April 7, 2014

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

SUBJECT:

Announcement of Calendar Year (CY) 2015 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 2015 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2015 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 National Per Capita MA Growth Percentage for 2015 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2015. These growth rates will be used to calculate the 2015 capitation rates. As discussed in Attachment I, the final estimate of the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is -4.07 percent, and the final estimate of the FFS Growth Percentage is -3.3 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.

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 2012 are being posted on the above website.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2015 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 2015. Attachment V contains tables with the Part D benefit parameters.

Attachment VI contains details on Part D benefit parameters.

Attachment VII 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 21, 2014. 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.

CMS-HCC Risk Adjustment Models for CY2015: For reasons discussed in Attachment II, for the 2015 payment year we will blend the risk scores calculated using the 2013 CMS-HCC and 2014 CMS-HCC models by 67 percent and 33 percent, respectively.

Medicare Advantage Enrollee Risk Assessments: CMS is not implementing, for 2015, the proposed policy to exclude, for payment purposes, diagnoses identified during a home visit that are not confirmed by a subsequent clinical encounter.

Normalization Factors: The final 2015 normalization factors are:
CMS-HCC model implemented in 2013: 0.992
Clinically Revised CMS-HCC model implemented in 2014: 0.978
CMS-HCC model for PACE plans: 1.028
ESRD Dialysis/Transplant model: 1.004
ESRD Functioning Graft model: 1.028
RxHCC model: 0.961

RxHCC Risk Adjustment Model: CMS will not implement the updated RxHCC model in 2015. We will continue to use the RxHCC model used in 2014, as published in the 2014 Rate Announcement (Attachment VII, Tables, 6-10).

International Classification of Diseases-10 (ICD-10) Code Sets and Diagnosis Data Sources for 2015 Risk Scores: As proposed in the Advance Notice, CMS will use the prior calendar year as the data collection year for 2015 risk scores (specifically, we will use CY 2014 diagnoses to calculate the risk scores used in 2015 payment). In addition, as proposed in the Advance Notice, CMS will use diagnoses from the Encounter Data System submissions for the calculation of 2015 risk scores (2014 dates of service), in addition to diagnoses submitted to the Risk Adjustment Processing System. In the Advance Notice, we anticipated that data from both of these data sources would include diagnoses from ICD-10 code sets beginning with October 1, 2014 dates of service. Section 212 of the "Protecting Access to Medicare Act of 2014" delayed the adoption of ICD-10 standard code sets to no earlier than October 1, 2015. Therefore, only ICD-9 standard code sets will be used for diagnoses for 2014 dates of service and, therefore, for 2015 risk scores.

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.

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 was also announced, along with the end of the Quality Bonus Payment demonstration. This Announcement finalizes these proposals.

Calculation of FFS Rates: We rebased the FFS capitation rates for 2015, using historical claims data for 2008 through 2012. We are finalizing, as proposed, transitioning to 100 percent repricing of the historical claims data to reflect the most current wage and cost indices. For 2015, we repriced the claims to account for the changes made by the ACA to payments to disproportionate share hospitals. We also repriced durable medical equipment claims to account for the change in prices associated with the competitive bid program.

IME Phase Out: For 2015, CMS will continue phasing out indirect medical education amounts from MA capitation rates.

ESRD State Rates: We will continue to determine the 2015 ESRD dialysis rates by state as we specified in the Advance Notice.

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 2016: The list of network areas for plan year 2016 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 5.16 percent for payment year 2015.

Frailty Adjustment for PACE organizations and FIDE SNPs: We are finalizing as proposed the 2015 frailty factors.

MSP Factor: The MSP adjuster for 2015 is 0.173 for working aged and working disabled beneficiaries and the ESRD MSP factor for 2015 is 0.215.

Medical Loss Ratio Credibility Adjustment: We are finalizing the credibility adjustment factors as published in the MLR final rule (CMS-4173-F).

Payment Reconciliation: The 2015 risk percentages and payment adjustments for Part D risk sharing will be finalized as stated in the Advance Notice.

Part D Benefit Parameters: Attachment V provides the updated 2015 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

/ s /
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Attachments

2015 ANNOUNCEMENT

Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 1

Key Changes from the Advance Notice: 2

Proposals Adopted as Issued in the Advance Notice: 2

Attachment I. Final Estimate of the National Per Capita MA Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for 2015 7

Attachment II. Key Assumptions and Financial Information 9

Attachment III. Responses to Public Comments 17

Section A. Final Estimate of the National Per Capita Growth Percentage and the Fee-for-Service (FFS) Growth Percentage for Calendar Year 2015 17

Section B. MA Benchmark, Quality Bonus Payments and Rebate 20

Section C. Calculation of Fee for Service Rates 22

Section D. IME Phase Out 25

Section E. ESRD State Rates 26

Section F. Clinical Trials 26

Section G. CMS-HCC Risk Adjustment Model for CY 2015 26

Section H. Medicare Advantage Enrollee Risk Assessments 27

Section I. Adjustment for MA Coding Pattern Differences 28

Section J. Normalization Factors 29

Section K. Frailty Adjustment for PACE organizations and FIDE SNPs 30

Section L. MSP Factor 31

Section M. Medical Loss Ratio Credibility Adjustment 31

Section N. International Classification of Diseases-10 (ICD-10) Code Sets and Diagnosis Data Sources for 2015 Risk Scores 32

Attachment IV. Changes in the Payment Methodology for Medicare Part D for CY 2015 . . . 34

Section A. Update of the RxHCC Model 34

Section B. Payment Reconciliation 35

Section C. Part D Benefit Parameters for the Defined Standard Benefit: 35

Annual Adjustments for 2015 35

Attachment V. Final Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy 37

Section A. Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary 39
Section B. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average) 39
Section C. Calculation Methodology 40
Annual Percentage Increase 40
Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average) 41
Section D. Retiree Drug Subsidy Amounts 42
Section E. Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries 42
Attachment VI. 2015 Call Letter 45
How to Use This Call Letter 46
Section I – Parts C and D 47
Annual Calendar 47
Incomplete and Inaccurate Bid Submissions 53
Providing Materials to Individuals with Disabilities 82
Summary of Benefits 83
B. Transferability of MOOP Contributions When an Enrollee Changes Plans During the Contract Year 95
Part C Change of Ownership Transactions Requiring Service Area Expansions. 108
Part D Benefit Parameters for Non-Defined Standard Plans 123
Appendix 1 – Contract Year 2015 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals 132
Appendix 2 – Contract Year 2015 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals - Table 136
Appendix 3 - Summary of Comments on the Draft Call Letter to Proposed Enhancements to the 2015 Star Ratings and Beyond. 141

Attachment I. Final Estimate of the National Per Capita MA Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for 2015

The Table I-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2015. Consistent with the 2014 payment announcement, the basis for the growth percentage reflects an assumption that Congress will act to prevent the projected 24.1 percent reduction in Medicare physician payment rates from occurring in 2015. 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. We have calculated the final MA Growth Percentage and the FFS Growth Percentage based on the assumption of a zero percent update for the physician fee schedule for 2015.

An adjustment of -4.00 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 change is used in the development of the ratebook.

Table I-1 - National Per Capita MA Growth Percentage for 2015

	Prior Changes	Current Changes			
	2003 to 2014	2003 to 2014	2014 to 2015	2003 to 2015	NPCMAGP for 2015 With §1853(c)(6)(C) adjustment[1]
Aged+Disabled	49.06%	43.10%	-0.07%	43.00%	-4.07%

[1]Current changes for 2003-2015 divided by the prior changes 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 change in the FFS USPCC which will be used for the county FFS portion of the benchmark. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2015 divided by projected FFS USPCC for 2014 as estimated in the 2014 Rate Announcement released on April 1, 2013.

Table I-2 – FFS USPCC Growth Percentage for CY 2015

	Aged + Disabled	Dialysis –only ESRD
Current projected 2015 FFS USPCC	$768.84	$6,951.56
Prior projected 2014 FFS USPCC	$795.11	$7,063.55
Percent change	-3.30%	-1.59%

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2014 and 2015. In addition, for 2015, the actuarial value of deductibles and coinsurance is

being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2015. These data were furnished by the Office of the Actuary.

Table I-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2014 and 2015

	2014	2015	Change	2015 non-ESRD
Part A Benefits	$39.13	$37.23	-4.9%	$35.34
Part B Benefits[1]	$114.99	$111.14	-3.4%	$102.22
Total Medicare	$154.12	$148.37	-3.7%	$137.56

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2015 is $10,750.

Attachment II. Key Assumptions and Financial Information

The USPCCs are the basis for the National Per Capita MA Growth Percentage. Attached is a table that compares last year's estimate of United States Per Capita Costs (USPCC) with current estimates for 2003 to 2016. In addition, this table shows the current projections of the USPCCs through 2017. 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 2017.

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	$247.41	$249.37	$543.18	$545.14	0.996
2004	$313.80	$313.80	$270.70	$273.97	$584.50	$587.77	0.994
2005	$334.52	$334.52	$292.49	$293.53	$627.01	$628.05	0.998
2006	$344.97	$344.97	$313.33	$314.44	$658.30	$659.41	0.998
2007	$355.59	$355.59	$330.32	$332.26	$685.91	$687.85	0.997
2008	$371.88	$373.36	$350.66	$352.68	$722.54	$726.04	0.995
2009	$385.42	$385.74	$367.56	$369.93	$752.98	$755.67	0.996
2010	$384.96	$385.58	$376.37	$378.57	$761.33	$764.15	0.996
2011	$387.89	$390.04	$385.86	$388.44	$773.75	$778.48	0.994
2012	$375.27	$382.67	$392.69	$398.54	$767.96	$781.21	0.983
2013	$376.48	$386.10	$397.25	$409.27	$773.73	$795.37	0.973
2014	$366.12	$382.36	$411.17	$430.24	$777.29	$812.60	0.957
2015	$360.16	$383.54	$416.59	$442.62	$776.75	$826.16	0.940
2016	$366.13	$396.10	$428.68	$457.28	$794.81	$853.38	0.931
2017	$377.41		$447.97		$825.38		

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	$372.39	$373.21	$374.18	$377.18	$746.57	$750.39	0.995
2011	$371.16	$373.94	$383.77	$387.71	$754.93	$761.65	0.991
2012	$353.75	$363.60	$391.46	$398.83	$745.21	$762.43	0.977
2013	$359.28	$371.79	$393.53	$409.18	$752.81	$780.97	0.961
2014	$358.09	$375.59	$399.37	$419.52	$757.46	$795.11	0.953
2015	$358.67	$380.58	$410.17	$436.60	$768.84	$817.18	0.941
2016	$363.95	$393.40	$421.63	$451.66	$785.58	$845.06	0.930
2017	$374.25		$439.41		$813.66		

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	$6,770.39	1.000
2012	$6,719.08	$6,834.71	0.983
2013	$6,780.23	$7,039.85	0.963
2014	$6,813.82	$7,063.55	0.965
2015	$6,951.56	$7,324.21	0.949
2016	$7,239.14	$7,945.05	0.911
2017	$7,529.40		

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
2013	1.0057	1.0034	1.0091
2014	1.0073	1.0068	1.0141
2015	1.0241	1.0103	1.0346
2016	1.0627	1.0138	1.0774
2017	1.1015	1.0173	1.1206

Note: 2012 All ESRD FFS USPCC is $4870.99

Summary of Key Projections

Part A[1]

Year	Calendar Year CPI Percent Change	Fiscal Year PPS Update Factor	FY Part A Total Reimbursement (Incurred)
2003	2.2%		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%	7.6%
2009	-0.7%	2.7%	7.1%
2010	2.1%	1.9%	2.9%
2011	3.6%	-0.6%	4.2%
2012	2.1%	-0.1%	0.3%
2013	1.4%	2.8%	3.7%
2014	1.6%	0.9%	1.4%
2015	1.9%	1.5%	1.5%
2016	2.2%	2.0%	4.1%
2017	2.4%	1.5%	5.6%

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%	8.9%	3.8%
2010	2.5%	1.4%	5.8%	2.3%
2011	0.9%	2.2%	7.6%	2.3%
2012	-1.1%	0.9%	7.4%	1.7%
2013	-0.1%	-0.5%	6.4%	0.1%
2014	-0.1%	1.9%	12.2%	2.6%
2015	-0.5%	-2.9%	6.2%	0.3%
2016	0.0%	2.1%	7.0%	3.3%
2017	0.1%	2.5%	6.7%	4.2%

[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	35.120	6.404
2009	38.234	7.530	35.810	6.628
2010	39.066	7.788	36.493	6.900
2011	39.904	8.116	37.203	7.208
2012	41.639	8.332	38.496	7.449
2013	42.885	8.467	39.721	7.618
2014	44.389	8.683	41.022	7.771
2015	45.874	8.842	42.305	7.917
2016	47.403	8.973	43.627	8.033
2017	48.997	9.067	45.004	8.117

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	26.281	5.276
2009	28.541	6.245	26.049	5.337
2010	28.879	6.410	26.237	5.518
2011	29.164	6.604	26.396	5.691
2012	29.913	6.613	26.694	5.726
2013	30.128	6.530	26.889	5.677
2014	30.434	6.556	26.992	5.640
2015	31.819	6.664	28.143	5.760
2016	32.916	6.717	29.027	5.801
2017	33.860	6.706	29.751	5.781

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	0.472	0.451	0.429	0.407
2009	0.492	0.470	0.440	0.418
2010	0.511	0.489	0.457	0.435
2011	0.529	0.506	0.471	0.448
2012	0.545	0.523	0.483	0.460
2013	0.561	0.539	0.492	0.470
2014	0.579	0.556	0.503	0.481
2015	0.595	0.572	0.519	0.496
2016	0.610	0.587	0.532	0.509
2017	0.624	0.601	0.542	0.519

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	2,693.34	536.99	151.21	1,076.79	11,404
2009	2,664.96	553.22	154.32	1,248.66	12,290
2010	2,633.53	573.81	155.74	1,252.87	13,088
2011	2,574.94	626.67	143.89	1,303.32	14,034
2012	2,448.05	546.33	136.51	1,365.91	15,184
2013	2,422.54	552.60	134.47	1,401.86	16,106
2014	2,345.50	552.73	131.20	1,357.91	17,118
2015	2,351.07	578.32	133.07	1,253.83	18,279
2016	2,366.91	605.18	134.33	1,282.84	19,622
2017	2,406.13	632.16	136.11	1,350.04	21,160

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	1,225.23	365.14	196.72
2004	1,342.09	419.28	195.26
2005	1,395.45	478.18	196.42
2006	1,394.37	498.05	197.30
2007	1,366.40	527.57	195.14
2008	1,365.81	555.83	200.32
2009	1,373.18	601.62	183.08
2010	1,414.39	633.46	183.47
2011	1,441.17	678.95	175.21
2012	1,398.06	717.22	173.05
2013	1,348.65	750.78	149.25
2014	1,329.68	826.10	128.75
2015	1,351.78	894.27	131.75
2016	1,363.73	960.38	116.18
2017	1,393.17	1,015.48	118.62

Calendar Year	Carrier Lab Aged + Disabled	Other Carrier Aged + Disabled	Intermediary Lab Aged + Disabled
2003	73.26	327.63	75.25
2004	77.94	351.26	80.56
2005	82.15	359.73	84.26
2006	85.03	357.79	84.60
2007	90.06	360.00	84.48
2008	93.86	362.53	85.89
2009	101.17	380.51	90.75
2010	100.83	391.16	91.88
2011	101.80	404.50	95.30
2012	109.33	407.93	96.81
2013	107.82	405.84	93.27
2014	108.58	403.94	33.04
2015	113.46	417.19	34.59
2016	119.04	426.21	36.35
2017	124.60	439.50	38.11

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	158.35	252.76	1,105.70
2009	167.76	282.48	1,206.26
2010	170.29	283.88	1,224.33
2011	169.63	263.32	1,280.20
2012	171.04	249.56	1,373.84
2013	157.61	245.11	1,495.11
2014	146.20	239.82	1,703.91
2015	147.47	243.62	1,650.75
2016	154.37	246.18	1,707.08
2017	159.59	249.66	1,821.65

Average reimbursement per enrollee on an incurred basis.

2015 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service Type	Current Estimate	Last Year's Estimate	Ratio
Part A			
Inpatient Hospital	2,351.07	2,559.11	0.919
SNF	578.32	623.57	0.927
Home Health	133.07	141.18	0.943
Managed Care	1,253.83	1,273.94	0.984
Part B			
Physician Fee Schedule	1,351.78	1,474.17	0.917
Part B Hospital	894.27	887.80	1.007
Durable Medical Equipment	131.75	165.33	0.797
Carrier Lab	113.46	120.12	0.945
Other Carrier	417.19	450.71	0.926
Intermediary Lab	34.59	105.16	0.329
Other Intermediary	147.47	179.49	0.822
Home Health	243.62	265.75	0.917
Managed Care	1,650.75	1,639.62	1.007

* 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	0.001008	0.003288
2013	0.000994	0.002846
2014	0.000994	0.002846
2015	0.000994	0.002846
2016	0.000994	0.002846
2017	0.000994	0.002846

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 2015 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2015 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2014.

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 2015

Comment: Several commenters had concerns about the magnitude of changes proposed in the Advance Notice and the potential impact to Medicare beneficiaries and plans. Commenters raised concerns that the payment reductions described in the Advance Notice would lead to significantly higher MA premiums, significantly reduced benefits, or both. Some commenters argued that these cuts would lead to MA plans exiting the market. Some providers noted that the reductions to MA contained in the Advance Notice would seriously threaten their ability to provide 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. Commenters requested that we keep Medicare Advantage revenue flat for 2015.

Response: We are committed to a strong, stable Medicare Advantage program and to continued access to high quality plan choices for Medicare beneficiaries. Over the past several years, even as the Medicare Advantage program transitioned to payments that are more aligned with FFS Medicare costs, enrollment in Medicare Advantage has increased to an all-time high of approximately 15 million beneficiaries. Today, nearly 30 percent of Medicare beneficiaries are enrolled in a Medicare Advantage plan and benefits remain stable. We believe that the proposals outlined in the Advance Notice will continue the transition to payments that are more comparable to FFS costs, while at the same time continuing the trend toward greater enrollment in high quality plans.

Comment: Many commenters expressed their support for CMS' proposal to calculate the MA Growth Percentage and the FFS Growth Percentage based on the assumption of an SGR override for the physician fee schedule for 2015. Commenters also asked whether CMS will be making this assumption permanent.

Response: We appreciate the support. Given that Congress has changed the law every year since 2003 such that the projected SGR cut to the physician fee schedule does not occur, we believe the assumption of an SGR fix is the best estimate of what actually will occur. In each future year, we intend to use our most accurate projection of physician payments to calculate the growth percentages, including our assessment of possible Congressional intervention.

Comment: A number of commenters expressed their concern that cuts to the MA program affect Medicare-Medicaid (dual) beneficiaries and plans that primarily enroll Medicare-Medicaid beneficiaries. These commenters asked CMS to use our discretion when determining the county rates for Medicare-Medicaid plans participating in the Financial Alignment Demonstrations.

Response: The county rates are estimated on a standardized basis. As a result, CMS does not set specific county rates for Medicare-Medicaid beneficiaries but rather adjusts payment through the CMS-HCC risk model. The methodology for calculating the county rates for the Financial Alignment demonstrations is laid out in each memorandum of understanding between CMS and the participating state. These demonstrations do not use the same bid process as in Medicare Advantage, nor do the quality bonus payments (QBPs) work in the same way. Therefore, the impact of the 2015 policies is different in the Financial Alignment demonstrations than in Medicare Advantage writ large.

Comment: Many commenters expressed their support of CMS policies and proposed payment rates that continue to align MA reimbursements with costs in FFS Medicare.

Response: We appreciate the support.

Comment: A number of commenters pointed out that Medicare cost growth and national health expenditures have grown at historically low rates over the last several years; therefore, it is appropriate that this slower growth is reflected in the MA payment methodology.

Response: We appreciate the support.

Comment: Many commenters expressed concern and confusion in regards to the change in the MA Growth Percentage and FFS Growth Percentage, from the estimates discussed on the December actuarial user group call and updated estimates published in the Advance Notice. Commenters requested clarification and more information on the reasons for these different estimates.

Response: The early preliminary growth rate announced on the December 3, 2013 actuarial user group call was based on experience supporting the development of the Part A deductible and Part B premiums for 2014. Since that time we have updated our tabulation of historical fee-for-service (FFS) experience and have revised the corresponding projection factors. The most significant change in the estimate is with respect to actual calendar year 2012 and 2013 inpatient utilization being lower than previously estimated. Similarly, the updated tabulation of Part B volume and intensity for 2012 and 2013 is also lower than the prior estimate, but less so than the reduction for inpatient utilization.

Comment: A few commenters asked CMS to include in the final Rate Announcement a full description of how the prior year corrections were calculated and why corrections of this magnitude were necessary.

Response: The magnitude of the adjustments from the 2014 payment announcement are reflected in Attachment II of this payment announcement. As mentioned above, the update reflects more complete program experience. When the 2014 rates were finalized in April 2013, complete 2012

experience data was not yet available and projections had to be made for 2013 and 2014. The most significant prior year corrections included in this notice include a more complete 2012 experience, more 2013 actual experience and an update to the 2014 projected experience.

Comment: A number of commenters have asked CMS to phase in the impact of prior year corrections whenever the impact of those corrections on the final trend is greater than the underlying trend. For example, one commenter suggests a five year phase in period in order to mitigate the impact of these prior period adjustments on beneficiaries.

Response: The statute does not provide discretion to phase-in prior year corrections. The totality of the prior year corrections and underlying trend estimates ensure that the projected total and FFS USPCCs reflect our best estimates of per capita spending in the upcoming payment year.

Comment: One commenter has asked that we quantify the impact of demographic changes on the FFS Growth Percentage.

Response: As reflected in Attachment II of this payment announcement, the five-year (2010-2015) trend in Part A fee-for-service (FFS) USPCC is -3.7 percent. We estimate that changes in population characteristics, or demographics, has resulted in a -2.9 impact on Part A trend for the period. Thus, the Part A trend for factors other than demographics for 2010-2015 is estimated to be -0.8 percent. Similarly, the Part B FFS trend for 2010-2015 is estimated to be 9.6 percent. Demographic changes during the period are estimated to impact the Part B trend by -1.0 percent, yielding a trend for non-demographic factors of 10.7 percent.

Comment: One commenter requested CMS to reconsider the underlying assumptions used in the development of the preliminary estimates of the MA Growth Percentage and FFS Growth Percentage, particularly as they relate to data from more recent years, in order to avoid or mitigate the impact of the reduction in the growth percentages. Another commenter expressed concern that the ratio of the current FFS growth rate to last year's estimate has decreased and to a greater degree than in projected years. Commenters requested further clarification on whether CMS is projecting sustained negative trends and what supports this assumption.

Response: The growth percentages and total USPCC and FFS USPCCs reflected in tables included in Attachment II of this payment announcement are based on the Office of the Actuary's (OACT's) best estimate of enrollment and expenditures. These projections take into account emerging utilization trends, impacts of legislation, economic forecasts, and other appropriate factors. The key assumptions will be discussed in an upcoming actuarial user group call, will be posted on the OACT website and will be contained in other OACT publications.

Comment: Several commenters asked that we provide final growth rate percentages and analyses prior to the release of the Rate Announcement on April 7, 2014.

Response: The final growth percentages reflect the most recent projection of Medicare experience. Release of the growth percentages prior to April 7, 2014 would hamper our ability to project the most accurate USPCCs for calendar year 2015.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: CMS received several comments supporting the ending of the Quality Bonus Payment Demonstration.

Response: We appreciate the support.

Comment: CMS received many comments raising concerns about the end of the Quality Bonus Payment demonstration. In particular, commenters were concerned about the immediate end of quality bonuses for three and three and a half star plans and reductions in payments to four and five star plans serving enrollees in six-year transition counties and in counties affected by the application of the pre-ACA rate cap.

Some commenters recommended that CMS extend the demonstration in its entirety for one or more years. Other commenters recommended that we extend the demonstration in order to provide a more gradual phase-out of the quality adjustments under the demonstration. Some commenters recommended that we extend certain provisions of the demonstration, e.g., the waiver of the pre-ACA rate cap. Other commenters recommended that we conduct a new demonstration for the Commonwealth of Puerto Rico and other territories. Several commenters recommended that we continue the demonstration for plans that serve a disproportionate share of dual-eligible beneficiaries.

Response: While we appreciate the concerns of commenters regarding the end of the quality bonus payment demonstration, we believe that the three-year duration of the demonstration will be sufficient to test the hypothesis of whether providing scaled quality bonuses leads to greater quality improvement. Given that the purpose of the demonstration is to test this hypothesis, we do not believe it would be appropriate to extend the demonstration beyond 2014, either in whole or in part.

Comment: A commenter asked for clarification on which enrollment month and year is used for calculating the weighted average Star Ratings for new MA contracts in an existing Parent Organization. In addition, the commenter requested clarification on the data source used for the enrollment figures used in these calculations.

Response: CMS uses November 2013 enrollment from the Medicare Advantage and Prescription Drug system to calculate the weighted average star ratings for new MA contracts.

Comment: One commenter stated that they disagree with CMS' treatment of new MA plans as eligible for 3.5 QBP percentage points. Under this proposal, an existing MAO that has an

average Star Rating of 3.5 stars across all of its existing contracts and is considering entering a new market would be at a disadvantage compared to a new MA plan offered by a parent organization without any existing contracts that is entering that same market.

Response: Our treatment of new plans is consistent with the statutory definition of a new plan.

Comment: One commenter stated that a default 3.5 star rating for low enrollment plans is unsatisfactory because it does not allow low enrollment plans to be rewarded for performing above average.

Response: We believe that the default star rating for low enrollment plans is consistent with the statute.

Comment: One commenter stated that, when determining which counties are eligible for a double quality bonus percentage, we should include Cost plan enrollees in the determination of the MA penetration rate because many of these members would enroll in MA plans if the Medicare Cost plan was not an alternative available to the member. The commenter requested that the MA penetration rate calculation methodology be revised so either Cost plan members are included or excluded from both the numerator and denominator.

Response: We believe that excluding Cost plan enrollees from the Medicare Advantage penetration rate calculation is appropriate as cost plans are not Medicare Advantage plans.

Comment: One commenter indicated that the column headings on Table II-3 (pg. 13 of the Advance Notice) were incorrect.

Response: We agree that the column headings are incorrect and have provided a revised version of the table below.

Table III-1. Blended Benchmark Calculations

	Two Year County Blend		**Four Year County Blend**		**Six Year County Blend**	
Year	Pre-ACA	ACA	Pre-ACA	ACA	Pre-ACA	ACA
2012	1/2	1/2	3/4	1/4	5/6	1/6
2013	0	100%	1/2	1/2	2/3	1/3
2014	0	100%	1/4	3/4	1/2	1/2
2015	0	100%	0	100%	1/3	2/3
2016	0	100%	0	100%	1/6	5/6
2017	0	100%	0	100%	0	100%

Comment: We received a few requests for CMS to indicate in the Rate Announcement, with the publication of the county benchmarks, which counties have blended benchmarks that are capped at the pre-ACA rate. Commenters also requested that CMS publish the county benchmark that would have been applied in these counties under the pre-ACA rules.

Response: We will indicate which counties are capped in the ratebook calculation files posted on the CMS website.

Comment: Many commenters expressed concern about the application of the pre-ACA rate cap, stating that the cap could reduce or eliminate the value of the quality bonus payments for four or five star plans. Several commenters asked CMS not to apply the pre-ACA rate cap.

Response: While we appreciate the concerns of commenters, we do not believe we have the discretion under section 1853 of the Social Security Act (Act) to waive application of the pre-ACA rate cap at this time.

Comment: One commenter suggested that CMS apply the cap before applying any Star Rating Bonus payment. Then after a transition period, CMS could calculate the capped blended benchmark with the bonus included.

Response: We believe that applying the cap in this way would be inconsistent with section 1853(n)(4) of the Act.

Section C. Calculation of Fee for Service Rates

Comment: We received a number of comments asking for more transparency on the calculation of the FFS rates. Commenters asked for detailed, county level information on the repricing of claims data proposed in the Advance Notice, including the repricing of DME claims and the uncompensated care payment (UCP) adjustments. Several commenters asked that CMS release the historical FFS claims data used to determine the Average Geographic Adjustment (AGA) by county before the Advance Notice so that plans can estimate the potential impacts of rebasing.

Response: We are publishing with the final Rate Announcement files that contain the wage indices in each claim year (*i.e.*, 2008-2012), and the wage indices for 2014, 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. We will also look into releasing historical FFS claims data prior to the Advance Notice.

Comment: One commenter asked that CMS consider not rebasing in 2015 as it is not required by statute. Another commenter asked that CMS institute a regular schedule of rebasing once every three years. One commenter asked that CMS not rebase in 2018 in order to allow a year for plans to accurately predict the rates. We received one comment that asked CMS to smooth

the rebasing impacts on a sliding scale if the 2015 FFS rate is more than two percent different than the 2014 FFS rate.

Response: Given that all MA county rates are now based exclusively or primarily on FFS costs, we believe it is important to update the FFS rates using the most current FFS data available and we anticipate rebasing in each future year as a result. We do not believe that smoothing the impacts of rebasing would be consistent with the statute's requirement of calculating the specified amount based on the estimated FFS rate for that county. We are not in a position to comment on the 2018 rates at this time.

Comment: One commenter asked CMS to modify the specified and applicable amounts to account for changes in Medicare Disproportionate Share Hospital (DSH) payments and Uncompensated Care Payments (UCPs). Another commenter asked why DSH and UCP changes would be reflected in the specified amount and not also in the applicable amount.

Response: As stated in the Advance Notice, the applicable amount is the pre-Affordable Care Act rate established under section 1853(k)(1) of the Act. For 2015, it is the greater of: 1) the county's 2015 FFS rate or 2) the 2014 applicable amount increased by the CY 2015 National Per Capita Medicare Advantage Growth Percentage. As such, the applicable amount would not, by definition, reflect the 2015 FFS rate (including any DSH or UCP changes) unless that rate were higher than the previous year's rate increased by the CY 2015 National Per Capita Medicare Advantage Growth Percentage.

Comment: One commenter noted that CMS should address hospice payment issues in the rates. The commenter noted that Puerto Rico has approximately twice as many hospice admissions that last longer than 180 days compared to the rest of the United States.

Response: The development of the FFS USPCC has excluded Hospice claims since rates were developed on an adjusted average per capita cost basis. Excluding claims for beneficiaries in Hospice status from the AGA calculation aligns the calculation of the AGAs with how they are applied. As a result, we exclude these claims. CMS has looked at this issue extensively and all indications are that the carve-out amounts are an accurate reflection of hospice spending in Puerto Rico.

Comment: One commenter asked that CMS not make repricing changes if the changes are at the margin; that is, if they do not affect most county-level FFS costs. The commenter noted that the fewer the changes, the more likely plans can use historical data to forecast FFS costs.

Response: As noted earlier, we are working towards increased transparency and hope to provide more detailed information on FFS costs prior to the publication of the Advance Notice in the future. With respect to repricing, we also are working towards having data earlier on county level changes. The repricing being done is needed in order to best capture the relative county

costs for 2015 based on updated pricing inputs (e.g., hospital wages and physician practice costs).

Comment: One commenter indicated that CMS should adjust FFS data to include costs associated with mandatory features of operating a Medicare Advantage plan, including the effect of offering a Maximum Out-of-Pocket limitation (MOOP), and the required administrative costs unique to Medicare Advantage.

Response: We believe that the statute requires CMS to set the specified amount at levels equal to what FFS Medicare would have paid. As such, we do not think these adjustments are appropriate. We believe that this approach would result in FFS rates that would not accurately represent the expected FFS cost for a plan.

Comment: One commenter asked that CMS not reprice DME claims from 2008 to 2010 because the competitive bidding for DME was not in effect in those years.

Response: The purpose of repricing is to calculate a geographic cost index for each county that best represents that county's relative cost structure in the payment year–2015. Repricing DME claims from 2008 to 2010 to account for competitive bidding allows for more accurate claim estimates for 2015 than not repricing, because in 2015 DME prices from competitive bidding will be in effect. In this sense, the historical data need to be adjusted to reflect what we expect to happen in 2015.

Comment: One commenter asked that CMS make retroactive adjustments to the 2014 rates to account for larger costs associated with the new DSH/UCP methodology in Puerto Rico.

Response: We do not have the administrative discretion to retroactively change the county benchmark methodology. Under the statute, CMS must announce the Medicare Advantage payment rules for each year in advance through the Advance Notice and Rate Announcement documents. The statutory deadline for the 2014 Rate Announcement was last April which was before the methodology for applying the DSH/UCP adjustments had been finalized. Therefore, the 2014 Rate Announcement did not include any proposed adjustments to the county benchmarks for DSH/UCP.

Comment: Several commenters offered support for repricing historical claims data, including the DSH/UCP repricing and the DME repricing. One commenter noted that the repricing represents a significant improvement in the accuracy of these rates.

Response: We appreciate the support.

Comment: One commenter noted that CMS proposes to calculate an "adjustment ratio," and then substitute a UCP amount for the DSH amount in the claims. The commenter asked CMS, in describing this provision, to be clear that this formula is a lagging reduction to MAOs in that it is

less than the Factor 2 reduction applied in the applicable Hospital IPPS Pricer system for the year during which the MAO makes provider payments.

Response: We believe that the adjustment as described in the Advance Notice is the best approximation of what would have been paid if the UCP policy had been in effect in that year. In addition to adjusting the payments for providers eligible for DSH in both the base year and FY 2014, the methodology accounts for those hospitals eligible for DSH in FY 2014 that did not receive DSH in the base year, as well as those hospitals eligible for DSH in the base year that are not eligible in FY 2014. As such, the repricing approach is not less than the Factor 2 reduction.

Comment: One commenter asked that CMS use the published 2015 data in phasing in additional re-pricing for wage index and GPCI.

Response: The pricing is based on the 2014 wage indices and the 2014 GPCIs.

Comment: One commenter expressed concern about the impact of the UCP adjustment. This commenter stated that UCP pool payments should be carved out of MA plan premiums and paid directly to hospitals, similar to the treatment of Indirect Medical Education payments. UCP payments are explicitly for the purpose of supporting uncompensated care while the expansion of insurance through the ACA occurs. The commenter noted that a carve-out requires legislation and that CMS does not have the authority to implement this on its own, and asked that CMS should advocate for a carve-out.

Response: We agree with the commenter that a carve-out would require legislation and that CMS cannot make this change through its administrative authority.

Comment: One commenter expressed concern about repricing based upon the following: (1) the impact of 2014 Wage Indices in Connecticut; (2) the recent merger between hospitals in Connecticut; and (3) the trend of hospital purchases of provider groups in Connecticut. This commenter asked that when using 2008 through 2012 data for re-pricing, CMS reclassify all claims for services provided at acquired hospitals reflect the appropriate post-merger rate. Second, the commenter asked that, if Uncompensated Care Payments are included in the re-pricing CMS assign all claims for services provided at the acquired hospital the new post-merger DSH payment. Third, the commenter asked CMS take into consideration the provider market consolidation currently taking place in various counties in Connecticut.

Response: Our current methodology for repricing does not support making these adjustments. We will explore making these types of adjustments in future years.

Section D. IME Phase Out

Comment: One commenter has asked CMS to clarify how the timing of the IME reduction will correspond with the timing for county quartile assignments.

Response: As previously, the IME is carved out of the FFS rate in the year of rebasing to determine the quartiles.

Section E. ESRD State Rates

Comment: One commenter asked CMS to apply similar repricing to the ESRD state average geographic adjustments as is being used to update the age and disabled county rates. The commenter is concerned that if this is not done for the DSH and UCP payments then the Puerto Rico ESRD AGA will be understated.

Response: We do not have an established methodology for making this adjustment to the ESRD rates, but will explore making this change in the future.

Section F. Clinical Trials

Comment: One commenter expressed appreciation about CMS clarifying the continuation of the policy to pay for clinical trial items on a fee-for-service basis.

Response: We appreciate your support.

Section G. CMS-HCC Risk Adjustment Model for CY 2015

Comment: We received a few comments opposing our proposal to use a blend of the 2013 CMS-HCC model and 2014 CMS-HCC model in 2015, and supporting instead calculating risk scores using exclusively the 2013 CMS-HCC model. Many commenters were in support of continuing to use a blend of risk scores from two different models. Two commenters were in favor of ending the phase-in of the clinically revised model introduced in 2014 and calculating risk scores in 2015 using only this model.

Response: As we remain committed to the clinically revised model introduced for the 2014 payment year, we will not use risk scores exclusively from the 2013 CMS-HCC model as recommended by some commenters. Because we still believe that additional time to transition to the 2014 model is needed, we also will not use risk scores from the 2014 model exclusively as recommended by two commenters, and will continue for 2015 payment year to blend the risk scores calculated using the 2013 CMS-HCC and 2014 CMS-HCC models.

In light of the impact of the final payment updates and changes for 2015, however, we are concerned that the use of the 2014 blend percentages of 75% and 25% that we proposed to continue in the Advance Notice would not have the same effects on payment stability that they had last year, and that we assumed they would have when proposing them this year. As in 2014, we will continue to blend the risk scores from the old and new models, in order to both support our intention to move to the updated model while also providing time for plans to transition to its use in payment. Thus, to further our goal of promoting stability and given concerns about the

impact of payment changes for 2015, we will blend the two scores using a 67 percent and 33 percent blend, respectively. Specifically, we will blend the risk scores calculated using the 2014 CMS-HCC model with risk scores using the 2013 CMS-HCC model, each appropriately normalized, weighting the normalized risk scores from the 2013 model by 67 percent and the normalized risk scores from the 2014 model by 33 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. See Section II.G of the 2014 Advance Notice and Section III.D of the 2014 Rate Announcement for more details on the clinically revised CMS-HCC model.

Comment: We received several comments in support of continuing to pay PACE organizations using the same risk adjustment model that we have used from 2012-2014.

Response: We did not propose to make changes to the risk adjustment model that we use for PACE organizations, and will continue to use this model for 2015. This model is described in the 2012 Rate Announcement in Tables 9 through 11.

Comment: One commenter referenced our 2015 Notice proposal to exclude diagnoses from the home, as defined by place of service code 12 (POS=12), and asked whether the CMS-HCC models were calibrated on data that also excluded POS=12 diagnoses.

Response: Please see the following section on Medicare Advantage Enrollee Risk Assessments, in which we explain that we are not finalizing this policy as proposed.

Section H. Medicare Advantage Enrollee Risk Assessments

Comment: Many commenters opposed the proposal to exclude diagnoses that resulted from home visits, including enrollee risk assessments, unless there was a subsequent clinical encounter.

Response: CMS continues to support the use of enrollee risk assessments for wellness, care coordination, and disease prevention; however, we remain concerned that many home visits are being used primarily for the gathering of diagnoses for payment rather than to provide treatment and/or follow-up care to beneficiaries. We recently instituted a new requirement for MA organizations to identify, in the diagnoses they submit to CMS, which diagnoses are from home visits. These new data will enable CMS, for the first time, to evaluate how many diagnoses are identified in home visits and to assess what effect the home assessments have on the care provided to beneficiaries. In order to allow our policy to be informed by this analysis, we have decided not to implement the proposal to exclude diagnoses from home visits for 2015 payments. We will study the data submitted by MA organizations to determine appropriate policy options for consideration for 2016 and future years.

Comment: In response to our request for comments for specific and measurable ways CMS could operationalize the use of any of the diagnoses gathered from home visits, we received various proposals about the nature of the visit (for example, an Annual Wellness Visit), or the provider making the visit (for example, a network provider), or the patient being visited (for example, a homebound beneficiary) that commenters believed were reasonable to allowing the use of the diagnoses collected.

Response: We thank commenters for their responses and will continue to study this issue for future implementation. We are particularly interested in whether we can identify and measure improvement in care as a result of these home visits, and will continue to welcome suggestions for how we can measure such improvement.

Comment: Several commenters shared CMS' concern that enrollee risk assessments were being used as a vehicle to collect diagnosis data for payment without providing treatment or follow-up care, and supported our proposal to exclude these diagnoses for risk adjustment purposes.

Response: CMS appreciates the support.

Section I. Adjustment for MA Coding Pattern Differences

Comment: A few commenters were pleased with the proposed coding adjustment factor.

Response: CMS appreciates the support of the commenters.

Comment: One commenter requested that CMS substantiate the adjustment calculation; another requested more study of the factor.

Response: CMS appreciates the comment and will continue to regularly examine and study the coding intensity data.

Comment: Several commenters feel that the coding adjustment factor should be lower and asked that the following be taken into consideration: limitation on enrollee risk assessments for diagnosis submission, implementation of ICD-10, and the absence of incentives for FFS to code diagnoses correctly (resulting in understated FFS risk scores).

Response: We are not finalizing our 2015 Notice proposal to exclude for risk adjustment purposes diagnoses from the home, including those from in-home enrollee risk assessments without a subsequent clinical encounter (please see Section H. on Medicare Advantage Enrollee Risk Assessments for more information). Additionally, it is unclear how the implementation of ICD-10 would impact MA coding. Moreover, Section 212 of the "Protecting Access to Medicare Act of 2014" delayed the adoption of ICD-10 as the standard code sets to no earlier than October 1, 2015. Therefore, ICD-10 code sets will not be used for 2015 risk scores.

Comment: One MAO noted that since its risk scores are below average, it does not feel the adjustment should be applied across the board.

Response: While CMS understands the commenter's concern, we have determined that the optimal way to apply the adjustment is to do so uniformly and industry wide.

Section J. Normalization Factors

Comment: The majority of commenters supported CMS' proposal to calculate the normalization factors for the CMS-HCC and RxHCC risk scores using a methodology to better capture the increased proportion of younger beneficiaries known as the "baby boomers." Several commenters recommended that CMS make retroactive adjustments to the normalization factors.

Response: We appreciate the support for modifying the normalization factor methodology to account for the influx of baby boomers to the Medicare population. CMS uses historical data to develop normalization factors prior to a payment year in order to promote stability for bidding purposes. Given this policy, CMS will not retroactively change the normalization factors for prior years. However, we did consider whether using more historical data could better inform the calculation of the 2015 normalization factors (in the Advance Notice we proposed using 2012 and 2013 risk scores to estimate annual trends for the CMS-HCC models). By using a quadratic functional form fit to risk scores from 2010 through 2013, the normalization factors will better reflect more recent changes in the population trends. Thus, we are finalizing the 2015 normalization factors for the CMS-HCC and RxHCC models as shown in Table III-2:

Table III-2. 2015 Normalization Factors

CMS-HCC or RxHCC Model	2015 Normalization Factor
CMS-HCC model implemented in 2013	0.992
Clinically revised CMS-HCC model implemented in 2014	0.978
CMS-HCC model for PACE plans	1.028
ESRD Dialysis/Transplant model	1.004
ESRD Functioning Graft model	1.028
RxHCC model	0.961

Comment: A commenter highlighted the difference in the years of data we used when calculating the proposed normalization factors for the CMS-HCC and RxHCC models (CY2012 and CY2013 vs. CY2011 and CY2012, respectively), suggesting that we should be consistent in the years of data we use to develop the RxHCC normalization factors.

Response: We agree with the commenter, and we have changed the data years used to calculate the 2015 RxHCC normalization factor to match those used for the CMS-HCC models, as shown in Table III-2. Please see Table III-3 for the 2015 RxHCC normalization factors.

Comment: A commenter requested further clarification between the relationship of the enrollee risk assessments and the impact on the normalization factor.

Response: We are not finalizing our 2015 Advance Notice proposal to exclude for risk adjustment purposes diagnoses from the home, including those from in-home enrollee risk assessments without a subsequent clinical encounter (please see Section H. on Medicare Advantage Enrollee Risk Assessments for more information).

Comment: A number of commenters asked for more transparency around the calculation of the normalization factors.

Response: In Table III-3. below, we show the risk scores used to calculate the normalization factors for 2015.

Table III-3. 2010-2013 Risk Scores Used to Calculate 2015 Normalization Factors

CMS-HCC or RxHCC Model	2010	2011	2012	2013
CMS-HCC model implemented in 2013	0.986	0.997	1.009	1.008
Clinically revised CMS-HCC model implemented in 2014	0.978	0.988	0.997	0.995
CMS-HCC model for PACE plans	1.018	1.031	1.042	1.042
ESRD Dialysis/Transplant model	0.950	0.959	0.976	0.984
ESRD Functioning Graft model	1.018	1.031	1.042	1.042
RxHCC model	0.994	1.001	1.005	0.996

Section K. Frailty Adjustment for PACE organizations and FIDE SNPs

Comment: A few commenters support the continued use of the blended frailty calculation, while one commenter requested that only the 2014 factors be used in calculation.

Response: CMS appreciates the support. The risk scores for MA beneficiaries are being calculated for 2015 using a blend of the CMS-HCC models used for payment in 2013 and 2014. Because frailty factors are calibrated in relationship to a specific CMS-HCC risk adjustment model, we will also need to apply the blending approach to the calculation of the frailty scores in parallel to the calculation method of the risk scores, which for 2015 is respectively 67 percent and 33 percent for the CMS-HCC models used for payment in 2013 and 2014.

Comment: Some commenters requested that all Special Needs Plans (SNPs) receive frailty payments. Additionally, some commenters requested that frailty be calculated and applied at the beneficiary level, specifically to those that meet the nursing home level of care.

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: Another commenter requested that fully integrated dual eligible special needs plans (FIDE SNPs) that have chosen to participate in the Health Outcomes Survey-Modified (HOS-M), be provided with the corresponding beneficiary level data and/or reports that PACE organizations currently receive.

Response: CMS is allowing use of 2014 HOS or HOS-M to determine frailty scores for FIDE SNPs for payment year 2015. CMS will consider whether to provide HOS-M reports and corresponding data for participating FIDE SNPs once the determination has been made on the use of this survey in future years. We have concerns about sharing beneficiary contact information with FIDE SNPs because we do not want to unintentionally reveal the sample for quality reporting.

Section L. MSP Factor

The MSP adjuster for 2015 is 0.173 for working aged and working disabled beneficiaries and the ESRD MSP factor for 2015 is 0.215.

Section M. Medical Loss Ratio Credibility Adjustment

Comment: One commenter stated their support for maintaining the same MLR credibility adjustment for CY 2015 as CMS is applying in CY 2014.

Response: CMS appreciates the support.

Comment: We received one comment requesting that CMS reconcile the bid mechanism rules with the medical loss ratio (MLR) requirements and identify those that are duplicative, conflicting, or no longer necessary. The commenter stated that simplifying the bid submission and MLR requirements would reduce administrative burden for both CMS and plan sponsors.

Response: Thank you for your comment. CMS will take this into consideration. For further questions regarding the Medical Loss Ratio please email us at MLRreport@cms.hhs.gov.

Comment: CMS received a comment asking to allow health plans to include the costs associated with wrap around benefits in the MLR calculation. The commenter expressed particular concern with Puerto Rican plans' ability to meet MLR criteria based on lack of funding.

Response: We appreciate the comment. For further information please email us at MLRreport@cms.hhs.gov.

Section N. International Classification of Diseases-10 (ICD-10) Code Sets and Diagnosis Data Sources for 2015 Risk Scores

Comment: Some commenters suggested we accept ICD-9 codes in some fashion after the October 1, 2014 transition date by either allowing plans to crosswalk ICD-9 codes submitted by providers to ICD-10 codes, or accept both ICD-9 and ICD-10 for a set period of time. Some commenters requested that we delay the use of ICD-10 until January 2015. A few commenters suggested that CMS consider extending the deadlines for the calculation of mid-year and final risk scores.

Response: Section 212 of the "Protecting Access to Medicare Act of 2014" delayed the adoption of ICD-10 as the standard code sets to no earlier than October 1, 2015. Therefore, ICD-10 code sets will not be used for 2015 risk scores.

Comment: Several commenters expressed concern over the steep learning curve and lack of knowledge around ICD-10 and the quality of coding they would receive from providers.

Response: We understand that the healthcare industry has been working with providers to prepare for the transition to ICD-10 since the final rule was published on January 16, 2009 (45 CFR 162), and encourage continued provider education to meet the targeted transition date of October 1, 2015.

Comment: Many commenters raised questions about the use of Encounter Data System submissions versus Risk Adjustment Processing System submissions in the calculations of risk scores for payment year 2015.

Response: To clarify, when calculating risk scores for 2015 payment, CMS will extract all diagnoses that meet our risk adjustment criteria from EDS, FFS and RAPS and use all of these diagnoses in equal measure to calculate risk scores. In other words, we will not differently weight the diagnoses from any one source over the other. Once diagnoses from all sources have been gathered, a master file of diagnoses for each beneficiary will be created, from which risk scores will be calculated.

Comment: A few commenters requested that we continue to run the Encounter Data System (EDS) and the Risk Adjustment Processing System (RAPS) in parallel for a minimum of two years.

Response: We have been accepting Encounter Data submissions since 2012, and have continued to collect RAPS data. We will continue to run both the EDS and RAPS for 2015, and will inform the plan community prior to transitioning exclusively to the EDS.

Comment: There were several comments that requested technical or operational information related to encounter data use or submission, such as the timing and content of Encounter Data System reports, and the MAO-004 report in particular, details on how data would be extracted from the Encounter Data System and be filtered before being used to develop a risk score, submitting diagnoses from unlinked chart reviews, and whether CMS will conduct future Encounter Data user group calls.

Response: We will continue to develop technical and operational guidance, and we plan to host future Encounter Data user group calls. We understand the request for the specific logic that we will use to extract diagnoses from the Encounter Data System for risk adjustment, and we will provide guidance to MA organizations and other entities submitting Encounter Data as final decisions are made about this process.

Attachment IV. Changes in the Payment Methodology for Medicare Part D for CY 2015

Section A. Update of the RxHCC Model

Comment: A majority of commenters prefer delaying the implementation of the updated RxHCC model.

Commenters generally requested that CMS seek additional industry input, provide the expected impact of the proposed model change, as well as provide additional time for plans to conduct impact analyses prior to implementation. One commenter requested that CMS phase-in the proposed model. Commenters expressed concern about the cumulative impact of the model changes on the risk scores given the volume of payment related changes occurring for PY 2015. Commenters requested additional details and the rationale behind including MA-PD data and concern that the adjustment may negatively impact plans due to the historical cost differences between MA-PDs and PDPs.

Response: Given concerns about the variety of payment changes for 2015, CMS will not implement the updated RxHCC model in 2015 in order to provide payment stability; instead, we will continue to use the RxHCC model used in 2014. Please see Section J for additional information on normalization.

As noted in the 2015 Advance Notice, CMS is aware that MA-PDs have unique cost and utilization patterns. As such, in the future we plan to propose an RxHCC model that uses this more comprehensive data for the population of Part D enrollees, in both standalone Prescription Drug Plans and MA Prescription Drug Plans. As is true of all risk adjustment models, impacts are plan and beneficiary specific, and plan distribution of certain beneficiary types may result in varying risk score impacts.

Comment: Commenters requested additional detail regarding the process and basis of changes included in the clinical update. In addition, commenters expressed concern about diagnoses related to some specific diseases being removed from the model, including lower-level Chronic Kidney Disease (CKD) diagnoses (CKD Stage 3 and Stage 1, 2 or Unspecified) and diagnoses associated with diabetes.

Response: While we are not implementing the proposed RxHCC model in 2015, when CMS makes clinical updates to the HCCs models, changes are based in part on clinical similarities and are made in conjunction with the input of a panel of clinical experts. Decisions to include or exclude a specific diagnosis in the model is based on balancing a variety of considerations, including: clinical significance, the categories ability to accurately predict costs, coding patterns, whether or not the diagnosis has significant cost implications beyond screening and/or diagnostic

pertinence, and the levels of diagnoses in which the most aggressive drug treatment is likely to occur.

Comment: Several commenters requested that the updated RxHCC model software and ICD-9 to RxHCC mappings be released.

Response: While we are not implementing the proposed model in 2015, the comparison of the current and proposed RxHCC Risk Adjustment Model RxHCCs was provided in the 2015 Advance Notice. In addition, the updated RxHCC model mappings (for future implementation) were posted on the CMS Risk Adjustment Webpage, http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html.

Comment: Two commenters recommended that CMS consider establishing processes or model adjustments to address newly approved high-cost medications and medications approved through the accelerated U.S. Food and Drug Administration approval process.

Response: We appreciate this recommendation and will take it into consideration.

Section B. Payment Reconciliation

Comment: One commenter stated that the Part D risk corridors are no longer as necessary, as plans have now had several years of experience with Part D bidding. In addition, the commenter recommended that CMS consider widening the risk corridors for 2015.

Response: CMS disagrees that risk corridors are no longer necessary. CMS has reviewed the annual reconciliation data and there are significant variances between the target amount and the adjusted allowable risk corridor costs, which supports the need for risk-sharing. At this time CMS is not widening the risk corridors for 2015.

Comment: One commenter suggested that CMS allow plans to use negative Part D premiums to subsidize Part C supplemental benefits due to the payment reductions.

Response: As per 423.286(d)(1), if the resulting premium is negative, the excess amount is applied to supplemental Part D benefits. As a result, the suggestion made by the commenter is not allowed.

Section C. Part D Benefit Parameters for the Defined Standard Benefit:

Annual Adjustments for 2015

Comment: A number of comments were received asking CMS to confirm the copayment amounts shown for Generic/Preferred Multi-Source Drug for "Full Subsidy-Non-FBDE

Individuals" in Table III-1. Specifically, the copayment amount is listed as $2.60 whereas elsewhere in the Table it is shown as $2.65.

Response: CMS appreciates this comment and we have updated the copayment amount to the correct figure of $2.65.

Comment: CMS received one comment asking CMS to use discretion and not increase co-payments. The commenter stated that there are times when discretion around co-payments for low income members could lead to better outcomes.

Response: CMS is required by statute to update the co-payments.

Comment: One commenter asked for verification that, regardless of the contribution by third parties, it is actually the members' OOP contribution that moves them through the benefit, inclusive of the catastrophic stage.

Response: Regardless of benefit design, gross covered prescription drug costs are used to determine when the beneficiary reaches the coverage gap phase; however, TrOOP is used to determine when the beneficiary has reached the catastrophic coverage phase.

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

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

Annual Percentage Increases	Annual percentage trend for 2014	Prior year revisions	Annual percentage increase for 2014
Applied to all parameters but (1)	4.07%	-0.05%	4.02%
CPI (all items, U.S. city average): Applied to (1)	1.48%	-0.60%	0.87%

Part D Benefit Parameters	2014	2015
Standard Benefit		
Deductible	$310	$320
Initial Coverage Limit	$2,850	$2,960
Out-of-Pocket Threshold	$4,550	$4,700
Total Covered Part D Spend at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)	$6,455.00	$6,680.00
Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)	$6,690.77	$7,061.76
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.55	$2.65
Other	$6.35	$6.60
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals		
Deductible	$0.00	$0.00
Copayments for Institutionalized Beneficiaries (category code 3)	$0.00	$0.00
Copayments for Beneficiaries Receiving Home and Community-Based Services (4) (category code 3)	$0.00	$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries		
Up to or at 100% FPL (category code 2)		
Up to Out-of-Pocket Threshold (1)		
Generic/Preferred Multi-Source Drug (2)	$1.20	$1.20
Other (2)	$3.60	$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	$2.55	$2.65
Other	$6.35	$6.60
Above Out-of-Pocket Threshold	$0.00	$0.00

Part D Benefit Parameters	2014	2015
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	$2.55	$2.65
Other	$6.35	$6.60
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,300 (individual) or $26,580 (couples) (6)		
(category code 4)		
Deductible	$63.00	$66.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.55	$2.65
Other	$6.35	$6.60
Retiree Drug Subsidy Amounts		
Cost Threshold	$310	$320
Cost Limit	$6,350	$6,600

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

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

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

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

(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2014 values of $63.47, $1.18, and $3.55, respectively.

(6) The actual amount of resources allowable will be updated for contract year 2015.

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 $310 in 2014 and rounded to the nearest multiple of $5.
Initial Coverage Limit: From $2,850 in 2014 and rounded to the nearest multiple of $10.

Out-of-Pocket Threshold: From $4,550 in 2014 and rounded to the nearest multiple of $50. The "annual percentage increase" applied to the out-of-pocket threshold includes the additional negative 0.25% adjustment required by the ACA.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.55 per generic or preferred drug that is a multi-source drug, and $6.35 for all other drugs in 2014, 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 $2.55 per generic or preferred drug that is a multi-source drug, and $6.35 for all other drugs in 2014, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $63[1] in 2014 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.55 per generic or preferred drug that is a multi-source drug, and $6.35 for all other drugs in 2014, 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

[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 2014 value of $63.47

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 $1.20 per generic or preferred drug that is a multi-source drug, and $3.60 for all other drugs in 2014[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. Beginning with the 2009 contract year, the annual percentage increases are based on Part D program data. For the 2015 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August2013-July2014}{August2012-July2013} = \frac{\$2{,}920.29}{\$2{,}806.05} = 1.0407$$

In the formula, the average per capita cost for August 2012 – July 2013 ($2,806.05) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2013 – July 2014 ($2,920.29) is calculated based on actual Part D PDE data incurred from August – December, 2013 and projected through July, 2014.

The 2015 benefit parameters reflect the 2014 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 cost and PDE data, the annual percentage increases are now estimated as summarized by Table V-2.

[2] Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2014 values of $1.18 per generic or preferred drug that is a multi-source drug, and $3.55 for all other drugs.

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

Year	Prior Estimates of Annual Percentage Increases	Revised Annual Percentage Increases
2007	7.30%	7.30%
2008	5.92%	5.92%
2009	4.25%	4.17%
2010	3.09%	3.02%
2011	2.45%	2.44%
2012	2.46%	2.44%
2013	1.83%	2.01%
2014	-2.76%	-2.82%

Accordingly, the 2015 benefit parameters reflect a multiplicative update of -0.05 percent for prior year revisions. In summary, the 2014 parameters outlined in Section A are updated by 4.02 percent for 2015 as summarized by Table V-3.

Table V-3. Annual Percentage Increase

Annual percentage trend for July 2014	4.07%
Prior year revisions	-0.05%
Annual percentage increase for 2015	4.02%

Note: Percentages are multiplicative, not additive.

Values are carried to additional decimal places and may not agree with 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 2015, the September 2014 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 2014 CPI based on the projected amount included in the President's FY2015 Budget.

The September 2013 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2015 is calculated as follows:

$$\frac{\text{Projected September 2014 CPI}}{\text{Actual September 2014 CPI}} \; or \; \frac{237.624}{234.149} = 1.0148$$

(Source: President's FY2015 Budget and Bureau of Labor Statistics, Department of Labor)

The 2015 benefit parameters reflect the 2014 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2013 annual percentage increase. The 2014 parameter update reflected an annual percentage trend in CPI of 1.80 percent. Based on the actual reported CPI for September 2013, the September 2013 CPI increase is now estimated to be 1.18 percent. Thus, the 2015 update reflects a multiplicative -0.60 percent correction for prior year revisions. In summary, the cost sharing items outlined in Section B are updated by 0.87 percent for 2015 as summarized by Table V-4.

Table V-4. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2014	1.48%
Prior year revisions	-0.60%
Annual percentage increase for 2014	0.87%

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

Section D. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of $5 and the cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $325 and $6,600, respectively, for plans that end in 2013, and, as $310 and $6,350, respectively, for plans that end in 2014. For 2015, the cost threshold is $320 and the cost limit is $6,600.

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

For 2015, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $7,061.76. 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 beneficiary cost sharing in the deductible phase, 25 percent in the initial coverage phase and in the coverage gap, 65 percent for non-applicable (generic) drugs and 95 percent of the ingredient cost and sales tax for applicable (brand) drugs and 45 percent of the dispensing and vaccine administration fees for applicable (brand) drugs. In this estimate, it is assumed that the dispensing and vaccine administration fees account for 0.18 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 55 percent reduction

in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.09 percent to 94.91 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:

$$\text{ILC} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \text{ or } \$2{,}960 + \frac{\$3{,}720}{90.693\%} = \$7{,}061.76$$

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

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

OOP threshold – OOP costs up to the ICL *or* $4,700 - $980 = $3,720

Weighted gap coinsurance factor is calculated as follows:

(Brand GDCB % for non-LIS × 94.91% cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 65% cost sharing for non-applicable drugs)

or

(85.9% × 94.91%) + (14.1% × 65%) = 90.693%

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 2013 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

94.91% = [(99.82% × 95%) + (0.18% × 45%)]

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 2013 PDEs.

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

Attachment VI. 2015 Call Letter

2015 Announcement
Table of Contents

How to Use This Call Letter 46

Section I – Parts C and D 47

Annual Calendar 47

Incomplete and Inaccurate Bid Submissions 53

Providing Materials to Individuals with Disabilities 82

Summary of Benefits 83

B. Transferability of MOOP Contributions When an Enrollee Changes Plans During the Contract Year 95

Part C Change of Ownership Transactions Requiring Service Area Expansions 108

Part D Benefit Parameters for Non-Defined Standard Plans 123

Appendix 1 – Contract Year 2015 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals 132

Appendix 2 – Contract Year 2015 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals - Table 136

Appendix 3 - Summary of Comments on the Draft Call Letter to Proposed Enhancements to the 2015 Star Ratings and Beyond 141

Attachment VI: 2015 Call Letter

How to Use This Call Letter

The 2015 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 2015 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 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.

This year's final Call Letter content is limited to clarification of current policy and operational guidance.

If you have questions concerning this Call Letter, please contact: Nishamarie Sherry at Nishamarie.Sherry@cms.hhs.gov (Part C issues) and Heather Rudo at Heather.Rudo@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, Medicare-Medicaid Plan (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.

2015*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**	**Cost**
January 13, 2014	Release of the 2015 MAO/MA-PD/PDP/Service Area Expansion Applications.	✓	✓	✓
January 15 & 22, 2014	Industry training on 2015 Applications.	✓	✓	✓
February 25, 2014	2015 Applications are due to CMS.	✓	✓	✓
February 25, 2014	Renewing D-SNPs required to complete attestations in HPMS	✓		
February 25, 2014	SNPs, whose MOC approval expires at the end of CY 2014, are required to resubmit their MOCs for NCQA review.	✓		
Late February 2014	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals.	✓		
March 1, 2014	CMS releases guidance concerning updates to Parent Organization designations in HPMS.	✓	✓	✓
March 4, 2014	Deadline for D-SNPs meeting a high level of integration, as determined by CMS, to notify CMS of intent to offer additional supplemental benefits as a result of meeting the qualifying criteria.	✓		
March 17, 2014	Parent Organization Update requests from sponsors due to CMS (instructional memo released in February 2014).	✓	✓	
Mid-Late March, 2014	Release of CY 2015 Formulary Training Video and 2015 Formulary Reference File (FRF)	✓	✓	
March 22, 2014	Release of the Fiscal Soundness Module in HPMS.	✓	✓	
March/April, 2014	CMS contacts Medicare Advantage Organizations (MAO) and Prescription Drug Plan (PDP) Sponsors with low enrollment plans.	✓	✓	✓
Early April 2014	CY 2015 Out-of-pocket cost (OOPC) estimates for each plan and an OOPC model will be made available to MAOs and Part D sponsors to download from the CMS website that will assist plans in meeting meaningful difference and MA total beneficiary cost requirements prior to bid submission.	✓	✓	

2015*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**	**Cost**
Early April, 2014	Information about renewal options for contract year 2015 (including HPMS crosswalk charts) will be provided to plans.	✓	✓	
April 2014	Conference call with industry to discuss the 2015 Call Letter.	✓	✓	✓
April 2014	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	
April 7, 2014	2015 Final Call Letter released. Announce CY 2015 MA Capitation Rates and MA and Part D Payment Policies. *(Applies to Part C and Part D Sponsors only)*	✓	✓	✓
April 9, 2014	Industry training on CY 2015 Formulary Submission	✓	✓	
April 11, 2014	Release of the 2015 Plan Benefit Package (PBP) online training module	✓	✓	✓
April 11, 2014	Release of the 2015 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS.	✓	✓	✓
Mid April, 2014	Release of HPMS Memo: Contract Year 2015 Medicare Advantage Bid Review and Operations Guidance.	✓		
Mid/Late April, 2014	Submission of tiering request and justifications to the Regional Office for review and consideration.	✓		
Late April, 2014	Total Beneficiary Cost (TBC) data for CY 2015 Bid Preparation Release	✓		
May, 2014	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, and pharmacy directory models for 2015 will be available for all organizations.	✓	✓	✓
Early May, 2014	D-SNPs that applied to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications	✓		
May 2, 2014	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, 2014. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June.	✓	✓	✓
May 9, 2014	Release of the 2015 Bid Upload Functionality in HPMS	✓	✓	✓
May 9, 2014	Release of 2015 Actuarial Certification Model	✓	✓	✓
May 9, 2014	Release of Health Plan System (HPMS) Formulary Submission Module	✓	✓	
May 19, 2014	Release of the 2015 Medication Therapy Management (MTM) Program Submission Module in HPMS.		✓	
May 31, 2014	Release of the 2012 DIR Submission Module in HPMS	✓	✓	

2015*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**	**Cost**
May 31, 2014	Plans / Part D Sponsors may begin to upload agent/broker compensation information in HPMS	✓	✓	✓
May 31, 2014	Release of the 2015 Marketing Module in HPMS. Note: Plans / Part D Sponsors may begin to submit 2015 marketing materials.	✓	✓	✓
Late May/Early June, 2014	Release of the 2015 Medicare Marketing Guidelines in HPMS (Chapter 3 of the Medicare Managed Care Manual/Chapter 2 of the Prescription Drug Benefit Manual)	✓	✓	✓
Late May/June, 2014	CMS sends qualification determinations to applicants based on review of the 2015 applications for new contracts or service area expansions.	✓	✓	
Late May/June to Early September, 2014	CMS completes review and approval of 2015 bid data. Submit attestations, contracts, initial actuarial certifications, and final actuarial certifications.	✓	✓	✓
June 2, 2014	Deadline for submission of CY 2015 bids for all MA plans, MA-PD plans, PDP, cost-based plans offering a Part D benefit, Medicare-Medicaid Plans (MMPs), "800 series" EGWP and direct contract EGWP applicants and renewing organizations; deadline for cost-based plans wishing to appear in the 2015 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT). Deadline for submission of CY 2015 Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Deadline for submission of CY 2015 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT). Deadline for submission of a CY 2015 contract non-renewal, service area reduction notice to CMS from MA plans, MA-PD plans, PDPs and Medicare cost-based contractors and cost-based sponsors to 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 2015.	✓	✓	✓
June 3, 2014- June 6, 2014	Window for submitting crosswalk exception requests through HPMS.	✓	✓	✓
June 6, 2014	Deadline for submission of CY 2015 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 (12 p.m. EDT).	✓	✓	✓
June 6, 2014	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)*(12 p.m. EDT)	✓	✓	

2015*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**	**Cost**
Late June, 2014	Release of the CY 2015 Summary of Benefits (SB) hard copy change request module in HPMS.	✓	✓	✓
Late June, 2014	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, 2014	Final date to submit CY 2014 marketing materials to ensure timely CMS review and approval. NOTE: Plans/Part D Sponsors may continue to submit CY 2015 file and use materials as these may be filed in HPMS five calendar days prior to their use.	✓	✓	✓
Early July, 2014	2015 Plan Finder pricing test submissions begin	✓	✓	✓
July 1, 2014	Deadline for D- SNPs to have uploaded their required State Medicaid Agency Contract and Contract Matrix to HPMS	✓	✓	✓
July 1, 2014	Deadline for D-SNPs requesting to be reviewed as Fully Integrated Dual Eligible (FIDE) SNPs to submit their FIDE SNP Matrix to HPMS.	✓		
July 5, 2014	Plans are expected to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓		
Mid-Late July, 2014	CY 2015 Limited Formulary Update Window	✓	✓	
Late July, 2014	Submission deadline for agent/broker compensation information via HPMS.	✓	✓	✓
Late July / Early August, 2014	CMS releases the 2015 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.	✓	✓	✓
Late July / Early August, 2014	Rebate reallocation period begins after release of the above bid amounts.	✓	✓	✓
August 1, 2014	Plans are expected to submit model Low Income Subsidy (LIS) riders in HPMS.	✓	✓	✓
August 1, 2014	CMS informs currently contracted organizations of its decision to not renew a contract for 2015.	✓	✓	✓
August 22-26, 2014	First CY 2015 preview of the 2015 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs).	✓	✓	
August 28 – August 30, 2014	First CY 2015 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
August 31, 2014	2015 MTM Program Annual Review completed.		✓	
Late August 2014	Contracting Materials submitted to CMS.	✓	✓	✓

2015*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**	**Cost**
End of August/Early September 2014	Plan preview periods of Star Ratings in HPMS.	✓	✓	✓
Early-September 2014	CMS begins accepting plan correction requests upon contract approval.	✓	✓	✓
Mid- September 2014	All 2015 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS).	✓		✓
September 10 - September13, 2014	Second CY 2015 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS.	✓	✓	✓
September 16 – 30, 2014	CMS mails the 2015 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓
Late September, 2014	D-SNPs that requested review for Fully Integrated Dual Eligible (FIDE) Special Needs Plan (SNP) determination notified as to whether they meet required qualifications.	✓		
September 24, 2014	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.	✓	✓	✓
September 30, 2014	CY 2015 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.	✓	✓	✓
Early October, 2014	Release of the online CY 2016 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)	✓	✓	✓

2015*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**	**Cost**
October 1, 2014	Organizations may begin marketing their CY 2015 plan benefits. Note: Once an organization begins marketing CY 2015 plans, the organization must cease marketing CY 2014 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2014 materials upon request, conduct one-on-one sales appointments and process enrollment applications.	✓	✓	✓
October 1, 2014	Tentative date for 2015 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs).	✓	✓	✓
October 2, 2014	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, 2014.	✓	✓	✓
October 10, 2014	Star Ratings go live on medicare.gov on or around October 10, 2014.	✓	✓	✓
October 15, 2014	Part D sponsors must post PA and ST criteria on their websites for the 2015 contract year.		✓	
October 15, 2014	2015 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 14, 2014	Notices of Intent to Apply (NOIA) for CY 2016 due for MA, MA-PD, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓	
Early November, 2014	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval	✓	✓	✓
Late November, 2014	Display measures data are posted in HPMS for plan preview.	✓	✓	✓
Late November, 2014	2015 Readiness Assessment due to CMS	✓	✓	✓
November – December, 2014	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, 2014	Enrollees in Medicare cost-based plans not offering Part D must receive the combined ANOC/EOC.			✓
December 1, 2014	Cost-based plans must publish notice of non-renewal.			✓
December 7, 2014	End of the Annual Election Period.	✓	✓	

2015*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	Cost
Mid- December, 2014	Display measures data on CMS.GOV updated.	✓	✓	✓
2015				
January 1, 2015	Plan Benefit Period Begins	✓	✓	✓
January 1 – February 14, 2015	Annual 45-Day Medicare Advantage Disenrollment Period (MADP).	✓		
Early January 2015	Release of CY 2016 MAO/MA-PD/PDP/SAE/EGWP applications.	✓	✓	
Mid-January, 2015	Industry training on CY 2016 applications.	✓	✓	✓
Late February 2015	Applications due for CY 2016.	✓	✓	✓

Incomplete and Inaccurate Bid Submissions

Incomplete Submissions

Under 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 CY 2015, the bid submission deadline is June 2, 2014 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)

MA, MA-PD, Section 1876 cost plan, and PDP entities ("entities") are responsible for ensuring complete and accurate bids are submitted by the June deadline. Like last year, CMS is making clear 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 is not submitted by the deadline, the bid submission will be considered incomplete and will not be accepted by CMS absent extraordinary circumstances. This policy is consistent with previous years (for example, please refer to the memo "Release of Contract Year (CY) 2014 Bid Upload Functionality in HPMS," dated May 10, 2013).

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 all components of a bid will be submitted successfully and accurately by the submission deadline.

All entities 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 entities 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 preventing the bid from proceeding to desk review.

Inaccurate Submissions

CMS approves a bid under 42 CFR §423.272(b) only if the plan and the sponsor offering the plan comply with all applicable Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations. Bids containing information that is clearly inaccurate under Part D requirements and established thresholds unnecessarily divert time and resources to getting the bids corrected and, among other things, call into question a plan sponsor's intent and ability to fully comply with Part D requirements.

Examples of bids containing information that is clearly inaccurate under Part D requirements and established thresholds are:

- An MA organization organization offering Part D benefits that does not offer required prescription drug coverage throughout its service area as required under §423.104(f)(2) (see also section 20.4.4 of Chapter 5 of the Prescription Drug Benefit Manual),
- A PDP submits a bid for a non-defined standard plan that does not meet the Part D Benefit Parameters set forth in the applicable law and defined benefit thresholds specified in this Call Letter, or
- A Part D bid that includes an incorrect PBP to formulary crosswalk.

This year, CMS is making clear that organizations and sponsors submitting clearly inaccurate bids under Part D requirements and established thresholds will receive a compliance notice in the form of a letter and/or a corrective action plan. Organizations and sponsors are also on notice that they might not be provided an opportunity to revise their bids to correct inaccuracies, and therefore, their bids will be denied. Organizations and sponsors should engage in sufficient due diligence to ensure their bid submissions are accurate before submission.

Formulary Submissions

The CY 2015 HPMS formulary submission window will open this year from 12:00 am PDT on May 9, 2014 to 11:59 pm PDT on June 2, 2014. In addition, CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 2, 2014 in order for the formulary to be considered for review. The formulary is part of a Part D plan's complete bid and therefore a failure to submit and link a formulary to each plan by the June 2nd deadline will result in denial of that bid submission.

We continue to expect that the formulary structure submitted for Defined Standard plans will be consistent with the plan benefit package (PBP) submission that does not include tiers. Consistent with previous years, CMS will make an exception for those Defined Standard plans that are linked to tiered formulary that is also being used by at least one other plan with a tiered benefit type (i.e., Actuarial Equivalent, Basic Alternative, or Enhanced Alternative). However, beginning in 2015 formularies that are only associated with Defined Standard plans must be limited to one formulary tier as submitted in their bids. In addition, all marketing materials for Defined Standard plans must reflect a single tier regardless of whether that Defined Standard plan is associated with a single or multi-tier formulary.

CMS released the first CY 2015 Formulary Reference File (FRF) in March 2014. The March FRF release will be used in the production of the OOPC model tool, scheduled to be released in April 2014, in order to assist plan sponsors in satisfying meaningful difference and MA total beneficiary cost (TBC) 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.

CMS is planning to provide a May 2014 release of the 2015 FRF just prior to the new formulary submission deadline. Given the limited timeframe between the May release of the 2015 FRF and the new formulary submission deadline, CMS will be unable to accommodate an updated version of the 2015 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 2015 FRF will not be included in the 2015 OOPC model.

CMS will continue to offer a summer formulary update; however, 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 2015 FRF, since additional limitations will be imposed on the summer formulary update window.

Plan Corrections

CMS expects that requests for MA, MA-PD, Section 1876 cost plans, and PDP corrections for CY 2015 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 early September to September 24, 2014. The only changes to the PBP that will be allowed during the plan correction period are those that will modify the PBP data to align with the Bid Pricing Tool (BPT). No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide to organizations and sponsors any guidance and tools necessary to ensure a complete and accurate bid submission. These tools will include a Medicare Plan Finder (MPF) summary table report that will be released in HPMS during May. Organizations and sponsors can upload their bid multiple times in HPMS prior to bid submission so that they can confirm that MPF data are being displayed accurately. Therefore, organizations and sponsors are encouraged to use this time prior to the bid submission deadline to ensure the bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance notice and will be suppressed in Medicare Plan Finder (MPF) until the first update in November. An organization or sponsor that has demonstrated a consistent pattern of bid submission errors over multiple contract years and/or that previously received a compliance notice for CY 2014 may receive a more severe type of compliance action if it requests a plan correction for CY 2015.

Contracting Organizations with Ratings of Less Than Three Stars in Three Consecutive Years – Effective Date of Termination Authority

CMS received comments to the draft Call Letter that indicated that some organizations mistakenly believed we would be using the revised contract termination authority stated in the NPRM published on January 10, 2014, to terminate contracts at the end of the 2014 contract year. In fact, CMS will use the termination authority at 42 C.F.R. 422.510(a)(14) and 423.509(a)(13),[3] adopted in the final rule titled, "Medicare Program; Changes to the Medicare

[3] These current regulations have been proposed to be recodified to 42 C.F.R. 422.510(a)(4)(xi) and 423.509(a)(4)(x) respectively.

Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes" published in the Federal Register on April 12, 2012 (77 FR 22072). Other comments indicated that some organizations misunderstood the kind of star ratings performance history that will qualify a contract for termination at the end of 2014. To address these comments, CMS has revised this passage to clarify the standard we will use to make star ratings-based contract termination decisions later in 2014.

CMS reminds MA organizations and PDP sponsors that our existing regulatory authority (42 CFR §§422. 510(a)(14) and 423.509(a)(13)) to terminate the contracts of organizations that fail for three consecutive years to achieve at least three stars on their Part C or D performance may be used at the end of 2014, based on three years of data, beginning with 2012. When we published the termination authority, we announced that we would afford contracting organizations a three-year transition period to bring their star rating performance up to a level that would justify their continued participation in the Part C and D programs. That transition period ends with the star ratings released in the fall of 2014. At that time, CMS plans to use its existing regulatory authority (not the revised authority proposed in the January 10, 2014 NPRM titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs")[4] to terminate, effective December 31, 2014, contracts with a consistent pattern of low star ratings. Specifically, CMS will terminate those MA-PD contracts that scored a Part C summary rating of less than three stars in each of the most recent three consecutive rating periods (i.e., 2013, 2014, and 2015 sets of ratings), regardless of their Part D summary rating performance during the same period. Also, CMS will terminate MA-PD contracts that scored Part D summary rating of less than three stars in each of the most recent three consecutive rating periods (i.e., 2013, 2014, and 2015 sets of ratings) regardless of their Part C summary ratings during the same period. Of course, stand-alone PDP sponsor contracts receive only a Part D rating, and CMS will terminate those contracts that scored less than three stars in each of the most recent three consecutive rating periods (i.e., 2013, 2014, and 2015 sets of ratings).

CMS advises contracting organizations to examine their star rating performance history and assess their level of exposure to the risk of having CMS terminate their Medicare contract based on star ratings before the start of the 2015 contract year. It may be in the best interests of organizations and sponsors with "at risk" contracts to consider electing to non-renew those contracts. Alternatively, organizations and sponsors could explore whether it is allowable to consolidate membership currently enrolled in plans offered under low-performing contracts into

[4] Our pending proposal is to modify this existing authority such that MA–PD organizations that do not achieve at least 3 stars in both their Part C and D ratings in the same year for 3 consecutive years may be subject to termination.

other plans that will be offered during 2015 in the same service area under a different contract rated at three stars or better.

Enhancements to the 2015 Star Ratings and Beyond

One of CMS' most important strategic goals is to improve the quality of care and general health status for Medicare beneficiaries. For the 2015 Star Ratings, CMS is continuing to make enhancements to the current methodology to further align it with our policy goals. Our priorities include enhancing the measures and methodology to reflect the true performance of organizations and sponsors, maintaining stability due to the link to payment, and providing advance notice of future changes.

As stated in the 2012 Call Letter, CMS incorporates the following principles when making enhancements to the Star Ratings. These principles are used across all quality programs in CMS.

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

One of the ways in which meaningful distinctions among plans' performance can be made is to incorporate improvement as an independent goal separate from achievement. Increasing the weight of improvement aligns with other CMS programs such as the Hospital Value-based Purchasing Program and ESRD Quality Incentive Program where improvement receives a significant weight in the total performance scores. Increasing the weight of improvement also rewards MA organizations and Part D sponsors for making progress in raising their performance, while maintaining one standard of care for all patient populations.

In this document, we describe the enhancements for the 2015 Star Ratings and beyond. Unless noted below, we do not anticipate changing the methodology from the 2014 Star Ratings. The 2014 methodology can be found at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html under the 2014 Star 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 for 2015 with the most current data available.

Appendix 3 includes a summary of the comments to the draft Call Letter.

We thank all of those individuals and organizations who sent in comments. Most commenters were appreciative of the advanced notice we have been providing on potential changes to the Star Ratings. We believe this approach is more appropriate for the administration of the Part C and D programs and is consistent with the use of the Advanced Notice and Call Letter as the means for managing the Medicare Advantage and the Prescription Drug Programs. *See also* § 1853 of the Act and 42 C.F.R. §§ 422.152(b) and 422.516(a). We have initiated twice yearly comment periods on the Star Ratings in response to the need for transparency and advance notice. In the annual Request for Comments and the Call Letter we lay out the Star Ratings methodology for two or more years ahead. For example, the Request for Comments recently released in November 2013 announced potential changes for 2015, 2016, and beyond. When there are changes in clinical guidelines that impact the Star Ratings measures, we make these updates more quickly to align with the revised clinical standards. If we were to use a more formal rulemaking process for Star Ratings changes, we would not be able to quickly adjust the Star Ratings to reflect changes in the clinical guidelines. In fact this approach could lead to more instability in ratings as there would be no means to quickly eliminate changed measures. We have included more detail in this Call Letter about moving measures to the display page when significant changes in measure specifications happen during the measurement year without advance notice. We additionally publish detailed technical specifications and provide contract specific technical guidance in understanding how a contract scored on a measure.

CMS' initial work last year to identify and understand some best practices of high-performing plans found that their models of care and continuous quality improvement were not focused on year to year changes, but rather they identified areas for long-term improvements in clinical outcomes, access to care and beneficiary satisfaction. High-performing plans did not wait until the announcement of industry initiatives, rather their approaches to these areas were often made in advance of technical changes announced by CMS. We therefore believe our current processes of proposing and planning modifications to the Star Ratings are best continued as they are.

A number of commenters were concerned also about whether beneficiaries can respond to surveys and whether this is the appropriate method for gathering information for Star Ratings. Surveys are a valid way to gather information; the types of questions included in the CAHPS and HOS surveys are ones where the beneficiary is the best or only source for the information.

We continued to receive several comments about Special Needs Plans (SNPs). Medicare Advantage organizations are permitted to design SNPs that target individuals dually eligible for Medicare and Medicaid, beneficiaries that have certain chronic conditions, or those receiving care in institutions. These options let plans target these populations, develop and implement approaches that enhance access to and coordination of care, and improve quality of care. Over the past several years, organizations have argued that CMS should make special allowances in the Star Ratings program for these plans and others that enroll hard-to-reach populations. These suggestions have included bonus points for SNP-specific measures, requests for case-mix

adjustment for member characteristics, comparisons only to similar SNP subtypes, separate listings in plan finder and other displays, displaying SNPs separately, and a Star Ratings system distinctly and uniquely for SNPs. Some contracts with high dual or LIS populations are doing very well on Star Ratings. In addition, there are also some contracts with low dual or LIS populations who do very poorly. CMS is aware of studies cited by commenters, but many of the studies in this area have methodological shortcomings. However, we are increasing the weight of the improvement measures to help contracts that are experiencing challenges increasing their Star Ratings due to their patient populations served. CMS is continuing to conduct additional analyses in this area.

We maintain that all organizations can develop and implement approaches that enhance access to and coordination of care and improve the quality of care, which would then be reflected in higher Star Ratings. We believe that our existing payment and Star Ratings methodologies adequately address differences between these populations and other MA enrollees. For example, an analysis of SNP performance in the 2011 Plan Ratings found that increasing levels of SNP enrollment in contracts did not lead to lower ratings on either Part C or Part D. In fact, as we have stated previously, the number of contracts with less than a 3-star rating (below average performance) drops when SNP enrollment increases from 50 percent or more to 100 percent (77 FR. 22114, Apr. 12, 2012). Thus, SNP enrollment in a contract does not adversely affect a contract's Star Rating. The 2014 Star Ratings data also show that contracts with large dual SNP populations can do well on the Star Ratings. We believe that our current methodology supports a single standard of care for all Medicare beneficiaries, and analysis of Star Ratings results suggests Medicare Advantage organizations can focus on SNP population needs without compromising broader population health goals.

We note that we rely on consensus based organizations' decisions about whether a measure should or should not be case-mix adjusted. If the decision is made to include case-mix adjustment in a measure, the case-mix adjustment model is part of the published measurement specifications so no additional adjustment by CMS would be needed. Since the presence or absence of case-mix adjustment is part of the measure specifications, any change (or introduction) of the model needs to be vetted through the same consensus process. CAHPS measures (except annual flu vaccine), and HEDIS/HOS outcome measures are already case-mix adjusted.

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

A. New 2015 Measure:

CMS stated in the 2014 Call Letter that the Special Needs Plan (SNP) Care Management (Part C SNPs) measure would be added to the 2015 Star Ratings. We first introduced the possibility of including this measure in the Star Ratings in the 2013 Call letter. Since this will be a first year measure in 2015 ratings, it will be assigned a weight of "1".

Special Needs Plan (SNP) Care Management (Part C SNPs). This measure captures the completion of initial and annual standardized health risk assessments among SNPs. This measure is defined as the percent of eligible SNP enrollees who received a health risk assessment (HRA) during the measurement year. The denominator for this measure is the sum of the number of new SNP enrollees for the organization and the number of SNP enrollees eligible for an annual reassessment for the organization. The numerator for this measure is the sum of the number of initial assessments performed on new SNP enrollees during the measurement period and the number of annual reassessments performed on SNP enrollees eligible for a reassessment. An organization must have a minimum of 30 SNP enrollees eligible to have a SNP assessment for the rate to be calculated. Organizations that did not score at least 95% on data validation for their reporting of the SNP care management reporting section and organizations not compliant with data validation standards will be shown with the following phrase instead of a rating: "CMS identified issues with this plan's data." (See http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.html for more information about data specifications.) For the 2015 Star Ratings, we will use data reported for 2013. There were no substantive differences between the CY2013 Technical Specifications issued in February and May.

B. Changes to Measures for 2015

2015 Star Ratings will be released in fall 2014 and are used for 2016 Quality Bonus Payments.

CMS is providing additional information about when a Star Ratings measure will be moved to the display page with a specification change. Most commenters were supportive of the additional information provided about when measures will be moved to the display page. If the specification change has been announced in advance of the measurement period, there is no need to move the Star Ratings measure to the display page. If the specification change is announced during the measurement period ***and*** impacts the denominator or population covered by the measure, the measure will be moved to the display page for at least one year. If the change does not impact the denominator of the measure, CMS will continue to include it in the Star Ratings. For example, if during the measurement period, additional codes are added that would increase the number of numerator hits for the measure, CMS will continue to include the measure in the Star Ratings.

The methodology for the following measures is being modified:

1. *Breast Cancer Screening (Part C).* The specification for the Breast Cancer Screening measure is being modified to reflect changes in HEDIS 2014. In HEDIS 2013 the measure was defined as the percentage of women 40 to 69 years of age who had a mammogram for breast cancer every two years. The specification for 2014 revises the age range from 40 to 69 years old to 50 to 74 years old and increases the numerator time frame for documentation of a mammogram from 24 months to 27 months. These changes were a result of NCQA's measure re-evaluation process that included: a scan of clinical guidelines and evidence; feedback from variety of stakeholders, including women's health experts, clinicians, consumer advocates, and health plans; and a public comment period. The revised age range aligns with current recommendations from the U.S. Preventive Services Task Force (Grade B recommendation), American Academy of Family Physicians, and others. The increased numerator time frame from 24 to 27 months provides a 3-month grace period to account for logistics of obtaining a mammogram and is in response to concerns that the lack of a grace period results in women being screened more often than every two years. This change in specifications aligns the measure with the clinical guidelines that were first available in 2009. Since the measure specification changed during the measurement year and includes additional members for the denominator of the measure, we will move this measure to the display page for one year (2015). We plan to include this measure again in the 2016 Star Ratings.

2. *Annual Flu Vaccine (Part C).* NCQA is changing the flu shot question used in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey so respondents will be asked whether they received a flu shot since July of each year (instead of September) because the timeframe when people get flu shots has been getting earlier each year. This does not change the denominator for this measure, but members who get their flu shots earlier will be included. We will eliminate the pre-determined 4-star threshold for this measure for the 2015 Star Ratings due to the measure specification change.

3. *High Risk Medication (Part D).* As stated in the 2014 Call Letter, the updated Pharmacy Quality Alliance (PQA) HRM list, based on the American Geriatric Society (AGS) recommendations to the Beer's List, will be applied to calculate the HRM measure for the 2015 Star Ratings using 2013 Prescription Drug Event (PDE) data. CMS first alerted plans about this change in the 2013 Call Letter, and has provided monthly HRM patient safety reports using the updated list since 2012. Also, at the beginning of 2012, the AGS published the updated 2012 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults in the *Journal of the American Geriatrics Society*. Therefore, sponsors were aware of the updated Beer's Criteria to consider updates to their procedures ahead of the 2013 contract year. CMS will not modify or remove medications from the PQA-endorsed

HRM list. All Part D covered drugs, including barbiturates for which Part D coverage began in 2013, in the PQA HRM list will be included in the calculation for the 2015 Star Ratings (using 2013 PDE data).

4. *Medication Adherence for Diabetes Medications (Part D).* We reiterate that this measure evaluates adherence to diabetes medications, and not adherence to a specific drug class used to treat diabetes. As stated in the 2014 Call Letter, CMS will adopt PQA's changes to this measure's specifications for the 2015 Star Ratings (using 2013 PDE data), specifically the addition of two additional drug classes to the numerator and denominator (meglitinides and incretin mimetic agents). These changes will result in a more complete measure of beneficiaries' adherence to diabetes therapy. Previously, beneficiaries changing to these medications could have been marked as non-adherent. This change will account for that utilization. We note that the PQA updated their specifications for 2014 to include sodium glucose co-transporter 2 (SGLT2) inhibitors. We plan to add this new drug class to the measure calculation for the 2016 Star Ratings using 2014 PDE.

5. *Beneficiary Access and Performance Problems (Part C and D).* Based on the comments received, CMS will move the Beneficiary Access and Performance Problems to the display page since there were significant methodological changes to the audit process during the measurement period. We will incorporate the changes in the audit scoring methodology announced in the March 17, 2013 "Final Program Audit Scoring Methodology" memo (see http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS-Memo-Final-Program-Audit-Scoring-Methodology.pdf for more information). This change introduced a scoring system that generates an audit score for every organization/sponsor audited based on the number and severity of conditions detected in an organization/sponsor's operations. In this new scoring system, a lower score represents better performance on the audit. As indicated in the HPMS memo, CMS will no longer use the number of samples passed or failed in determining audit scores for the Star Ratings.

   Starting with the data for the 2015 display measure, an audit score will be calculated by utilizing the audit results for each of the following program areas: Part D Formulary and Benefit Administration; Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organizational Determinations, Appeals, and Grievances (ODAG); and Part C and Part D Compliance Program Effectiveness. These four core program areas are used because they are consistently audited each year and have limited changes to the audit protocols from year to year.

   The final display page audit score for an organization/sponsor will be calculated using the total number of audit points (determined based on both the number of unique conditions

identified and the severity of those conditions) in these four areas, divided by the total number of audit elements tested (again in the four core program areas).

Depending on the final audit score, organizations/sponsors could be reduced by up to 50 points from the starting score of 100 as a result of poor audit results. Appropriate cut points will be determined by an analysis of cumulative data, beginning with sponsors audited in 2012. The cut points will be established annually based on an analysis of cumulative industry performance. There will be no changes to the calculation and point deductions for sanctions, CMPs, and compliance letter (CAM Score) portions of the audit measure.

We will continue to look at methodological issues surrounding this measure to make a determination about inclusion in Star Ratings in future years.

6. *Medication Adherence Measures (Part D).* Based on stakeholder feedback, beginning with the 2015 Star Ratings using 2013 PDE, we will adjust the three Medication Adherence measures to account for beneficiaries with hospice enrollment or Skilled Nursing Facility (SNF) stays, during which the Part D sponsor would not be responsible for providing prescription fills for relevant medications. These adjustments are an extension of a similar adjustment currently applied to adherence measures to adjust for beneficiary stays in inpatient (IP) facilities. We tested these adjustments using 2013 data (with dates of service between January 1, 2013 and July 31, 2013, submitted by August 31, 2013), and we found a small proportion of beneficiaries included in the adherence measure that are enrolled in hospice. Adjustments to the measure for hospice enrollment have a negligible impact on overall adherence rates, increasing the rate on average by approximately 0.16 - 0.19 percentage points. After the SNF adjustment, overall adherence rates increase by approximately 0.37 - 0.45 percentage points. Although the impact of these two specification changes is small, they improve the validity of the measures.

   We do not feel that the recent clarifications to address Part D payment for drugs for beneficiaries enrolled in hospice or how the guidance is finalized will conflict with this modification to account for hospice stays. On the contrary, adjusting for hospice stays, as we already do for inpatient stays, should more accurately reflect drugs covered under the hospice benefit or waived through the beneficiary's hospice election. This adjustment should benefit the sponsor regardless of which party pays for the drugs.

   While hospice information from the Medicare Enrollment Database (EDB) and inpatient claims from the Common Working File (CWF) are available for both PDPs and MA-PDs, SNF claims are only available for Medicare Fee-for-Service (FFS) beneficiaries who are also enrolled in PDPs. Therefore, the SNF adjustment will only impact PDP sponsors; when such data are available for MA-PD organizations, this adjustment will be expanded to include those organizations as well. We are unable to set-up processes for specific

SNFs to provide their records of such data. We disagree that the application of SNF stays for PDPs is inequitable, as CMS' cut-points are determined for PDPs and MA-PDs separately.

CMS' patient safety reports provide information about adjustments for inpatient stays. We will modify the 2013 reports to reflect these additional adjustments.

Adjustments to the proportion of days covered (PDC) calculation will be made using the following steps:

1. Identify start and end dates of relevant types of stays for beneficiaries included in adherence measures.

    a. Use IP claims from the CWF to identify IP stays.
    b. Use SNF claims with positive payment amounts from the CWF to identify SNF stays.[5]
    c. Use hospice records from the EDB to identify hospice stays.

2. Remove days of relevant stays occurring during the measurement period from the numerator and denominator of the proportion-of-days covered calculation.

3. Shift days' supply from Part D prescription fills that overlap with the stay to uncovered days after the end of the relevant stay, if applicable. This assumes the beneficiary receives the relevant medication from a different source during the stay and "stockpiles" the Part D prescription fills for later use.

We continued to receive a number of comments regarding supplemental pharmacy data. CMS uses PDE data to calculate some of the measures for the Part D Star Ratings, including the Adherence measures. Every time a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record called the PDE to CMS. The PDE data are not the same as individual drug claim transactions, but are summary extracts using CMS-defined standard fields. The PDE record contains prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. We do not accept any other supplemental pharmacy data to calculate these measures.

Please refer to the HPMS memo, "Prohibition on Submitting PDEs for non-Part D Prescriptions" (May 11, 2012). The reporting of any PDE data that have not been submitted directly by network pharmacies or beneficiaries is prohibited, consistent with

[5] Although we do not generally observe SNF claims for Part C beneficiaries, due to enrollment changes and data anomalies we may observe a negligible number of claims for Part C beneficiaries.

our existing guidance. We encourage Part D sponsors to develop incentives for network pharmacies to submit claims under the plan unless beneficiaries have explicitly requested otherwise. Also, please refer to the HPMS memo, "May 2013 Updates to the Drug Data Processing System" (April 23, 2013). In 2013, CMS began to allow PDE records where the sum of the cost fields equals zero on all PDEs regardless of date of service (DOS). The memo discusses situations where this may be appropriate.

In addition, the PQA updated their specifications for calculating PDC for 2014 specifically making the following revisions to Step 2 of the numerator statement:

- Overlap adjustment should be based on generic ingredient rather than GCN when the product has a single medication. (This aligns with CMS' current calculation which uses generic name (ingredient name)).

- Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the drugs is common.

We are considering making this change for the 2016 Star Ratings using 2014 PDE to factor combination products into the PDC calculation, and we are exploring enhancements with the PQA to their Adherence medication NDC lists to include ingredient name flags to be able to perform this adjustment programmatically.

7. *Obsolete NDCs.* Beginning with the 2015 Star Ratings and display measures (using 2013 PDE data), we will implement the PQA's 2013 specification change to account for obsolete NDCs. NDCs with obsolete dates will be included in the measure calculation if their obsolete dates are within the period of measurement (measurement year) as reported by PQA.

   For the 2016 Star Ratings and display measures (using 2014 PDE data), we will implement PQA's 2014 obsolete date methodology. Specifically, the PQA's 2014 obsolete date methodology includes the following steps:

   1. Query the MediSpan and First DataBank databases to develop an NDC list.

   2. Cross-check the NDC list developed at step 1 against the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE) and its effective dates.

   3. Include the NDC in the file if:

      - There is no obsolete date noted by MediSpan or First DataBank or NSDE; or

      - The obsolete date in any of the databases is within the measurement year; or

- The obsolete date is within six months prior to the beginning of the measurement year.

C. Retirement of Measures

We will remove the Glaucoma Testing (Part C) measure from the 2015 Star Ratings due to the U.S. Preventive Services Task Force's recent conclusion that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary open-angle glaucoma in adults.

D. Contracts with Low Enrollment

To help beneficiaries make more informed choices and to be as fully transparent as possible about the performance of all plans, CMS is moving toward including low enrollment contracts in the Star Ratings. Low enrollment contracts, as defined in §422.252, are those where enrollment is such that HEDIS and HOS data collections cannot be used to reliably measure the performance of the health plan. In the past, we have believed that contracts with less than 1,000 enrollees would meet that definition but we have reevaluated whether that threshold is an appropriate implementation of the regulatory standard. Contracts with less than 1,000 enrollees first submitted HEDIS data to CMS in the summer of 2013. As a precursor to including low-enrollment contracts in the Star Ratings, CMS included HEDIS scores for low-enrollment contracts as part of the 2014 display measures. Based on the data we received, going forward CMS has determined that there are sufficient data to reliably measure and report on contracts in the Star Ratings with 500 or more enrollees in July of the HEDIS measurement year.

Beginning with the 2016 Star Ratings, contracts with 500 or more enrollees as of July 2014 will be included in the 2016 Star Ratings on the Medicare Plan Finder, and these ratings will be used for QBPs. Contracts with 500 or more enrollees in most cases will have sufficient data to produce both overall and Part C and D summary ratings. The HEDIS data for contracts with less than 500 enrollees will continue to be posted on the display page as these will continue to be considered low enrollment contracts.

The 2014 and 2015 display pages will include simulated Star Ratings for contracts with 500 to 999 enrollees, following a preview period. Using the most recent data for the 2014 Star Ratings, simulated overall ratings for 31 contracts with less than 1000 enrollees show the following:

- 13% would have received 2.5 stars,
- 26% would have received 3 stars,
- 39% would have received 3.5 stars,
- 10% would have received 4 stars, and

- 13% would not have enough measures to be rated.

Contracts with less than 1,000 enrollees will not be included in the cut point calculations for the 2014 and 2015 Star Ratings. Prior to the 2016 Star Ratings, CMS will continue to analyze the data from smaller contracts to ensure there are no data issues. It is important to note that only the measures where the contract meets the minimum denominator requirements are included in the Star Ratings. Thus, if a contract with 500 to 999 enrollees does not meet the minimum denominator requirements for a measure, the particular measure will not be included in its overall rating calculation. For example, the measure, "Complaints about the Health Plan" excludes contracts with enrollment less than 800 beneficiaries.

E. Data Integrity

Protecting data integrity is a high priority for CMS, especially for measures using non-validated data. CMS' current policy is to reduce a contract's measure rating to 1 star if it is identified that biased or erroneous data have been submitted. This policy ensures that CMS is measuring true performance. Contracts are able to review and discuss CMS' findings prior to the final release of the Star Ratings. While CMS maintains that it is the plans' responsibility to provide evidence that they have followed CMS' requirements, we understand plans' request for CMS to identify systemic issues.

We note that HEDIS data, plan-reported data, and survey data already undergo data validation processes. While CMS does not audit the processing of coverage determinations/exceptions and organization determinations for all sponsors each year, we have frequently found evidence that sponsors fail to follow requirements to forward Part C denials and to auto-forward untimely Part D initial coverage determination or redetermination requests to the IRE. Consequently, the data we receive do not represent the actual processes followed by these organizations—that is they do not accurately represent how timely the decisions were made by these sponsors. Because we feel that timely processing of these decisions is critical to ensuring access to care, the measure continues to be important to evaluating quality. However, we cannot at this time directly measure the processes used by these contracts. Thus, we need to identify falsely high ratings and reduce a sponsor's ratings for the inaccurate data.

Based on stakeholder feedback, at this time we will not pursue the option for independent audits to dispute CMS' reductions. Comments suggested that these were additional costs that sponsors did not want to incur at the time of payment reductions. However, we will continue to study this issue. Also, we will not apply incremental reductions, as commenters warned this could introduce additional risks for bias. Data integrity reviews by CMS will focus on findings that represent systemic issues with data reporting, collection, and compliance to program requirements in order to conclude a Sponsor's data are incorrect or subject to bias and therefore as a result, one star is being applied to the associated measure.

F. Changes for Measures Posted on the CMS Display Page

Display measures on www.cms.gov are not part of the Star Ratings. These include measures that have been transitioned from the Star Ratings, new measures being tested before inclusion into the Star Ratings, or other measures used for informational and monitoring purposes. Similar to the 2014 display page, organizations/sponsors have the opportunity to preview their data on the display measures prior to release on the CMS website. Data on measures moved to the display page will continue to be collected and monitored, and poor scores on display measures may be subject to compliance actions by CMS. It is expected that all 2014 display measures will continue to be shown on www.cms.gov unless otherwise noted in this Call Letter. National averages for the measures will be added to the display page as requested.

The following measures will remain on the display page for 2015.

1. *Pharmacotherapy Management of COPD Exacerbation (PCE) (Part C).* This measure is defined as 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 2014 Technical Specifications, Volume 2 for more information about data specifications.) Both rates from the HEDIS 2013 data are shown on the 2014 display page and will continue to be shown for 2015 on the display page. NCQA will be working with its advisory panels to investigate whether use of intravenous steroids and nebulizers can be added to the numerator of this measure. They anticipate any changes will be reflected in the October update to the HEDIS 2015 volume.

2. *Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (Part C).* This measure encourages people who have a new treatment episode to initiate and engage in treatment. However, CMS acknowledges concerns that the measure does not include self-help groups such as AA and NA. Therefore, CMS will keep both the measure of Initiation of Alcohol and Other Drug Dependence Treatment and the measure of Engagement of Alcohol and Other Drug Dependence Treatment on the display page. (See HEDIS 2014 Technical Specifications, Volume 2 for more information about data specifications.) This measure will focus on individuals age 18 and older. The 2013 HEDIS data for this measure are shown on the 2014 display page.

3. *Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).* This measure is based on the Pharmacy Quality Alliance (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 defer adding this measure until the 2016 Star Rating, and maintain this as a display measure for 2015 using 2013 data. This decision is based on a number of factors including: feedback received from the Star Ratings Request for Comments and draft Call Letter regarding differences in rates of MTM eligibility, and changes to the MTM requirements beginning 2013 which included the requirement to provide a CMR to LTC beneficiaries. Currently, analyses have not found a correlation between a sponsor's rate of MTM program eligibility and the CMR completion rate. For the 2015 display measures, we will post sponsors' MTM eligibility rates along their CMR rates. Once this measure is added as a Star Rating, the CMR measure will be weighted as a process measure (1x). We believe that this measure represents an initial step in measuring MTM performance, and we will consider other outcomes-based MTM measures when developed and endorsed through a consensus process.

The denominator of this measure is the number of 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. We reiterate that only those beneficiaries that meet the contracts' specified targeting criteria pursuant to §423.153(d) of the regulations are included in this measure. Patients enrolled in MTM based on other expanded or plan-specific targeting criteria are not included. Furthermore, the CMR measure includes those beneficiaries who were enrolled in the MTM program for at least 60 days during the reporting period. Beneficiaries who opt out of the MTM program after 60 days are still included in the measure. The numerator is the number of beneficiaries included in the denominator who received a CMR during the reporting period. Only a CMR that complies with the requirements set forth in the regulations which include providing an individualized, written summary of the CMR in CMS' standardized format shall be reported and counted as a CMR[6]. LTC beneficiaries will be included in the measure calculation, since Part D sponsors have been required since 2013 to offer CMRs at least annually to all beneficiaries enrolled in the MTM program regardless of setting.

Hospice patients will be excluded from this measure. Sponsors are not permitted to exclude hospice patients from their MTM program, and section 423.153(d) requires that CMRs be offered to all targeted beneficiaries enrolled in the MTM program. However, as the beneficiary's drugs may be covered under the hospice benefit or waived through the beneficiary's hospice election and sponsors may not be fully responsible for the management of the beneficiary's medication use during this time, we will exclude from the

[2] Refer to Annual Medication Therapy Management (MTM) Program Submission guidance memo. Accessed at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html

measure calculation those beneficiaries that have elected to receive hospice care. Using data from the Enrollment Database (EDB), CMS will exclude an enrollee reported to have entered hospice at any point during the measurement year, regardless of whether the contract reported him/her as receiving a CMR.

An organization/sponsor must have 31 or more 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 to have an MTM CMR rate calculated. Sponsors that did not score at least 95% on data validation for their reporting of the MTM program section or did not meet CMS' additional audit criteria will be shown with, "CMS identified issues with this plan's data." Sponsors are reminded that they should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs and to whom they must offer a CMR.

We expect to introduce the following measures to the 2015 display page.

A final determination about inclusion of these measures on the 2015 display page will be made based on analyses of the quality of the data, variation among organizations and sponsors, and the measures' accuracy and validity.

1. *CAHPS measures about contact from a doctor's office, health plan, pharmacy, or prescription drug plan (Part C).* Parts C and D sponsors are accountable for the care provided by physicians, hospitals, and other providers to their enrollees. These measures have been included in the CAHPS survey since 2013.

2. *CAHPS – Health Information Technology – EHR measures (Part C).* There are many local, regional, and national initiatives to accelerate the adoption of electronic health records that we anticipate 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 added a small set of questions to the 2014 CAHPS survey to obtain information on the use of electronic health records from the patient perspective. For example, measures include questions that ask about whether a computer or handheld device was used during office visits; whether the patient found the provider's use of a computer or handheld device helpful; and whether the patient found it harder or easier to talk to provider when the provider used a computer or handheld device. These display measures are for informational purposes only. CMS recognizes that this is an evolving area so initially these measures will be collected and fed back to plans as part of their annual CAHPS Plan Reports for quality improvement.

3. *Transition monitoring (Part D).* We will release two display measures using results of the Transition Monitoring Program Analysis (TMPA). The TMPA investigates whether Part D sponsors, in accordance with 42 CFR §423.120 (b)(3), are adequately administering

formulary transition requirements, providing enrollees with a one-time temporary supply of requested non-formulary drugs to allow time for the enrollees to switch to alternative therapies. We will display two separate contract-level measures: 1) failure rates for drugs within the classes of clinical concern, and 2) failure rates for all other drugs.

4. *Combined MPF Price Accuracy (Part D).* Based on industry feedback about the feasibility of combining the two accuracy indices into one measure in the future, CMS will not pursue this measure concept at this time. CMS will continue to release contract-level results for the display measure, "Plan Submitted Higher Prices for Display on MPF".

5. *Disenrollment Reasons (Part C and D).* CMS implemented the PDP and MA Plan Disenrollment Reasons survey in 2013. A random sample of voluntary disenrollees at each contract is 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. This is similar to the disenrollment reasons information that CMS formerly made public for health plans prior to 2006 when the reasons for disenrollment were linked to the disenrollment rates information. CMS will be providing individual reports back to contracts with results for their enrollees with comparisons to state, regional, and national estimates in August 2014. The primary purpose of the reports is to assist MA and PDP contracts with quality improvement efforts, and to that end, we will provide both composite measures of the primary reasons for disenrollment and drill-down item information. Composite measures of the primary reasons for disenrollment will be introduced to the 2015 display page. The current disenrollment rate measure will remain a Star Ratings measure, and in the future this additional information would be a drill down to that Star Ratings measure on the MPF. Prior to including these data on the MPF in the future, CMS will conduct testing with potential users of the site to ensure that they understand the information. Any further changes will be announced in a future Request for Comments or Call Letter.

The following changes will be made to measure specifications on the 2015 display page:

6. *Drug-Drug Interactions Measure (Part D).* This measure uses the PQA Drug-Drug Interactions (DDI) measure specifications. 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 will implement the updated PQA DDI measure list for the 2015 display measure (using 2013 PDE data), as proposed in the 2014 Call Letter. The changes made to the DDI list include:

I. Delete the DDIs - carbamazepine and propoxyphene; tamoxifen and bupropion, duloxetine, fluoxetine, and paroxetine; warfarin and cimetidine; warfarin and fibrates (fenofibrate, fenofibric acid, gemfibrozil).

II. Add the DDIs - carbamazepine and clarithromycin, erythromycin and telithromycin.

We note that PQA's 2014 specifications will delete the age criteria for this measure. Historically, we have not applied an age criteria for this measure, and will continue not to.

7. *Diabetes Medication Dosing (Part D).* CMS will align with the PQA's measure specifications for this display measure by adding a minimum age criteria of 18 years of age. We expect this change for the 2015 Display Measure (using 2013 PDE) to have minimal impact

8. Enrollment Timeliness (Part C and D). CMS previously excluded SNPs from this measure. For the 2015 display measure, we will include SNPs but use for their numerator the number of plan-generated enrollment transactions submitted to CMS within 21 calendar days of the application date.

G. Weighting Changes

We solicited feedback on alternative weighting of measures, specifically: 1) modifying the current weight (3x) of the improvement measure(s) in order to further recognize organizations/sponsors' efforts in improving quality and 2) modifying the weight (3x) of the three Part D Medication Adherence measures.

CMS received mixed reactions to changing the weighting of the improvement measure. Some wanted the weight reduced to 1, some preferred the current weight of 3, and others supported increasing the weight to anywhere from 5 times a process measure to 75% of a contract's overall Star Rating. CMS has listened to a number of MA organizations and Part D sponsors concerning their efforts to improve the level of quality in their organization. In particular, plans that have a large proportion of low income subsidy individuals have expressed concerns regarding the difficulties they experience in locating and effectively treating these beneficiaries in particular. These plans frequently must develop and maintain more intensive strategies to achieve higher quality ratings. In response to concerns expressed by these organizations and in light of these more intensive efforts, CMS is increasing the weight of the improvement measure (from a weight of 3 to a weight of 5). We will only include the improvement measures for plans that have at achieved at least 2.5 stars in their highest quality ratings (i.e., Part C rating for MA-only contracts, Part D rating for PDPs, and overall rating for MA-PDs). In response to comments, CMS is requiring a minimal standard be attained by the organization before improvement is considered in the quality rating. This change will be made for the 2015 Star Ratings. We will continue to hold high performing contracts with 4 or more stars harmless. Our

simulation using 2014 Star Ratings data of the effect of this change suggests that about a third of LPI contracts would lose their LPI status, and a few MA-PD contracts would now be eligible for QBPs.

CMS received more support to maintain the current weight of the three Part D Adherence measures as outcome measures than to decrease their weight to 1.5 as access measures. While the current PQA-developed measures are claims-based, there is evidence that higher medication adherence rates are linked with improvements in clinical outcomes. MA plans and PDP sponsors expressed concerns that this type of change would be contrary to efforts to encourage coordination of care, as well as decrease performance in other quality measures. CMS simulations of the effects of decreasing the weight of Adherence measures using 2014 Star Ratings data, found this change would affect the stability of contracts' Part D summary Star Ratings as well as overall Star Ratings significantly. While a small group of contracts' ratings would improve to the degree of losing their LPI status, becoming eligible for QBPs, or achieving an overall 5-star rating, changes to the Adherence measures weight would reduce a larger group of MA-PDs' overall Star Ratings to the point they would no longer be eligible for QBPs. Due to these considerations, we will maintain the weight of 3 for the Adherence measures for the 2015 Star Ratings.

H. Forecasting to 2016 and Beyond

These changes will be described again in the 2016 Call Letter. We discuss future modifications here to provide advance notice.

1. *2016 Changes in the Calculation of the Overall Rating and the Part C and D Summary Ratings*

a. Background

CMS wants to improve the accuracy of the assignment of overall and Part C and D summary ratings used for public reporting to Medicare beneficiaries and as the basis for Quality Bonus Payments (QBPs) for MA organizations. In constructing Star Ratings, a key concern is the potential for generating Star Ratings that do not reflect a contract's "true" performance, otherwise referred to as the risk of "misclassifying" a contract's performance (e.g., scoring a "true" 4-star contract as a 3-star contract, or vice versa). Misclassification occurs in any measurement system because all performance measurement is a mixture of *signal* (true performance) and *noise* (random measurement error due to rounding, variation due to who is sampled, and similar factors). Over the years several features have been implemented in the quality rating system to simplify the information for consumers, as well as to make the ratings process and methodology more transparent for sponsors. For example, we group the measure scores into star categories and round the data to make it easier for consumers to understand what a particular score means. We have

also implemented pre-determined 4-star thresholds for some measures since the 2011 Star Ratings to increase transparency for organizations/sponsors and set a priori expectations for high performance. However, all of these features create more "noise" or measurement error in the system.

b. Current Scoring Method

The 2014 overall Star Rating is a composite measure constructed from 36 measures for Part C and 15 measures for Part D. The measures are numeric scores such as counts and percentages of screening and testing, handling of chronic care, patient experience, customer service, and patient safety measures. Currently, each measure is assigned a rating from 1-5 stars. The principle for assigning a Star Rating for a measure is based on evaluating the maximum score possible and testing initial percentile star thresholds with the actual score. Scores are grouped using statistical techniques to minimize the distance between scores within a grouping (or "cluster") and to maximize the distance between scores in different groupings.

There are two methods for calculating the measure stars:

1. Clustering. Clusters are defined as contracts with similar distances between their data values and the center data value. The measure scores are inputs for a clustering algorithm, which determines break points in the distribution and groups the scores into star categories.

2. Significance testing. The measure scores are assigned stars with a combination of percentile-based categories and whether the score is significantly different from the mean of all contracts.

For the 2014 Star Ratings, 25 Part C and 5 Part D measures have pre-determined 4-star thresholds (68% of Part C measures, and 33% of Part D measures) not set by the clustering algorithm. For the 2015 Star Ratings, no new 4-star thresholds will be introduced. The previously set 4-star threshold for the Annual Flu Vaccine (Part C) measure will be eliminated for 2015 due to specification changes.

For those measures with pre-determined 4-star thresholds, any contract with a measure score above the threshold receives 4 or 5 stars, and any contract with a score below the threshold receives 1, 2, or 3 stars. This pre-determined 4-star threshold is applied before the clustering or significance testing. For example, for clustered measures, first the contracts that score above the pre-determined threshold are selected, and then this subset is clustered into two categories to determine which contracts receive 4 stars and which receive 5 stars.

Performance consistency across measures is considered an important indicator for the reliability of quality measurement. The individual measures selected by CMS for Star Ratings are proxies for the underlying central concept of high quality care. As such, consistently high performance across our measures is an indication that we can be more confident that an organization/sponsor's underlying operations and clinical services reflect the high quality of care they provide. In contrast, an organization/sponsor that demonstrates more erratic behavior in measures may not offer the same consistent quality, due to non-aligned operations or clinical services. An organization/sponsor's inconsistent performance – high on some measures, low on others – could also mean mismanagement of some areas by internal staff or subcontractors.

To incorporate this consistency indicator into the rating process, CMS has applied an i-Factor, renamed as the "Reward Factor", to the mean overall and Part C and D summary ratings since 2009 in order to reward contracts if they have both consistently high and stable relative performance. Specifically, the i-Factor calculation adds a value of 0, 0.1, 0.2, 0.3, or 0.4 to each contract's overall and summary ratings according to the variability and mean performance of its measure stars, and in doing so it increases the number of contracts at the high end of the rating scale for contracts that have low variation and high mean performance in their individual measure scores. The 2014 Part C & D Star Rating Technical Notes provide more information about the calculations.

c. Concerns with Current Scoring Method

Using the whole-star individual measures, as well as pre-determined 4-star thresholds, results in a loss of information when aggregating up to the overall and summary ratings. Whole stars contain less information than the corresponding measure data because there is information loss associated with converting a numeric scale to a 1- to 5-star rating. That is, the range of values between whole numbers is not differentiated (e.g., a "high 3" looks the same as a "low 3"). While we understand sponsors' perceptions that pre-determined 4-star thresholds provide stability in setting performance expectations, in reality the use of pre-determined thresholds violates our principle of assigning stars that maximize the difference between star categories. Pre-determined 4-star thresholds can thus cause contracts to receive different ratings when there is no significant difference in their scores (e.g., if a 4-star threshold is 80%, a contract that scores 79% would receive 3 stars while a contract that scores 81% would receive 4 stars when there may be no meaningful difference between a score of 79 and a score of 81). This is counter to the industry feedback given to CMS that these thresholds assist organization/sponsors in targeting their improvement efforts. The use of pre-determined 4-star thresholds is also problematic when there is general improvement in measure performance over time or when there are changes to a measure's specifications. In this case, there may not be any contracts with 4

or 5 stars, or any contracts with 1, 2, or 3 stars, for a particular measure. These examples illustrate how pre-determined thresholds increase noise in the Star Ratings.

Some plans were concerned that it is difficult to improve without published targets for achieving 4 or more stars on a measure. However, data analyses of past Star Ratings found plans on average have more significant levels of improvements in Part C and D measures without pre-determined thresholds, as compared to measures where there are pre-set thresholds. We found that on average only 32% of contracts improved significantly across the 23 Part C measures with 4-star thresholds, compared to 52% of contracts that improved significantly across the eight Part C measures without 4-star thresholds. For Part D, on average, only 21% of contracts showed significant improvement across the five measures with 4-star thresholds, while 56% of contracts showed significant improvement across the five Part D measures without 4-star thresholds. A number of the measures without pre-determined thresholds have been used on the display page and as Star Ratings measures for a number of years, so they are not new measures to the Part C and D programs. CMS has provided a document showing trends overtime in cut points that is available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html. We will continue to update this document to help plans target their quality improvement efforts.

d. Changes to Thresholds for 2016

Based on extensive analyses of several options, we will move from the current scoring methodology to a new methodology for the 2016 Star Ratings by removing the pre-determined measure thresholds. We will continue to use the "Reward Factor" for contracts with consistently high performance and continue our evaluations if changes are needed. As part of the Part C & D Star Ratings Technical Notes, we will add trends in cut points over time for each of the Star Ratings measures to help contracts see how cut points change overtime.

2. Expected Changes to Measure Specifications or Calculations

a. For HEDIS 2015, NCQA is considering or has already made revisions to several measures included in the Part C Star Ratings. CMS also is also monitoring any additional measures developed by NCQA for incorporation into the Star Ratings. For example, NCQA is currently testing a measure of potentially avoidable hospitalizations based on the AHRQ Prevention Quality Indicators (PQI). The proposed measure has two composites that assess the rate of hospitalization for acute and chronic ambulatory care-sensitive conditions. Depending on the outcome of testing and the development of appropriate risk-adjustment models, these would be potential measures for inclusion in the future. Additionally, NCQA is currently developing potential new health plan quality

measures that address the continuum of depression care from screening to outcomes. Specifically, they are exploring quality measures of depression screening with a standardized tool, developing a follow-up plan, monitoring of depressive symptoms with a standardized tool, and remission of depressive symptoms. Where possible they are planning to align these measures with existing quality measures included in Meaningful Use, such as measures developed by CMS for clinician quality evaluation and measures developed by Minnesota Community Measurement. We have shared any HEDIS-related comments received with NCQA.

New guidelines on treatment of blood cholesterol and hypertension may impact the following HEDIS measures and indicators beginning with the 2016 Star Ratings[7]:

- Cholesterol management for Patients with Cardiovascular Conditions (CMS),
- Comprehensive Diabetes Care (CDC) – LDL-C Screening and LDL-C Control indicators,
- Controlling High Blood Pressure (CBP), and
- Comprehensive Diabetes Care (CDC) – Blood Pressure Control indicators.

The public comment period for these proposed HEDIS changes began on February 19, 2014. CMS encourages stakeholders to review the HEDIS 2015 public comment material and submit comments, as appropriate, to NCQA. The final HEDIS 2015 measure set will be released by NCQA in July 2014.

Treatment of Blood Cholesterol

In November 2013, the American College of Cardiology / American Heart Association Task Force on Practice Guidelines released updated guidance for the treatment of blood cholesterol. The new recommendations differ greatly from the previous National Heart, Lung, and Blood Institute (NHLBI) guidance by removing treatments for LDL-C for the primary or secondary prevention of atherosclerotic cardiovascular disease (ASCVD) and instead, recommending high or moderate intensity statin therapy based on patient risk factors.

As part of NCQA's HEDIS 2015 public comment process, NCQA is seeking comments about the retirement of the Cholesterol Management for Patients with Cardiovascular Conditions (CMC) measure and the LDL-C Screening and LDL-C Control indicators from the Comprehensive Diabetes Care (CDC) measure. These potential changes would

[7] We discussed these new guidelines in the draft Call Letter in the context of proposed changes to the 2015 Star Ratings.

impact the 2016 Star Ratings. These measures would continue to be included in the 2015 Star Ratings.

Treatment of Hypertension

In December 2013, the panel members appointed to the eighth Joint National Committee (JNC 8) released updated guidance for the treatment of hypertension. The new recommendations set the treatment goal for patients 60 years of age and older to <150/90 mm Hg and keep the treatment goal for patients ages 18-59 years at <140/90 mm Hg. The latest guideline also recommends that all diabetic patients age 18 and older should be treated to a goal of <140/90 mm Hg and calls into question the use of other targets.

NCQA is seeking comments on whether it should stratify the ages and treatment goals for the Controlling High Blood Pressure (CBP) measure to match the new guidance. If NCQA goes ahead with this change, this would just change the numerator and not the population in the Blood Pressure Control measure. Therefore, CMS would keep the measure in the 2016 Star Ratings.

b. Osteoporosis Management in Women who had a Fracture (Part C).

This measure assesses the percentage of women who had a fracture and received either screening or treatment for osteoporosis. One of the treatments for osteoporosis listed in the measure is a prescription for estrogen. However, estrogen is included in the American Geriatrics Society's recently published list of potentially harmful medications in the elderly (i.e., Beers criteria). NCQA is reviewing the most recent evidence for osteoporosis treatment with experts in the field to determine if treatment with estrogen should be removed from this measure. Other revisions under consideration include adding an upper age limit to the measure and adding an exclusion for dementia.

c. Monitoring Physical Activity (Part C).

This measure, collected through HOS, assesses the percentage of beneficiaries who discussed their level of physical activity with their health care provider and were advised to start, increase, or maintain their level of physical activity. NCQA is currently exploring the possibility of revising the underlying survey questions used in this measure. These revisions would facilitate the possible addition of an outcome indicator that assesses whether patients increased their level of physical activity.

d. Plan All-Cause Readmissions (Part C).

This is a measure of the percentage of hospital discharges resulting in a readmission for any cause within 30 days of discharge. This measure is reported as a ratio of a health plan's observed rate of readmission compared to an expected rate of readmission based on

a risk-adjusted model. NCQA is considering two potential changes to this measure: 1) excluding planned readmissions from the measure and 2) removing the current exclusion from the denominator for hospitalizations with a discharge date in the 30 days prior to the Index Admission Date. NCQA and its Measurement Advisory Panels believe these changes will improve the validity of the measure.

e. Improving Bladder Control (Part C).

This measure, collected through HOS, assesses the percentage of beneficiaries with a urine leakage problem who discussed their problem with their provider and received treatment for the problem. NCQA made three changes to this measure. First, NCQA changed the denominator of both indicators to include all adults with urinary incontinence, as opposed to limiting the denominator to those who consider urinary incontinence to be an issue. This will remove a potential bias toward only sampling patients who were treated unsuccessfully. Second, NCQA changed the treatment indicator to assess whether treatment was discussed, as opposed to received. This will change the measure focus from receiving potentially inappropriate treatments, which often have adverse side effects, to shared decision making between the patient and provider about the appropriateness of treatment. Third, NCQA added an outcome indicator to assess how much urinary incontinence impacts quality of life for beneficiaries. This outcome indicator will not be part of the Star Rating system until additional analyses have been done. These changes required revising the underlying survey questions in HOS. The revised questions will be first collected in 2015. As a result of these changes, there will be no data for this measure for the 2016 and 2017 Star Ratings.

f. Plan Makes Timely Decisions about Appeals (Part C).

Effective January 1, 2014, CMS has revised the procedures relative to appeal dismissals. Beginning January 1, 2014 organizations are responsible for dismissing invalid appeal requests, rather than forwarding requests to the Independent Review Entity (IRE) for the dismissal decision. Therefore, the IRE will not be capturing data around the timeliness of dismissal cases, and consequently, dismissals will be excluded from this measure for the 2016 Star Ratings. CMS will not be moving this measure to the display page since this change was announced in advance.

g. Appeals Upheld (Part D).

For the 2016 Star Ratings, we will modify this measure from using the current 6-month snapshot to use the same 12-month measurement period as the Part D Appeals Auto-forward measure. This change will allow consistency between the two appeals measures as well as expand the measurement period. Expanding the measure dataset to a full 12 months of data will provide a more comprehensive and objective evaluation of a plan's

performance than the current six month period. We will re-evaluate and adjust as necessary the minimum number of cases. The pre-determined 4-star threshold for this measure will be eliminated for the 2016 Star Ratings due to this specification change. For the 2015 Appeals upheld measure, CMS will continue to use the first 6 months of 2014 IRE data.

h. Adherence (DM and Hypertension) and Diabetes Treatment (Part D):

PQA updated their specifications for 2014 to exclude End-Stage Renal Disease (ESRD) patients from the denominator of these measures based on the ICD-9 code 585.6 and/or by the RxHCC 121.

CMS will use the beneficiary ESRD coverage start and termination dates reported in the Medicare Enrollment Database (EDB) rather than the ICD-9 code or RxHCC to identify beneficiaries for exclusion. This change will be made for the 2016 Star Ratings using 2014 PDE.

EDB data are available for all Part D beneficiaries and, are also current (after considering data lag), whereas RxHCCs do not reflect current diagnoses. CMS' testing of these indicators found a very high level of overlap between the ESRD indicators in the EDB and ICD-9 codes in in-patient and out-patient claims when calculating the final rates for these measures for purposes of the Star Ratings. While there is some lag in data updates, we found the overlap between the two data sources was greater than 95%.

i. Complaints about the Health/Drug Plan (CTM) (Part C and D):

For the 2016 Star Ratings, CMS will modify the CTM measurement period from 6 months of the current contract year to 12 months of the prior contract year. Expansion of the data used for this measure will provide a more comprehensive evaluation of the plan. Currently complaints filed in the 2nd half of a year are not accounted for in a contract's performance rating when only the 6-month period is used. CMS will continue to use complaint data from January-June 2014 for the 2015 Star Ratings.

j. MPF Accuracy (Part D):

This measure incorporates data from Part D sponsors' and MA-PD organizations' Medicare Plan Finder (MPF) files, specifically information about the types of claims dispensed by each pharmacy in an organization/sponsor's network. Currently, we exclude PDE claims from retail pharmacies that are also reported by sponsors as being long term care, mail order, or home infusion pharmacies. We will evaluate removing this restriction in the future, and use PDE data to appropriately identify retail claims for evaluation in this measure. This measure would continue to be focused on retail claims; claims filled as other

pharmacy types would be excluded. We will also remove the restriction limiting evaluation to claims for 30-day supplies, and will evaluate claims for 30, 60, and 90-day supplies.

k. CAHPS measures (Part C and D):

We will slightly modify the CAHPS methodology to permit low-reliability contracts to receive 5 stars or 1 star. Some low-reliability contracts with 5 base stars, while imprecisely measured, nonetheless have good evidence of performance that is well above the 4-star threshold. We will modify the CAHPS methodology to permit low-reliability contracts with 5 base stars that also exceed the 4-star threshold by 1 standard error to retain 5 stars for their final measure star. Similarly, low-reliability contracts with 1 base star that also fall below the 2-star cutoff by 1 standard error will retain 1 star for their final measure star.

I. Measurement Concepts

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. We appreciate the comments received regarding alternative levels of evaluation for Star Ratings, new measures, SNP-specific measures, including CAHPS measures regarding the SNP Care Teams, and alternative ways to measure improvement. We will consider them as we continue to look at these measurement concepts.

Providing Materials to Individuals with Disabilities

MA organizations (MAOs) and Part D sponsors are reminded that they must comply with Section 504 of the Rehabilitation Act of 1973, a federal law that protects individuals from discrimination based on their disability. This law also applies to organizations, such as MA organizations (MAOs) and Part D sponsors, that receive financial assistance from any Federal department or agency.

In addition, MAOs and Part D sponsors agree, in their contracts with CMS, to operate in accordance with all applicable Federal statutes, regulations, and policies, which would include the provision of the Rehabilitation Act of 1973 described above.

CMS guidance regarding Medicare Advantage anti-discrimination requirements for MAOs and Part D sponsors is also enumerated in Section 30.4 of the Medicare Marketing Guidelines – Anti-Discrimination. Specifically, MAOs and Part D sponsors may not discriminate based on race, ethnicity, national origin, religion, gender, age, mental or physical disability, health status, claims experience, medical history, genetic information, evidence of insurability or geographic location. This includes the requirement that MA organizations and Part D sponsors ensure that information such as marketing materials, including, but not limited to, the Summary of benefits, the Annual Notice of Change, and Explanation of Benefits, among others are made available in

an appropriate, understandable format to individuals with disabilities (for example, those with visual and hearing impairments) upon request.

Summary of Benefits

Based on industry feedback and CMS research, CMS is revising the Summary of Benefits (SB) template document beginning with CY 2015. Under §§ 422.111 and 423.128, as explained in the Medicare Marketing Guidelines, the SB is a standardized document that must be distributed with each enrollment form, and provides consumers an overview of plan benefits in a consistent and uniform manner so that individuals can compare plans offered by different MAOs.

Over the past few years, CMS has sought feedback from both beneficiaries and the industry about the utility of the SB. In 2011, CMS issued a Federal Register Notice for Comment regarding challenges faced by Medicare-Medicaid enrollees, including difficulties with cost-sharing information in the SB. In 2012, CMS consumer tested the SB through one-on-one participant interviews to determine whether beneficiaries could identify the purpose of the SB and identify opportunities for increasing beneficiary comprehension. In 2013, CMS sought industry feedback on draft templates significantly revised to address beneficiaries' difficulty using the SB to understand plan benefits or compare plan benefits against Original Medicare (OM). CMS reviewed all comments received as part of these feedback periods and has revised the template, which will be released in April 2014 with the PBP and SB software.

We anticipate that the revisions will focus largely on two areas: (1) limiting the description of benefits to those covered under the plan, addressing the scope, and removing the comparison of benefits against coverage under Original Medicare; and (2) describing plan benefits and cost-sharing using beneficiary-friendly language.

Section II – Part C

Overview of CY 2015 Benefits and 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 mostly duplicative plans under §422.256(b)(4), also referred to as the "meaningful difference" evaluation. Similarly, employer group plans and section 1876 cost plans are not evaluated for low enrollment. Please note: CMS reserves the right to review employer group plans for low enrollment and/or meaningful difference in future years.

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.

CMS has made all of the necessary tools and information available to MAOs in advance of the bid submission deadline, and therefore expects all MAOs to submit their best, accurate, and complete bid(s) on or before the Monday, June 2, 2014 deadline. Any organization whose bid fails the published Part C Service Category Cost Sharing, PMPM Actuarial Equivalent Cost Sharing, Meaningful Difference, Total Beneficiary Cost (TBC), and/or Optional Supplemental Benefit requirements will receive a compliance notice, even if the organization is allowed to correct the deficiency.

The following chart displays key 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
Part C Optional Supplemental Benefits	Yes	Yes	No	No

[1] 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 2015 and have provided explanations of these changes in each applicable section below. Consistent with last year, MAOs must also address requirements implemented under the Affordable Care Act, such as the medical loss ratio and health insurance providers fee, and are expected to do so independently of our requirements for benefits or bid review. Therefore, we are not making specific adjustments or allowances for these changes in our benefits review requirements.

A. 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 2014 (three annual election periods) and have fewer than 500 enrollees for non-SNP plans or fewer than 100 enrollees for SNP plans. The list did not include plans with low enrollment that CMS determined were located in service areas that do not have a sufficient number of competing options of the same plan type.

Under 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 2015, or provide a justification for renewal. If CMS does not find there is a unique or compelling reason for maintaining a plan with low enrollment, we will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting business cases and what information is required in those submissions will be included with the list of low enrollment plans sent to the MAO.

CMS recognizes there may be certain factors, such as the 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 should follow the CY 2015 renewal/non-renewal guidance (outlined in Section 140 of Chapter 4 and Section 60.3 of Chapter 16b of the Medicare Managed Care Manual) to determine whether a low enrollment plan may be consolidated with another plan(s). Any updates to Chapter 4 or 16B will be made in advance of bid submission.

We remind you that MAOs must adhere to all applicable MA regulations, including 42 CFR §422.504(a). At the time of this communication, there is a pending proposal to amend §422.504(a)(19) to place a two-year limitation on submitting a new bid in an area where an MA plan has been required to terminate due to low enrollment. The proposal is that an MA organization would agree not to submit a new bid of the same plan type that has been non-renewed under § 422.506(b)(1)(iv) in the same service area as the non-renewed plan for two years after such a non-renewal. MAOs must comply with the regulation, as finalized and as of its effective date.

In response to comments, CMS did not identify any MA Medical Savings Account (MSA) plans in the low enrollment review for CY 2015. Additionally, CMS will continue to evaluate and implement low enrollment requirements on an annual basis to address these issues and will take into consideration the comments received on MSA and employer plans.

B. Meaningful Difference (Substantially Duplicative Plan Offerings)

Pursuant to §422.254(a)(4), MAOs offering more than one plan in a given service area must ensure the plans are substantially different; 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 2015, CMS will use plan-specific per member per month (PMPM) out-of-pocket cost (OOPC) estimates to identify meaningful differences in beneficiary costs among the same plan types. 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 stated in the draft Call Letter, CMS will combine HMO and HMO-POS as one plan type for evaluating meaningful difference, unless the HMO-POS plan covers all Parts A and B services outside the network, in which case the HMO-POS plan will continue to be considered meaningfully different from an HMO plan. For CY 2016, CMS may also require HMO-POS plans to not place geographic or provider limitations on the out-of-network benefits in order to be considered meaningfully different.

CMS will evaluate meaningful differences among CY 2015 non-employer and non-cost contractor plans offered by the same MAO, in the same county, as follows:

1. The MAO's plan offerings will be separated into five plan type groups on a county basis: (1) HMO and HMO-POS not offering all Parts A and B services out-of-network; (2) HMO POS offering all Parts A and B services out-of-network; (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 OOPC (Part C and Part D) PMPM estimate will be calculated for each plan. We consider a difference of at least $20.00 PMPM between the OOPC for each plan offered by the same MAO in the same county to be meaningful for purposes of applying the meaningfully different standard. Plan premium is not included in the meaningful difference evaluation.

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

CMS expects MAOs to submit CY 2015 plan bids that meet the meaningful difference requirements, but will not prescribe how the MAOs should redesign benefit packages to achieve such differences. Furthermore, MAOs have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission and CMS will not approve plan bids that do not meet these requirements. MAOs must follow the renewal/non-renewal guidance (outlined in Section 140 of Chapter 4 and Section 60.3 of Chapter 16b of the Medicare Managed Care Manual) to determine whether their plans may be consolidated with other plans.

For purposes of the meaningful difference evaluation for CY 2015, we received comments regarding our proposal to no longer evaluate HMO and HMO-POS plans that do not cover all Parts A and B services outside the plan's network as different types of plans, as well as comments on our proposed changes for CY 2016 that would not allow geographic and/or provider limitations to serve as criteria for meaningful difference. We remind organizations that this change is limited to meaningful difference evaluations and CMS is not changing the requirements and flexibilities afforded by the POS supplemental benefit as defined in Chapter 4 of the Medicare Managed Care Manual. Organizations may continue to offer HMO-POS designs that do not cover all Parts A and B services outside the plan's network, but must ensure that those plans, when offered in conjunction with an HMO in the same county, are meaningfully different. CMS will also consider comments on policy changes related to geographic and/or provider limitations for CY 2016.

C. Total Beneficiary Cost (TBC)

CMS will exercise its authority under section 1854(a)(5)(C)(ii) of the Act to deny MAO bids, on a case-by-case basis, if it determines 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 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).

We received numerous comments from Medicare Advantage Organizations that described potential challenges complying with the TBC requirement, in light of other payment-related changes. Consistent with past years, CMS will continue to incorporate adjustments in the TBC calculation for payment rate and quality bonus changes, in addition to an adjustment for a change

in the national factor for the MA coding pattern difference and other technical adjustments for changes in the PBP software. As stated in the draft Call Letter, CMS will use a TBC threshold at $32.00 PMPM for CY 2015. Thus, a plan experiencing a net increase in adjustments must have an effective TBC change amount below the $32.00 PMPM requirement. Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the $32.00 PMPM requirement. In response to comments, we remind MAOs that the Office of the Actuary extends flexibility on margin requirements so 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. 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 organizations consolidating multiple CY 2014 plans into a single CY 2015 plan, CMS will use the enrollment-weighted average of the CY 2014 plan values to calculate the TBC. Otherwise, these plans will be treated as any other plan for the purpose of enforcing the TBC requirement. Please note for CY 2016, CMS is considering (a) requiring each individual plan to be "crosswalked" into another plan to meet the TBC threshold on its own merit and (b) discontinuing use of the enrollment-weighted average for multiple plans "crosswalked" into one plan to determine TBC. We will consider the comments we received on the draft call letter in determining whether to implement this policy in CY2016.

D. Maximum Out-of-Pocket (MOOP) Limits

Table 2 below displays the CY 2015 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to LPPOs and RPPOs. A plan's adoption of a MOOP limit that qualifies as a voluntary MOOP ($0 - $3,400) results in greater flexibility for individual service category cost sharing.

As codified at 42 CFR §422.100(f)(4), (5) and §422.101(d)(2) and (3), all 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. Although the MOOP requirement is for Parts A and B services, an MAO can include supplemental benefits as services subject to the MOOP. MA plans may establish as their 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 2015 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

In response to comments, although it may be rare that a dual-eligible enrollee would be responsible for paying any cost sharing because the State Medicaid program is making those payments on his/her behalf, all MA plans must track enrollees' actual out-of-pocket spending for covered services in order to ensure an enrollee does not spend more than the MOOP amount limit established by the plan. If the plan charges cost sharing for covered services, some dual-eligible enrollees may incur cost sharing and any enrollee losing his/her Medicaid eligibility would be responsible for cost sharing. Currently, SNPs have the flexibility to establish $0 as the MOOP amount, thereby guaranteeing there is no cost sharing for plan enrollees. Otherwise, if the SNP does charge cost sharing for covered services, it must track enrollees' out-of-pocket spending and it is up to the plan to develop the process and vehicle for doing so.

E. Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost Sharing Limits

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 2015: Inpatient, 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 2015.

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 *(BPT Col. n)*[2]	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	1.393	$35.24	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.069	$10.57	$0.26	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).

[2] PMPM values in column 3 for Inpatient and Skilled Nursing Facility only reflect Part A fee-for-service actuarial equivalent cost sharing for that service category.

F. Part C Cost-Sharing Standards

As stated in the draft Call Letter, we will continue 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 that we will not consider discriminatory or violative of the applicable standards. CY 2015 bids must reflect enrollee cost sharing for in-network services no 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 2015:

- Inpatient and home health requirements have been updated to reflect estimated changes in Original Medicare costs for 2015.
- The Skilled Nursing Facility (SNF) cost sharing limit for the first 20 days has been reduced from $50 to $40 per day for voluntary MOOP plans and from $25 to $0 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 2015. Since cost sharing for the overall SNF benefit (i.e., both benefit periods) must be no higher than the actuarially equivalent cost sharing in Original Medicare, the cost sharing requirement change for the first benefit period should not impact the overall plan costs associated with the SNF benefit.
- Occupational Therapy, Physical Therapy and Speech-language Pathology have been added requirements for CY 2015.

Table 4. CY 2015 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	$4,123
Inpatient - 10 days	1a	$2,392	$1,913
Inpatient - 6 days	1a	$2,171	$1,737
Mental Health Inpatient - 60 days	1b	$2,544	$2,035
Mental Health Inpatient - 15 days	1b	$1,911	$1,528
Skilled Nursing Facility – First 20 Days[1]	2a	$40/day	$0/day
Skilled Nursing Facility – Days 21 through 100[2]	2a	$156.50/day	$156.50/day
Emergency Care/Post Stabilization Care	4a	$65	$65
Urgently Needed Services[3]	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
Occupational Therapy	7c	$40	$40
Physician Specialist	7d	$50	$50
Psychiatric and Mental Health Specialty Services	7e and 7h	$40	$40
Physical Therapy and Speech-language Pathology	7i	$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[4]	15	20% or $75	20% or $75
Part B Drugs-Other	15	20% or $50	20% or $50

[1] 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. 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 no higher than the actuarially equivalent cost sharing in Original Medicare, pursuant to §1852(a)(1)(B).

[3] Emergency Care and Urgently Needed Care benefits are not subject to a service category or plan level deductible amount.

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

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 up to a 20% coinsurance or $75 copayment to that particular benefit. Please note MAOs with benefit designs using a coinsurance or copayment amount for which CMS does not have an established amount (e.g., coinsurance for inpatient or copayment for durable medical equipment) must submit with their initial bid a document that clearly demonstrates how the coinsurance or copayment amount satisfies CMS service category requirements. This document must be submitted as part of supporting documentation for the Bid Pricing Tool as described in the Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2015, Appendix B-Supporting Documentation.

We received comments regarding lowering the cost sharing requirement for the first 20 days of SNF care and would like to clarify our guidance. Pursuant to section 1852(a)(1)(B) of the Act, MAOs 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 the structure of the benefit in 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 with a voluntary MOOP may include some cost sharing during the first 20 days, in accordance with standards defined annually by CMS. If a plan with the lower, voluntary MOOP decides to charge 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 $156.50 per day in order to satisfy the pmpm Actuarial Equivalence requirement. We agree with commenters who recommended a balance between protecting beneficiaries and plans' ability to provide affordable benefit packages and believe that this policy for how MA plans may impose cost sharing for SNF benefits strikes that balance.

We also received comments about the cost sharing standards for chiropractic, physical therapy, emergency care, and urgently needed services. CMS annually evaluates available Medicare data to establish our requirements in accordance with applicable law. We remind organizations that MA plan offerings are not required to have the same cost sharing amounts for both emergency care and urgently needed services. Organizations are afforded the flexibility to design their benefits as they see fit as long as they satisfy Medicare coverage requirements.

G. Part C Optional Supplemental Benefits

As part of our evaluation as to whether the bid and benefits are not discriminatory against enrollees with specific health needs, CMS will continue to review non-employer bid submissions to ensure enrollees electing optional supplemental benefits are receiving reasonable value. We consider a plan to be not discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meet the following thresholds: (a)

margin is no greater than 15% and (b) retention, defined as margin plus administrative expenses, is no greater than 30%.

We understand some supplemental benefits are based on a multi-year basis, but the plan bids submitted each year are evaluated based on that particular plan year.

Part C Policy Updates

A. Increasing Transparency for Beneficiary Part C Cost Sharing for Inpatient Stays

As we explained in our draft Call Letter, we have become aware that some MA plans' representation of cost sharing for inpatient services is not as transparent as it should be, particularly in MA plans that do not use original Medicare benefit periods as the basis for charging cost sharing. As an example, an MA plan may charge inpatient cost sharing for each inpatient admission that includes the inpatient deductible and per diem cost-sharing beginning with admission to an inpatient acute hospital. In the event that the enrollee is subsequently transferred to an inpatient rehabilitation hospital, the plan may then charge a second round of cost-sharing (e.g., a second inpatient deductible and other cost-sharing) upon admission to the rehabilitation hospital. Thus, the enrollee is charged two inpatient deductibles and per diem cost-sharing, even though the second stay (at the rehabilitation hospital) is a transfer that is required by the enrollee's medical condition.

In contrast, under Original Medicare, beneficiaries pay only one inpatient deductible (Part A) during a benefit period, even if the beneficiary is transferred from one inpatient hospital type to another (e.g., from an inpatient acute hospital to an inpatient rehabilitation hospital) or has multiple stays, for any reason, during the benefit period. That is, the cost sharing is charged based on the original Medicare-defined benefit period.

Thus, we believe it is important to increase beneficiary awareness of such alternative benefit structures because of the potential for higher-than-expected out-of-pocket spending associated with inpatient hospitalization in those plans.

In order to increase beneficiary and other stakeholder awareness of the differences in cost sharing structures across plans, we are revising the templates for Evidence of Coverage (EOC), and Annual Notice of Change (ANOC) to more clearly show each plan's inpatient cost sharing structure. We added instructions and language to the EOC and ANOC for MA plans to clearly identify all cost sharing (deductible, copayments/coinsurance) for inpatient stays and the period for which such cost sharing would be charged, if applicable. Similarly, as part of the upload process for CY 2015 plan benefit packages, plans will answer a question about inpatient cost sharing so that this information will be made available in the MPF.

In the draft Call Letter, we also shared our intention to consider future rulemaking in order to provide stronger beneficiary protections from excessively high inpatient cost sharing. We appreciate the comments received on the draft Call Letter, and will take these into account as we consider whether to engage in rulemaking on this issue for CY 2016.

B. Transferability of MOOP Contributions When an Enrollee Changes Plans During the Contract Year

In the draft Call Letter, we proposed that MAOs provide for the transfer of enrollees' out-of-pocket spending so that it would apply when enrollees disenroll from one plan and enroll in a different plan type offered by the same MAO. Thus, if an enrollee makes a mid-year change from an HMO to a PPO offered by the same MAO, his/her accumulated out-of-pocket spending so far in the contract year should follow the enrollee and be counted towards the MOOP limit in the new MA plan. This was to allow those enrollees who are eligible to make mid-year plan changes to freely select among the diverse MA plan options offered by an MAO. In their comments on our proposal, some MAOs said that transfer of the enrollees' out-of-pocket spending across plan types is very complicated because the benefits, cost sharing and deductible requirments are more variable across plan types than across plans of the same type. We are sensitive to the commenters' concerns but believe that this is an important beneficiary protection and there finalize this guidance as proposed.

C. Memory Fitness Activities

MAOs have previously proposed to offer memory fitness activities (e.g., brain/memory exercises*)* as stand-alone supplemental benefits. In consideration of emerging research, CMS will accept memory fitness activities as part of a broader health education supplemental benefit (as described in Chapter 4 of the Medicare Managed Care Manual (MMCM). A supplemental health education benefit that includes memory fitness activities may be offered to all enrollees or marketing may be targeted to specific enrollees identified by the plan to assist them in building the skills necessary to enhance preventive and self-care capabilities. Please note that any proposed stand-alone, memory fitness benefit will not be approved as a supplemental health benefit.

We received comments supporting the proposed policy as a holistic approach to brain health. Commenters described how education programs could help enrollees understand the importance of controlling other related conditions (e.g., cardiovascular disease, diabetes, depression, stress) as they relate to brain health. Please note that Chapter 4 of the MMCM will be revised to reflect that guidance.D. Part C PBP Notes Update for CY 2015

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 should not contain

any cost sharing for the benefit/service not reflected in the PBP data entry field for the benefit/service or conditions for coverage because such information is not captured in Summary of Benefits sentences. In addition, any information in a notes field must be consistent with the benefit/service as it is reflected in the PBP data entry fields. This is to ensure all cost sharing information is transparent to beneficiaries as they make plan comparisons.

Thus, an appropriate note contains only information applicable to the service category in which the note section is located and provides relevant information reviewers need for bid evaluation; it does not repeat the cost sharing information entered in the data entry field. Over the years, we have taken several steps to help plans present benefits in the PBP without the need for extensive notes.

We have also made multiple changes to the PBP for CY 2015 that address supplemental benefits described in Chapter 4 (Section 30.3). In developing supporting notes in the PBP, MAOs must use text fields to describe benefit attributes that cannot be discerned from either Chapter 4 guidance or the corresponding data entry fields. We realize, in the past, notes have often been used to support marketing material; however, we continue to coordinate with our marketing review staff so that plans aren't expected to include marketing information in their PBP notes. MAOs are encouraged to review the forthcoming HPMS memo, which we expect to release in mid-April, for more information regarding CMS' expectations with respect to appropriate PBP notes.E. Part C ER/Urgent Care Deductible

As stated in the draft Call Letter, we are clarifying that enrollees utilizing the Emergency Care or Urgently Needed Care benefits are not subject to a service category or plan level deductible amount; however enrollee cost sharing associated with Emergency Care and Urgently Needed Care visits always apply toward a plan level deductible.

In response to comments, we are confirming that the plan level deductible includes in-network, out-of-network, and combined (in- and out-of-network) deductibles. As a reminder, all costs associated with emergency care/urgently needed care are applicable to the maximum out-of-pocket (MOOP) limit.

Consistent with this guidance, CMS has made changes in the CY 2015 Plan Benefit Package (PBP) including the removal of deductible questions in Section B for Emergency Care and Urgently Needed Care and adjusting "pick lists" for plan level and differential deductibles in Section D. F. Requirements for Home Health Services

We have received a number of questions during the past year about certification of home health services for enrollees of MA plans and clarified our policy in the draft Call Letter. We reiterate here that regulations at 42 CFR §424.22, which require that the Original Medicare program pay for home health services only if a physician certifies and recertifies that the home health services are needed by the beneficiary and that the beneficiary qualifies for those services, also apply to

the basic benefit provided by MA plans. We wish to clarify the requirements of this regulation also apply to Medicare Advantage plans as home health services are a basic benefit under §422.100.

D. Part C PBP Notes Update for CY 2015

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 should not contain any cost sharing for the benefit/service not reflected in the PBP data entry field for the benefit/service or conditions for coverage because such information is not captured in Summary of Benefits sentences. In addition, any information in a notes field must be consistent with the benefit/service as it is reflected in the PBP data entry fields. This is to ensure that all cost sharing information is transparent to beneficiaries as they make plan comparisons.

Thus, an appropriate note contains only information applicable to the service category in which the note section is located and provides relevant information reviewers need for bid evaluation; it does not repeat the cost sharing information entered in the data entry field. Over the years, we have taken several steps to help plans present benefits in the PBP without the need for extensive notes. We will include additional, minor clarifications regarding a number of supplemental benefits in a future HPMS memo to address our approval standards for mandatory supplemental benefits and the permissible scope of optional supplemental benefits.

We have also made multiple changes to the PBP for CY 2015 that address supplemental benefits described in Chapter 4 (Section 30.3). In developing supporting notes in the PBP, MAOs must use text fields to describe benefit attributes that cannot be discerned from either Chapter 4 guidance or the corresponding data entry fields. We realize, 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. MAOs are encouraged to review the forthcoming HPMS memo, which we expect to release in mid-April, for more information regarding CMS' expectations with respect to appropriate PBP notes.

E. Part C ER/Urgent Care Deductible

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In response to comments, we are confirming that the plan level deductible includes in-network, out-of-network, and combined (in- and out-of-network) deductibles. As a reminder, all costs associated with emergency care/urgently needed care are applicable to the maximum out-of-pocket (MOOP) limit.

Consistent with this guidance, CMS has made changes in the CY 2015 Plan Benefit Package (PBP) including the removal of deductible questions in Section B for Emergency Care and Urgently Needed Care and adjusting "pick lists" for plan level and differential deductibles in Section D.

F. Requirements for Home Health Services

We have received a number of questions during the past year about certification of home health services for enrollees of MA plans and clarified our policy in the draft Call Letter. We reiterate here that regulations at 42 CFR §424.22, which require that the Medicare program pays for home health services only if a physician certifies and recertifies that the home health services are needed by the beneficiary and that the beneficiary qualifies for those services, also apply. We wish to clarify the requirements of this regulation also apply to Medicare Advantage plans as home health services are a basic benefit under §422.100.

G. Tiered Cost Sharing of Medical Benefits

In the draft Call Letter we clarified the guidance provided in Chapter 4 of the Medicare Managed Care Manual (MMCM) regarding tiering of medical benefits. We are finalizing our clarification in this Call Letter and in revisions to Chapter 4 of the MMCM.

MAOs may charge different cost sharing amounts for physicians or groups of physicians in order to encourage members to seek care from providers the MAO identifies based on quality and efficiency criteria. Tiered cost sharing may apply to primary and/or specialty care physicians. The cost sharing must be applied so that all plan enrollees are charged the same cost sharing amount for any specific physician and all physicians are available and accessible to all enrollees in the plan.

We believe that allowing plans to establish different cost sharing tiers for physicians is consistent with the uniformity requirements at 42 CFR 422.100(d) when MAOs have established quality and efficiency standards for physicians and wish to create incentives for enrollees to seek care from physicians that meet or exceed such standards. In response to comments, CMS expects that tiered cost sharing of medical benefits may not be possible for all plans, due to limitations in their provider network. As a part of our enforcement of the uniformity requirement, MAOs must submit their tiering proposals for CMS review as described in our HPMS memo titled, "CY 2014 MA Bid Review and Operations Guidance," dated April 17, 2013 and in the upcoming guidance for CY 2015 to be issued as an HPMS memo in mid-April 2014.

H. Part C Services Via Remote Access Technologies

Technologies that enable health care providers to deliver care to patients in locations remote from providers (hereafter referred to as "remote access technologies") are increasingly being used to complement face-to-face patient-provider encounters. We believe that the use of remote access technologies as a care delivery option for MA enrollees may improve access to and timeliness of needed care, increase communication between providers and patients, and enhance care coordination.

Commenters were supportive of, and appreciated, CMS's recognition of the potential for such technologies to support coordinated health care but expressed concern about CMS's proposal to allow these technologies as mandatory supplemental benefits rather than basic benefits provided by the MA plan. In the draft Call Letter, we stated that Part C basic benefits are Medicare Parts A and B services and, except for the Medicare narrowly-defined telehealth benefit, services furnished via remote access technologies are not covered by Medicare. Thus, while MA plans are encouraged to develop and implement innovative services and benefit design, at this time, we are limited by the statutory definitions of services that are covered by Medicare.

CMS received several comments from MAOs that do not believe CMS is bound by the statutory definition of Part C "basic benefits" and urged CMS to allow incorporation of remote access technologies into MA plan basic benefits. CMS appreciates the input and has carefully considered the comments and legal analysis provided. CMS has concluded, however, as stated in the draft Call Letter, that we do not have the authority to define Part C basic benefits as being broader or different than the Parts A and B benefits provided under original Medicare. Presently, controlling law states that the basic benefit is defined based on original Medicare Part A and Part B coverage rules and we therefore do not have the authority to supersede original Medicare coverage requirements or otherwise enable MA plans to provide basic benefits that extend beyond those authorized under original Medicare, as suggested by commenters. *See* section 1852(a)(1) of the Act.

As part of prior rulemaking, CMS has made it clear that, if original Medicare covers a service only when certain conditions are met, as is the case with the currently-defined "telehealth" benefit (section 1834 (m) of the Act and 42 CFR§410.78), those conditions must be met in order for the service to be considered part of the Part C basic benefits. 65 FR 40170, 40207. If an MA plan provides services that extend beyond those conditions, those benefits may only be provided as supplemental benefits.

CMS intends to allow MAOs to use such technologies in CY 2015 as mandatory supplemental benefits and encourages MA plans to develop and implement innovative services and benefit designs. We currently define the following as remote access technologies as supplemental benefits: Telemonitoring, and Web- and Phone-based Technologies, Nurse Hotline,' and other

similar services. For CY 2015, we would also allow MA organizations to furnish medical services to enrolled beneficiaries via real-time interactive audio and video technologies as a mandatory supplemental benefit.

Services that are furnished via such means should not replace face-to-face (or "hands on") provider/patient interactions but rather supplement and complement traditional office visits, as appropriate. In addition, MAOs would be able to use remote access technologies as an option for enrolled beneficiaries who are willing and able to participate in this mode of service delivery. MA plans' networks must continue to meet our access standards; any remote access technologies would be in addition to, not a replacement of, an adequate provider network. Furthermore, MAOs must ensure that providers who furnish services through such technologies are practicing within their scope of license or certification as defined by their licensing or certifying state.

I. Exceptions to Policies Permitting Plans to Limit Durable Medical Equipment (DME) 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 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. Details regarding applicable items for CY 2015 are provided below; the items identified remain unchanged from CY 2014.

We have identified one category of DME that may not be subject to full limitation based on brand/manufacturer for CY 2015. 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 may not limit coverage to a specific brand or type of device; rather, they 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.

J. Reauthorization of Special Needs Plans (SNPs)

Section 107 of the "Protecting Access to Medicare Act of 2014" (H.R. 4302) reauthorizes MA SNPs through December 31, 2016.

K. Innovations in Health Plan Design

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models that will lower costs and improve quality for Medicare, Medicaid, and CHIP beneficiaries. In the draft Call letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries, including but not limited to value-based arrangements, beneficiary engagement and incentives, and/or care coordination. We appreciate input and will carefully consider the feedback provided as part of a formal Request for Information that CMS will be issuing in the coming months.

L. Minimum Enrollment Guidance

An organization must meet minimum enrollment requirements in order to hold a Medicare Advantage contract with CMS (see 42 CFR §422.514). The minimum enrollment requirement is an indicator that the organization applying for a Medicare Advantage contract is able to handle risk and capitated payments. CMS expects that an organization is able to effectively manage a health care delivery system including the enrollment and disenrollment of members and the timely payment of claims, provide quality assurances, and have systems to handle grievances and appeals.

CMS recognizes that new applicants may believe they are capable of administering and managing an MA contract although they do not meet the minimum enrollment requirements. Our regulations at 42 CFR §422.514(b) provide for a transition period allowing

CMS to waive the minimum enrollment requirements during an organization's first three years of operation.

For each waiver request, the applicant must provide, as an upload in HPMS, a statement that demonstrates to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. Please see 42 CFR §422.514(b) for factors that CMS may consider in evaluating any waiver request.

M. Part C Provider Contract Termination Guidance

CMS Guidance Related to MAO Network Changes

MAOs have considerable discretion to select the providers with whom to contract in order to build high-performing, cost effective provider networks and are able to make changes to these networks at any time during the contract year, as long as they continue to furnish all Medicare covered services in a non-discriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees. (These requirements are discussed in more detail in Chapter 4 of the Medicare Managed Care Manual.) Recent significant mid-year changes to MAOs' provider networks have prompted CMS to reexamine its current guidance on these requirements and to consider augmenting such guidance in response to such changes.

In the draft Call Letter, we proposed both a new procedural rule to facilitate CMS oversight of MAOs' compliance with access requirements and the adoption of certain best practices when MAOs consider significant changes to their provider network. We received a number of comments from the industry, professional associations, and beneficiary advocacy organizations on these proposals, which are discussed further below.

Defining "Significant" Network Changes

We solicited comments on how to define "significant" network change. We stated that MAOs may be in the best position to determine whether or not a planned provider termination(s) without cause is significant and that CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of the MAO's enrollees. There was no consensus among commenters regarding how to define a "significant" network change. Therefore, beginning in CY 2015, we will require MAOs to notify CMS when they are planning network changes that the MAO deems significant and CMS will determine, after consultation with the MAO, whether the planned change requires certain additional actions on the part of the MAO in order for the organization's network to continue to meet Medicare standards.

We intend to take appropriate compliance action against an MAO that fails to notify CMS of network changes that we ultimately deem significant. Therefore, we expect MAOs to take a conservative approach in determining whether a network change is significant and notify CMS if there is any doubt as to whether the planned contract termination(s) represent significant change to the network.

Notifying CMS of MAO-Initiated Significant Terminations without Cause

We proposed to institute a new procedural rule requiring MAOs to notify their respective CMS Regional Office Account Managers (AMs) no less than 90 days prior to the effective date of significant planned network termination(s). This prior notification would facilitate CMS oversight and verification of MAO compliance with provider network access requirements when a significant change is contemplated. As part of this process, the MAO would demonstrate its continued compliance with applicable network access requirements (e.g., through the submission of GeoNetwork reports, Quest reports, or Health Service Delivery (HSD) tables or other data sources that demonstrate the adequacy of the remaining provider network.

The MAO would also develop and submit to CMS, upon request, a written plan that provides a detailed description of the steps the MAO will take to ensure that affected enrollees are able to locate new providers that meet their individual needs and describe how continuity of care would be maintained for affected enrollees. Furthermore, we stated our expectation that MAOs provide, upon request, information about the number and dispensation of continuity of care requests that they receive so that CMS may confirm that the MAO is in compliance with all applicable requirements.

Beneficiary advocates and some professional associations were highly supportive of the proposed procedural rule and encouraged CMS to further limit MAOs' flexibility to make no-cause network changes and to provide Special Enrollment Periods (SEPs) to all enrollees who are affected by significant contract terminations. However, industry commenters expressed strong objections to the proposals that they notify CMS at least 90 days prior to a planned significant network change for no cause, additional reporting on how the MAO will continue to meet network adequacy standards, providing detailed reports about plans for ensuring enrollees' access to appropriate providers, and reporting on the number and dispensation of continuity of care requests. Those commenters' opposition was largely based on their beliefs that CMS already has broad authority to enforce network adequacy and enrollee access to care and there is no need for expanded requirements to ensure MAO compliance. In addition, they expressed concern that CMS' proposed adoption of new and expansive requirements, based on a recent incident, would inappropriately interfere with MAOs' business relationship with their providers.

While we are sensitive to concerns raised about the ability of organizations to know about significant changes more than 90 days in advance, we would note that our existing requirements

(at 42 CFR 422.202(d)(4)) require that organizations notify affected providers at least 60 days in advance of the effective date of the termination. Thus, organizations that are planning significant network changes should have knowledge of those planned changes at least 90 days in advance so that they could take the necessary actions to review their networks to ensure that they remain adequate; prepare notices to affected providers; identify affected enrollees; and prepare the appropriate enrollee notices, call center scripting, and other necessary materials. Similarly, we would expect that, in order to ensure they are continuing to meet CMS' network adequacy requirements (as currently required at 42 CFR 422.112(a)(1)), organizations planning significant network changes would use any of a number of software products, including those mentioned above, to verify that their network continues to remain adequate. Presumably, these organizations would have developed a plan and proposed timeline for making significant changes. Finally, we would also expect an organization contemplating network changes to have considered how to ensure continuity of care for affected enrollees. Thus, our proposed procedural rule should not interfere with organizations' ability to make significant changes to their network, nor would it impose a significant administrative burden on organizations that are already adhering to CMS' requirements. Rather, the rule would reasonably require that these organizations notify CMS at the time that they are already planning such changes and share with CMS the same information they should have collected and analyzed. Therefore, beginning in CY 2015, we will require MAOs to notify CMS at least 90 days prior to network changes for any no cause termination that they deem significant. Organizations planning such changes would be expected to first contact their RO AM and discuss the timeline for submitting the necessary information to CMS, including the information described in this Call Letter.

Furthermore, in response to comments from beneficiary advocates and some professional associations, CMS will, pursuant to 42 C.F.R. § 422.62(b)(4), find that an enrollee meets exceptional conditions sufficient to justify a special enrollment period (SEP) when the enrollee is affected by substantial mid-year provider network terminations initiated by an MAO without cause. CMS will determine whether the terminations are substantial and require the granting of an SEP. CMS will use a variety of criteria for determining whether or not the network terminations are substantial, such as: (1) the number of enrollees affected; (2) the size of the service area affected; (3) the timing of the termination; (4) whether adequate and timely notice is provided to enrollees, (5) and any other information that may be relevant to the particular circumstance(s). In addition, the enrollee must demonstrate that the enrollee has been affected by this change. SEPs will not be granted when MAOs make changes to their network that are effective on January 1 of the following contract year, as long as affected enrollees are notified of the changes prior to the start of the AEP. This new SEP policy will be effective for CY 2015.

Notification to Enrollees Affected by Provider Contract Terminations

We believe that, as a "best practice," MAOs that are making significant network changes for no cause should provide enrollees more than the required 30 days advance notice. Our experience

has shown that a longer notification period is important, not only to address enrollee concerns, furnish enrollees with needed assistance in selecting new providers and manage the continuity of care for those undergoing medical treatment, but also for maintaining enrollee satisfaction. Furthermore, we believe that a longer notification period would afford enrollees additional time to transition to the new provider(s).

In the draft Call Letter, we noted that we are considering whether to use the notice and comment rulemaking process to require more than 30 days advance notice to enrollees, and solicited comments on the appropriate advance notice for enrollees affected by provider contract terminations. We received a number of comments in support of requiring more than 30 days advance notice to enrollees, and one commenter suggested that we require multiple notices to enrollees, the first 60 days in advance, and then 30 days in advance of the effective date of the change.

We will take these suggestions into consideration in our ongoing work to ensure that organizations' networks are adequate and beneficiary access to all needed care is protected.

We also stated that, as a best practice, MAOs should include the following information in notices to enrollees in addition to the mandatory identification of the provider(s) being terminated from the network:

- Names and phone numbers of in-network providers that enrollees may access for continued care;
- Information regarding how enrollees can request continuation of ongoing medical treatment or therapies with their current providers; and
- Customer service number(s) where answers to questions about the network changes will be available.

MAOs should develop detailed scripts, call center talking points and frequently asked questions so they can effectively respond to phone inquiries from enrollee and other stakeholders.

We also solicited comments about our consideration of whether to use the rulemaking process to broaden our authority to limit MAOs' ability to terminate provider contracts without cause at any time during the year. CMS has been asked by some stakeholders to prohibit MAOs from terminating provider contracts during the AEP or to require that notice of such terminations be provided prior to the start of the AEP so that enrollees have additional time to review their plans' network and consider other available plan options.

Limiting MAOs' ability to make network changes during the AEP and/or requiring enrollee notification prior to the AEP would be a viable way to provide enrollees with some level of certainty regarding the provider network for a contract year. We believe that the only way we could provide a higher level of stability in an organization's network throughout the calendar

year would be to prohibit MAO-initiated, not-for-cause network changes after a certain date in each calendar year. However, we believe that prohibiting no-cause network changes for part of the contract year would interfere unduly with organizations' ability to establish cost-effective, high-performing networks under such limitations, and thus, would have negative consequences for all MA enrollees.

We also are strengthening our current requirements regarding plans' responsibilities to notify enrollees of network changes in their Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) materials, which are provided to all enrollees each Fall. These modifications will require MA plans to explicitly notify enrollees of their rights should a plan make changes to their provider network during the year. The required language is included below:

It is important that you know that we may make changes to the hospitals, doctors and specialists (providers) that are part of your plan during the year. There are a number of reasons why your provider might leave your plan but if your doctor or specialist does leave your plan you have certain rights and protections summarized below:

- Even though our network of providers may change during the year, Medicare requires that we furnish you with uninterrupted access to qualified doctors and specialists.
- When possible we will provide you with at least 30 days' notice that your provider is leaving our plan so that you have time to select a new provider.
- We will assist you in selecting a new qualified provider to continue managing your health care needs.
- If you are undergoing medical treatment, you have the right to request, and we will work with you to ensure, that the medically necessary treatment you are receiving is not interrupted.
- If you believe we have not furnished you with a qualified provider to replace your previous provider or that your care is not being appropriately managed you have the right to file an appeal of our decision.
- If you find out your doctor or specialist is leaving your plan please contact us so we can assist you in finding a new provider and managing your care.

Commenters did not object to the ANOC/EOC revisions and were supportive of the best practices related to the call centers. However, some industry commenters stated that it is not feasible, especially in large service areas, to include the information suggested by CMS about available in-network providers in notices to enrollees. Nonetheless, we would encourage MAOs to include that information where feasible, especially in those cases in which the enrollee is losing access to his/her primary care provider. Including information about available in-network providers would facilitate the enrollee's selection of a new primary care provider, helping to ensure continuity of care.

We encourage MAOs to adopt the best practices described above starting in CY 2015.

Contracted Provider Notification and Right of Appeal

In the draft Call Letter, CMS solicited comments about proposing that MAOs provide more than 60 days prior notice to providers whose contracts the MAO is terminating without cause. CMS believes that a longer period would give providers sufficient time to exercise their appeal rights and for the appeals process to conclude, perhaps before affected enrollees are notified of the change. Under the current timeframes, there are instances in which the notice of a termination reaches the affected enrollees while the provider is appealing the termination. If the termination is later overturned and the provider is reinstated, the enrollee may be unaware of that reinstatement and may, at that point, have already chosen a new provider. We believe that our proposal would promote a more structured, efficient process that will minimize confusion and disruption for MAO operations, enrollee care, providers and CMS.

Beneficiary advocacy groups generally supported our proposal to require more than 60 days' advance notice to providers. Commenters from the industry, however, were strongly opposed to a longer required notice period for providers and noted that any change to the 60-day period would have to be effectuated through notice and comment rulemaking. They also expressed concerns regarding the effect that longer notification periods may have on their negotiations with providers. We will take these comments into account should we decide to make changes to the existing notice requirements in the future. For CY 2015, we continue to encourage MAOs to provide more than 60 days prior notice to providers whose contracts are being terminated without cause to allow for a complete appeals process prior to beneficiaries being notified.

Part C ANOC/EOC Review Timeframe

CMS would like to notify MAOs and Plan sponsors that they must complete retrospective reviews of ANOC and/or EOCs and submit errata sheets correcting identified errors by November 1, 2014 for those documents due in member hands by September 30, 2014. This date will provide sufficient time to ensure members still have enough opportunity to review their choices during the Annual Enrollment Period (AEP) after receiving the corrected materials. Review and submission of errata sheets for documents due in member hands at a later date (e.g. D-SNP EOCs) should be completed within 30 days of mailing.

Part C Third-Party Marketing of Non-Health-Related Benefits

CMS has become aware of numerous instances in which health clinics are advertising non-health-related services to Medicare beneficiaries. Some of the services are being advertised by clinics that are contracted providers of MAOs. Such services cannot be paid for with Medicare dollars. Non-health related items may not be part of an MAO's bid.

In addition, MAOs may not advertise non-health related items or services as plan benefits, and are responsible for ensuring that their downstream entities also adhere to this prohibition. Advertisements for non-health related items or services by an MAO, or one of its contracted clinics, to MAO enrollees could be construed as, among other things, inappropriate steerage to particular clinics and, ultimately, into a specific MAO that contracts with that clinic. CMS regulations at 42 CFR §422.2268 specifically prohibit engaging in activities which could mislead or confuse Medicare beneficiaries and marketing non-health care related products to prospective MA enrollees. Further guidance will be included in the Medicare Marketing Guidelines.

Ongoing, Off-cycle Submission of Summaries of MOC Changes

CMS has emphasized the importance of the Model of Care (MOC) as a fundamental component of the SNP quality improvement framework. CMS continues to encourage SNPs to develop and submit comprehensive and thoughtful MOCs for initial NCQA approval. However, we also recognize that, in order to continue providing high quality improvement, the SNP may need to revise its approved MOC to address the particular needs of its beneficiaries. CMS intends to implement a process for SNPs that revise their MOC during an approval cycle to submit a summary of those changes to CMS.

The summary will focus on pertinent revisions to the approved MOC. CMS is contemplating the creation of a new component in the HPMS MA Quality Module where SNPs can submit, as applicable, these summaries at any time during an approved MOC cycle. We envision that NCQA will review the summaries to determine that the revisions are consistent with acceptable high-quality standards as indicated in the original MOC and the associated score/approval period. There will be no rescoring of the MOC based on the revisions; therefore, the existing approval period (i.e. 1-year or multi-year) would not change as a result of NCQA's review of the summary.

This process will ensure that CMS and NCQA are apprised of up-to-date information regarding a SNP's MOC and strengthens CMS's ability to fulfill its obligation to adequately monitor the MOC and ensure that it continues to meet established standards. CMS will provide additional information once available.

Part C Change of Ownership Transactions Requiring Service Area Expansions

CMS requires that MAOs that are planning to undergo a change of ownership transaction notify CMS at least 60 days prior to the date of the planned change of ownership. In instances where such a transaction would require a CMS approved novation of the MAO's contracts, CMS will find under §422.552 that the novation is in the best interest of the Medicare program if the entity acquiring the novated contracts is an existing MA organization that has offered a MA plan that, at a minimum, has the same service area as the contracts that are being novated. Normally, organizations seeking a service area expansion (SAE) are required to submit a service area

expansion application during CMS's yearly MA application cycle. Although, in special circumstances, CMS has allowed MAOs to file an "off-cycle" SAE application (i.e., at other times during the year, instead of during our annual application cycle) in order to align their organization's service area with the service area of a contract that they wish to acquire through a novation, we continue to encourage MAOs that require an SAE in order to match the service area of contracts they are receiving to request such an expansion during our annual SAE application cycle. CMS is reminding organizations that it is not inclined to approve off-cycle SAE requests unless special circumstances warrant such approval.

Section 1876 Cost Contract Provisions

Part C 1876 Cost Plan Contract Application

We want to remind organizations that CMS will not accept any new cost plan applications. CMS will continue to accept applications to modify cost plan contracts in order to expand service areas in accordance with 42 CFR §417.402. In addition, for CY 2016, CMS will apply the Cost Plan Competition Requirements in the review and evaluation of any applications to expand a Cost Plan's existing service area. CMS will deny any cost contractor's application for a service area expansion to the extent that the application is for a service area 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.

Cost Contract Plan Competition

In accordance with the Protecting Access to Medicare Act of 2014, beginning Contract Year (CY) 2016, 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 impacted service areas in 2017.

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 2015 enrollment data to determine the cost plans subject to non-renewal and contact affected plans at the end of 2015 to permit cost contractors wishing to convert to Medicare Advantage plans for CY 2017 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 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 as noted above. Cost plans that offer Part D as Cost-PD plans are also subject to the same restriction on mid-year service area expansions as MA-PD plans in that they cannot expand into an area served by an MA-PD or PDP plan.

Section III – Part D

Additional Guidance for All Enhanced Alternative (EA) Plans

CMS will not be finalizing the proposed CY2015 policy in which we would indicate our expectation that all EA plans provide additional cost-sharing reductions in the coverage gap for all formulary generic and brand drugs. A number of comments objected to the additional gap cost-sharing reduction proposal and emphasized the potential for disruption to beneficiaries with respect to their existing plans. Reasons for disruption included the need to non-renew or terminate plans because of increased bid costs or the inability to meet meaningful difference requirements should sponsors' EA plans be expected to cover all formulary drugs in the gap. We are equally concerned about minimizing beneficiary disruption, especially the loss of a beneficiary's existing plan, and thus we will not proceed with the proposed gap cost-sharing policy.

In addition, as part of our effort to minimize beneficiary disruption for 2015 we no longer intend to approve a change from a basic PDP benefit to an enhanced PDP benefit. Historically few PDP sponsors have demonstrated an interest in making this benefit design conversion and as noted in the draft Call Letter, PDPs interested in this option have had difficulty demonstrating that they can meet the cost-sharing OOPC meaningful difference test or that the benefit design change would comply with our conditions for approval. In our experience, sponsors requesting an exception to convert a basic plan benefit to an enhanced plan benefit in previous years have been unable to provide an enhanced plan with the same or lower premiums than the basic plan, or demonstrate that the proposed enhanced plan benefits, including formulary and copays, would provide equal or better benefits to their members. Therefore, beginning in 2015, CMS does not intend to approve a bid that includes a benefit design change from a basic (defined standard, actuarially equivalent or basic alternative) PDP benefit to an enhanced alternative PDP benefit.

Furthermore, CMS advises sponsors that we do not intend to approve bids under which a PDP sponsor would propose to non-renew its current basic plan in a PDP region, thus disenrolling all the plan's current members at the end of the year, and offer a brand new basic plan during the upcoming benefit year. As numerous commenters advised CMS in response to our recent regulatory proposal to limit the number of PDP sponsors' plan offerings, the Part D bid review

and approval process should minimize the disruption that beneficiaries might experience as the result of plan changes from year-to-year. To that end, we believe that it is against the best interests of beneficiaries and the Part D program to approve bids that create a scenario that would impose a burden on beneficiaries who would be forced out of their current plan and required to make a timely plan election for the new year to ensure continued prescription drug coverage while their plan sponsor was permitted to continue to offer stand-alone plans in those beneficiaries' service area.

Also as discussed in the draft Call Letter, beginning CY 2015 gap coverage descriptions (few, some, many, all brand/generic drugs) will no longer be displayed in marketing materials or on Plan Finder. These gap coverage descriptions were developed prior to the incremental closure of the coverage gap in order to describe the proportion of formulary drugs covered in the gap through an EA plan's supplemental benefit. These labels are no longer particularly relevant because cost-sharing reductions are required under the ACA for applicable beneficiaries for all formulary drugs.

Access to Preferred Cost Sharing

The number of Part D and MA-PD plans offering preferred cost sharing for prescription drugs has increased significantly in the past few years, from just 163 in 2011 to 853 in 2014. In 2014, over 70% of standalone Part D plans offer preferred cost sharing. Under these arrangements, to access the preferred (lower) cost sharing, beneficiaries must obtain their prescriptions from a selected subset of pharmacies in the plan's network. As the number of plans offering preferred cost sharing has increased, various parties have drawn our attention toward concerns with these arrangements, particularly regarding beneficiaries' access to the advertised lower cost sharing in these plans. Some plans provide very limited access to preferred cost sharing; for instance, we became aware of one plan that offered preferred cost sharing at only seven pharmacies in a PDP region. We have also heard concerns about access to preferred cost sharing from beneficiaries, particularly in rural areas, and a number of pharmacy trade groups have complained that retail pharmacies have not been given the opportunity to accept the terms necessary to offer preferred cost sharing. We are concerned that offers of preferred cost sharing may be influencing beneficiaries to enroll in plans in which they do not have meaningful and/or convenient access to preferred cost sharing. This may have the effect of misleading or otherwise making material misrepresentations to beneficiaries in violation of our marketing requirements at 42 CFR §423.2264(d).

Although we have announced that we do not plan to finalize certain proposals related to preferred cost sharing included in our proposed rule published in the Federal Register on January 10, 2014, we continue to be concerned about beneficiary access to and understanding of preferred cost sharing arrangements. In order to further analyze this issue, we have awarded a contract to study beneficiary access to preferred cost sharing. This study will analyze

beneficiaries' geographic access (i.e., time and distance) to pharmacies offering preferred cost sharing in plans' networks. Based on the results of this study and comments received to date on the draft Call Letter and the proposed rule, we will evaluate whether we should set standards for network adequacy for pharmacies offering preferred cost sharing, similar to current standards for retail network adequacy.

Although we are not adopting any network adequacy standards at this time, sponsors should be aware that we are continuing to monitor beneficiary access to preferred cost sharing in plans that purport to offer it. For the 2014 and 2015 plan years, we will continue to review the retail networks of plans offering preferred cost sharing and will continue to take appropriate action regarding any plan whose network of pharmacies offering preferred cost sharing appears to offer too little meaningful access to the preferred cost sharing. For instance, a stand-alone PDP that offers preferred cost sharing at only seven pharmacies in a PDP region may be asked to increase the number of pharmacies offering preferred cost sharing or to restructure its benefit design during the bid negotiation process. The intent of these negotiations will be to ensure that beneficiaries are not misled into enrolling in a plan only to discover that they do not have meaningful access to the advertised lower cost sharing.

Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status

Consistent with 42 CFR §423.153(b), Part D sponsors must establish utilization management controls, such as prior authorizations (PA), in order to reduce costs when medically appropriate and to prevent over- and under-utilization of prescribed medications. We currently allow plans to implement Point-of-Sale (POS) PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication (as defined in section 1860D-2(e)(4) of the Act) or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1860D-2(e)(2) of the Act (e.g., symptomatic cold treatment). While POS PA edits must be reviewed and approved by CMS, we have previously left the determination of which drugs should be subjected to these POS edits to the individual plans.

Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual (available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf) discusses medically-accepted indications. Sponsors are reminded that they are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications. Although they are not required to, Part D sponsors may rely on utilization management policies, including PAs, to make such determinations.

With almost 8 years of experience with the Part D program, CMS and Part D sponsors have (or should have) a good understanding of which drugs have the highest likelihood of non-Part D

covered uses. Therefore, we believe that all Part D sponsors should consistently utilize PAs for such drugs, including drugs that are not likely to be covered under Part D in the sponsor's experience or as directed by CMS. While most plans appear to effectively utilize these edits to prevent Part D coverage of non-Part D drugs, other plans have failed to implement edits for such drugs or to take other measures such as retrospective review to ensure Part D coverage before submission of related PDEs. Consequently, we have seen instances where the lack of a POS PA edit or other check has resulted in inappropriate Part D coverage of non-Part D drugs.

For example, the labeled indications and compendia citations for Transmucosal Immediate Release Fentanyl (TIRF) drugs only support their use for the management of breakthrough pain in patients with cancer, who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent pain. Additionally, the risks associated with TIRF medications are so severe that the FDA required a Risk Evaluation and Mitigation Strategy (REMS) program designed to ensure informed risk-benefit decisions before initiating treatment with these drugs and during treatment to ensure appropriate use of TIRF medicines. The purpose of the TIRF REMS access program is to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications, including death, due to medication errors with the use of TIRF medicines. As a result, we were surprised to find in an internal analysis that although most Part D plans have implemented POS PA edits for TIRF medicines, not all have done so.

Similarly, Cialis (tadalafil) has an FDA-approved indication at 5mg per day (2.5 mg per day for patients with renal insufficiency) for benign prostatic hypertrophy (BPH), which would constitute an approved Part D use. However, these same daily doses are also approved to treat erectile dysfunction (ED), which is not an approved Part D use, pursuant to section 1860D-2(e)(2)(A) of the Act. Again, we find most, but not all, Part D plans have instituted PA to ensure appropriate Part D use.

As a result, we are establishing in this final Call Letter criteria for which CMS would expect plan sponsors to implement POS edits for PA on qualifying drugs and/or drug classes that pose the greatest risk for non-Part D covered uses according to the following criteria:

- High likelihood that coverage is available under Parts A or B (versus D) for the drug as prescribed and dispensed or administered,
- High likelihood that the drug is excluded from Part D coverage (e.g., a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act), or
- High likelihood of use for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act.

We received some comments from Part D sponsors requesting more specificity regarding the drugs or drug classes that should be subject to prior authorization. However, as we indicated in

the draft Call Letter, we intend to conduct outlier checks during our annual formulary review process and will share information with sponsors, so that sponsors may determine if they wish to submit a PA for approval or continue ensuring Part D coverage through other means, such as retrospective review. There has also been confusion from plan sponsors about how such edits are appropriately used during transition periods. Section 30.4.8 of Chapter 6 of the Prescription Drug Benefit Manual (available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf) discusses edits for transition fills.

The requirements to verify payment for Part D uses, maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and establish quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use apply regardless of the transitional status of an enrollee's medication(s). In other words, such POS PA edits are appropriate, even during transition.

In particular, some sponsors have interpreted the section 30.4.8 language, "Drug utilization management edits that are appropriate during a beneficiary's transition period include … edits to prevent coverage of non-Part D drugs (i.e., excluded drugs)" to mean that excluded drugs[8] is the only condition for which they should implement POS PA during transition pursuant to this criterion. This is incorrect. Drug utilization management edits to prevent coverage of non-Part D drugs include those which prevent coverage of a formulary drug that is being dispensed for an indication that is not medically accepted. Because our clarified guidance of this criterion is focused on those drugs that pose the greatest risk for non-Part D-covered indications, CMS would not expect to see excessive use of POS PA edits during transition for drugs as a result of this clarified guidance.

With respect to EGWPs and this section of the Call Letter, we recognize that EGWPs may not want to implement prior authorization edits to determine whether a drug is a Part D covered drug, if they cover non-Part D covered drugs under supplemental non-Medicare benefits. However, in this situation, we remind sponsors that they are responsible for determining whether a drug is a Part D covered drug before submitting a PDE to CMS. In addition, we note that brand drugs that are not Part D covered drugs are not eligible for the 50% manufacturer discount, and EGWPs must have a mechanism to ensure the discount is not applied once the determination has been made that a brand drug is not a covered Part D drug.

[8] A drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act.

Enhancements and Clarifications on Improving Utilization Review Controls

In this section we describe the results of sponsors' implementation of improved drug utilization controls and case management to prevent overutilization of medications in Part D in 2013,the findings of the Overutilization Monitoring System (OMS), and our additional expectations for further reductions of overutilization based on enhancements and clarifications of the policy. We appreciate the comments and suggestions submitted by sponsors, PBMs, and other organizations about the proposals to strengthen the overutilization policy in order to reduce the unsafe overutilization of medications by Part D beneficiaries.

Background

In the section entitled, "Improving Drug Utilization Review Controls in Part D" of the Final CY 2013 Call Letter issued on April 2, 2012 and in supplemental guidance issued on September 6, 2012, CMS described 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 opioids. In addition, sponsors were reminded to prevent the dispensing of acetaminophen (APAP) above the U.S. Food and Drug Administration (FDA) daily maximum dose of 4 grams to any beneficiary. In general, the guidance addressed the following expectations for sponsors to address overutilization of opioids effective January 1, 2013:

• Appropriate controls at point of sale (POS), including safety edits and quantity limits.
• Improved retrospective drug utilization review (DUR) to identify at-risk beneficiaries.
• Case management with the beneficiaries' prescribers.
• Data-sharing between Part D sponsors regarding beneficiary overutilization.

Under the guidance, sponsors may implement beneficiary-specific POS edits as appropriate after case management to control access to medications containing opioids. Sponsors are expected to send 30-day advance written notice of the planned POS edit to the beneficiary, the beneficiary's prescribers who request the results of case management, and to the CMS account manager and the central office mailbox PartDPolicy@cms.hhs.gov in a secure manner. The written email notices to CMS containing personally identifiable information (PII) must be encrypted and password protected to be considered secure.

That guidance also stated that CMS would develop monitoring protocols to ensure sponsors were implementing effective but appropriate controls to prevent opioid overutilization. Subsequently, on July 31, 2013, CMS implemented the Overutilization Monitoring System (OMS) to operationalize our monitoring protocols and ensure that sponsors have established reasonable and appropriate drug utilization management programs to prevent the overutilization of prescribed medications as described above (see HPMS memo, Medicare Part D Overutilization Monitoring System, released on July 5, 2013). Additional information about the OMS and the CMS overutilization policy are available on the CMS website at:

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.

Acetaminophen (APAP)

The use of more than 4 grams of APAP daily is contraindicated by the FDA due to the significant potential for severe liver injury and death. We remind sponsors that they are expected to implement sufficient controls to prevent the cumulative dispensing to any beneficiary of more than 4 grams of APAP per day across all products containing APAP. Analysis of 2011 Part D prescription drug event (PDE) data indicated that nearly 650,000 beneficiaries may have exceeded the maximum APAP dose for at least 5 consecutive days, 221,000 beneficiaries received more than 4 grams per day for at least 10 consecutive days, and 150,760 received more than 4 grams per day for at least 30 total days. From January through December 2013, the OMS identified 56,414 potential APAP overutilization tickets (a "ticket" is a combination of contract ID and HICN), representing 54,569 unique beneficiaries (0.14% of Part D enrollees) who received more than 4 grams of APAP per day for at least 30 days within a six-month period.

Although the use of improved DUR edits in 2013 may have reduced overutilization of APAP, CMS expects Part D sponsors to implement soft[9] formulary-level safety edits at POS at a minimum to further reduce cumulative APAP overutilization among their enrollees. Sponsors may implement hard formulary-level safety edits; however, most commenters were opposed to CMS expecting the use of hard formulary-level safety edits at this time due to the difficulty of programmatically preventing false positives (e.g., early refills, take as-needed dosing, and medication changes due to allergy or intolerance) through the POS claims processing system and the resulting delays in beneficiary access to needed medications. Therefore, sponsors' P&T committees should develop the specifications for formulary-level POS edits to prevent cumulative APAP overutilization based upon their own enrollee data, while minimizing false positives by accounting for known exceptions, such as reasonable early refills. A soft POS edit may still result in a rejected claim, but the pharmacist may exercise professional judgment to override the rejection if clinically appropriate. If the pharmacist does not override the reject, the beneficiary may request a coverage determination. We note that P&T committees may consider a mix of a formulary-level soft edits designed compel the pharmacist's clinical evaluation of APAP usage, and hard edits to prevent APAP doses at and above amounts for which there would be no reasonable medical or dispensing explanation. In addition, as sponsors become more effective at reducing overutilization of APAP among their enrollees, their P&T committees

[9] More information about soft and hard rejects and edits is available from the National Council for Prescription Drug Programs: "Telecommunication Version D and Above Questions, Answers and Editorial Updates," *NCPDP*, February 2014, http://www.ncpdp.org/NCPDP/media/pdf/VersionD-Editorial.pdf (accessed 3/20/2014).

should periodically re-evaluate the type of formulary-level APAP POS edits that are in place and the APAP amounts at which they are triggered.

While we are concerned about the risk of APAP overdose in beneficiaries, we recognize that there are circumstances that justify dispensing a prescription that would otherwise appear to be inappropriate based solely on claims data. However, we remind sponsors that a pattern of overutilization related to repetitive early refills or other reasons may be an indication of actual overutilization, stockpiling, or diversion, which should prompt additional investigation by the sponsor and verification of the ongoing medical necessity with the prescribers. For example, a beneficiary who receives an original prescription plus five refills of a 30-day supply of medication and refills the prescription each time after 75% of the days' supply has expired from the date of dispensing will actually receive 180 days' supply within 111 days. In this example, if each fill is for 100 tablets, the cumulative excess supply is potentially 133 tablets.

While sponsors may determine how to define the allowance for early refills, sponsors should identify, address, and resolve potential overutilization issues, including developing criteria for evaluating if a beneficiary's pattern of early refills warrants additional review. In addition, in the event that formulary-level safety edits at POS for all enrollees fail to address all cases of potential APAP overutilization, we remind sponsors that they may apply case management principles and implement a beneficiary-specific hard POS edit to address overutilization of APAP, as they may for any other medication. However, formulary-level safety edits based on FDA dosage limits may be implemented by sponsors without advance written notice to the beneficiary or submission to CMS.

CMS expects the use of additional POS edits will reduce the overutilization of APAP. Through the OMS we will continue to monitor sponsors' efforts to prevent overutilization of APAP and opioids based on criteria described in the Overutilization Monitoring System User Guide, which is available to all plan sponsors through the Patient Safety Analysis Website. If the soft formulary-level POS edits do not significantly reduce overutilization of APAP, CMS will re-consider the use of hard edits for contract year 2016.

Finally, we remind Part D sponsors of FDA's additional APAP safety initiatives (http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm165107.htm). The FDA asked manufacturers of approved prescription drug products containing more than 325 mg of APAP to request the withdrawal of approval of the product's application by January 14, 2014. According to their Federal Register Notice (http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0021-0001), FDA intends to utilize their authority to initiate withdrawal proceedings for the combination products that contain greater than 325 mg of APAP that remain on the market after January 14, 2014. The FDA also has recommended that health care professionals discontinue prescribing and dispensing combination drug products containing more than 325 mg of APAP. As a result of these safety initiatives, CMS will be removing all

combination prescription drug products that contain more than 325 mg of APAP from the CY 2015 Formulary Reference File.

Opioids

In the supplemental guidance issued in September 2012 (HPMS memo, September 7, 2012, Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html), CMS described a drug utilization review methodology based on morphine equivalent dose (MED) to identify beneficiaries who are at high risk for an adverse drug event due to their use of opioids and for whom focused case management may be appropriate. Analysis of 2011 Part D PDE with this methodology identified 22,222 Part D beneficiaries (0.07% of Part D enrollees) at high risk for an opioid-related adverse drug event. CMS also indicated that each sponsor's targeting criteria should be set by its P&T committee to identify patterns of apparent duplicative therapy over sustained periods of time from multiple prescribers and at high daily doses using MED methodology.

CMS' current opioid overutilization methodology identifies beneficiaries whose daily MED is greater than 120 mg for at least 90 consecutive days, and who used more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims. In January 2014, the OMS identified 27,275 potential opioid overutilization tickets for beneficiaries who exceeded the opioid threshold between January 1, 2013 and December 31, 2013. While direct comparison of these data to the 2011 findings does not show a significant positive trend, the 2013 methodology would be expected to identify a larger number of potential opioid overutilizers than the initial 2011 methodology, primarily due to the significantly expanded list of opioids and the count of beneficiaries' prescribers and pharmacies for their opioid fills through the entire year in the 2013 methodology. When applying the 2013 opioid methodology and comparable PDE cut-off dates to 2011 data, the OMS identified 29,358 beneficiaries (0.093% of enrollees) in 2011 who exceeded the current threshold for opioid overutilization, as compared to 25,246 (0.065%) in 2013. CMS appreciates the efforts of sponsors to reduce the overuse of opioids in Part D, but we believe more can be done.

CMS is concerned by responses received from some sponsors in OMS that a beneficiary's opioid use does not meet the sponsor's internal criteria for review, when that beneficiary's opioid utilization is clearly in excess of the methodology CMS described. For the January 2014 OMS reports, 67% of the potential opioid overutilization responses were BSC - No further review planned; Beneficiary did not meet the sponsor's internal criteria. It appears that some sponsors' criteria or processes to identify and address potential opioid overutilization may be insufficient.

Recent studies referenced in educational materials from the Centers for Disease Control and Prevention indicate that morphine equivalent doses as low as 100mg per day are associated with

a significant increased risk for opioid overdose and death (see http://www.cdc.gov/primarycare/materials/opoidabuse/ and http://www.cdc.gov/primarycare/materials/opoidabuse/docs/managingpain-508.pdf). Further, a recent study in Tennessee indicated that there is an increased risk of opioid-related overdose death associated with the use of 4 or more prescribers, 4 or more pharmacies, and a mean daily dosage greater than 100mg morphine equivalents.[10] Although some commenters opposed a reduction in the MED value for targeting purposes, in light of the potential safety issues for beneficiaries, Part D sponsors should lower their internal opioid criteria for retrospective identification of opioid overutilization and subsequent case management to be no less restrictive than 120mg MED daily dose over at least 90 consecutive days as used by CMS. Sponsors may use lower MED (e.g., 100mg MED suggested by CDC) and/or consecutive day thresholds to be more inclusive, and may vary other criteria including the number of prescribers and pharmacies. CMS will consider adopting 100mg MED in our threshold as early as contract year 2016. One commenter suggested that CMS collaborate with organizations such as the Pharmacy Quality Alliance to develop measure specifications which include criteria such as the 100mg MED threshold; CMS appreciates this comment and will consider new measures when developed and endorsed.

Revisions to Outlier Methodology and Policy

In January 2014, the OMS was enhanced to collect potential opioid overutilization issues that were identified through Part D sponsors' own internal criteria and reviewed, but not previously identified by CMS. No later than January 1, 2015, sponsors should begin submitting their internally-identified potential overutilization issues to the OMS quarterly along with the response code indicating the status of each beneficiary case. The overutilization issues submitted with response codes that are known exceptions may be excluded from future OMS reports.

Improved Drug Utilization Controls for Other Drug Classes

Sponsors are reminded that if they choose to implement improved drug utilization controls and case management for medications that do not contain opioids, the sponsor should apply the same level of diligence and internal documentation with respect to those medications that we expect for medications containing opioids. At this time, our guidance applies only to opioids, and thus it should not be characterized as applying to overutilization of other medications.

Medication Therapy Management

In this section, we describe steps we are taking to ensure that Medication Therapy Management (MTM) programs are in compliance with the regulations and related guidance, increase standardization among these programs, and encourage the use of MTM services to reduce the

[10] JAMA Intern Med. doi:10.1001/jamainternmed.2013.12711. Published online March 3, 2014.

overutilization of opioids. We thank the 45 sponsors, organizations, patient advocates, and PBMs who commented on MTM.

MTM Program Requirements

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. Pursuant to § 423.153(d)(2)(B), 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 2014 MTM program annual cost threshold was $3,017.

Part D sponsors are required to provide an individualized, written summary in CMS' standardized format to beneficiaries after a Comprehensive Medication Review (CMR) as part of the MTM program. Pursuant to the Paperwork Reduction Act (PRA), we proposed minor changes for 2015 to the text of the standardized format based upon feedback from beneficiaries and stakeholders about their experience with the standardized format since implementation (https://federalregister.gov/a/2014-00916). Sponsors have the opportunity to submit comments through the PRA process, and final changes will be effective January 1, 2015.

MTM Monitoring

Last year, CMS sponsored an MTM monitoring effort to assess Part D sponsors' ability to implement their CMS-approved MTM programs in accordance with §423.153(d) and related CMS guidance. Beneficiary-level and parent organization (PO)-level data for contract years (CY) 2011 and 2013 were reviewed for a total of 25 sponsors across four domains: Enrollment and Targeting, CMR, Targeted Medication Reviews (TMR), and Additional MTM Services. It should be noted that the CY 2013 data reviewed precedes any data validation efforts as part of the Part D Reporting Requirements.

The main findings from this study were:

- MTM Enrollment and Targeting: In CY 2011 and CY 2013, the majority of sponsors we monitored were able to provide a valid MTM opt-out reason and MTM opt-out documentation that supported beneficiaries' MTM opt-out reasons and dates.
- CMR Offers: In CY 2011 all eligible beneficiaries in the sample were offered a CMR; in CY 2013, 91 percent of all eligible beneficiaries sampled were offered a CMR. However, in CY 2013, 26 percent of all CMR offers were untimely.
- CMR Written Summaries: Three out of 21 sponsors in CY 2011 and six out of 25 sponsors in CY 2013 did not provide a written summary to all beneficiaries who received a CMR consultation. Moreover, of the 19 sponsors in CY 2013 that did provide CMR

written summaries, seven did not use the approved standardized format or did not provide timely CMR written summaries. Less than half of the sampled CY 2013 sponsors were in full compliance with the CMR written summary regulations and guidance.

- TMRs: Nine out of 21 sponsors did not perform quarterly TMRs in CY 2011 with at least one of their MTM enrollees. The most common reason provided by plan sponsors for not performing quarterly TMRs was a change in the TMR computer system or IT code that prevented the plans from conducting or recording TMR performance.

We remind sponsors that they must auto-enroll the targeted beneficiaries when they meet the eligibility criteria, and upon enrollment in the MTM program, begin performing TMRs at least quarterly with follow-up interventions as necessary, begin providing prescriber interventions, and offer the annual CMR in a timely manner per the guidance. Sponsors should not wait for the beneficiary to accept the offer for the CMR before performing TMRs or providing interventions to the beneficiary's prescriber. A CMR must comply with the requirements established by §423.153(d) and cannot be counted as a CMR unless a summary in CMS' standardized format is delivered to the beneficiary following the consultation. The standardized format for the CMR summary is a requirement, and not an option, and should be delivered to the beneficiary within 14 calendar days of the CMR.

As a result of the findings of the MTM Monitoring project described above, sponsors identified as non-compliant with MTM program requirements may be subject to compliance actions. In addition, CMS will develop new audit performance elements for MTM programs. Findings from the audits may also impact sponsors' Part D Star Ratings for MTM for 2016 or beyond.

We received several comments from organizations and sponsors requesting additional information about the proposed audit elements and opportunities to provide input. Prior to piloting this audit area, CMS will publically release the audit protocols. CMS may pilot MTM program audits as early as the 2014 or 2015 audit season. The results of any new, piloted audit protocol, including the proposed MTM audits, will not count towards the sponsor's program audit score or Part D Star Ratings for at least the first year that the protocol is piloted. Sponsors that participate in the pilot will be contacted directly by CMS after the pilot audit is completed and given the opportunity to provide feedback on their experience with the pilot audit process and the protocols. Additionally, once the audit protocols are published, we welcome feedback at any time from sponsors and stakeholders on Parts C and D program audit protocols via email at part_c_part_d_audit@cms.hhs.gov.

Sponsors must operate their MTM programs in compliance with §423.153(d) and related CMS guidance. A memo containing MTM program guidance and submission instructions is released each year by CMS and is available on the CMS.gov MTM page at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The guidance memo for CY 2015 will be released approximately one month before

the 2015 MTM program submission deadline. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Standards

We continue to encourage industry to develop and use standards for Health Information Technology (HIT) for MTM service documentation. The Office of the National Coordinator for Health Information Technology (ONC) is responsible for selecting standards for HIT in the United States. ONC has developed the Standards and Interoperability Framework (http://www.siframework.org/) that facilitates and coordinates stakeholder engagement in the definition, revision and piloting of health IT standards. We also encourage the industry to reach consensus on more robust definitions for MTM, CMRs, and drug therapy recommendations and resolutions for service delivery and performance measurement. Otherwise, CMS, in coordination with ONC, will work with the industry to develop additional standards and definitions which will be proposed in future rulemaking for adoption by all Part D sponsors.

Commenters overwhelmingly supported the development and use of HIT standards for MTM and working towards reaching consensus on service-level definitions to streamline delivery, documentation, and reporting. We appreciate the thoughtful discussions regarding current barriers and opportunities for collaboration. We look forward to continuing these discussions, and encourage future activities to be coordinated with the work of ONC.

MTM Administrative Costs in Bids

CMS considers MTM program services provided to targeted beneficiaries as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit. An MTM program is based on the contract year. The plan's bid should take into account MTM costs for the applicable contract year, as MTM programs can change from year to year.

However, the CMS eligibility targeting requirements are established as the minimum threshold. Therefore, we believe that as part of their broader efforts with respect to drug utilization management and quality assurance, sponsors may also elect to offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under section 423.153(d). Sponsors may incorporate these additional costs of providing MTM services to an expanded population in the administrative costs in their bids.

A majority of comments were supportive but asked for clarification on reporting MTM activities as "quality improvement activities" (QIAs) for purposes of calculating the Medical Loss Ratio (MLR). Guidance is forthcoming, and questions may be submitted to MLRreport@cms.hhs.gov.

Management of Opioids

Overutilization of opioids is a significant concern, especially in the treatment of patients with noncancer chronic pain, as discussed in the Enhancements and Clarifications on Improving Utilization Review Controls section of this Call Letter. Noncancer chronic pain is currently not one of the core chronic diseases per the guidance for targeting beneficiaries for the MTM program (HPMS memo, April 5, 2013, CY 2014 Medication Therapy Management Program Guidance and Submission Instructions, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html). Therefore we encourage (but do not require) sponsors to also offer MTM services to beneficiaries who meet the sponsors' internal criteria for retrospective identification of opioid overutilization, but do not otherwise qualify for MTM. These beneficiaries may benefit from MTM services including the CMR, targeted medication reviews, and interventions with their prescribers.

We believe that offering MTM to this population could complement the current drug utilization management requirements to reduce overutilization of opioids, assist in coordination of care, and improve pain management. Commenters were mixed with regard to their support for this proposal. Sponsors who were opposed generally agreed with the goals, but questioned the benefit and effectiveness of providing MTM services to engage this patient population to address overutilization of opioids. Sponsors may offer MTM services to beneficiaries who meet the sponsors' internal criteria for retrospective identification of opioid overutilization, but do not otherwise qualify for MTM, at their discretion.

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 2015, or in the applicable regulations, the benefit parameters for CY 2015 are set forth in Table 1 below. We note that beginning in 2015, we will no longer use the terms "preferred" and "non-preferred" to describe network pharmacies, but rather will describe such pharmacies as offering standard or preferred cost-sharing.

We 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%, we 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%, we will conduct the same cost-sharing analysis for these tiers). We will also continue to disallow 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.

The methodology for developing the CY 2015 out-of-pocket costs (OOPC) model is consistent with last year's methodology except for inclusion of free first fill benefits in the OOPC calculations. Customary updates for utilization data as well as PBP and formulary data used for CY 2015 bid submissions are also included in the 2015 model. Using this model, the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $20. The minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $25. These meaningful difference requirements apply to all stand-alone PDPs including those belonging to sponsors under a consolidation plan. Furthermore, we are reinstating the meaningful difference policy described in the CY2012 Call Letter related to stand-alone PDP sponsors with more than one EA plan within a service area. That is, we will continue to expect that the additional EA PDPs within a service area will have a higher value than the first EA plan and will include additional gap cost-sharing reductions for at least 10 percent of their formulary brand drugs.

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 defined standard benefit across all tiers. As in all previous years, sponsors may continue to include a mix of both plan defined brand and generic drugs on each tier; however, for purposes of determining whether coverage gap cost-sharing thresholds specified in Table 1 have been met we will continue to rely on the FDA marketing status to identify formulary drugs as applicable or non-applicable. We remind sponsors that when cost-sharing reductions beyond the standard benefit are offered through a supplemental Part D benefit, the plan liability is applied to applicable drugs for applicable beneficiaries before the manufacturer discount.

Our regulation at 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 $320 deductible and 25% cost-sharing of an initial coverage limit of $2960 is essentially the equivalent of $980 in out-of-pocket expenses, whereas no deductible and 33%

cost-sharing of the same initial coverage limit is essentially the equivalent of $976.50 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). To make the Specialty Tier methodology transparent, we will post it at the following site: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html.

Table 1: Benefit Parameters

	CY 2015 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$20
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$25
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S[2,3]
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[4]	$10
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S[2,3]
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[4]	15%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs) [5]	S[3]
Preferred Generic/Generic Tier	45%

	CY 2015 Threshold Values
Non-Preferred Generic Tier	45%
Preferred Brand/Brand Tier	65%
Non-Preferred Brand Tier	65%
Injectable Tier	65%
Select Care/Diabetic Tiers[4]	65%
Minimum Specialty Tier Eligibility	
1 month supply at in-network retail pharmacy	$600

[1]These thresholds are based on the 95th percentile of the October CY 2014 Bid Data run through the CY 2014 OOPC MPF model which incorporates CY 2014 Formulary Data, 2009/10 MCBS Data, and FDA data for brand/generic determinations related to coverage gap cost-sharing estimates. For each parent organization, any cost-sharing OOPC comparison between a basic plan and EA plan in the same region must meet the minimum Enhanced Alternative Plan vs. Basic Plan threshold. For each parent organization, any cost-sharing OOPC comparison between two EA plans in the same region must meet the minimum Enhanced Alternative Plan vs. Enhanced Alternative Plan threshold.

[2] These thresholds are based on the 95th percentile of the CY 2014 Bid Data. 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). We continue to expect cost sharing for the Vaccine tier to be $0.

[3]"S" in the above chart refers to "standard retail cost-sharing" at a network pharmacy. Standard retail cost-sharing (S) is cost-sharing other than preferred retail cost-sharing offered at a network pharmacy.

[4]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.

[5] Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this gap benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier (partial tier coverage). If the additional gap cost-sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 45% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 50% manufacturer discount for applicable drugs.

Employer Group Waiver Plan (EGWP) Policy Reminders

Part D Benefits and Additional Benefits

Beginning January 1, 2014, CMS implemented a change to the definition of the Part D supplemental benefits in 42 CFR §423.100 that specifically excludes all supplemental benefits offered through EGWPs. Therefore, as of January 1, 2014 the Part D component of EGWP prescription drug plans is reported on PDEs as the defined standard benefit. Any additional benefits are reported on PDEs as Other Health Insurance (OHI). We also remind Part D sponsors that since the beginning of the Part D program EGWPs have not been permitted to

increase the deductible or catastrophic limit of their Part D benefits. [See section 20.9 of Chapter 12 of the *Medicare Prescription Drug Benefit Manual*, states that "to assure that the actuarial equivalence of the standard Part D benefit design is maintained, CMS requires all PDP sponsors offering EGWPs to ensure that the total employer/union sponsored plan (including adjusting for any supplemental coverage) provides at least the standard Part D coverage, including a deductible no higher than that of defined standard Part D, and catastrophic coverage after the true-out-of-pocket limit is met."] Therefore, for 2015 EGWP sponsors may not offer any benefit plans (the combination of the defined standard Part D benefit and any additional retiree OHI) to Part D beneficiaries that have a deductible higher than $320 or an out-of-pocket threshold for catastrophic coverage higher than $4,700.

Formularies

We would also like to remind sponsors about the expectations regarding formulary changes to base-level EGWP formularies. While CMS waives the requirement to submit a unique formulary for each individual employer/union sponsored group health plan, sponsors are required to submit at least one base-level formulary to represent these plans. The base-level formulary should represent the most restrictive formulary in terms of the drug content and utilization management criteria that will be used by the associated EGWPs.

EGWPs may only make enhancements to their approved formularies that increase the value for any beneficiary who uses the drug(s). This means that the only enhancements allowed without our approval are adding Part D eligible drugs to the formulary, moving Part D formulary drugs to lower cost-sharing tiers, and removing utilization management edits. For CY 2015 we thus remind sponsors that the base-level formulary submitted for EGWPs must meet the minimum drug coverage requirements applicable to all Part D plans. These base-level formularies are subject to the same rules for formulary enhancements applicable to all Part D plans. Furthermore, the enhancements offered may not be based on an average or actuarially equivalent increase in value for some EGWP members or as compared to commercial offerings. In other words, the EGWP formulary enhancements must incontrovertibly enrich the Part D benefit for any beneficiary who uses the drugs affected by the formulary change. Such enhancements are limited to increases in the overall number of formulary drugs, reductions in cost-sharing as a result of tier changes, and elimination of utilization management edits. Any other formulary change would be considered a negative change and therefore subject to the negative change request and approval process applicable to all Part D plans.

CMS received a number of comments objecting to having to submit a base formulary for each tier structure due to increased administrative burden and the significant increase in the number required plan benefit package submissions. Therefore we are specifying that the EGWP base formulary be submitted with the highest number of tiers that may be offered. In addition, EGWP formularies with different tier structures may only be offered when the change in the number of

tiers provides an enhancement to any beneficiary who uses the drugs affected by the formulary change, as described in the paragraph above. Finally, EGWPs may not utilize a formulary with more Part D drug tiers than the number of tiers on the CMS approved EGWP formulary.

Drugs Not Covered Under Part D

Lastly, we point sponsors' attention to the Section, "Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status**"** for specific information about this policy clarification and EGWPs. To summarize here: An employer that offers a plan that includes drugs that are not covered under Part D as described in that section are not able to submit PDEs to CMS for such drugs. In addition, brand drugs that are not covered under Part D are not eligible for the 50% manufacturer discount.

Antipsychotic Drug Use Data

A recent study published in Psychiatric Services analyzing 2009 claims data from private insurance claims found that 58 percent of individuals prescribed psychotropic medication in 2009 had no psychiatric diagnosis during the year (*Psychiatric Services 2013*; doi:11.1176/appi.ps.201200557). Additionally, on September 20, 2013, the American Psychiatric Association released a "list of specific uses of antipsychotic medications that are common, but potentially unnecessary and sometimes harmful", including a recommendation not to prescribe these drugs "as a first-line intervention to treat behavioral and psychological symptoms of dementia" (http://www.psychiatry.org/choosingwisely).

CMS is particularly concerned with unnecessary use of antipsychotic drugs in nursing homes and, as a result, continues to pursue strategies to increase awareness of antipsychotic use in long term care (LTC). We began in 2013 to calculate a general atypical antipsychotic utilization rate for the 2013 Part D Display Measures using 2011 data. Contract-level rates were also calculated using 2012 data and included in the 2014 Part D Display Measures now available on the CMS Web site at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

The measure is 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. The numerator for the measure is the number of Part D beneficiaries in the denominator who received at least a 90-day supply of AA medication(s) during the nursing home stay in the measurement period. The denominator includes beneficiaries who:

- Beginning in January, had institutional 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; and
- Whose first reason for Medicare enrollment was aging-in.

Table 1: 2011 and 2012 Rates of Atypical Antipsychotic Drugs by Organization Type

Organization Type	Atypical Antipsychotic Drug Rate	
	2011	2012
MA-PD	21.28	21.13
PDP	24.29	24.22
Low Income Newly Eligible Transition (LINET) Contractor	24.47	22.59
Total	23.90	23.76

Although we have seen a small decline in the rate as a result of MTM services and other increased efforts to curtail AA drug use in LTC, as Table 1 shows, the average rate remained relatively constant. As a result, CMS is working with LTC and mental health stakeholders to further raise awareness of the lack of improvement in the rate. We solicited comments on what interventions plans and providers can implement to lower AA utilization, and appreciate the thoughtful comments in response to our request. We will consider those as we continue our work in this area.

Coordination of Benefits (COB) User Fee

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. The 2015 COB user fee will be collected at a monthly rate of $0.136 for the first 9 months of the coverage year (for an annual rate of $0.102 per enrollee per month) for a total user fee of $1.22 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2015 bids.

In contract year 2015, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The new Benefit Coordination and Recover Center (BCRC) operation and maintenance; the BCRC combines most of the operations of the Coordination of Benefits Contract (COBC) and the Medicare Secondary Payer Recovery Contract (MSPRC);
- Drug data processing system management, which is used to collect prescription drug event (PDE) data for Part D payment purposes and to produce invoices for the coverage gap discount program;

- Medicare Advantage and Prescription Drug (MARx) system management of COB data;
- Enhancements to the collection of other health insurance data to improve the efficiency of enrollees' benefits paid in the proper order; and
- Review of Workers' Compensation settlement set-aside funds, which ensure that medical services are paid for by the appropriate party.

Extended Days' Supply Indicator

In the draft Call Letter we proposed that drugs offered at an extended day supply be provided with a symbol and the days' supply amount in the Part D plan sponsor's marketing formulary documents. We received a number of comments and requests for clarification on this policy. Providing a drug level symbol to indicate an extended day supply was described by commenters as being difficult and burdensome to operationalize because extended day supply is defined differently by organizations and sponsors and can be applied based on the pharmacy network or the location of dispensing (retail versus mail order), and not solely the specific drug level. Therefore CMS will not be implementing this policy for 2015 and will take more time to collect additional information on the most effective way to annotate extended days' supply in sponsor marketing materials and ensure it is transparent to Medicare beneficiaries.

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. By April 2014, 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.

Renewal of LI NET Demonstration

The Medicare Part D Demonstration for Retroactive and Point of Sale Coverage for Certain Low-Income Beneficiaries (Medicare's LI NET Demonstration) is a demonstration designed to eliminate gaps in coverage for low income beneficiaries by providing temporary Part D drug coverage. The current demonstration ends December 31, 2014. In order to ensure availability of the benefits provided by Medicare's LI NET Demonstration, CMS is working toward renewing the demonstration for a period of five years (January 1, 2015 through December 31, 2019).

Commenters voiced support for the demonstration renewal. One commenter requested enhanced efforts to reach out to and educate pharmacies about the Medicare LI NET Demonstration procedures. Much of Medicare's LI NET Demonstration's Communication and Outreach Plan consists of continuing to focus on raising awareness of the demonstration among the stakeholders. We will continue to work to address the communication/information needs of key audiences, including advocacy groups, physicians, state health insurance assistance programs, state pharmacy associations, professional associations, state pharmaceutical assistance programs, state Medicaid agencies, state Medicaid pharmacy directors, beneficiaries and their caregivers, National Caseworkers, companies offering pharmacy practice management systems, and national pharmacy colleges and universities. We thank the commenters for their feedback.

Appendix 1 – Contract Year 2015 Guidance for Prescription Drug Plan (PDP) 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 2, 2014). The same procedure applies to PDPs converting contracts from offering both individual and employer products to employer-only products because the individual plan is being non-renewed. However, even absent written notification to CMS, a PDP sponsor's failure to submit a timely bid to CMS constitutes a voluntary non-renewal of the plan 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 2015 is summarized below and defined in Appendix 2. 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 and benefit design (basic or enhanced alternative) 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 merge 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 two or more entire PBPs must ensure that the consolidated renewal PBP ID is the same as one of the original consolidating PBP IDs. 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.

CMS will no longer approve bids that include a PBP that would change a basic plan to an EA plan because of the potential for beneficiary confusion and disruption, as noted above.

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 ID 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 2, 2014. CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan. 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 merge 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 merged 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.

Appendix 2 – Contract Year 2015 Guidance for Prescription Drug Plan (PDP) 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 2015 that is not linked to a 2014 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 2014 PBP in CY 2015. The same PBP ID number and benefit design (basic or enhanced alternative) must be retained in order for all current enrollees to remain in the same PBP in CY 2015.	HPMS Plan Crosswalk Definition: A 2015 plan that links to a 2014 plan and retains all of its plan service area from 2014. The 2015 plan must retain the same plan ID as the 2014 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 PDP sponsor does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in 2015. 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 2014 into a single renewal PBP for CY 2015. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2015 after consolidation.	HPMS Plan Crosswalk Definition: Two or more 2014 plans that merge into one 2015 plan. The 2015 plan ID must be the same as one of the consolidating 2014 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 2015.	Current enrollees are sent a standard ANOC.

	Activity	Definitions	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
4	Renewal Plan with an SAE (applicable only to employer/union group waiver plans)	A PDP sponsor continues to offer an 800 series CY 2014 prescription drug PBP in CY 2015 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 2015.	HPMS Plan Crosswalk Definition: A 2015 800-series plan that links to a 2014 800-series plan and retains all of its plan service area from 2014, but also adds one or more new regions. The 2015 plan must retain the same plan ID as the 2014 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 2015. 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 2014 PBP.	HPMS Plan Crosswalk Definition: A 2014 plan that is no longer offered in 2015. HPMS Plan Crosswalk Designation: Terminated Plan	CMS expects the sponsor to crosswalk the affected enrollees into the most comparable 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 merges 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 2015 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 merger of two 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 2015. New enrollees must complete enrollment request.	Current enrollees are sent a special notice along with a standard ANOC.

Appendix 3 - Summary of Comments on the Draft Call Letter to Proposed Enhancements to the 2015 Star Ratings and Beyond

On February 21, 2014 CMS sent out an Advance Payment Notice and draft Call Letter to Part C and D sponsors, stakeholders and advocates that included a description of CMS' proposed methodology for the 2015 Star Ratings for Medicare Advantage (MA) and Prescription Drug Plans (PDPs). The draft Call Letter took into account comments received on an earlier Request for Comments (released on November 22, 2013) on enhancements to the Star Ratings. We received 68 comments on the draft Call Letter from organizations representing Part C and D sponsors, stakeholders, pharmaceutical companies/pharmacies, physician/provider groups, patient advocates, and measurement development organizations. This appendix provides a summary of the comments received and how we addressed these comments in the Final Call Letter.

Special Needs Plan (SNP) Care Management (Part C SNPs).

Summary of Comments:

We received mixed comments with some supporting this measure, others making very specific suggestions for changes to the specifications, a couple wanting it to remain a display page measure, and others concerned about changing specifications. Some of the suggestions include excluding from the denominator members that refuse an assessment and comments around allowing Medicaid and NCQA interpretations of timely assessment to mean assessments that are completed at any time within the "anniversary month" of the last assessment. A few commenters said providing a 30-day window from the 365-day timeline would align with some state requirements for the SNP program.

Revised Proposed Change:

CMS will proceed with including this measure in the 2015 Star Ratings. The technical specifications for the 2013 reporting year have been stable. We will consider recommendations that pertain to improvements in defining timely assessments for future reporting periods. The earliest any such improvements could be implemented would be for reporting year 2015.

Breast Cancer Screening (Part C).

Summary of Comments:

The feedback was very mixed in terms of moving this measure to the display page for one year due to a mid-year specification change. Some supported moving it to the display page. Those that wanted it to remain as a Star Ratings measure believed plans had already adapted to the new guidelines and CMS just needed to eliminate the pre-determined 4 star threshold.

Revised Proposed Change:

As described in the Call Letter, we evaluate measure specification changes for their timing with respect to the measurement period as well as impact to the denominator. Since this specification change occurred during the measurement period and impacts the population covered by the measure, CMS is proceeding as proposed to move this measure to the display page for one year.

Annual Flu Vaccine (Part C).

Summary of Comments:

Most agreed that the timeframe should be extended. Some commenters stated a preference for a claims-based flu vaccine measure and suggested that survey measures could be biased due to beneficiary recall and differences in socioeconomic characteristics.

Revised Proposed Change:

CMS is proceeding as planned to include members who got a flu shot earlier and eliminate the pre-determined 4-star threshold for this measure.

High Risk Medication (Part D).

Summary of Comments:

Some commenters suggested excluding some drugs from PQA's list, or modifying Part D policies to allow removal of all High Risk Medications (HRMs) from formularies. Many opposed the adoption of the updated PQA list (or specific drugs), or HRM overall as a Star Rating measure. A minority of comments supported the changes, and a couple of commenters were mixed. Some stated that this change met CMS' policy for moving a measure to the display page.

Revised Proposed Change:

CMS is proceeding as planned to update the HRM list with PQA's list. This is CMS' third formal announcement of this change. CMS first alerted plans about this change in the 2013 Call Letter and has been providing monthly HRM patient safety reports to sponsors using the updated list since 2012. These changes do not warrant moving the measure to the display page. We acknowledge the AGS may update the HRM list further, and will continue to monitor along with PQA acknowledge the AGS may update the HRM list further, and will continue to monitor along with PQA any AGS' changes and any updates as necessary. We will announce timelines as they become available. We have clarified that CMS adopts PQA's specifications including drug lists.

Medication Adherence for Diabetes Medications (Part D).

Summary of Comments:

Most commenters supported the proposed changes. A few technical clarifications were requested, and one commenter requested this be a display measure in 2015, and moved back to Star Ratings in 2016.

Revised Proposed Change:

CMS is proceeding as planned to add two additional drug classes in line with PQA's specifications.

We have added language to the Final Call Letter that this measure evaluates compliance to all DM therapy, not a drug class. Two years advance notice was given with the 2014 and 2015 Call Letters; thus, CMS is proceeding with applying PQA's drug list for the 2015 measures.

Beneficiary Access and Performance Problems (Part C and D).

Summary of Comments:

All commenters were supportive of this measure going to the display page. Most wanted the audits removed from the measure entirely and to just use the remaining measure data. Some commenters were still not clear about how the new methodology would work. A few commenters wanted to know if the measure was going back to the Star Ratings in 2016. One commenter wanted an HPMS module to track the data that go into the measure.

Revised Proposed Change:

CMS is proceeding with moving this measure to the Display Page. We will continue to look at methodological issues surrounding this measure to make a determination about inclusion in Star Ratings in future years.

Medication Adherence Measures (Part D). Hospice and SNP adjustments

Summary of Comments:

The majority of commenters supported the changes; however, two commenters requested this to be delayed until 2016, and/or moved to the display page.

Revised Proposed Change:

CMS is proceeding as planned for adjustments to the 2015 Adherence measures. It is important to note that hospice payment policies are not tied to these changes.

Obsolete NDCs.

Summary of Comments:

A couple of commenters disagreed with the proposal due to potential differences between First Data Bank and Medispan data, or the recommendation to use GCNs instead of NDCs. One commenter thought this was a proposed measure.

Revised Proposed Change:

CMS is proceeding as planned with aligning this methodology with PQA's for all measures using PDE data. We clarify that this is not a Star Ratings measure.

Retirement of Measures: Glaucoma testing

Summary of Comments:

One comment was received suggesting that this measure should remain in the Star Ratings for one more year since the retirement was announced during the measurement period.

Revised Proposed Change:

CMS plans to proceed with retiring the Glaucoma testing measure.

Contracts with Low Enrollment

Summary of Comments:

We received mixed responses: some were very supportive of including contracts with 500-999 enrollees in the Star Ratings since this will increase the information available for beneficiaries choosing a plan. Some suggested this information should just be used for quality improvement. Some were concerned about the impact on cut points and suggested CMS make the enrollment cut off at 600. Some commenters suggested that specific measures should have enrollment-based thresholds and outlier and trending analyses should be conducted over time to see stability of scores.

Revised Proposed Change:

CMS plans to proceed with including contracts with 500 to 999 enrollees in the 2016 Star Ratings and will post simulated ratings for these contracts on the display page for 2015. When data are available later this year, CMS will examine the stability of the scores, and whether they should be excluded when determining star cut-points. Many measures already have minimum enrollment requirements that will continue to be applied.

Data Integrity

Summary of Comments:

While commenters supported CMS' desire to protect the integrity of data used for Star Ratings, there was no clear consensus for future steps. Some opposed the independent audit due to incurring additional costs, and the risk associated with small sample size. Some supported incremental reductions, as applied to audit findings but others opposed incremental reductions because they stated that could introduce inappropriate reductions or bias. Some supported both options.

Revised Proposed Change:

To avoid incurring increased costs for plans or CMS, we will not pursue the option of independent audits at this time. Moving forward, when CMS' review identifies systemic issues with data collection, CMS will continue the current reductions. That is, a plan with systemic errors resulting in inaccurate data will be reduced to 1 star.

Pharmacotherapy Management of COPD Exacerbation (PCE) (Part C).

Summary of Comments:

Most commenters were supportive of keeping this measure on the display page, while one commenter wanted it removed from the display page.

Revised Proposed Change:

CMS will continue to keep this measure on the display page and has shared with NCQA specific feedback from commenters on the measure specifications.

Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (IET) (Part C).

Summary of Comments:

Most commenters were supportive of keeping this measure on the display page, while one commenter shared concerns about the specifications of this measure.

Revised Proposed Change:

CMS will continue to keep this measure on the display page and has shared with NCQA specific feedback from commenters on the measure specifications.

Medication Therapy Management Program Completion Rate for Comprehensive Medication Reviews (Part D).

Summary of Comments:

Responses were split with slightly more opposing the proposal to defer changing this measure to a Star Rating in 2016-17. Opposition was based on requests to recognize and reward plans' initiatives in this area in the 2015 Star Ratings. Those that supported CMS deferring this to 2016 cited it would allow time to address issues. Commenters also suggested CMS establish a minimum number of enrollees who meet MTM program eligibility criteria for the future measure to help avoid small plans from disproportionately affecting industry averages on the Star Ratings measure, and to also revise the MTM requirement to one CMR every two years.

Revised Proposed Change:

CMS will continue to keep this as a 2015 Display measure due to the MTM program eligibility changes in 2013. CMS will proceed with the plan to introduce this as a 2016 Star Rating measure. CMS will determine the appropriate minimum MTM enrollment criteria. CMS has continued analyses related to this measure; current analyses have shown no correlation between a MTM program's enrollment and CMR rate.

CAHPS measures about contact from a doctor's office, health plan, pharmacy, or prescription drug plan (Part C).

Summary of Comments:

We received mixed responses: some commenters supported inclusion of the CAHPS contact measures in the display page while others opposed these display measures because of the length of the CAHPS survey, subjectivity of responses, and because contacting patients with reminders and positive test results is not industry standard. One commenter requested performance thresholds for display measures.

Revised Proposed Change:

CMS is proceeding as planned to include on 2015 display page. These measures are for informational purposes. We will be adding national averages to the 2015 display page.

CAHPS – Health Information Technology – EHR measures (Part C).

Summary of Comments:

Some commenters expressed mixed support for these CAHPS measures with some feeling they are too limited. Some commenters were opposed to the measures because they preferred administrative measures or surveys of providers.

Revised Proposed Change:

CMS is proceeding as planned to include on 2015 display page for informational purposes.

Transition monitoring (Part D).

Summary of Comments:

Some commenters opposed the display measure due to data lag, or limited sample of claims. Some supported the measure for beneficiary protections. It was requested that CMS provide opportunities to review/dispute results.

Revised Proposed Change:

CMS will continue to develop these two new display measures for 2015.

Combined MPF Price Accuracy (Part D).

Summary of Comments:

We received opposition from most commenters for a variety of reasons, including timing of point of service (POS) updates versus MPF, pharmacy discount programs that are independent from sponsors, and the assertion that beneficiaries are not harmed if POS prices are lower than MPF.

Other comments included requests to make cut points less strict; increase the allowed threshold between the MPF and PDE prices, weight the MPF<PDE score higher than MPF>PDE score; and that all accuracy measures should be posted to the Display page.

Revised Proposed Change:

Based on industry feedback about the feasibility of combining the two accuracy indices into one measure in the future, CMS will not pursue this measure concept at this time. CMS will continue to release contract-level results for the display measure, "Plan Submitted Higher Prices for Display on MPF" for informational purposes.

Disenrollment Reasons (Part C and D).

Summary of Comments:

We received mixed comments; some were supportive. Some commenters supported having this as a display measure but were against adding it to the Medicare Plan Finder (MPF) because they were concerned about too much information confusing beneficiaries. A couple of commenters shared concerns that some disenrollment reasons could be beyond the control of the MA organizations or Part D sponsors, and therefore they were opposed to having it as a Star Ratings measure or display measure.

Revised Proposed Change:

CMS is proceeding as planned to include this information on the 2015 display page. The disenrollment reasons measures are not Star Ratings measures but are for display only. The current disenrollment rate measure will remain a Star Ratings measure, and in the future this additional information about disenrollment reasons would be a drill down to that Star Ratings measure on the MPF. Until 2005, CMS included this information on medicare.gov for beneficiaries to use when making plan decisions. Feedback from beneficiaries showed this was very useful information for them.

Drug-Drug Interactions (DDI) Measure (Part D).

Summary of Comments:

Some commenters supported the measure, while others requested CMS to exclude DDI overridden at POS, or those without actual patient risk. Some supported the DDI deletions, but opposed additions, stating many were acute antibiotics that could not be substituted.

Revised Proposed Change:

CMS will proceed with these announced changes.

Diabetes Medication Dosing (Part D).

Summary of Comments:

All supported the changes.

Revised Proposed Change:

CMS will proceed with these announced changes.

Enrollment Timeliness (Part C and D).

Summary of Comments:

One comment was received stating that the 21 days for enrollment submissions is not enough to account for the structural enrollment processes in their state.

Revised Proposed Change:

CMS plans to proceed with the Enrollment Timeliness specification change, expanding submission from 7 to 21 calendar days for SNPs. Our data do not show an issue in the structural enrollment processes. We will continue to monitor this over time.

Proposed Weighting Changes – Improvement

Summary of Comments:

We received mixed reactions. Several commenters supported the change. Some commenters opposed this change because they did not want plan improvement to outweigh the impact of clinically-significant outcome measures. There was some concern that high performing plans would be hurt by this change. A few commenters expressed mixed reactions mostly concerning the uncertainties of potential shifts in the distribution and asked for more time and information.

Revised Proposed Change:

We are proceeding with increasing the weight of the improvement measure to 5 times that of a process measure for the 2015 Star Ratings, for those contracts rated 2.5 stars or more (prior to the inclusion of the improvement measure). We will continue to hold harmless high performing contracts with 4 or more stars. This change will help recognize and reward contracts' strides to improve their performance.

Proposed Weighting Changes – Adherence

Summary of Comments:

Several commenters supported this change, while the majority of commenters opposed it. A few of the supporters requested we defer the change to 2016 to avoid penalizing plans that have successfully improved in this area for the 2015 Star Ratings. A few commenters supporting the change stated the reduction would help account for the impact of member demographics, socio-economic status, and educational attainment on medication adherence. Commenters opposing this change cited reasons regarding improving health outcomes and quality of care, and lowering overall health care costs. They also stated these measures have an indirect impact on other Part C quality measures. One requested that CMS raise the weight of these measures.

Revised Proposed Change:

CMS will not proceed with the proposed reduction to the weight of the Adherence measures. Feedback from the sponsors supports the status quo for these weights.

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

Summary of Comments:

About half of the commenters were fine with the proposed changes but asked for two-year phase in. Other commenters were not in favor of removing the pre-set 4-star thresholds because they believed the thresholds help set goals or expectations, and removing them will lower transparency. Therefore, they asked CMS to explore other ways of improving the calculation of overall ratings. A couple commenters raised questions about whether reward factor and other cut points would be affected by this change.

Revised Proposed Change:

CMS will proceed as planned for the 2016 Star Ratings. CMS will provide plans with another set of simulations in Fall 2014 for this change.

HEDIS Changes due to Cholesterol Guideline Changes.

Summary of Comments:

Most of the commenters were supportive of CMS following the NCQA HEDIS changes once they are made. A couple of commenters wanted clarification whether specification changes and retirement of measures would be for the 2015 or 2016 ratings.

Revised Proposed Change:

CMS will follow NCQA deliberations regarding these measures. Any changes will not be implemented until the 2016 Star Ratings.

Rules around measure changes and when to move to display page.

Summary of Comments:

Several commenters were supportive of the rules and one commenter wanted the measure steward to make the decision when a measure should be moved to the Display page. One thought it should be decided on a measure by measure basis.

Revised Proposed Change:

CMS plans to proceed as proposed setting rules around measure changes to provide clear guidance when we will move a measure to the display page.

Osteoporosis Management in Women who had a Fracture (Part C).

Summary of Comments:

Commenters were supportive of the proposed changes by NCQA.

Revised Proposed Change:

CMS will continue to follow guidance from NCQA on potential changes to this measure.

Monitoring Physical Activity (Part C).

Summary of Comments:

Some commenters were supportive of potential changes, while one opposed the measure stating plans cannot impact it.

Revised Proposed Change:

CMS will continue to follow guidance from NCQA on potential changes to this measure.

Plan All-Cause Readmissions (Part C).

Summary of Comments:

One commenter wanted a regional adjustment to this measure. One commenter was supportive of the potential changes.

Revised Proposed Change:

CMS will continue to follow guidance from NCQA on potential changes to this measure.

Improving Bladder Control (Part C).

Summary of Comments:

One commenter was supportive of the changes to this measure.

Revised Proposed Change:

CMS will proceed as planned.

Plan Makes Timely Decisions about Appeals (Part C).

Summary of Comments:

Support was received for this proposal.

Revised Proposed Change:

CMS will proceed as planned.

Appeals Upheld (Part D).

Summary of Comments:

All comments supported the proposed change; some questioned which data would be used for the 2015 Star Ratings.

Revised Proposed Change:

CMS will proceed as planned. The 2015 Star Rating measure will be based on the first 6 months of 2014, while the 2016 Star Ratings measure will be based on the full 12 months of calendar year 2014 data.

Adherence (DM and Hypertension) and Diabetes Treatment (Part D).

Summary of Comments:

Some commenters requested these changes to be delayed past 2016, and requested clarification for accounting for data lag, and accurately capturing exclusions.

Revised Proposed Change:

CMS will proceed as planned.

Complaints about the Health/Drug Plan (CTM) (Part C and D):

Summary of Comments:

All comments supported the proposed change; some questioned which data would be used for the 2015 Star Ratings.

Revised Proposed Change:

CMS will proceed as planned. The 2015 Star Rating measure will be based on the first 6 months of 2014, while the 2016 Star Ratings measure will be based on the full 12 months of calendar year 2014 data.

MPF Accuracy (Part D).

Summary of Comments:

We received opposition from organizations and sponsors. More PBMs were supportive of the changes than were opposed.

Some requested clarification about which claims would be included in the measure, and how pharmacy type would be identified. As with the other Pricing accuracy proposal, other commenters requested CMS make the cut points less strict; increase the allowed threshold between the MPF and PDE prices, weight the MPF<PDE score higher than MPF>PDE score; and post all accuracy measures on the Display page.

Revised Proposed Change:

We will continue to evaluate changes to the methodology in order to use PDE data to more accurately identify retail pharmacy claims for the measure. We will also move to include 60 and 90 day supply claims, in addition to 30 day claims.

CAHPS measures (Part C and D).

Summary of Comments:

We received a few comments about this change, including whether this change would impact the objectivity of this metric, whether the simulated scores provided by CMS incorporate the new CAHPS methodology, and questions about further clarifications.

Revised Proposed Change:

We will proceed as planned to permit low reliability contracts to receive 5 stars or 1 star in 2016 Star Ratings if the score is at least one standard deviation above the 4 star cut point or below the 2 star cut point, respectively, when we drop pre-determined 4-star thresholds. This change was incorporated into the simulations provided to contracts in February 2014.

SNP and LIS Beneficiaries

Summary of Comments:

We received several requests on adjusting Star Ratings measures or overall stars for SNP and/or LIS beneficiary enrollment. They requested that CMS consider the following options: apply case-mix adjustment to the stars or measures for SNP/LIS enrollment, benchmark SNPs against other SNPs, separate cut points for dual SNPs, implement measures more appropriate for duals, revise HCC risk adjustment methodologies to account for SNPs/LIS, apply a SNP/LIS factor, similar to the i-Factor, to the overall star calculation, extend QBP demonstration for plans serving dual SNPs, contract with an independent entity to further evaluate the performance gap, weight population-relevant Star metrics more heavily, and add a half-star to overall star ratings for dual plans and those with high concentration of dual enrollees.

For most measures CMS relies on consensus based organizations' decisions about whether a measure should or should not be case-mix adjusted. Currently, CMS adjusts CAHPS measures and HOS outcome measures for case mix. CMS is continuing to do analyses in this area.

Measurement Concepts

CMS is continuing to explore the following new measurement concepts.

- ***Alternatives to individual measures' current level of evaluation:*** We received several supportive comments, with two regarding SNP-related issues and one expressing concern that Plan Benefit Package (PBP) data may be contracted out and not "owned' by the contract, thereby introducing logistic issues. The two SNP comments recommended the inclusion of PBP-level data to more accurately reflect the SNP population. A concern was also mentioned with regard to low denominator sizes. One commenter requested CMS provide evidence to support a change of measurement.

- ***Additional measures of care coordination focusing on how well providers and organizations coordinate services:*** Several commenters expressed support.

- ***Measures of care transitions from one healthcare setting to another:*** Some supported the development of new measures regarding care transition, especially with respect to

mental health. One commenter supported creating a SNP-specific measurement system to more accurately measure care transitions in the SNP population.

- ***Measures of patient-reported outcomes/intermediate outcomes collected through enrollee surveys:*** Most commenters were supportive.

- ***Measures that are condition-specific (e.g., mental health such as depression screening, HIV/AIDs, COPD, cancer):*** Several commenters expressed support and recommended a variety of conditions we could measure. For depression, measures of screening were recommended more than outcomes.

- ***Combined member dissatisfaction measure:*** **N**o comments were received.

- ***SNP-specific measures that would focus on any unique aspects of care provided by SNPs:*** One commenter wanted structure and process measures and measures based on the model of care.

- ***Alternative methods for measuring improvement:*** Some commenters supported exploring other ways of measuring improvement.

Feasibility of replicating current HEDIS measures by using FFS administrative data: One commenter raised the concern that PDPs have no contracted relationships with providers.