAOs to take part in this voluntary initiative; MAOs are not required to implement this functionality in CY 2014.

We believe the type of functionality offered by the BlueButton® Initiative has the potential to further advance CMS's overall quality strategy and supports efforts to empower beneficiaries to

understand their health information and make informed decisions. Moreover, this functionality has the potential to improve care coordination by allowing beneficiaries to readily and easily share up-to-date health information with their health care providers, health care team, as well as family members. We solicited and received many comments from MAOs on how best to expand the use of the Blue Button® Initiative. Through the comments, we learned there are other existing and emerging tools which are similar in functionality that exist within the industry. We do not wish to limit MAOs to any specific tool and clarify that MAOs have the flexibility to utilize other available tools that provide the same or similar functionality as the Blue Button® Initiative. Furthermore, we will continue working with industry to promote practices such as the Blue Button® Initiative in order to improve care coordination.

We share commenters' concern regarding potential fraud opportunities and will ensure any future policy enables MAOs to maintain compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Medicare Advantage Part C EOB

In the draft Call Letter, CMS noted that, in our October 18, 2012 HPMS memo entitled, "Final Part C EOB Models and Implementation of the Part C EOB, we originally expected to require use of the model EOB by October 2, 2013. (Note that Section 1876 cost plans are not required to issue a Part C EOB, and, as explained in the above-mentioned HPMS memo, we have decided to not require plans (including D-SNPs) to provide an EOB to dual eligible enrollees. We are continuing to review comments that were submitted in response to our memorandum and the Paperwork Reduction Act notice published in the Federal Register on November 26, 2012, and will issue further guidance regarding the Part C EOB (including the final EOB templates) in June 2013. In response to comments received, we intend to shorten the draft templates considerably. We are also delaying implementation until January 1, 2014.

Summary of Benefits (SB) Update

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

CMS sought feedback from beneficiaries, advocates, Medicare Advantage Organizations, and Prescription Drug Plans regarding the SB in a variety of ways, including the draft Call Letter.

Overall, plans and partner organizations favored revisions to the SB. Specifically, respondents agreed that the document should be streamlined, and that much of the technical language should be replaced with plain language for ease of beneficiary understanding.

CMS will consider incorporating many of the comments received and provide simplified language for ease of beneficiary understanding. In addition, CMS posted a subset of SB templates in HPMS for industry feedback in March 2013, and will consider these comments as we refine the SB templates. We expect to release the new templates in the April 2014 HPMS PBP/SB production release for required use beginning in the 2015 contract year.

PBP Notes Update for CY 2014

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

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

Section 6055 of the Internal Revenue Code

In the draft Call Letter, CMS provided an update on Section 6055 (Reporting of Health Insurance Coverage) which requires every health insurance issuer to provide notice of minimum essential coverage to the Internal Revenue Service (IRS) and impacted individuals on an annual basis beginning in 2015. We thank the commenters for their feedback and will consider their suggestions as we implement the reporting requirements. Additional guidance will be forthcoming.

Section III – Part D

Payment for Hospice and ESRD Beneficiaries under Part D

Introduction

Drugs and biologics covered under the Medicare Part A per-diem payment to a hospice program or included in the Part B bundled payment to an end-stage renal disease (ESRD) dialysis facility

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

When we initially proposed the "pay-and-chase" approach, we thought that in the vast majority of situations, the respective parties would reliably follow Medicare rules and bill appropriately. For ESRD, the Medicare bundled payment to the dialysis facility includes all drugs and biologics used in the treatment of ESRD except "oral-only" drugs. For hospice, the Medicare per-diem payments cover drugs and biologics used primarily for the relief of pain and symptom control related to the terminal condition as well as related conditions. We now better understand that a hospice or ESRD dialysis facility may be uncertain about these definitions. A Part D sponsor will therefore be similarly uncertain about whether payment is the responsibility of either the hospice or dialysis facility or Part D. Therefore, we have learned this approach is often placing a significant financial burden on the pharmacy and beneficiary when payment for a drug is later determined to be the responsibility of the hospice or dialysis facility. In those instances, the Part D sponsor would have recovered the erroneous payment from the pharmacy, leaving the pharmacy to attempt recovery from the hospice or dialysis facility. The beneficiary who had paid the Part D cost sharing to the pharmacy would have instead been liable for the coinsurance payment to the hospice (which may not exceed $5) or the ESRD cost sharing (which is 20% of the total bundled payment for ESRD-related services, which includes ESRD-related drugs). The pay-and-chase approach also continues to provide the erroneous impression to hospice providers or ESRD facilities and their patients that the drugs are coverable under Part D.

2014 Hospice Drug Policy

CMS requires that Part D sponsors ensure that Part D does not pay for drugs and biologics that may be covered under the Medicare Part A per-diem payment to a hospice program. (As specified in section 1861(dd) of the Social Security Act and in Federal regulations at Part 418, the hospice is responsible for covering all drugs or biologics for the palliation and management of the terminal and related conditions. In its 1983 Final Rule, which implemented the hospice benefit, CMS interpreted related conditions broadly, and wrote that hospices are required to cover virtually all the palliative care needed by terminally ill patients (48 FR 56010).) Drugs for the palliation and management of the terminal illness and related conditions are the responsibility of the hospice, and as CMS has noted in rulemaking, at the end of life, most conditions are

related. Thus, when a sponsor receives a transaction reply report (TRR) showing a beneficiary has elected hospice, the sponsor must have controls in place to comply with this requirement. Although we strongly encourage sponsors to place beneficiary-level PA requirements on four categories of prescription drugs, including: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs, we permit sponsors to use other approaches, such as pay-and-chase, to resolve payment responsibility in these situations. The four categories for prior authorization are drugs identified by the DHHS Office of Inspector General (OIG) as typically used to treat the symptoms generally experienced by hospice beneficiaries during the end of life. The OIG documented this finding in their review of Medicare payments for prescription drugs for beneficiaries in hospice in their final report (A-06-10-00059) dated June 28, 2012.

In their review, the OIG also identified 8 drug classes that included 54 drugs prescribed for chronic obstructive pulmonary disease (COPD) and 1 drug class for the 1 drug prescribed for amyotrophic lateral sclerosis (ALS). We solicited comment on whether to extend the beneficiary-level prior authorization proposal to include these COPD and ALS drugs as well, but based on the comments we received, we will neither require nor encourage extraordinary utilization management of these drugs for beneficiaries receiving hospice services at this time. We note, however, that CMS may strengthen this guidance in the future.

Some commenters noted that delays in the flow of hospice election information cause retroactive updates to the information sent to sponsors on the TRR and requested that CMS improve the timeliness of the hospice data and include additional information, such as identification of the hospice provider, on the TRR. We agree there are issues with the data flow. A sample of data suggests that currently, when a hospice program receives a signed notice of election, since the notice must be submitted prior to the first billing many organizations customarily either submit the notice promptly or hold it to submit to the Medicare Administrative Contractor (MAC) with its next billing for other patients. However, our sample showed that approximately 12 percent of notices were held for periods longer than a month and the timely filing limits permissible for hospice claims allow the notice to be held as long as a year. Once received, the MAC sends the notice to CMS for processing and posting to the Common Working File (CWF); a process which takes 1-5 days. The election is then entered into the CWF Master beneficiary Record and a daily extract record from the CWF is sent to update the Medicare Beneficiary Database (MBD). The MBD normally updates within 12 hours, and the Medicare Advantage/Prescription Drug system (MARx) includes the hospice election information on the next daily TRR to the Part D sponsor.

We are exploring ways to expedite the information flow to ensure timelier reporting of the data to plan sponsors, including specifying shorter timeframes for submission of the notice of election by the hospice to the MAC and for reporting from the MAC to CMS. CMS strongly encourages the hospice programs to submit the notices of election as soon as they are received to prevent the delays which affect the ability to correctly determine payment responsibility for drugs for hospice beneficiaries.

We are also exploring adding fields to the TRR or to the eligibility query (E1) response to identify the beneficiary's hospice provider. It is important to note that improvements to the data flow may shorten the delays, but will not eliminate them. As a result, sponsors will continue to receive retroactive updates to the hospice information on the TRR. Thus, all sponsors, including those electing to impose PA requirements on hospice drugs, must retroactively determine responsibility for claims paid during the retroactive election period and recover erroneous payments from the pharmacy. Prompt updating of sponsor systems with the hospice information on the daily TRR will enable sponsors to minimize the number of these retroactive adjustments.

Some commenters expressed concern that PA requirements would impose a significant burden on pharmacies, prescribers and sponsors. In 2012, a total of 1.2 million beneficiaries elected the Medicare hospice benefit. If all of these were enrolled in Part D plans, they would represent approximately 3.5 percent of Part D enrollees; however, not all of the beneficiaries electing hospice have Part D coverage. Moreover, we have no reason to believe that all beneficiaries receiving hospice services are being asked to fill hospice-related prescriptions outside a hospice pharmacy. Since these would be beneficiary-level PA requirements that would require additional effort only if a prescription was directed to Part D, and that would affect only a small percentage of any one sponsor's total enrollment, we do not believe the level of effort associated with prior authorization will be more burdensome than making conditional payment, retrospectively determining payment responsibility and recovering erroneous payments has been.

For sponsors electing this approach, the imposition of PA requirements means that payment for drugs in the hospice categories would stop and the pharmacy would receive a reject code on the response to the pharmacy's billing transaction indicating that prior authorization is required for adjudication of the claim. The pharmacy would need to initiate dialogue between the parties to resolve payment responsibility. This approach will prevent the payment of drugs by Part D that should have been covered by the hospice program facility. Sponsors choosing to do so may also implement these PA requirements in 2013. Drugs not paid by Part D would be furnished by the hospice facility or dispensed by the pharmacy and billed to the hospice facility. Hospices remain responsible for all drugs needed for palliation and management of the terminal illness and related conditions.

A commenter questioned whether these PA requirements would apply to transition fills. As noted in CMS guidance, a drug for which coverage is available under Part A, as it is being "prescribed and dispensed or administered" with respect to the individual, is excluded from the definition of a Part D drug. Transition requirements apply only to Part D drugs. Therefore, the PA requirements will apply to transition fills to allow the A vs. D determination to be made prospectively.

2014 ESRD Drug Policy

Part D sponsors must ensure that they do not pay for drugs and biologics that are included in the Medicare Part B bundled payment to an ESRD dialysis facility (as specified in section 1881(b)(14) of the Social Security Act and in Federal regulations at Part 413). Thus, when a sponsor receives a TRR showing an ESRD beneficiary is receiving renal dialysis services, the sponsor must have controls in place to comply with this requirement. Similar to the approach for hospice, we strongly encourage sponsors to place beneficiary-level PA requirements on seven categories of prescription drugs that may be ESRD-related; however, we permit sponsors to use other approaches, such as pay-and-chase, to resolve payment responsibility for these drugs. The seven categories of drugs listed in Table 5 in the preamble to the prospective payment final rule (CMS-1418-F, which appeared in the Federal Register on August 12, 2010), are determined to be ESRD-related when furnished to an ESRD patient and used as specified in the table. These include:

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

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

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

Some commenters noted that delays in the flow of ESRD information cause retroactive updates to the information to sponsors on the TRR and requested that CMS improve the timeliness of the data and include additional information, such as identification of the ESRD dialysis facility, on the TRR. We agree and are exploring ways to expedite the communication of information to sponsors. We are also exploring adding fields to the TRR or to the eligibility query (E1)

response to identify the beneficiary's dialysis facility. It is important to note that improvements to the data flow may shorten the delays, but will not eliminate them. As a result, sponsors will continue to receive retroactive updates to the dialysis data on the TRR. Thus, all sponsors, including those electing to impose PA requirements on ESRD-related drugs, must retroactively determine responsibility for claims paid during the retroactive election period and recover erroneous payments from the pharmacy. Prompt updating of sponsor systems with the ESRD data reported on the daily TRR will enable sponsors to minimize the number of these retroactive adjustments.

Some commenters expressed concern that PA requirements would impose a significant burden on pharmacies, prescribers and sponsors. Approximately 365,000 beneficiaries are receiving ESRD dialysis services. This represents approximately 1.0 percent of Part D enrollees; however, not all of the beneficiaries receiving dialysis have Part D coverage. Since these would be beneficiary-level PA requirements and would only be expected to affect a small percentage of any one sponsor's total enrollment, we do not believe the level of effort associated with prior authorization will be significantly more burdensome than the current approach of making conditional payment, retrospectively determining payment responsibility and recovering erroneous payments.

For sponsors electing this approach, beneficiary-level prior authorization will require that pharmacies facilitate a dialogue with prescribers at point-of-sale for drugs that may be ESRD-related for ESRD beneficiaries receiving renal dialysis services. This will limit the financial risk for pharmacies and beneficiaries in comparison to the pay-and-chase approach. Given the extensive reports of payment errors that have resulted from conditional payment, we believe this is a better and more efficient approach. We expect that the prior authorization process will prompt discussion between the prescriber and the plan sponsor in order to establish whether the drug is, in fact, Part D or Part B. Thus, once the sponsor, pharmacy and prescriber have established payment responsibility, there will be no further delay in the beneficiary appropriately accessing the drug on this and future occasions. Sponsors choosing to do so may also implement these PA requirements in 2013.

A commenter questioned whether these PA requirements would apply to transition fills. As noted in CMS guidance, a drug for which coverage is available under Part B, as it is being "prescribed and dispensed or administered" with respect to the individual, is excluded from the definition of a Part D drug. Transition requirements apply only to Part D drugs. Therefore, the PA requirements will apply to transition fills to allow the B vs. D determination to be made.

Daily Cost Sharing Requirements

Beginning January 1, 2014, Part D sponsors are reminded that they must establish and apply a daily cost sharing rate whenever certain prescriptions (depending on the drug dispensed) are dispensed by a network pharmacy for less than a 30 days' supply in accordance with

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

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

Although this section is only a reminder of an upcoming regulatory requirement, we received a number of comments about it on the draft version of this Call Letter. We appreciate the supportive comments but note that several comments were similar to ones we addressed in the rule that implemented the daily cost sharing requirement. Therefore, we refer sponsors to the rule, which is available at 77 Fed. Reg. 22072 (April 12, 2012).

Also, we want to specifically note that the daily cost sharing requirement does not address how pharmacy dispensing fees are to be negotiated, calculated or paid. However, we have heard that some sponsors are prorating dispensing fees as part of implementing the short cycle dispensing requirement in long-term care facilities in 2013 and may be incorrectly referencing the upcoming

daily cost sharing requirement as the reason. To be clear, there is no necessary connection between daily cost sharing amounts charged to beneficiaries and how dispensing fees are paid to pharmacies. Further, if the reports of prorating dispensing fees are accurate, we are disappointed that sponsors would reimburse dispensing fees in a way that incentivizes wasteful dispensing of maximum amounts and at the same time financially penalizes the most efficient dispensing methodologies to reduce unnecessary waste and cost in the Part D program.

Hospital Outpatient Drug Supplies During Observation Services

Medicare patients utilizing hospital observation services will generally continue their maintenance medications that are not necessarily related to the observation services themselves. Generally, only medications related to observation services are covered under Part B. Moreover, hospital billing systems, Part D reimbursement rates, and drug utilization review requirements make it difficult for hospitals to participate as a Part D provider for drugs dispensed in these non-pharmacy outpatient settings. Maintenance medications not related to the observation services, when obtained from the hospital's inpatient pharmacy, often come at much greater cost, and must be paid directly by the patient. Complicating matters, consistent with 42 CFR §423.124(b), Part D sponsors are only required to reimburse out-of-network claims at the amount they would have been paid in-network. Thus, many beneficiaries cannot recover a significant portion of their out-of-pocket expenses for these drugs.

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

Part D pharmacy access standards do not require Part D plans to contract with hospitals for dispensing drugs in these situations, and most hospitals have not been interested in contracting with Part D sponsors. If the beneficiary is unable to take his or her own supply of maintenance medications and has to obtain the medications from the hospital's inpatient pharmacy, the beneficiary may submit a request for reimbursement to the Part D plan for out-of-network reimbursement. We would expect that Part D plans will reimburse the beneficiary if the situation warranted out-of-network access (i.e. beneficiary could not reasonably have received

drug from a network pharmacy and access is not routine), and if the dispensed drug is on the Part D plan's formulary or is otherwise covered under the plan pursuant to a formulary exception. Consistent with §423.124(b), the Part D plan is only required to reimburse the beneficiary the amount that it would have paid had the beneficiary obtained the drugs at a network pharmacy. The beneficiary remains responsible for any differential between what the hospital charged and the Part D plan reimbursement, although the entire amount paid by the beneficiary would count toward the true-out-of-pocket (TrOOP) expenses.

We expect plan sponsors to ensure that customer service representatives are aware of this policy change so they may assist beneficiaries in understanding their options. When beneficiaries contact the plan with questions about coverage of Part D drugs during hospital observation services, customer service representatives should be prepared to advise the callers to discuss with the hospital to determine if they have the option to avoid paying out-of-network differential charges by self-administering their own supply of Part D medications (not related to observation services) as a result of this important change in Medicare CoPs.

CMS shares commenters' concerns about beneficiary foresight to bring medications to the hospital with them. CMS also recognizes that Part D sponsors do not receive timely notification of a beneficiary's need for observation services. Thus, we wish to clarify that our guidance to plan sponsors is that they should be prepared to address beneficiary questions that may arise.

Withdrawal of Part D Bids after CMS Approval

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

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

Throughout the application and bid process, new applicants attest that the information they submit for the bid and application is accurate and reflects the anticipated cost of administering the benefit for the full range of Medicare beneficiaries in the regions in which they intend to operate. Applicants also attest that they are prepared to administer the benefit in accordance with all applicable requirements, including accepting auto-enrollments and reassignments of LIS

beneficiaries as applicable. The bid submissions and attestations are not supposed to be based on any assumptions about whether the applicant will be eligible for auto-enrollments and reassignments in the following contract year. When an applicant withdraws after the LIS benchmark is announced, this act calls into question whether the applicant attested truthfully and whether the assumptions and data underlying its bid accurately represented the cost of administering the benefit.

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

Inappropriate Use of Prior Authorization (PA) Forms

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

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

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

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

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

Auto-Ship Refill Programs in Part D

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

As a result of the automatic delivery practices described above, CMS has received complaints that beneficiaries have had medications delivered that had been previously discontinued or were otherwise unwanted and unnecessary at the time of delivery. Once the prescription is delivered, pharmacies are unable to return the medication to stock and generally do not reverse the claim if the patient does not want the prescription. Consequently, automatic delivery practices are potentially generating significant waste and unnecessary additional costs for beneficiaries and the Part D program overall. While proponents of these programs tout improved adherence, it remains unclear to us that they can provide evidence of actual improvement in adherence, or that permitting such programs to continue without reorder confirmation is cost-effective.

Therefore, to help control fraud, waste, and abuse as required by 42 CFR §423.504, and ensure that Medicare beneficiaries only receive new prescriptions and refills that are requested, for coverage year 2014, Part D sponsors should require their network retail and mail pharmacies to

obtain patient consent to deliver a prescription, new or refill, prior to each delivery. We believe unintended waste and costs could be avoided if pharmacies confirmed with the patient that a refill, or new prescription received directly from the physician, should be delivered. Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request. This policy does not affect retail refill reminder programs that require the patient to pick-up the prescription and does not apply to long-term care pharmacy dispensing and deliveries.

While we expect this policy to be implemented no later than January 1, 2014, we strongly encourage sponsors to make this a requirement of their network pharmacies that offer such automatic refill programs for the rest of 2013 as well.

We received some comments citing concerns that requiring beneficiary confirmation prior to each delivery will negatively affect beneficiary adherence based upon the current adherence measures. On the contrary, we believe this policy will make the adherence measure more meaningful by at least ensuring the beneficiary confirms a need for the medication. Although auto-ship programs undoubtedly improve adherence measure scores by simply ensuring more refills are processed on a schedule, such automatic refills may diminish the accuracy of the adherence measure by including unwanted and unnecessary refills that do not reflect actual adherence. Shipment of unwanted medications is not only wasteful, but also a source of significant beneficiary aggravation and a financial imposition that can negatively affect enrollee satisfaction with the plan. Supporting this idea, we received a number of comments that indicate beneficiaries return large quantities of unneeded medications to community pharmacies for take-back programs because they were unable to stop auto-ship refill programs. Commenters were divided as to whether the policy should apply to all fills, refills, or only first-fills. The policy will apply to all fills, and CMS will re-evaluate its efficacy at a future time.

We invited commenters to propose alternative interventions that would be effective in addressing this problem. Several plans shared their current systems for obtaining enrollee consent in automatic refill services. Although some sponsors have existing systems, those systems should be improved, such that, at the initial enrollment, it is impressed upon enrollees that if they wish to use the service, they must provide a reliable means of communication that will enable effective confirmation outreach. If the beneficiary is unable or unwilling to do so, then mail-order or pharmacy delivery services may not be the appropriate way for that individual to access this benefit. We maintain that shipments should be predicated on a beneficiary's confirmation that he or she still wants the medication.

Some commenters stated that this policy undermines the goals of e-prescribing. E-prescribing provides a more efficient way of transmitting information between prescribers and dispensers, thereby decreasing errors and costs. However, prescribing and dispensing remain distinct operations. Providers sometimes prescribe in anticipation of a condition becoming worse.

Moreover, a beneficiary has the right to put filling a prescription on hold or even to refuse a treatment. Therefore, it is counter-intuitive and contrary to its goals to use e-prescribing as a rationale for automatically delivering prescriptions that the beneficiary may not need or want.

Finally, we are concerned that the practice of plans offering powerful incentives such as $0 or other very low cost sharing for 30-day supplies at mail-service, without offering the same cost sharing at their retail network, is driving purchasing behavior for beneficiaries for whom mail-service may not be a good option. This would include beneficiaries that have limited means of communication, some LIS beneficiaries, and beneficiaries filling non-maintenance medications who may need them immediately. Significant mail-service incentives make it difficult for any of these beneficiaries to choose to obtain 30-day supplies of their medications at retail even if it otherwise is in their best interest. Moreover, mail-service historically has been designed for extended-day supplies of maintenance medications, which allow for appropriate reorder and delivery timeframes. Generally, we do not believe that mail-service order processes and delivery timeframes are conducive to ensuring beneficiaries receive their 30-day prescriptions timely. We have already seen high complaint rates and numerous access problems around this issue in 2013. Furthermore, we received comments from community pharmacies indicating that their staff spend a lot of time helping their customers resolve problems with switching to mail-order service. Consequently, we are reconsidering the appropriateness of such 30-day mail-service benefit designs for the Part D program and Part D sponsors should anticipate that CMS may not approve 2014 benefit designs with extremely attractive mail-service cost sharing incentives for 30-day supplies if such cost sharing is not also available throughout their retail network.

Incremental Fills of Schedule II Controlled Substances Prescriptions

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

We encourage the industry to promptly address the known limitation of the current HIPAA prescription drug billing standard with respect to distinguishing partial or incremental fills of an original prescription from refills. CMS understands that this limitation may currently result in partial fills of Schedule II controlled substances being billed in a manner that cannot be distinguished from refills, particularly in the LTC setting. Partial fills of Schedule II controlled substances are permissible under Federal law under certain circumstances and occur when a pharmacist does not dispense all doses of the prescribed medication at one time. Partial fills are

not considered refills. A September 2012 OIG report found that three-quarters of Part D sponsors inappropriately paid $25 million for Schedule II controlled substances that were billed as refills in 2009. The OIG acknowledged that some of these drugs may have been inaccurately billed, and CMS believes these claims more likely represent legally dispensed partial fills as opposed to illegal refills. (See https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp).

CMS understands from comments received on the draft version of this Call Letter that the industry is actively addressing the limitation in the billing standard through the National Council for Prescription Drug Programs. Nevertheless, the limitation in the billing standard does not obviate the requirement for sponsors to have internal controls in place that prevent Part D payment for illegal refills of Schedule II controlled substances prescriptions. Until a billing solution is implemented by the industry that permits sponsors to compare the amounts billed to the total amount prescribed on the original prescription at the time of claim processing, CMS expects sponsors to ensure compliance through retrospective auditing. We also expect sponsors to ensure that any PDEs that have been erroneously submitted for illegal refills of Schedule II drugs are promptly adjusted or deleted.

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

CMS is concerned that certain Part D sponsors have been unable to monitor effectively or respond promptly to problems created by the performance of the first tier, downstream, and related entities (i.e., "delegated entities") to which the sponsors have delegated the performance of claims adjudication or appeals and grievances processing. CMS has seen that problems often arise in these areas because sponsors do not have real-time access to the systems delegated entities use to perform these functions on the sponsor's behalf. CMS is therefore clarifying that it expects sponsors to have real-time access to these and other critical systems in order to effectively monitor the performance of their delegated entities.

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

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

entities to have direct, real-time access to these critical systems in order to perform their responsibilities under their Part D contract with CMS.

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

Applicability of Rewards and Incentives in Part D

In the draft Call Letter, CMS expressed an interest in exploring if something analogous to the existing rewards and incentives section in the Medicare Marketing Guidelines could be implemented in the Part D program. In order to fully consider whether, and how, we could offer corollary guidance to Part D sponsors on the existing rewards and incentives policy, we asked for information from Part D sponsors regarding the experience and impact of rewards and incentives programs currently offered in the commercial market. We will consider the comments we received, and may issue guidance on rewards and incentives in the Part D program in the future.

Payment of Extemporaneous Compounds from Compounding Pharmacies

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

In 2012, less than 0.1% of Part D claims were reported to CMS on prescription drug events (PDEs) as multi-ingredient compounds (Part D compounds). Our initial analyses of these compound PDEs show that more than 50% of the Part D compounds were from either a long term care (LTC) or home infusion pharmacy, which can be attributed in part to the increased use of sterile compounds dispensed in these settings. While only 33% of all Part D compounds likely were sterile compounds based on the drug reported on the PDE, more than 80% of these sterile compounds were from LTC and home infusion pharmacies. Of the remaining likely sterile compound claims from pharmacies that were not easily identifiable as home infusion or LTC based on NPI taxonomy, further analysis of the pharmacy names and types of drugs associated with these claims would appear to indicate that the vast majority likely originated from home infusion and specialty pharmacies as well. Of those Part D compounds that were filled at pharmacies other than LTC or home infusion, it appears that almost 90% are non-sterile Part D compounds, the majority of which have a Part D drug that is typically used to make

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

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

In order to ensure that Part D only covers medically necessary Part D compounds, in the draft Call Letter, we solicited comments on whether we should require Part D plans to consistently obtain justification via prior authorization from the prescriber as to why no FDA approved product is clinically suitable for the patient, or on any other ideas to increase controls over the quality and safety of extemporaneously compounded products covered under Part D. We agree with a number of commenters to wait for the results of other pending Federal actions. We thank the stakeholder community for their comments and will review comments received for potential future policy making.

Million Hearts™ Initiatives

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

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

Along with community-focused efforts to reduce tobacco use and sodium and trans fat consumption, the primary clinical aim in Million HeartsTM is to achieve excellence in the ABCS: aspirin for those at risk, blood pressure control, cholesterol management, and smoking

cessation. Getting to excellence means making the ABCS a priority for professionals, health systems, insurers, employers, and people with or at risk for cardiovascular disease and by deploying effective teams, health information technology, and incentives for high performance.

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

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

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

Viewed through the insurance lens, of those with uncontrolled hypertension:

- 14. 1 million are Medicare beneficiaries;
- 14.06 million have private insurance;
- 2.3 million have other public insurance; and
- 5.26 million have no insurance.

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

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

First, for those plans that offer a $0 or a very low cost-share tier, we encourage, but do not require, sponsors to place blood pressure medications on this tier.

Second, we encourage, but do not require, sponsors to offer Medication Therapy Management (MTM) to beneficiaries who fill one or more prescriptions for anti-hypertensive medications. The CMS requirements for targeting beneficiaries for the MTM program are considered to be a

minimum; sponsors are encouraged to offer MTM services to an expanded population of beneficiaries who may not meet the eligibility criteria per CMS' specifications, but who could benefit from MTM services. Offering MTM, including a comprehensive medication review, to this population could help improve their blood pressure control, increase their adherence to these vital medications, and empower these beneficiaries to self-manage their medications and their health condition. However, this would not result in additional payment under Medicare Part D. We also encourage sponsors to consider other interventions, aside from a comprehensive medication review as part of MTM, such as adherence programs, targeted medication reviews, etc., which may improve outcomes for this population and support the initiative.

Expansion of Part D Policy on Improving Utilization Review Controls

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

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

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

The comments we received on the draft version of this Call Letter both supported and opposed our expanding the Part D Policy on Improving Utilization Review Controls to other drugs or classes of drugs, such as anti-psychotic drugs, amphetamine derivatives, benzodiazepines and non-benzodiazepine sleep aids. In addition, the supportive comments were not in agreement on which drugs or classes of drugs would be appropriate or inappropriate to target. Therefore, we will not expand our guidance beyond the opioid class at this time, but note that a sponsor may voluntarily do so, which would include notifying CMS and the affected beneficiaries of any beneficiary-level claim edits that will be implemented.

Drug Class Quantity Limits

In the supplemental guidance to the "Improving Drug Utilization Review Controls in Part D" section of the CY 2013 Call Letter, we stated that we would develop a submission mechanism

for plan-level point of sale (POS) edits based upon cumulative daily morphine equivalent dose (MED) across the opioid class. We did not receive any comments on the draft version of this Call Letter supportive of a cumulative MED level that could be implemented at POS that would not only be an effective safety measure, but also one that would not inappropriately restrict access to medically necessary drugs. Rather, comments received indicated that sponsors are generally not ready to implement plan-level cumulative MED point of sale edits across the opioid class. While this will not be a requirement for CY 2014, we will accept plan-level POS edits based upon cumulative MED across the opioid class for review from sponsors who will have the capability to implement them for CY 2014. Such information will not be provided as part of the HPMS formulary submission process; however, we will provide instruction on how to submit them to CMS for review. CMS strongly encourages all sponsors to develop the ability to implement plan-level POS edits based upon cumulative MED across the opioid class as soon as possible.

We also note that sponsors who implement a plan-level POS edit based upon cumulative MED across the opioid class will be expected to submit QLs for all individual opioids as part of the HPMS formulary submission for our review. Utilizing the existing QL fields, QL amount and QL days, these Part D sponsors will submit the lesser of either the plan-approved QL for individual opioids or the QL that is equivalent to the cumulative MED level to be applied across the opioid class. This will provide for transparency in that both types of QLs would be displayed in Medicare Plan Finder. We recognize that claims for quantities below the QL could reject at point-of-sale (POS) depending upon previously dispensed quantities of other opioids due to the plan-level POS edit based upon cumulative MED. However, it is not feasible to collect additional quantity limit information based on all of the various possible combinations of opioids.

With respect to sponsors who do not plan to submit plan-level POS edits based upon cumulative MED across the opioid class, we would encourage these sponsors to submit QLs for opioids with their HPMS formulary submission. As we noted in the CY 2013 Call Letter, Part D sponsors may apply QLs to opioids even though there is no clearly defined maximum dose in the approved labeling.

Change in Part D Barbiturate Coverage

Under the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, as codified in 42 CFR §423.100, Medicare Part D began covering barbiturates (used for epilepsy, cancer, or chronic mental health disorder) and benzodiazepines as of January 1, 2013. Effective January 1, 2014, section 2502 of the Affordable Care Act (ACA) of 2010 revised §1927(d)(2) of the Social Security Act (the Act) by removing smoking cessation agents, barbiturates and benzodiazepines from the list of drugs that states may exclude from coverage under the Medicaid Program. By

removing barbiturates and benzodiazepines from §1927(d)(2), these drug categories are no longer included in the list of drugs excluded from Medicare Part D under 1860D-2(e)(2).

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

Part D Benefit Parameters for Non-Defined Standard Plans

Each year, in order to implement certain regulations, we set forth certain benefit parameters, which are based on updated data analysis, and therefore, are subject to change from year to year. Specifically, pursuant to §423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package (other than defined standard) or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost sharing, formulary structure, or benefits offered; and, pursuant to 42 CFR §423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. Since no changes have occurred in how we establish these parameters for CY 2014, nor in the applicable regulations, the benefit parameters for CY 2014 are set forth in Table 1 below.

CMS will continue to scrutinize the expected cost sharing amounts incurred by beneficiaries under coinsurance tiers in order to more consistently compare copay and coinsurance cost sharing impacts. If a sponsor submits coinsurance values (instead of copayment values) for its non-specialty tiers that are greater than the standard benefit of 25%, CMS will compare the average expected cost sharing amounts submitted by sponsors in the PBP to the established copay thresholds to determine whether the coinsurance values are discriminatory. (Please note that for the Select Care/Diabetic Drug Tiers, although the maximum allowable coinsurance value is less than 25%, CMS will conduct the same cost sharing analysis for these tiers).

As for CY 2013, the CY 2014 out-of-pocket costs (OOPC) model incorporates updated PBP and formulary data used for CY 2014 bid submissions, as well as more precise brand and generic drug determinations for gap coverage cost sharing estimates, which utilize Food and Drug Administration (FDA) data and are more in line with the way the Part D benefit is administered. Using this model, the minimum monthly cost sharing OOPC difference between basic and

enhanced plan offerings will be $21. The minimum monthly cost sharing OOPC difference between enhanced plan offerings will be $18. In addition, CMS still expects PDP sponsors that are offering two enhanced alternative plans within a service area, to include additional gap coverage of at least "some" (>10% to <65% of formulary drugs) brand drugs on the second enhanced plan. (Please see a request for industry comments on OOPCs for CY 2015 at the end of this section.)

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

Regulation (42 CFR §423.578(a)(7)) allows Part D sponsors to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost sharing exceptions. This tier is referred to as the "specialty tier". Cost sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit or to an equivalent total amount for sponsors with decreased or no deductible under alternative prescription drug coverage designs. (Example: a $325 deductible and 25% cost sharing of an initial coverage limit of $2790 is essentially the equivalent of $986.25 in out-of-pocket expenses, whereas no deductible and 33% cost sharing of the same initial coverage limit is essentially the equivalent of $980.10 in out-of-pocket expenses.)

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

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

Table 1: Benefit Parameters

	CY2014 Threshold Values
Minimum Meaningful Differences (OOPC)[1]	
1st Enhanced Alternative Plan vs Basic Plan	$21
1st Enhanced Alternative Plan vs 2nd Enhanced Alternative Plan	$18
Maximum Pre-ICL and Additional Gap Coverage[2] Copay (R & NP) - 3 or more tiers	R/NP[3, 4]

	CY2014 Threshold Values
Preferred Generic/Generic Tier	$10
Non-Preferred Generic Tier	$33
Preferred Brand/Brand Tier	$45
Non-Preferred Brand Tier	$95
Injectable Tier	$95
Select Care/Diabetic Tiers[5]	$10
Maximum Pre-ICL Coinsurance (R &NP) 3 or more tiers	R/NP[3, 4]
Preferred Generic/Generic Tier	25%
Non-Preferred Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Select Care/Diabetic Tiers[5]	15%
Maximum Additional Gap Coverage[2] Coinsurance R &NP) - 3 or more tiers	R/NP[3, 4]
Preferred Generic/Generic Tier	50%
Non-Preferred Generic Tier	50%
Preferred Brand/Brand Tier	69%
Non-Preferred Brand Tier	69%
Injectable tier	69%
Select Care/Diabetic Tiers	69%
Minimum Specialty Tier Eligibility	
1 month supply at in-network retail pharmacy	$600

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

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

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

[4]"R" in the above chart refers to "in-network retail pharmacy" and "NP" refers to "in-network non-preferred retail pharmacy." An in-network retail (R) can only be designated as an in-network preferred retail pharmacy (P) if it

offers a lower level of cost sharing than an in-network non-preferred pharmacy (NP) in accordance with Section 50.9 of Chapter 5 of the Medicare Prescription Drug Benefit Manual.

[5]The Select Care Drug and Select Diabetic Drug Tiers must provide a meaningful benefit offering with low or $0 beneficiary cost sharing for drugs targeting specific conditions (e.g. $0 tier for drugs related to diabetes and/or smoking cessation). The coinsurance threshold for these tiers is derived from an average expected copayment amount using PDE data for drugs submitted on preferred cost sharing tiers.

With respect to our concerns with plans offering benefits with extremely attractive incentives such as $0 or very low cost sharing for 30-day supplies at mail service, unless offering the same cost sharing at their retail network, we refer sponsors to the section Auto-Ship Refill Programs in Part D, above.

CMS received one supportive comment on the coinsurance threshold maximum proposed for the Select Care and Select Diabetic Drug tiers requested in the draft version of this Call Letter. Other comments reflected that sponsors were unaware that this tier option already existed.

CMS did receive industry comments regarding a possible change to the OOPC calculation methodology for CY 2015 as requested in the draft version of this Call Letter. We thank the industry for these comments and will consider them for CY 2015.

Employer Group Waiver Plan (EGWP) Supplemental Prescription Drug Benefits

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

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

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

Purposes of the PDE Record

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

Existing PDE Rules

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

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

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

guidance: either (1) deletion of the original PDEs and the resubmission of corrected PDEs, or (2) the submission of adjusted PDEs. Either of these approaches will ensure that CMS data reflect the corrected amounts actually paid to the provider.

Discussions between CMS and both pharmacies and sponsors reveal that retrospective audits of previous years' claims are resulting, in some cases, in complete recoupment of the amount originally paid to the pharmacy when data that do not affect the financial calculations on a claim ("non-financial data," or "administrative data"), such as prescription origin codes or prescriber identifiers, are determined to be erroneous. The increasing incidence of these adjustments for "routine clerical errors" rather than errors in data that result in incorrect payment amounts ("financial data") may be related to the incentives in contingency reimbursement arrangements with claim audit vendors. We are concerned that the growing practice of post-audit total claim recoupments from pharmacies is distorting Part D payment, as well as compromising Part D data integrity and impairing our ability to oversee the program.

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

is incompatible with our requirements to submit a PDE record that simultaneously represents (1) how the benefit was administered and (2) costs actually paid that are eligible for reconciliation.

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

In this final Call Letter, we are therefore clarifying our requirements for the submission of PDE data with respect to corrections of three types of claim errors: financial, administrative, and coverage errors. Financial errors are errors that result in incorrect payment calculation on claims that were otherwise appropriate for coverage; administrative errors are errors in fields that do not affect the financial calculations required on a claim; coverage errors are errors in paid adjudication of claims that should not have been covered under Part D because, for instance, they are fraudulent. Specifically, we are clarifying that:

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

Issues with Earlier Guidance

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

Since the beginning of the program, the DIR instructions have provided the opportunity to report DIR in the category of "pharmacy payment adjustments". When we originally designated this category, we anticipated these would be rare events, such as the results of risk sharing adjustments, not claims corrections – although adjustments for claims corrections have been permitted to date. We have observed that these amounts have been growing, and understand that many of these adjustments are occurring as the result of retrospective audits of previous years' claims. Numerous pharmacy complaints, discussions with several sponsors and analysis of data

submitted to CMS reveal that some sponsors have been retracting or "recouping" 100% of prior payment on claims from pharmacies because of "payment inaccuracies" due to "routine clerical errors", rather than incorrect payment amounts and including these amounts as "pharmacy payment adjustments" when reporting their DIR.

If such adjustments are reported to CMS in DIR, as opposed to corrected PDE submissions, both the accuracy of Part D payment, as well as the reliability and utility of PDE data, are compromised. While DIR amounts directly offset drug costs in risk-sharing reconciliation, DIR amounts do not fully offset reinsurance subsidies and do not at all offset LICS subsidies. Thus, reporting of claims adjustments via DIR reporting as opposed to corrected PDE submissions may result in overpayment of these subsidies to the plan sponsor. Therefore, as discussed above, any adjustments to amounts paid on claims must be reflected in adjusted or deleted PDEs. In order to provide for accurate payment reconciliation, any adjustments to financial fields on Part D claims that continue to result in a positive non-zero payment amount after adjustment must be addressed through deletion of the original PDEs and the resubmission of corrected PDEs that reflect the corrected amounts actually paid to the provider. While we acknowledge that our guidance has been ambiguous for DIR reporting for coverage years 2006 through 2011, we believe this guidance clarifies our requirements for reporting of claim adjustments to financial amounts on paid claims going forward. We will further clarify the purpose of the "pharmacy payment adjustments" field in the 2012 DIR reporting instructions.

We received a large number of comments on this section; most of these were from pharmacies. Pharmacies all offered strong support for our clarification that total claim recoupments should only be allowed to occur when the claim never should have been paid, such as when true fraud has happened. They stated that when a patient, upon their request, receives the medication that has been prescribed for them, there is no fraud involved. Most pharmacies also requested that CMS introduce consistent standards across Part D plans regarding all PBM audit practices, but such action is beyond the scope of this call letter.

Several Part D sponsors and several PBMs submitted comments on this section. Most of these comments were partially supportive of our clarification and requested additional clarifications. Payers were primarily concerned about those situations where, despite good faith efforts by the Part D sponsor, the pharmacy does not submit the correct information, and such information is required in order for CMS to accept the PDE. Anything short of full recoupment for defective claims, these payers assert, would result in the Part D sponsor bearing the cost of the pharmacy's error, which would not only be unfair, but would also fail to provide appropriate incentives to the pharmacy to correct such defects. We understand these concerns, but there is no reason to believe that, when given a reasonable amount of time, a network pharmacy would not amend and resubmit a claim for an error in administrative data fields required by CMS on PDEs when that data is generated by the pharmacy itself, including the prescription origin code, and effective 2/28/13: pharmacy service type, patient residence, and submission clarification code. However,

if for some unforeseen reason this occurs, CMS still requires the PDE record of how the claim was administered, so in accordance with this guidance, the PDE must be submitted as administered and the claim cannot be recouped on this basis alone.

We received several comments that utilized the example of an unrecoupable NPI error on a claim as leading to a Part D sponsor unfairly bearing the cost of the pharmacy's error. The prescriber identifier field is a special case that we have specifically addressed in final regulations at 42 CFR §423.120(c)(5). Like this PDE guidance, in order to preserve access to benefits and the integrity of the point-of-sale transaction, paragraph (iv) of that provision states that the Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor: (1) Has complied with the POS requirements under paragraphs (c)(5)(ii) and (iii) of that provision; (2) has verified that a submitted NPI was not in fact active and valid; and (3) the agreement between the parties explicitly permits such recoupment. [77 FR 22146] Thus, we caution sponsors that the regulations must be read in conjunction with our PDE requirements.

In light of the comments received on this section concerning NPI reporting, we would like to take this opportunity to correct an apparent misunderstanding. In particular, we would like to emphasize here the meaning of the word "verify," as set forth in 423.120(c)(5)(iv)(2). If the pharmacy and the sponsor have not been able to resolve any discrepancy concerning the NPI within 24 hours (or on weekends – by the next business day), the requirement to verify the NPI effectively requires sponsors (not pharmacies) to investigate an apparently erroneous NPI with the prescriber in order to affirmatively establish the status of the submitted NPI. The same is true for prescriptions written by prescribers who have not yet obtained an NPI; sponsors must also assume responsibility for contacting these prescribers to verify the status of their NPI, and if applicable, requesting that they obtain and disclose an NPI. Therefore, we have imposed the duty to resolve a missing or apparently incorrect NPI error on the sponsor, not the pharmacy. This is not unfair to sponsors, because after May 6, 2013, most prescribers who do not already have an NPI will have to obtain one pursuant to new requirements at 45 CFR §162.410(b). Under §162.410(b), organization covered health care providers must require prescribers that are members of the organization or whom the organization employs or contracts with, to obtain and disclose NPIs. Therefore, a prescriber's failure to obtain and disclose an NPI, in accordance with §162.410(b), may be reported to HHS/CMS/OESS as a possible violation of HIPAA Administrative Simplification requirements by an organization-covered health care provider. Please visit http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Enforcement/index.html to learn more about the HIPAA Enforcement process and how to file a complaint. CMS continues to work with industry representatives through the NCPDP Work Group 1 Definition of a Valid Prescriber Task Group to address industry questions on implementing the NPI reporting policy.

Other sponsor concerns involved:

- The effective date of this guidance—As we state above, while we acknowledge that our guidance has been ambiguous for DIR reporting for coverage years 2006 through 2011, we believe this guidance clarifies our requirements for reporting of claim adjustments on paid claims going forward. Since the 90-day minimum timely filing limits required under Part D for coverage year 2012 have barely expired, we have no reason to believe that any appreciable amount of claim auditing has already taken place. As one commenter stated, "retrospective audits of pharmacy providers are routinely conducted beyond the plan year". Therefore, there is no reason to believe that applying this clarification to claims submitted for coverage year 2012 would be problematic. Moreover, any total claim recoupments for errors in administrative data fields that may have already occurred for 2012 dates of service can still be restored and corrected in time for the 2012 reconciliation window.

  As previously noted, we will further clarify the purpose of the "pharmacy payment adjustments" field in the 2012 DIR reporting instructions in the near future. We would expect these instructions to address such issues as changes to pharmacy reimbursement that are not known at the time of the point-of-sale transaction.

- Whether CMS will allow plans more than 30 days to submit a valid PDE to CMS for those claims that are submitted with the submission clarification code where further outreach is required by the plan to obtain the valid NPI—Sponsors should make their best effort to follow our timely submission guidance, but we understand that there may be some exceptions to this rule and that rare extenuating circumstances, such as delays in obtaining an NPI from a provider who has not yet obtained one, will not be viewed as being out of compliance with the timely submission requirements.

- Comments suggesting that some did not fully understand the distinction we were trying to make between adjustments to "financial fields" for reasons such as changes in LIS levels or an overpayment to the pharmacy versus total claim recoupment for pharmacy errors in "non-financial" or "administrative" fields on a claim—Consequently we have made two changes to our guidance in this final version. First, we have substituted more precise language in the policy description, above. Second, we provide examples of the policy applied to specific scenarios raised in payer comments to better clarify our intent in the following chart.

Table 1. Examples of PDE Requirements for Various Types of Errors on Claims

#	Situation	Financial Error	Admin Error	Coverage Error	Amend Claim & Adjust PDE	Recoup Claim & Delete PDE**
1	An incorrect compound code (i.e. pharmacy billing a compounded product with compound code 1)	✓			✓	
2	Claim submitted by an LTC pharmacy using an inappropriate override code	✓			✓	
3	Claim submitted with an incorrect DAW code (and the claim would have rejected had the correct DAW code been entered originally)	✓			✓	
4	Claim that was billed for the incorrect drug and/or directions as verified against the hard copy prescription	✓			✓	
5	Claim for a compounded medication that is billed with an NDC number that was not used in the actual compound	✓			✓	
6	Claim that was billed with the incorrect quantity and/or days' supply when the claim would have rejected for refill too soon had and the quantity and/or days' supply been submitted accurately by the pharmacy	✓			✓	
7	Wrong prescription origin code		✓		✓	
8	Wrong NPI		✓		✓	
9	Wrong pharmacy service type		✓		✓	
10	Wrong patient residence		✓		✓	
11	Fraudulent claim			✓		✓
12	Claim or prescription from excluded provider			✓		✓
13	Duplicate claim			✓		✓
14	No valid prescription can be produced by the pharmacy (i.e., copies of original prescription or physician order)			✓		✓
15	Prescription that is missing components required on a valid prescription under applicable state or federal law			✓		✓

#	Situation	Financial Error	Admin Error	Coverage Error	Amend Claim & Adjust PDE	Recoup Claim & Delete PDE**
16	Prescription dispensed using an adulterated or outdated prescription drug			✓		✓

** PDE deletion also requires deduction of claim from benefit accumulators, including TrOOP and Total Drug Cost

Post Point-of-Sale Per Claim Administrative Fees

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

42 CFR §423.100—*Negotiated Prices*—are prices that… [the] network entity [pharmacy] will receive, in total, for a particular drug. (Emphasis added.)

We believe that the practical effect, if not the intention, of per-claim fees deducted post point-of-sale is overstatement of negotiated prices at point-of-sale. If negotiated prices are overstated, then beneficiary cost sharing, beneficiary advancement through the Part D benefit phases, and government payment subsidies are overstated in contravention of our rules on negotiated prices. Therefore, we do not believe that per-claim administrative fees that alter the price ultimately paid to the pharmacy are consistent with Part D rules. In the draft call letter, we solicited comments on this conclusion, as well as on whether and to what extent these types of adjustments have been or are currently in effect in the Part D market.

We received a large number of comments in response to our request; most of these were from pharmacies. Almost every commenter on this section acknowledged that such fees are being assessed currently, at least by some large payers. Some comments suggested these fees are associated primarily with preferred networks, and other comments suggested they are more widespread. One commenter characterized per-claim administrative fees as commonplace in the market for Medicare, Medicaid, and Commercial plans. A pharmacy trade association stated "We can confirm that such arrangements of plan sponsors charging pharmacies $1.00 (or more) per claim to participate in a preferred pharmacy network exist, and believe this current practice in the Part D market is more the rule rather than the exception. Such DIR fees are fairly common for preferred pharmacy network participation."

Most pharmacies characterized these fees as "pay to play" price concessions that should rightfully be considered part of the negotiated price. Several Part D sponsors and several PBMs submitted comments on this section. All but one of these payer commenters acknowledged these fees to be price concessions. However, they offered various arguments and regulatory interpretations permitting the reporting of these price concessions as DIR. Having reviewed these arguments, we acknowledge that our definition of negotiated prices at 42 CFR §423.100 could be interpreted as permitting these kinds of arrangements, despite our intent that negotiated prices transparently reflect all price concessions that a pharmacy has agreed to up-front on a per-drug-claim basis. Consequently, we believe that notice and comment rulemaking would be necessary in order to require sponsors to consider these fees as part of the negotiated price. We will consider the comments we have received on this question in weighing the policy basis for revising the definition of negotiated price. In the meantime, we will not consider sponsors non-compliant with our negotiated prices rules as long as all such fees are fully reported as price concessions through DIR reporting, effective with fees assessed on claims as of January 1, 2012.

Medication Therapy Management

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per Sec. 423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries is specified as costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in §423.104(d)(5)(iv). The 2013 MTM program annual cost threshold is $3,144. The MTM program annual cost threshold is updated for 2014 using the annual percentage increase of -4.03%, as specified in the Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2014 MTM program annual cost threshold is $3,017.

We thank the 49 organizations and individual entities who commented on MTM. There was support for general expansion of eligibility criteria for MTM targeting or offering MTM to all beneficiaries. Therefore, we continue to encourage sponsors to optimize their programs, including their targeting criteria, to offer MTM to beneficiaries who will benefit the most from these services. We remind sponsors that the CMS eligibility targeting requirements are established as the minimum threshold. Sponsors may also offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under section 423.153(d). The comments we received to broaden MTM eligibility requirements will also inform potential future rule-making.

Several commenters offered their support for the Million Hearts™ Initiatives, but questioned the burden and effectiveness of MTM and a comprehensive medication review (CMR) for beneficiaries who fill at least one prescription anti-hypertensive medication. We received some

comments that other mechanisms may be more appropriate to improve outcomes for this population instead of a comprehensive MTM approach such as adherence programs, targeted medication reviews, etc. We note that sponsors are encouraged, but not required, to offer MTM services or other interventions to this population to support this initiative to control high blood pressure and improve access and adherence to these medications.

We have heard that some high performing plans have used MTM to improve their Part D Star Ratings in certain areas. Growing evidence of the value of MTM to improve beneficiaries' therapeutic outcomes indicates that more beneficiaries may benefit from these services. Some organizations shared positive findings from their studies; we encourage them to publish their data on the value of MTM.

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

Based on this study, we found that MTM programs effectively targeted high-risk individuals who had problems with their drug-therapy regimens and had high rates of hospital and emergency room visits before enrollment as well as those that experienced a recent visit to the hospital or emergency room. There was evidence that Medicare beneficiaries with CHF and COPD who were enrolled in MTM programs in 2010 – particularly those who received annual comprehensive medication reviews (CMRs) – experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services. This supports the hypothesis that the annual CMR may be one of the more crucial elements of MTM. Improvements in drug therapy outcomes included increased adherence to evidence-based medications for individuals' chronic conditions, and discontinuation of high-risk medications. At the overall PDP and MA-PD levels, there were significant cost savings associated with all-cause hospitalizations but not with disease-specific (e.g., CHF-specific or COPD-specific) hospitalizations. This may be explained because MTM is a comprehensive approach to improve medication use, and reduce the risk of adverse events, and is not disease-specific disease management. Also, these findings support statements made in a recent Congressional Budget Office report that programs and services that manage the benefit well or improve prescription drug use might result in medical savings (Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services*, November 2012).

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

Coordination of Care

MTM can be used to promote the coordination of care. Beneficiaries should be encouraged to complete their annual CMR prior to their annual wellness visit, and to take their standardized medication action plan and personal medication list from their CMR to their annual wellness visit or any medical encounter (primary care physician or specialist visit, hospital admission, etc.). This summary can serve as a valuable tool to share information across providers and help reduce duplicate therapy and drug-drug interactions. CMS plans to include this message to beneficiaries beginning with the 2014 *Medicare & You Handbook* or other beneficiary communications. Part D sponsors are encouraged to communicate this recommendation to beneficiaries when notifying beneficiaries of their enrollment in the MTM program and when offering or scheduling CMRs, and to explore other opportunities to use MTM to better coordinate care. For example, CMRs may be beneficial after a transition in care or after a hospitalization. Commenters supported these recommendations to coordinate care. Some commenters recommended that CMS not specify specific timing requirements for a CMR after a transition of care, to allow physician referrals in addition to CMS' required targeting criteria, and require sponsors to send the CMR summary to the beneficiaries' prescribers. These recommendations will be considered in the future. However, the current Part D regulations would not prohibit sponsors from sharing the CMR summary with the beneficiaries' prescribers to coordinate care, provided all other legal requirements are satisfied, or offering MTM to beneficiaries outside of the CMS MTM eligibility requirements who may have been referred by their physicians.

Plan sponsors are encouraged to adopt standardized health information technology (HIT) for documentation of MTM services. Structured, universal codes (e.g., SNOMED) are available for clinical coding of MTM services delivered to beneficiaries, such as findings, recommendations, and outcomes. The use of standardized coding systems improves the efficiency of documentation by the MTM provider, supports consistent clinical record keeping, facilitates the transfer of information between health care providers and beneficiaries, and will allow better

collection and analysis of the impact of MTM services on beneficiaries' care. CMS is considering the expansion of the MTM reporting requirements to collect the findings and recommendations that are discussed during CMRs and listed in the beneficiary's medication action plan. Additional details on the 2014 Part D reporting requirements for MTM will be provided during the associated PRA public comment periods and OMB clearance process.

Combining standardized coding systems and industry-supported templates (e.g., NCPDP/HL7 MTM Template CDA, see http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=842) will also enable sponsors to update and print summaries of CMRs in a standardized format based on standard elements in databases and EHRs rather than manipulating free-form text documents. Commenters expressed general support for standardizing HIT for MTM service documentation. We will continue to work with the industry to encourage development and uptake of standards. We agree with commenters that significant lead time would be needed for plan sponsors to implement any standards if required in the future.

Optimizing the Delivery of MTM in LTC Settings

Sponsors must offer a CMR to all beneficiaries enrolled in their MTM program at least annually, and beginning January 1, 2013, this includes enrollees who are in long term care (LTC) settings. Although we received comments citing concerns or opposition to providing MTM to LTC beneficiaries, this is a statutory requirement. Otherwise, the comments were supportive of the guidance to improve the delivery of MTM in LTC and the need for any additional clarification will be considered for future guidance based on the recommendations received.

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

There may be different issues and opportunities to improve medication use through MTM for beneficiaries in the LTC setting compared to ambulatory settings. In the ambulatory setting, goals include ensuring the beneficiary is on the right drug and dose and improving medication

adherence. In LTC, adherence is less of an issue, and MTM can be used to identify overuse, medications without a clear indication, suboptimal dosing, and polypharmacy. Also, MTM could be used as an opportunity to align medication use with the beneficiary's goals and wishes in addition to the care team's. However, as noted by one commenter, adherence may still be a concern in settings such as assisted living facilities.

Sponsors should ensure that their policies and procedures for offering and delivering CMRs, per CMS requirements, are effective for beneficiaries taking into consideration how to reach the beneficiary according to their setting and needs. Regardless of setting, sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries (or their authorized representatives, if the beneficiary is cognitively impaired or otherwise unable to participate) to offer MTM services versus only reaching out via passive offers. In the LTC setting, a greater risk of both physical and cognitive issues may impact the beneficiary's ability to conduct a phone interview. Sponsors should consider using qualified providers to perform the CMR who have experience engaging beneficiaries and prescribers in the LTC setting, such as involvement of a pharmacist who has a relationship with the LTC facility. To avoid conflicting recommendations, the MTM provider should coordinate the recommendations for drug therapy changes as a result of a MTM encounter with the beneficiary's treating physician and healthcare team at the facility, their caregiver or authorized representative, when applicable, and consultant pharmacist. Additional consideration could be given to coordinate MTM activities with the care plan meeting to assess current treatment regimens. The beneficiary or authorized representative should be invited to these meetings, and often the facility has an understanding of which beneficiaries are interested in being involved in their care and which defer to their authorized representatives.

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

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

One tool that could be used in nursing homes to identify if a beneficiary is cognitively impaired or able to participate in the CMR is the Brief Interview of Mental Status (BIMS) in the Minimum Data Set 3.0. Currently, Surveyors determine whether a resident is "interviewable." Residents may be identified as "interviewable" if they have a BIMS score of 8-15; at a score of 0-7 or 99, the resident may be identified as a "Family Interview Candidate" or as needing some other authorized representative.[4] A similar process could be used by MTM providers to evaluate if a beneficiary is "interviewable" and can participate in the CMR. The following algorithm could be applied using MDS 3.0.

IF

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

BIMS Summary Scoring

13 - 15: Cognitively intact
8 - 12: Moderately impaired
0 -7: Severe impairment

AND

2. MDS Item B0700 ("Makes Self Understood") = 0 or l

"Makes Self Understood" Scoring

0 = Understood
1 = Usually understood
2 = Sometimes understood
3 = Rarely/never understood

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

AND

3. MDS Item B0800 ("Ability to Understand Others") = 0 or l

"Ability to Understand Others" Scoring

0 = Understands

1 = Usually understands

2 = Sometimes understands

3 = Rarely/never understands

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

Commenters supported the use of the algorithm above. We did not receive many comments regarding other tools that could be used in LTC settings and in the community and assisted living settings where greater variation in available tools exists. One commenter suggested that a 3-part HIPAA verification process from the ambulatory setting may be useful to determine cognitive status (i.e., if the member cannot verify their address, phone number and DOB, then consider cognitively impaired. Listing one of their medications could be substituted if one of the three pieces of information is missing from the plan's data).

We will also expand the distribution of the Long Term Institutionalized (LTI) Resident Report to plans from two times per year to quarterly to assist sponsors in the identification of enrollees in LTC. Some commenters requested more frequent reporting than quarterly, and this will be considered as the budget allows.

Promoting Beneficiary Awareness

To promote beneficiaries' awareness of these valuable programs, we will continue to enhance the information about MTM in the *Medicare & You Handbook* and on Medicare.gov. On the Medicare Plan Finder (MPF), a new MTM tab will be developed on the "Your Plan Details" page which will allow beneficiaries to view the plan's MTM program eligibility information and a link to the plan's MTM program web page. Therefore, beginning with the 2014 Health Plan Management System (HPMS) MTM Program Submission Module, sponsors will be required to report their MTM program web page URL with their program description (as part of the annual submission process). Additional MTM definitions will be added into the general tabs on Medicare.gov (such as Manage Your Health and Help & Resources) and glossaries. Examples include but are not limited to: "Medication Review" or "Manage your Medications." Currently, Part D sponsors are encouraged to post a blank Personal Medication List from the CMR standardized format on their website or provide information to beneficiaries about how to obtain a blank copy and to reach customer service. Commenters supported these efforts to promote beneficiary awareness of MTM, as well as the requirements for plan sponsors' MTM web pages listed below. However, there were a significant number of comments raising concerns about the feasibility, issues, and costs to implement an interactive tool for beneficiaries

to input their information and determine if they may be eligible for the plan's MTM program. CMS understands these concerns and is not implementing the requirement at this time.

Currently, the plan's 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.

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

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

If possible, this page should be accessible by clicking through a maximum of two links.

Antipsychotic Data

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

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

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

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

Table 1: Rates of Atypical Antipsychotic Drugs by Organization Type

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

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

Improvements to the Prescription Drug Plan Information Files

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

enhancement to be implemented in the first CY 2014 Quarterly - Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information public use file.

Coordination of Benefits (COB) User Fee

CMS is authorized to impose user fees on Part D sponsors for the transmittal of certain information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. Funding estimates for 2013 included some projects and contingent contract recompete transition costs for a number of COB-related systems that ultimately were not needed, resulting in a significant surplus. Upon this review of anticipated costs for COB activities for the upcoming contract year, we have determined that we will not be imposing COB user fees for contract year 2014. Please note that for contract year 2015, we anticipate imposing user fees again.

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

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

Part D Low Enrollment

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. While we are particularly concerned with plans that have fewer than 500 enrollees, we urge sponsors to voluntarily withdraw or consolidate any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html to determine if any of their plans meet this criterion. In April 2013, we will notify plans with less than 1,000 enrollees of available consolidation/withdrawal options. We reserve the right to require low enrollment plans to consolidate/withdraw in the future based on the marketplace at that time to ensure that all Part D

plans offered in the marketplace are attractive to beneficiaries and do not add to their confusion in selecting a plan best suited to their prescription drug coverage needs.

Preferred / Non-Preferred Pharmacy Networks

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

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

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

We received a large number of comments in responding to this section. A few commenters supported our concern, and one pharmacy association referred us to the findings of a study it had conducted which appears to corroborate our concerns. Most comments were from pharmacies complaining about barriers to participation in preferred networks. We strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor's preferred network is the best way to encourage price competition and lower costs in the Part D program. Doing so would also likely mitigate some beneficiary disruption and travel costs, especially in rural areas. However, mandating this policy is beyond the scope of this call letter.

Comments received in response to the section on Post Point-of-Sale Per-Claim Administrative Fees, above, suggest to us that some sponsors may consider the net result of the negotiated price applied at point of sale plus this type of per-claim price concession to meet the requirement not to increase CMS payments. For the reasons laid out in the section on PDE Guidance on Post-Point-Of-Sale Claim Adjustments, above, we believe the reporting of this sort of price

concession through DIR instead of through negotiated prices applied at the point-of-sale shifts costs to the beneficiary and the government, and potentially to pharmaceutical manufacturers in the Coverage Gap Discount Program as well. This is because price concessions reported in DIR do not offset all of the costs to which they are attributable in reinsurance and low-income-subsidy cost sharing subsidies. They also do not offset the additional degree to which the beneficiary is moved through the benefit from phases in which the plan liability is greater to those in which the plan's liability is substantially less. To the extent that this occurs in lieu of lower point-of-sale negotiated prices, CMS payments to the Part D plan will have been increased through higher reconciled reinsurance and LICS subsidy payments.

As noted in the previous section, we acknowledge that our definition of negotiated prices at 42 CFR §423.100 could be interpreted to permit these arrangements despite our intent that negotiated prices transparently reflect all the price concessions that a pharmacy has agreed to up-front on a per-drug-claim basis. However, despite that ambiguity, we believe that such arrangements are likely still not compliant with the requirement not to increase payments to the plan under 42 CFR §423.120(a)(9), due to the cost shifts explained above. Thus we caution sponsors that they must ensure that their preferred network pricing arrangements comply with this requirement. This will only be transparently the case when the negotiated prices applicable at point-of-sale in the preferred network are less than the negotiated prices applicable at point-of-sale in the non-preferred network.

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

We also remind sponsors that the designation of preferred and non-preferred networks in the plan benefit packages and Medicare Plan Finder pricing file submissions must be accurate. At the time of bid submission, each sponsor attests to the accuracy of all information submitted. If a plan sponsor does not have contracted preferred pharmacy arrangements at the time of bid submission, that sponsor may not indicate the offering of a preferred network in the PBP, in any associated marketing materials, or in Plan Finder pricing file submissions. Conversely, any preferred pharmacy arrangements must be accurately identified in the PBP, in any associated marketing materials, or in Plan Finder pricing file submissions in accordance with CMS instructions. A pharmacy may only be associated with the plan's preferred network in any of these materials if a lower differential cost sharing applies to some tiers of formulary drugs at that pharmacy than actually applies at pharmacies in the non-preferred network. If a sponsor does not differentiate cost sharing between preferred and non-preferred networks, it may not designate any pharmacies in its network as preferred.

Appendix 1 – Additional Gap Coverage

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. New Plan Added

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

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

2. Renewal Plan

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

3. Consolidated Renewal Plan

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

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

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

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

A PDP sponsor offering an 800 series EGWP PBP in the current contract year may expand its EGWP service area to include additional PDP regions for the following contract year through the

Part D application process. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year.

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

5. Terminated Plan (Non-Renewal)

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

6. Consolidated Plans under a Parent Organization

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

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

Requests to Change a Basic Plan to an Enhanced Plan

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

Such renewals or consolidations must always be pre-approved by CMS. We have approved such requests in a very limited number of situations when a sponsor has determined how to provide a significantly more efficient basic benefit in the next coverage year (including a meaningfully different OOPC). We would generally expect these to be one-time events for a sponsor. In these cases, the reclassification of the plan type and transfer of enrollees from a basic plan design to an enhanced plan has made sense because the enhanced plan provided a more comparable year-to-year benefit transition compared to the new level of benefits in the new proposed basic plan. The transfer of enrollees in these cases has kept the beneficiaries in a plan with comparable benefits, while allowing more efficient basic plans with lower premiums to be offered on the market.

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

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

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

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

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

Appendix 3 – Contract Year 2014 Guidance for Prescription Drug Plan (PBP) Renewals and Non-Renewals - Table

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
1	New Plan (PBP) Added	A PDP sponsor creates a new PBP.	HPMS Plan Crosswalk Definition: A new plan added for 2014 that is not linked to a 2013 plan. HPMS Plan Crosswalk Designation: New Plan	The PDP sponsor must submit enrollment transactions.	New enrollees must complete an enrollment request.	None.
2	Renewal Plan	A PDP sponsor continues to offer a CY 2013 PBP in CY 2014. The same PBP ID number must be retained in order for all current enrollees to remain in the same PBP in CY 2014.	HPMS Plan Crosswalk Definition: A 2014 plan that links to a 2013 plan and retains all of its plan service area from 2013. The 2014 plan must retain the same plan ID as the 2013 plan. HPMS Plan Crosswalk Designation: Renewal Plan	The renewal PBP ID must remain the same so that current enrollees will remain in the same PBP ID. The PBP sponsor does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2014. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
3	Consolidated Renewal Plan	A PDP sponsor combines two or more PBPs offered in CY 2013 into a single renewal PBP for CY 2014. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2014 after consolidation.	HPMS Plan Crosswalk Definition: Two or more 2013 plans that consolidate into one 2014 plan. The 2014 plan ID must be the same as one of the consolidating 2013 plan IDs. HPMS Plan Crosswalk Designation: Consolidated Renewal Plan	The PDP sponsor's designated renewal PBP ID must remain the same so that CMS can consolidate current enrollees into the designated renewal PBP ID. The PDP sponsor does not submit enrollment transactions for current enrollees. Sponsors may need to submit updated 4RX data for enrollees affected by the consolidation.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2014.	Current enrollees are sent a standard ANOC.
4	Renewal Plan with an SAE (applicable only to employer/union group waiver plans)	A PDP sponsor continues to offer an 800 series CY 2013 prescription drug PBP in CY 2014 and expands its EGWP service area to include additional regions. The PDP sponsor must retain the same PBP ID number in order for all current enrollees to remain in the same PBP in CY 2014.	HPMS Plan Crosswalk Definition: A 2014 800-series plan that links to a 2013 800-series plan and retains all of its plan service area from 2013, but also adds one or more new regions. The 2014 plan must retain the same plan ID as the 2013 plan. HPMS Plan Crosswalk Designation: Renewal Plan with an SAE	The renewal PBP ID must remain the same so that current enrollees in the current service area will remain in the same PBP ID. The PDP sponsor does not submit enrollment transaction for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2014. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
5	Terminated Plan (Non-Renewal)	A PDP sponsor terminated the offering of a 2013 PBP.	HPMS Plan Crosswalk Definition: A 2013 plan that is no longer offered in 2014. HPMS Plan Crosswalk Designation: Terminated Plan	The PDP sponsor does not submit disenrollment transactions. If the terminated enrollee elects to enroll in another PBP with the same or another PDP sponsor or MAO, the enrolling PDP sponsor or organization must submit enrollment transactions to enroll the terminated enrollees.	Terminated enrollees must complete an enrollment request if they choose to enroll in another PBP, even a PBP offered by the same PDP sponsor.	Terminated enrollees are sent a CMS model termination notice including SEP information and receive a written description of options for obtaining prescription drug coverage in the service area.

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

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

CMS Model Notice

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

IMPORTANT NOTICE: Your Medicare Prescription Drug Coverage Is Changing

Dear <member name>,

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

Your new plan coverage starts January 1

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

Here's what to do next

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

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

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

If you don't want to be in <receiving plan name> in 2014, you have the right to choose another Medicare Prescription Drug Plan **anytime between October 15 and December 7.** Your new coverage will start on January 1, 2014.

Here are your options for Medicare Prescription Drug coverage:

Option 1: If you do nothing, you'll get prescription drug coverage from <receiving plan> starting January 1, 2014.

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

Option 3: You may be able to join a Medicare Advantage plan.
You can join a Medicare Advantage plan if you have both Part A and Part B. Medicare Advantage plans cover all your Part A and Part B services and usually include additional coverage, such as prescription drugs (Part D). Costs, extra coverage and rules vary by plan. Joining a new plan will automatically disenroll you from <receiving plan name>. You should compare the plans available in your area. You can call the plans to get more information about their rules and coverage and find a plan that meets your needs.

Other information you need to know:
If you qualify for Extra Help (the low-income subsidy) for 2014, you have the right to change plans at any time.

If you have an employer or union group health plan, VA benefits, or TRICARE for Life, call your insurer or benefits administrator to find out how to join a new plan.

If you get help from the Medicaid program, contact <State Medicaid Agency and phone number> to learn how joining a new plan affects your Medicaid coverage.

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

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

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

Sincerely,

<CEO or other official of PDP organization>

[Insert Federal contracting statement.]
[Insert Material ID number][insert **CMS Approved** *followed by mm/dd/yyyy]*
["Model Beneficiary Notice for CMS Approved Crosswalk Situations"- (material submission code # 2054).]

Appendix 5 - Summary of Comments on the Draft Call Letter

On February 15, 2013 CMS sent out an Advance Payment Notice and Draft Call Letter to Part C and D sponsors, stakeholders and advocates that described CMS' proposed methodology for the 2014 Star Ratings for Medicare Advantage (MA) and Prescription Drug Plans (PDP), along with CMS' responses to comments received on an earlier Request for Comments (November 30, 2012). We received 72 comments on the Draft Call Letter from organizations representing plans, pharmaceutical companies, consumer groups and measurement development organizations. This attachment provides a summary of the comments received and how we addressed these comments in the final Payment Notice and Call Letter.

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

Summary of Comments:

Many commenters were confused by this proposal and requested clarification and a delay of implementation.
Some were concerned that it would penalize high-performing contracts.
A few suggested that low enrollment contracts should not be incorporated.

Revised Proposed Change:

CMS' proposal was intended to improve the precision of the calculation of the overall rating and avoid misclassification of contracts. In response to these comments, CMS will delay implementing any modification until additional research is done. We are concerned that the 4-star thresholds may be contributing to the issue of misclassification. Before we move forward on changing the overall rating methodology, we will give advance notice to contracts on the proposed methodology through the Advance Notice process. We will also help contracts understand the impact of any proposed changes by calculating their contract scores using the proposed method as part of an HPMS preview.

Four Star Thresholds

Summary of Comments:

Commenters did not have comments on the proposed 4-star thresholds for 2014 for measures that have been part of the Star Ratings for at least 2 years.
Some commenters supported the revised thresholds, which we intend to implement for 2015 Ratings
A few were very concerned that it would be difficult to meet the new thresholds and requested delayed implementation or limiting annual increases to only 1-percentage point.

Revised Proposed Change:

The changes we intend to propose for 2015 support the Million Hearts™ initiative. However, the concerns regarding the calculation of the overall rating lead us to evaluate the impact of setting any 4-star thresholds. We therefore do not recommend making any changes to thresholds in the final Call Letter. We will be conducting a comprehensive analysis of the 4-star thresholds.

Low Performer Icon (LPI)

Summary of Comments:

Some commenters supported the modified rules.
Some commenters proposed the LPI be assigned to plans with less than 3 stars for two consecutive years or to plans with three non-consecutive years less than 3 stars within a five-year period.
A few opposed due to Star Ratings calculation changes or because more plans would be assigned the LPI.

Revised Proposed Change:

We are planning to implement this change that affects few additional contracts. Contracts are responsible for providing adequate care and services across both Part C and D.

Changes to the Methodology of Current Measures

Summary of Comments:

Commenters generally supported the proposed Quality Improvement methodology, the proposal for rounding measure data, the proposal to maintain the current specifications for the High-Risk Medication Use measure for 2014 Ratings.
Most commenters support delaying changes to the drug list until 2015 Ratings, however some requested we further delay until 2016 Ratings.
Commenters supported the proposed addition of two drug classes for the Medication Adherence for Diabetes Medications measure for 2015 Ratings.

Revised Proposed Change:

CMS will implement the proposed Quality Improvement measure changes and rounding methodology. CMS will continue the HRM measure for 2014 Ratings, and intend to apply the updated drug list for 2015 Ratings. CMS also intends to implement the proposed changes to the Medication Adherence for Diabetes Medications measure for 2015 Ratings.

Weighting Categories of Measures

Summary of Comments:

The majority of commenters supported maintaining the same weighting categories.
A few commenters suggested that patient experience measures be given a weight of 1 or 3 instead, or measures with any technical specification changes be given a weight of 1.

Revised Proposed Change:

CMS will keep the same weighting categories used for the 2013 Star Ratings.

Integrity of Star Ratings

Summary of Comments:

Several commenters supported this policy.
A few requested more transparency and that it be applied only for egregious violations.

Revised Proposed Change:

CMS will continue its current approach to ensure that data are accurate and reliable.

Disaster Implications

Summary of Comments:

Commenters supported this clarification.
One commenter requested that CMS consider extending the 2/28/13 deadline and establishing a permanent process going forward.
Another commenter asked how national averages and cut points would be affected.

Revised Proposed Change:

Contracts are responsible for contacting CMS in the event of a disaster so that CMS can evaluate circumstances on a case-by-case basis.

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

Summary of Comments:

Several commenters supported the change.
A few commenters expressed concerns and requested more details about the specifications.

Revised Proposed Change:

CMS will provide technical specifications for these measures during the display measures plan preview period. A measure is moved from Star Ratings to display when most contracts are performing at a high level.

Measures to be Continued on Display Page and Possible 2015 Star Rating

Summary of Comments:

A few commenters requested further guidance for the SNP Care Management measure. They had concerns about the methodology and data lag.
There continues to be general support for CMS to evaluate MTM services as a component of the Star Ratings.
Many commenters suggested alternative methods of evaluating MTM outcomes than CMR completion rates. Some commenters questioned the inclusion of LTC residents for MTM services.

Revised Proposed Change:

CMS will move forward with these as display measures and will provide additional guidance as needed. The current measure of MTM CMR completion rate is the first phase of evaluating MTM services, and CMS will consider other outcomes-based MTM measures once endorsed by measure development organizations. MTM regulatory requirements, such as the inclusion of LTC residents, are outside the scope of Star Ratings and Call Letter.

Forecasting to 2015 and Beyond

Summary of Comments:

Some commenters contended that the *Disenrollment Reasons* survey would be subjective.
Some commenters had specific questions about the survey questionnaire and methodology.

Revised Proposed Change:

CMS is currently in the survey implementation stage. More information will be shared with contracts in the near future.

Changes to Measure Specifications or Calculations

Summary of Comments:

All commenters were supportive of CMS using NCQA's specifications for Breast Cancer Screening.

For the HOS calculations, commenters were concerned about the reliability and validity of the measures. One commenter urged CMS to work with the industry to develop these measures.

Revised Proposed Change:

CMS always welcomes feedback on these or any measure at any time. As stated in the Call Letter, CMS is testing the reliability and validity of an alternative scoring methodology for HOS.

Measures for Informational Purposes Only

Summary of Comments:

Commenters preferred that CMS use objective data instead of what they viewed as subjective survey data.
One commenter contended that health plans have little control over whether a provider uses EHR.
Some commenters did not want these measures to be included as display measures.

Revised Proposed Change:

These CAHPS surveys are for informational purposes only and should provide plans valuable feedback on how their beneficiaries feel about different aspects of the healthcare provided to them.