April 4, 2016

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

Subject: Announcement of Calendar Year (CY) 2017 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, we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2017 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2017 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 2017 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2017. These growth rates will be used to calculate the 2017 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 3.08 percent, and the final estimate of the FFS Growth Percentage is 3.12 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 2014 are being posted on the above website.

Attachment II details the key assumptions and financial information behind the growth percentages presented in Attachment I.

Attachment III presents responses to Part C payment related comments on the Advance Notice of Methodological Changes for CY 2017 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice).

Attachment IV presents responses to Part D payment related comments on the Advance Notice.

Attachment V shows the final Part D benefit parameters and contains details on how they are updated.

Attachment VI shows the CMS-HCC and RxHCC Risk Adjustment Factors

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 19, 2016. Comments were received from professional organizations, MA and Part D sponsors, advocacy groups, the pharmaceutical industry, members of congress, pharmacy benefit managers, pharmacies, and concerned citizens.

Key Changes from the Advance Notice:

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

Calculation of FFS Rates: We are finalizing the methodology that we proposed for calculating FFS rates with two modifications. First, the rebasing of DME claims in non-competitively bid areas (non-CBAs) are based on the blended fee amounts instead of the proposed use of the fully adjusted fees. The blended payments, which have been used in payment since January 2016, are based on 50 percent of the unadjusted fee schedule amount and 50 percent of the fully adjusted fee amounts scheduled to be implemented in July 2016. This change is being made because the fully adjusted fees for 2016 have not yet been announced. Second, the Secretary has directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of zero dollar claimants nationwide.

Medicare Advantage Employer Group Waiver Plans: We are finalizing the methodology that we proposed for calculating EGWP county payment rates with two modifications. First, in order to release final EGWP county payment rates in the Rate Announcement, we will use the average bid-to-benchmark ratio for individual market plan bids from the prior payment year to calculate the Part C base payment amounts for EGWPs. For example, the EGWP county payment rates for 2017 have been calculated using 2016 bid-to-benchmark ratios. Second, to provide employers and MAOs more time to adapt to this payment change, we are providing a two-year transition to the new EGWP county payment rate methodology. More details about the final policy are discussed in Section F of Attachment III below.

CMS-HCC Risk Adjustment Models for CY2017: We will fully implement the 2017 CMS-HCC Risk Adjustment model proposed in the Advance Notice, but have updated the coefficients using an updated denominator. Attachment VI contains the revised coefficients.

Normalization Factors: CMS is updating the 2017 normalization factors that were proposed in the Advance Notice. The 2017 Normalization factors are as follows:

CMS-HCC model used for MA plans is 0.998.

CMS-HCC model used for PACE organizations is 1.051.

CMS-HCC ESRD functioning graft model is 1.051.

CMS-HCC ESRD dialysis model is 0.994.

RxHCC model is 0.976.

Encounter data as a diagnoses source for 2017: CMS will calculate 2017 risk scores by adding 25% of the risk score using encounter data and FFS diagnoses with 75% of the risk score using RAPS and FFS diagnoses.

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 benchmark methodology beginning in 2012. In the Advance Notice we announced the continued implementation of the methodology used to derive the benchmark county rates, how the qualifying bonus counties will be identified, and how transitional phase in periods were determined. The continued applicability of the star system was also announced. This Announcement finalizes these proposals.

IME Phase Out: For 2017, CMS will continue phasing out indirect medical education amounts from MA capitation rates.

ESRD State Rates: We will continue to determine the 2017 ESRD dialysis rates by state as we specified in the Advance Notice.

Clinical Trials: We are continuing the policy of paying on an FFS basis for qualified clinical trial items and services provided to MA plan members that are covered under National Coverage Determination 310.1.

Location of Network Areas for PFFS Plans in Plan Year 2018: The list of network areas for plan year 2018 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 5.66 percent for payment year 2017.

Frailty Adjustment for PACE organizations and FIDE SNPs: We are finalizing the 2017 frailty factors as proposed.

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

RxHCC Risk Adjustment Model: We will implement the updated RxHCC Risk adjustment model proposed in the Advance Notice. Attachment VI contains the risk adjustment factors for the RxHCC model.

Part D Risk Sharing: The 2017 threshold risk percentages and parameters for Part D risk sharing will be finalized as stated in the Advance Notice.

Part D Benefit Parameters: Attachment V provides the 2017 Part D benefit parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy.

Part D Calendar Year Employer Group Waiver Plans: We are finalizing the Part D CY EGWP prospective reinsurance policy as proposed.

/ s /
Sean Cavanaugh
Deputy Administrator, Centers for Medicare and Medicaid Services
Director, Center for Medicare
/ s /
Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Attachments

2017 ANNOUNCEMENT
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Attachment I. Final Estimates of the National Per Capita Growth Percentage and the National Medicare Fee-for-Service Growth Percentage for Calendar Year 2017

The Table I-1 below shows the National Per Capita MA Growth Percentage (NPCMAGP) for 2017. We have calculated the final MA Growth Percentage and the FFS Growth Percentage based on the assumption of a 0.5 percent update for the physician fee schedule for 2017. An adjustment of 0.1 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 2017

	Prior Changes	Current Changes			
	2003 to 2016	2003 to 2016	2016 to 2017	2003 to 2017	NPCMAGP for 2017 With §1853(c)(6)(C) adjustment[1]
Aged+Disabled	50.20%	50.35%	2.98%	54.84%	3.08%

[1]Current changes for 2003-2017 divided by the prior changes for 2003 to 2016.

The Affordable Care Act of 2010 requires the Medicare Advantage benchmark amounts be tied to a percentage of the county FFS amounts. Table I-2 below provides the change in the FFS USPCC which will be used in the development for the county benchmark. The percentage change in the FFS USPCC is shown as the current projected FFS USPCC for 2017 divided by projected FFS USPCC for 2016 as estimated in the 2016 Rate Announcement released on April 6, 2015.

Table I-2 – FFS USPCC Growth Percentage for CY 2017

	Aged + Disabled	Dialysis –only ESRD
Current projected 2017 FFS USPCC	$825.20	$7,023.24
Prior projected 2016 FFS USPCC	$800.21	$7,155.20
Percent change	3.12%	−1.84%

Table I-3 below shows the monthly actuarial value of the Medicare deductible and coinsurance for 2016 and 2017. In addition, for 2017, the actuarial value of deductibles and coinsurance is being shown for non-ESRD only, since the plan bids will not include ESRD benefits in 2017. These data were furnished by the Office of the Actuary.

Table I-3 - Monthly Actuarial Value of Medicare Deductible and Coinsurance for 2016 and 2017

	2016	2017	Change	2017 non-ESRD
Part A Benefits	$39.57	$39.43	−0.4%	$37.52
Part B Benefits[1]	$118.86	$125.73	5.8%	$116.05
Total Medicare	$158.43	$165.16	4.2%	$153.57

[1]Includes the amounts for outpatient psychiatric charges.

Medical Savings Account (MSA) Plans. The maximum deductible for current law MSA plans for 2017 is $11,650.

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 2018. In addition, this table shows the current projections of the USPCCs through 2019. 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 2019.

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

	Part A		Part B		Part A & Part B		
Calendar Year	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Ratio
2003	$296.18	296.18	$247.66	247.64	$543.84	$543.82	1.000
2004	$314.08	314.08	$271.06	271.03	$585.14	$585.11	1.000
2005	$334.83	334.83	$292.86	292.83	$627.69	$627.66	1.000
2006	$345.30	345.30	$313.70	313.67	$659.00	$658.97	1.000
2007	$355.44	355.47	$330.68	330.65	$686.12	$686.12	1.000
2008	$371.90	371.93	$351.04	351.01	$722.94	$722.94	1.000
2009	$383.93	383.89	$367.93	367.92	$751.86	$751.81	1.000
2010	$382.99	385.42	$376.82	376.84	$759.81	$762.26	0.997
2011	$389.78	389.75	$386.31	386.33	$776.09	$776.08	1.000
2012	$379.28	379.07	$392.90	392.90	$772.18	$771.97	1.000
2013	$381.32	381.24	$399.73	400.31	$781.05	$781.55	0.999
2014	$371.80	371.91	$418.58	419.91	$790.38	$791.82	0.998
2015	$372.10	369.18	$432.53	430.51	$804.63	$799.69	1.006
2016	$375.95	375.14	$441.72	441.69	$817.67	$816.83	1.001
2017	$386.02	386.12	$456.04	460.23	$842.06	$846.35	0.995
2018	$397.89	405.23	$473.50	484.64	$871.39	$889.87	0.979
2019	$410.97		$503.55		$914.52		

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

	Part A		Part B		Part A & Part B		
Calendar Year	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Current Estimate	Last Year's Estimate	Ratio
2010	$369.90	$373.09	$374.91	$374.89	$744.81	$747.98	0.996
2011	$373.81	$373.73	$384.47	$384.47	$758.28	$758.20	1.000
2012	$359.57	$359.23	$392.07	$392.02	$751.64	$751.25	1.001
2013	$365.58	$365.16	$395.99	$396.51	$761.57	$761.67	1.000
2014	$365.88	$364.88	$408.86	$409.90	$774.74	$774.78	1.000
2015	$368.23	$362.92	$426.30	$422.05	$794.53	$784.97	1.012
2016	$370.33	$368.54	$431.08	$431.67	$801.41	$800.21	1.001
2017	$378.95	$380.46	$446.25	$451.24	$825.20	$831.70	0.992
2018	$390.23	398.27	$462.98	473.81	$853.21	$872.08	0.978
2019	$402.64		$491.86		$894.50		

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

	Part A+B		
Calendar Year	Current Estimate	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	$6,719.08	1.000
2013	$6,779.61	$6,779.61	1.000
2014	$6,762.22	$6,863.06	0.985
2015	$6,815.23	$6,997.24	0.974
2016	$6,862.30	$7,155.20	0.959
2017	$7,023.24	$7,413.51	0.947
2018	$7,213.94	$7,731.47	0.933
2019	$7,455.35		

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
2015	1.0151	0.9929	1.0078
2016	1.0294	0.9858	1.0148
2017	1.0610	0.9789	1.0386
2018	1.0975	0.9720	1.0668
2019	1.1422	0.9652	1.1025

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%	3.0%	3.5%
2004	2.6%	3.4%	8.4%
2005	3.5%	3.3%	8.8%
2006	3.2%	3.7%	5.9%
2007	2.9%	3.4%	5.7%
2008	4.1%	2.7%	7.6%
2009	−0.7%	2.7%	6.7%
2010	2.1%	1.9%	3.0%
2011	3.6%	−0.6%	4.9%
2012	2.1%	−0.1%	0.5%
2013	1.4%	2.8%	4.6%
2014	1.5%	0.9%	0.5%
2015	−0.4%	1.4%	2.2%
2016	0.9%	0.9%	3.9%
2017	2.8%	1.4%	5.5%
2018	2.6%	2.8%	6.1%
2019	2.6%	2.5%	6.2%

Part B[2]

Calendar Year	Physician Fee Schedule		Part B Hospital	Total
	Fees[3]	Residual[4]		
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	−0.3%	4.0%	6.3%	4.8%
2009	1.4%	1.6%	5.7%	4.0%
2010	2.3%	1.6%	6.6%	2.4%
2011	0.8%	2.3%	7.1%	2.3%
2012	−1.2%	1.0%	7.3%	1.7%
2013	−0.1%	0.2%	7.4%	0.8%
2014	0.5%	0.7%	12.6%	3.4%
2015	−0.4%	1.0%	6.0%	2.3%
2016	−0.4%	−0.6%	2.8%	1.6%
2017	0.4%	2.2%	8.0%	3.4%
2018	−0.3%	2.9%	7.2%	3.2%
2019	0.6%	6.3%	7.7%	6.0%

[1] Percent change over prior year

[2] Percent change in charges per Aged Part B enrollee.

[3] Reflects the physician update and all legislation affecting physician services—for example, the addition of new preventative services enacted in 1997, 2000, and 2010.

[4] 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	34.437	5.961	33.038	5.215
2004	34.849	6.283	33.294	5.486
2005	35.257	6.610	33.621	5.776
2006	35.795	6.889	33.975	6.017
2007	36.447	7.167	34.465	6.245
2008	37.378	7.362	35.140	6.438
2009	38.257	7.574	35.832	6.664
2010	39.091	7.832	36.516	6.938
2011	39.930	8.163	37.229	7.247
2012	41.666	8.403	38.526	7.496
2013	43.066	8.620	39.759	7.725
2014	44.516	8.733	41.041	7.879
2015	45.714	8.712	42.280	7.926
2016	47.514	8.749	43.616	7.951
2017	49.089	8.788	44.992	7.991
2018	50.709	8.866	46.419	8.056
2019	52.395	8.937	47.894	8.121

Non-ESRD Fee for Service

	Part A		Part B	
Calendar Year	Aged	Disabled	Aged	Disabled
2003	29.593	5.628	28.097	4.875
2004	29.946	5.931	28.300	5.128
2005	30.014	6.178	28.287	5.339
2006	29.365	6.146	27.462	5.267
2007	28.838	6.226	26.782	5.297
2008	28.613	6.241	26.301	5.311
2009	28.563	6.288	26.071	5.374
2010	28.903	6.455	26.261	5.556
2011	29.190	6.650	26.421	5.730
2012	29.940	6.685	26.724	5.772
2013	30.309	6.683	26.928	5.783
2014	30.586	6.576	27.038	5.718
2015	30.751	6.349	27.243	5.559
2016	31.721	6.246	27.748	5.445
2017	32.427	6.165	28.251	5.364
2018	33.255	6.134	28.882	5.321
2019	34.159	6.097	29.571	5.278

ESRD

Calendar Year	ESRD-Total		ESRD-Fee for Service	
	Total Part A	Total Part B	Total Part A	Total Part B
2003	0.340	0.331	0.319	0.309
2004	0.353	0.342	0.332	0.321
2005	0.366	0.355	0.344	0.332
2006	0.382	0.370	0.353	0.340
2007	0.396	0.383	0.361	0.347
2008	0.411	0.397	0.367	0.353
2009	0.426	0.412	0.374	0.360
2010	0.442	0.428	0.388	0.373
2011	0.456	0.441	0.398	0.383
2012	0.471	0.455	0.408	0.393
2013	0.483	0.468	0.414	0.398
2014	0.495	0.480	0.416	0.401
2015	0.504	0.489	0.415	0.400
2016	0.514	0.500	0.419	0.404
2017	0.525	0.511	0.424	0.410
2018	0.536	0.522	0.432	0.417
2019	0.548	0.533	0.438	0.424

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

Calendar Year	Inpatient Hospital	SNF	Home Health	Managed Care	Hospice: Total Reimbursement (in Millions)
	Aged + Disabled	Aged + Disabled	Aged + Disabled	Aged + Disabled	Aged + Disabled
2003	2,594.78	370.63	124.28	457.87	5,733
2004	2,714.57	413.44	133.89	500.73	6,832
2005	2,818.21	450.54	140.87	602.29	8,016
2006	2,764.82	475.07	141.30	757.20	9,368
2007	2,707.49	504.24	143.72	905.77	10,518
2008	2,695.88	536.68	151.00	1,075.01	11,404
2009	2,651.47	551.67	153.86	1,246.31	12,274
2010	2,615.34	571.72	155.17	1,250.04	13,126
2011	2,602.24	624.93	143.61	1,300.70	14,034
2012	2,504.45	543.60	136.02	1,360.79	15,045
2013	2,493.61	542.29	133.48	1,400.15	15,466
2014	2,430.53	536.00	128.47	1,360.42	15,506
2015	2,377.54	545.49	124.77	1,411.88	16,212
2016	2,354.83	559.05	124.16	1,469.13	17,264
2017	2,368.01	579.59	125.79	1,554.41	18,522
2018	2,416.83	594.39	128.29	1,630.61	19,713
2019	2,471.56	617.19	133.78	1,713.00	21,218

Average reimbursement per enrollee on an incurred basis, except where noted. Does not reflect the effects of the Independent Payment Advisory Board (IPAB)

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	1226.49	364.77	196.96
2004	1343.99	418.85	195.61
2005	1397.41	477.65	196.83
2006	1396.39	497.47	197.78
2007	1368.35	526.92	195.68
2008	1367.83	555.09	200.92
2009	1375.29	592.77	183.61
2010	1413.77	628.55	183.76
2011	1440.63	668.61	175.58
2012	1396.64	704.50	173.34
2013	1353.67	743.47	152.30
2014	1334.67	820.85	128.34
2015	1338.07	857.87	134.19
2016	1312.82	871.92	126.40
2017	1320.19	925.58	123.34
2018	1356.84	982.07	129.93
2019	1444.54	1047.00	135.51

Calendar Year	Carrier Lab Aged + Disabled	Other Carrier Aged + Disabled	Intermediary Lab Aged + Disabled
2003	73.73	329.81	75.18
2004	78.48	354.00	80.47
2005	82.71	362.81	84.16
2006	85.59	361.08	84.51
2007	90.65	363.52	84.38
2008	94.50	366.62	85.78
2009	101.80	385.20	79.19
2010	101.08	393.78	80.23
2011	102.08	406.81	83.19
2012	109.62	409.90	84.59
2013	109.51	409.29	81.78
2014	115.06	411.27	55.54
2015	118.87	416.70	56.21
2016	121.56	417.19	57.02
2017	117.81	423.92	54.73
2018	121.55	437.75	56.36
2019	125.25	451.37	58.09

Average reimbursement per enrollee on an incurred basis, except where noted. Does not reflect the effects of the Independent Payment Advisory Board (IPAB)

Calendar Year	Other Intermediary Aged + Disabled	Home Health Aged + Disabled	Managed Care Aged + Disabled
2003	113.99	136.75	421.40
2004	119.58	156.45	471.37
2005	139.78	179.44	560.31
2006	142.09	202.88	769.94
2007	151.16	232.33	931.18
2008	158.20	252.43	1104.26
2009	187.44	282.09	1203.83
2010	193.08	283.25	1221.65
2011	198.45	262.37	1277.69
2012	205.00	246.82	1368.93
2013	194.42	240.61	1498.09
2014	200.16	233.22	1709.38
2015	212.72	225.54	1816.00
2016	216.96	225.75	1936.62
2017	224.74	228.79	2038.46
2018	193.46	233.49	2155.04
2019	200.11	243.61	2333.89

Average reimbursement per enrollee on an incurred basis, except where noted. Does not reflect the effects of the Independent Payment Advisory Board (IPAB)

2017 Projections by Service Category for non-ESRD (Aged+Disabled)*

Service Type	Current Estimate	Last Year's Estimate	Ratio
Part A			
Inpatient Hospital	2,368.01	2,364.02	1.002
SNF	579.59	591.47	0.980
Home Health	125.79	130.30	0.965
Managed Care	1,554.41	1,542.97	1.007
Part B			
Physician Fee Schedule	1320.19	1,342.86	0.983
Part B Hospital	925.58	978.42	0.946
Durable Medical Equipment	123.34	118.56	1.040
Carrier Lab	117.81	116.00	1.016
Other Carrier	423.92	413.41	1.025
Intermediary Lab	54.73	55.41	0.988
Other Intermediary	224.74	183.63	1.224
Home Health	228.79	240.83	0.950
Managed Care	2038.46	2,060.97	0.989

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

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	0.001003	0.002884
2015	0.000952	0.002730
2016	0.000952	0.002730
2017	0.000952	0.002730
2018	0.000952	0.002730
2019	0.000952	0.002730

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 2017 (before adjustment for prior years' over/under estimates) is calculated by adding the USPCCs for Part A and Part B for 2017 and then dividing by the sum of the current estimates of the USPCCs for Part A and Part B for 2016.

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 on Part C Payment Policy

Section A. Final Estimate of the National Per Capita Growth Percentage and the Fee-for-Service (FFS) Growth Percentage for Calendar Year 2017

Comment: One commenter thanked CMS for providing timely data, including preliminary estimates of the growth rates.

Response: CMS appreciates the support and will continue to provide timely data when possible.

Comment: CMS received one comment expressing appreciation for the details provided on the factors used in the calculation of the growth rates.

Response: CMS appreciates the support.

Comment: Commenters requested more transparency regarding the calculation of the growth rate. Commenters requested that CMS provide plans with a full explanation of the methodology and assumptions underlying the growth rate, so that plans can conduct careful analysis and provide meaningful comment

Response: We believe that we are providing useful information and support pertaining to USPCC levels and trends. Key economic assumptions underlying the USPCCs are included in attachment II of this payment notice. Consistent with prior years, we will publish additional information regarding trends for the prior five years at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/FFS-Trends.html and will discuss this material on an actuarial user group call.

Comment: One commenter requested an explanation on why the National Health Expenditures forecasts show 3.3% per enrollee spending growth for Medicare in 2017, while the CMS projected benchmark growth is lower than this.

Response: A key difference between the two baselines is that that total USPCC growth rate is based on more complete historical experience than the NHE. Other differences between the projections include the treatment of hospice benefits, covered population (e.g., ESRD), administrative costs, sequestration, and bonuses for use of electronic health records.

Comment: Two commenters expressed concern that there may be significant adjustments between the growth rate in the Advance Notice and the growth rate in the Rate Announcement, as there has been in previous years. These commenters requested that CMS work to prevent adjustments in order to avoid disruption to the MA program.

Response: Each release of the growth rates reflects our best estimate at that time of historical program experience and projected trend. We always strive to improve our forecasting accuracy with incorporation of additional data and the refinement of our analytic modeling.

Comment: One commenter asked that CMS not make any major adjustments to the growth rate in the Rate Announcement because plans will not have a chance to review the changes and provide comments. This commenter also suggested that CMS review all of its assumptions, including any changes in assumptions from prior years, in order to avoid disruption in the MA program.

Response: The growth percentages and total USPCC and FFS USPCCs reflected in Attachment II of this payment announcement are based on the Office of the Actuary's (OACT's) best estimate of historical project experience and program trend. We continue to believe that the best practice is to base the growth rates on the most recent data and assumptions.

Comment: CMS received one comment asking for clarification on the meaningfulness of the MA growth percentage now that all counties are phased in. This commenter requested that CMS clarify whether the FFS growth percentage is now the driving number and if the MA growth rate percentage will now only be used for calculating the benchmark cap. This commenter also suggests that CMS present the FFS growth percentage before the MA growth percentage.

Response: The specified amounts, or FFS rates, are based on the FFS USPCC. Also, the applicable amount, or pre-Affordable Care Act rate, established under SSA section 1853(k)(1) is updated by the growth in the total USPCC. We will consider modifying the presentation of the USPCCs and growth rates in future rate announcements.

Comment: Several commenters expressed concern that the ESRD growth rate is significantly lower than the FFS and MA growth rates. Commenters requested additional information and explanation for this difference. Commenters stated that they are worried that this negative growth rate will have adverse effects on beneficiaries.

Response: The preliminary CY 2017 growth rate for the ESRD population reflects a prior period adjustment of −4.35 percent. This adjustment is primarily due to lower experience for the dialysis population for calendar year 2014 combined with a negative differential in the growth rate in 2015 and 2016 between the total ESRD and dialysis-only populations. The increase from 2016 to 2017 tabulated on the current baseline is 2.04 percent. Combining the prior period update of −4.35 percent and the current trend of 2.04 percent yields the preliminary 2017 ESRD growth rate of −2.39 percent.

Also, we agree that the negative ESRD FFS USPCC update for 2017 could have an adverse effect on beneficiary premiums and/or supplemental benefits. We encourage plan sponsors to take into account beneficiary impacts in their design of 2017 MA and MA-PD plan benefits, consistent with CMS' policies.

Comment: Two commenters noted that ESRD rates have fluctuated from year to year. These commenters stated that it is unclear why there would be such significant oscillation. These two commenters stated that the fluctuation in ESRD rates make it difficult for plans to design and

maintain stable benefit packages, especially for such a vulnerable population. The commenters requested that CMS provide additional details behind the significant year to year oscillations in the ESRD calculations, as well as review the rates for accuracy.

Response: We agree that predictable growth rates for the ESRD population are important to Medicare Advantage plans that cover the ESRD population. The recent trend in ESRD population reflects several recent program changes including the bundling of Part B services, audits conducted by Recovery Audit Contractors, the "two midnight" hospital policy, and the implementation of DMEPOS competitive bidding.

Section B. MA Benchmark, Quality Bonus Payments and Rebate

Comment: Several commenters expressed concern that the pre-ACA rate cap penalizes high quality plans and plans that offer services in higher-cost areas. Commenters suggested that CMS review its options for exercising discretionary authority to remove the quality bonuses from the benchmark cap calculation. One commenter believes that including the bonus in the cap calculation contradicts the intent of Congress to provide quality bonuses to high performing plans and to establish a value-based purchasing component in MA. Commenters believe that the statute can be interpreted to allow the Secretary the discretion to exclude quality bonuses from the benchmark cap calculation. One commenter indicated that the language used in section 1853(n)(4) refers to "taking into account" the quality bonuses, suggesting that the Secretary could consider the quality bonus payments but then exercise discretion to omit them from the cap calculation. Another commenter suggested that the Applicable Amount was a cap on the blended benchmarks only during the Applicable Amount's phase-out period; and since the Applicable Amount is no longer included in the benchmark calculation, the statute does not require the cap to remain in place for 2017.

Response: CMS shares the commenters' concern about any rate-setting mechanism that diminishes incentives for MA plans to continuously improve the care provided to Medicare beneficiaries. While we appreciate the concerns of commenters, we do not believe we have the discretion under section 1853(n)(4) of the Social Security Act to eliminate application of the pre-ACA rate cap or exclude the bonus payment from the cap calculation. The bonus payment is based on an increase to the "applicable percentage" which is a component of the benchmark calculation itself. Further, the plain reading of the statute does not indicate congressional intent to limit the benchmark cap to the transition period described in section 1853(n)(3) of the Act. When Congress has wanted to authorize or mandate MA payment rules that apply for specific periods of time, Congress has done so using specific date parameters; section 1853 of the Act includes numerous examples of this.

Comment: One commenter requested clarification regarding quality bonus payments for low enrollment plans. The commenter questioned whether quality bonus payments for low

enrollment plans should be based on an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts.

Response: Section 1853(o)(3)(A)(ii) does not address the amount of the quality bonus payment increase for low enrollment contracts. We interpret section 1853(o)(3) of the Act as establishing two types of qualifying plans for purposes of applying the quality bonus, with the amount of the quality bonus determined by the basis for treatment of the plan as a qualifying plan (i.e., whether the amount is based on the score produced under the Star Rating system or based on the default increase specified in the case of new MA plans). For the purpose of determining a quality bonus percentage, the Advance Notice uses the term "new MA plan" to refer to an MA plan offered by a parent organization that has not had another MA contract in the preceding three-year-period. As discussed in the Advance Notice, we treat new MA plans and low enrollment plans (i.e., plans offered under a contract that lacks sufficient enrollment and data for the calculation of a Star Rating) as qualifying plans that are eligible to receive a 3.5 percentage point quality bonus percentage increase to the county rates. We believe that new MA plans and low enrollment plans should receive the same treatment for the purpose of establishing the amount of quality bonus payments because each type of plan has insufficient data available for the calculation of a Star Rating. This is consistent with our treatment of low enrollment contracts for purposes of determining the rebate available to the plan.

Comment: Two commenters suggested that CMS establish a minimum benchmark level for counties in Puerto Rico, such as maintaining the MA benchmarks in Puerto Rico at previous levels.

Response: We appreciate the concerns raised by the commenters. However, we do not believe the approach suggested by these comments would be permissible under statute.

Comment: One commenter suggested that CMS reevaluate Puerto Rico's eligibility for the Qualifying County Bonus Payment. The commenter noted that, in 2016, Puerto Rico was the only jurisdiction where all of its counties achieved two of the three conditions required to be considered a qualifying county. The one criterion that Puerto Rico did not meet was that 2004 MA capitation must have been based on the amount specified in section 1853(c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000. While Puerto Rico has the highest level of MA penetration in the nation (over 75%), the commenter believes that Puerto Rico is disadvantaged by its population being divided into an unusually high number of counties (78). The commenter suggested that CMS evaluate Puerto Rico's eligibility for the Qualifying County Bonus Payment by considering population counts by the Census Bureau's Metropolitan Areas (rather than by county), or by removing one of the three qualifying criteria for Puerto Rico.

Response: We appreciate the concerns raised by the commenter. However, we do not believe the approach suggested by these comments would be permissible under statute.

Section C. Calculation of Fee for Service Cost

Comment: Several commenters expressed concern regarding CMS rebasing in 2017 due to rate unpredictability and fluctuation. Commenters noted that rebasing has occurred every year since 2012, and noted that it is not required annually by statute. One commenter proposed rebasing FFS county rates every other year. A few commenters asked that CMS institute a regular schedule of rebasing once every three years. Two commenters suggested that CMS adopt a corridor to smooth the rebasing fluctuations whereby county benchmarks would be prevented from increasing or decreasing by more than a specified amount.

Response: Given that MA county rates are based on FFS costs, we believe it is important to update the FFS rates using the most current FFS data available. We stated in previous Rate Announcements that we anticipate rebasing each 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 also note that our method for calculating the county level rates includes a five-year average that provides some measure of stability in the rates.

Comment: One commenter offered support for including shared savings and losses incurred under the Medicare Shared Savings Program (MSSP) and Pioneer ACO programs. The commenter requested that CMS consider including additional adjustments for other CMS/CMMI programs, such as the Comprehensive Primary Care Initiative.

Response: We appreciate the support regarding the inclusion in the fee-for-service experience the shared savings payment and shared losses made to MSSP and Pioneer ACOs. We recognize that there are other CMS/CMMI programs with incentive payments for the years 2010-2014. Such programs include the Comprehensive Primary Care Initiative, Physician Group Practice Demonstration, and the Independence at Home Demonstration. Incentive payments made under these programs are small relative to the MSSP and Pioneer ACO programs. Due to operational challenges, CMS will not reflect the payments made under these programs in the CY 2017 ratebook. We will consider including payments made under additional CMS/CMMI programs in future years.

Comment: One commenter requested more transparency on the calculation of the FFS rates, by releasing county-level FFS costs of the most recent 5-year period. A few commenters requested that information related to rebasing be released with the Advance Notice. One commenter asked for additional information pertaining to the adjustment for care through the Veterans Health Administration.

Response: We are publishing with the final Rate Announcement files that contain the wage indices in each claim year (i.e., 2010-2014), and the wage indices for 2016 by county. We annually publish, with the final Rate Announcement, files that contain the county-level adjustments that are applied to the FFS costs, including the adjustment for Veterans Affairs. We

will consider publishing additional data with the Advance Notice in future years that can help stakeholders understand the potential impacts of proposed changes in the Advance Notice.

Comment: One commenter requested that CMS apply a uniform approach in all counties to calculate benchmarks on beneficiaries with both Part A and Part B coverage, as is currently done in Puerto Rico. The commenter noted that other counties beyond Puerto Rico, such as in Hawaii, have high MA penetration rates and low FFS Part B enrollment.

Response: While most Medicare beneficiaries are automatically enrolled in Part B and must opt out to decline it, beneficiaries in Puerto Rico must take affirmative action to opt-in to Part B coverage. As a result, CMS believes it is appropriate to adjust the FFS rate calculation in Puerto Rico used to determine MA rates so that it is based on beneficiaries who are enrolled in both Part A and Part B. We will consider expanding this Part A and Part B adjustment to all counties in the future.

Comment: A few commenters expressed concern regarding the change of data source for county designation of beneficiaries used in the summarization of risk scores. Commenters requested that CMS provide more information regarding this change (such as information pertaining to the accuracy of each data source, the mismatch rate between the two sources, and county-level impacts of switching data sources).

Response: The change in county source for the risk score assignment will align the county codes used to assign risk scores, claims, and enrollment. Based on the CY 2016 ratebook county codes, risk score changes for 88 percent of the counties were within 2 percent. Further, only 5 percent of the counties had a change in risk score of greater than 5 percent due to the change in the source of the beneficiary's county code.

Comment: In the Advance Notice, CMS sought public comment on the possibility of adjusting FFS experience in Puerto Rico to reflect the propensity of zero claimants nationwide. Several commenters requested that CMS make an adjustment to the Puerto Rico MA rates to reflect the prevalence of zero-dollar-claimants. Commenters reiterated that there is a larger proportion of FFS Medicare beneficiaries in Puerto Rico with coverage for Medicare Parts A and B that have no Medicare claim reimbursements compared to other jurisdictions, which they believe is skewing the rate calculation for Puerto Rico. Commenters suggested that, to make such an adjustment, CMS should identify beneficiaries with zero Medicare claim experience over 24 consecutive months (i.e., zero claims during a two-year period), and exclude these zero-claim beneficiaries (and their risk score) when developing per capita costs. Commenters propose that CMS would then apply an adjustment for the zero-claim beneficiaries.

Response: The Secretary has directed the Office of the Actuary to adjust the fee-for-service experience for beneficiaries enrolled in Puerto Rico to reflect the propensity of zero dollar claimants nationwide. For purposes of making this adjustment, consistent with the Secretary's

instructions, the Office of the Actuary evaluated experience exclusively for beneficiaries that are enrolled in both Parts A and B and are not dually eligible for VA coverage.

The study analyzed experience for calendar years 2011 through 2013 and only considered FFS beneficiaries enrolled mid-year. On average, 14.3 percent of A&B Puerto Rico FFS beneficiaries were found to have no Medicare claim reimbursements per year. This compares to a nationwide, non-territory, proportion of 6.1 percent of FFS beneficiaries without Medicare spending. These results were applied to the Puerto Rico FFS experience by adjusting the weighting of the enrollment and risk scores for the zero-claim cohort to reflect the nationwide proportion of zero-claim beneficiaries. The resulting impact was an average increase in the standardized FFS costs in Puerto Rico of 4.4 percent for 2011 through 2013. Accordingly, a 4.4 percent adjustment was applied to the pre-standardized Puerto Rico FFS rates supporting the CY 2017 ratebook development.

Comment: A few commenters believe that FFS experience is not sufficient to establish accurate MA benchmarks in Puerto Rico. Commenters expressed concern that FFS data used by CMS to set the MA rates for Puerto Rico are not representative of the population to which rates are applied, citing the lower dual-eligible penetration in FFS than exists in MA. Commenters noted the low level of FFS enrollment in Puerto Rico, and furthermore noted that the FFS costs in Puerto Rico appear to have low levels of health care utilization. Commenters suggested that CMS not rebase rates in Puerto Rico for 2017 while there are concerns regarding the data used to set MA benchmarks. One commenter requested that CMS use another jurisdiction as a proxy to set benchmarks in Puerto Rico.

Response: We appreciate the concerns commenters have raised regarding Puerto Rico. As explained in the Advance Notice, CMS believes that the FFS data in Puerto Rico is sufficient for establishing accurate MA benchmarks as well as consistent with the statutory requirements. We will continue to analyze these issues and consider whether any refinements to the methodology may be warranted in future years.

Comment: One commenter requested that CMS adjust MA rates to account for anticipated changes in Part A (SSI eligible simulation for Uncompensated Care) and Part B (Practice Expense GPCI) rates through CMS rulemaking. The commenter noted that, as part of the FY FFS rulemaking process, two specific issues are still being evaluated that could generate Part A and Part B rate increases in the FFS program of Puerto Rico starting October 1st 2016 (Part A) and January 1st 2017 (Part B). The commenter mentioned the timing of the rulemaking process versus 2017 rate-setting, and was concerned about a potential imbalance in MA 2017 payments if no adjustment were made to FFS costs.

Response: Consistent with prior years, we have adjusted the historical ratebook FFS data to reflect payment parameters that are finalized at time of the Rate Announcement. Accordingly, the CY 2017 ratebook repricing reflects the latest regulations for fiscal year 2016 (for example:

inpatient hospital, outpatient hospital, and skilled nursing facilities) and calendar year 2016 (for example: geographic practice cost index, and DMEPOS payment schedules). Further, the Puerto Rico inpatient hospital claims have been repriced to reflect the provisions of the Consolidated Appropriations Act, 2016.

Comment: Two commenters expressed support regarding developing rates in Puerto Rico based on claims and enrollment for beneficiaries with Part A eligibility and Part B enrollment. A few commenters expressed support regarding the re-pricing of historical inpatient claims to include the recent legislation that increased the Medicare inpatient payment rates for hospitals in Puerto Rico.

Response: We appreciate the support.

Section D. ESRD Rates

Comment: Two commenters expressed concern regarding the volatility of the ESRD rates, citing the decrease from the 2017 projection in the 2016 Rate Announcement. One of the commenters suggested several rate-setting options such as not allowing ESRD rates to drop below the previous year's rate and/or carving-out organ acquisition costs from the ESRD rate.

Response: We appreciate the concerns the commenters raised. However, we do not believe the approach suggested by these comments would be permissible under statute.

Section E. Clinical Trials

Comment: One commenter opposed our proposal to continue to pay on a fee-for-service basis for qualified clinical trial items and services provided to MA enrollees in clinical trials that are covered under the National Coverage Determinations (NCDs) on clinical trials. The commenter recommended that we require MA plans to cover the cost of clinical trials. The commenter incorrectly stated that, under CMS' current policy, beneficiaries who wish to participate in clinical trials are forced to relinquish their MA coverage and switch to FFS Medicare, where they would be required to cover all deductibles, copays, and the 20 percent coinsurance for all charges associated with clinical trial care. The commenter stated that this policy creates a disincentive for Medicare enrollees with serious or life-threatening diseases, such as cancer, who may benefit from innovative treatments and health care services through clinical trials. The commenter indicated that, if individuals are discouraged from participating in clinical trials for cost reasons, it will be more difficult for physicians to appropriately assess the therapeutic value of new drugs and devices in the Medicare population until they are available in the general marketplace.

Response: As we stated in the Advance Notice, MA enrollees are able to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare. CMS does not require MA enrollees to disenroll from their MA plan if they wish to participate in a clinical trial.

We note that our policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA enrollees only applies to clinical trials that meet the criteria to qualify for coverage under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) (Medicare NCD Manual, Pub. 100-3, Part 4, Section 310.1). CMS has previously made the determination that all clinical trials that qualify for coverage under NCD 310.1 trigger the significant cost threshold such that coverage and payment are controlled by 42 CFR 422.109(c). With respect to individual NCDs requiring coverage with evidence development (CED), MAOs are responsible for covering items and services in CMS-approved clinical trials that meet the requirements defined in the NCD, unless CMS determines, for each NCD, that the significant cost threshold is exceeded for that item or service (see § 422.109).

We do not believe that our current policy creates a disincentive for MA enrollees to participate in clinical trials, or that MA enrollees would have a greater incentive to participate in clinical trials if MAOs were responsible for costs of qualified clinical trial items and services that are currently covered on an FFS basis in clinical trials that qualify for coverage under NCD 310.1. Under our clinical trials policy, for CY 2011 and subsequent years, MAOs must reimburse enrollees for the difference between the FFS cost sharing for covered clinical trial services and the plan's in-network cost sharing for services of the same type, and the member's cost sharing liabilities must count towards the MA plan's in-network out-of-pocket maximum. This cost-sharing requirement applies to all qualifying clinical trials; MAOs cannot choose the clinical trials or clinical trial items and services for which this policy applies. The requirement that MAOs provide in-network cost-sharing for all qualifying clinical trials services means, in effect, that MA plan enrollees incur the same cost-sharing for clinical trials services that they would incur if the services were covered by the MAO, rather than by FFS Medicare. As we stated in the CY 2011 Rate Announcement, we believe this policy increases MA enrollees' participation in, and access to, clinical trial services.

For more information on these policies, please refer to the Medicare Managed Care Manual, Pub. 100-16, Chapter 4 (Benefits and Beneficiary Protections), section 10.7 (Clinical Trials).

Section F. MA Employer Group Waiver Plans

We are finalizing the methodology that we proposed for calculating EGWP county payment rates with two modifications. First, in order to release final EGWP county payment rates in the Rate Announcement, we will use the average bid-to-benchmark ratio for individual market plan bids, including RPPOs, from the prior payment year to calculate the Part C base payment amounts for EGWPs. For example, the EGWP county payment rates for 2017 have been calculated using 2016 bid-to-benchmark ratios. Second, to provide employers and MAOs more time to adapt to this payment change, we are providing a two-year transition to the new EGWP county payment rate methodology. Under this approach, for 2017, we have moderated the impact of the new policy by blending individual market plan and EGWP bids to calculate the bid-to-benchmark

ratios (as described below). In 2018, we will fully implement the new policy and, therefore, will use only individual market plan bids to calculate the bid-to-benchmark ratios.

We are finalizing the following methodology for calculating EGWP county payment rates:

- First, a weighted average bid-to-benchmark ratio for the prior payment year is calculated at the quartile[1] level.

    - For 2017, the bid-to-benchmark ratio has been calculated using a blend of individual market plan bids and EGWP bids from 2016, with individual market plan bids weighted by 50 percent and EGWP bids weighted by 50 percent. The calculation is: [(weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for individual market plan bids by actual enrollment)/(weighted average of the county standardized benchmarks for individual market plan bids by actual enrollment)] x 50% plus [(weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts for EGWP bids by actual enrollment)/(weighted average of the county standardized benchmarks for EGWP plan bids by actual enrollment)] x 50% = percentage by quartile.[2]

    - For 2018 and future years, the bid-to-benchmark ratios will be calculated using individual market plan bids only. The calculation will be: (weighted average of the intra-service area rate adjustment (ISAR) adjusted county bid amounts by actual enrollment)/(weighted average of the county standardized benchmarks by actual enrollment) = percentage by quartile. [2]

- The percentages are applied to each of the published 5%, 3.5% and 0% bonus county ratebook rates for the payment year to establish Part C base payment amounts for EGWPs based on their star rating for each county.

- In order to calculate a county rebate payment, each county level EGWP Part C base payment amount is compared to the corresponding published 5%, 3.5% and 0% bonus county benchmarks for the payment year to determine the amount of savings. The savings

[1] As described in more detail in the Advance Notice, to determine the CY 2017 applicable percentages, CMS ranks counties from highest to lowest based upon their 2016 average per capita FFS costs and places the rates into four quartiles. When calculating the bid-to-benchmark ratios CMS grouped them by the 2016 unblended quartiles, these bid-to-benchmark ratios are then applied to the 2017 unblended quartiles.

[2] Territories will not be included in the weighted average bid-to-benchmark ratio, but will be assigned the weighted average of the quartile within which their counties fall.

amount is multiplied by the corresponding star rebate percentage to determine the Part C EGWP county level rebate amount.

- The EGWP Part C base payment amount is added to the Part C EGWP rebate amount to establish the county level EGWP total payment amount.

- The total payment amount will be risk adjusted in payment using beneficiary-specific risk scores. Therefore, the formula applied for payment will be: (base county payment rate + county rebate) * beneficiary level risk score

For RPPO EGWPs, the weighted average bid-to-benchmark ratios will be calculated as described in the first bullet above, then, as described in the Advance Notice, to establish the Part C base RPPO EGWP payment amount, we would also apply the same methodology as described above in the second bullet. In order to calculate the regional rebate amounts, these percentages will be applied for each county within a region to the published payment year regional benchmarks to establish the savings amount and rebate amounts by star rating and quartile. So the formula applied for payment for RPPO EGWPs would be: (base county payment rate + regional rebate) × beneficiary level risk score. As stated in the Advance Notice, the final MA regional standardized A/B benchmarks released in late summer will reflect the average bid component of the regional benchmark based on non-EGWP bid submissions.

The 2017 county payment rates for non-RPPO EGWPs can be found at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The 2017 EGWP RPPO payment rates will be released concurrently with the 2017 Regional MA benchmark release.

Comment: A few commenters support our proposal due to the government savings and greater payment equity between MA EGWP and MA non-EGWP plans.

Response: We appreciate the support.

Comment: One Medicare Advantage Organization in support of the proposal explained that the current approach to filing EGWP bids is cumbersome for both health plans and CMS. Plans often submit many bids accounting for different structural characteristics but without specified benefit level differences. Since benefits are not being decided during the bid process, beyond the technical requirements under the current compensation system, the purpose of this additional bid development work is not clear.

Response: We appreciate the support.

Comment: Many commenters requested that CMS delay implementation, or to consider a phase-in approach by setting the bid-to-benchmark ratios at a higher level than calculated then stepping them down over time at incremental target ratios. One commenter also suggested that CMS use

distributions or ratios from the 2016 bid year to publish rates in the 2017 Final Rate Announcement.

Response: We appreciate the flexibilities these commenters suggested be incorporated into the methodology. In order to address these requests, under the methodology we are finalizing as described above, we are releasing 2017 final non-RPPO EGWP county payment rates with this Rate Announcement and we will provide for a two-year transition to the new payment approach for EGWPs.

Comment: A large number of commenters maintained that CMS does not have the legal authority to make this payment change given that the purpose of employer group waivers, under the statute, is to enhance and promote the offering of these types of retiree plans. These commenters indicated in large part that Section 1857(i) does not give the Secretary the authority to offer a new payment methodology for EGWPs. Instead the authority given to the Secretary is to "facilitate" EGWPs by waiving or modifying requirements that "hinder" EGWPs. Commenters believe that the statutory waiver authority does not provide CMS with the authority to modify the core statutory payment terms in a manner that hinders EGWPs, by characterizing the change as a condition for waiving of other program requirements.

Many comments asserted that the CMS proposal does not seem to be waiving or modifying a methodology that hinders EGWPs. These commenters believe, instead, that it is the methodology being proposed by CMS that will hinder EGWPs by creating an obstacle to offering EGWPs, by increasing premiums and reducing benefits, which these commenters believe is contrary to Congress's intent in establishing CMS's waiver authority. Many commenters further stated that CMS acted in an arbitrary and capricious manner by not presenting data supporting its argument that the waiver was authorized by statute.

Finally, several other commenters asserted that the proposed changes are inconsistent with the regulations, asserting that CMS may not implement substantive changes to the MA bidding and payment process through sub regulatory guidance that contradicts, but leaves intact, existing regulations. These commenters believe that CMS must engage in rulemaking so that its regulations accurately reflect the distinct payment methodology CMS is proposing for EGWPs.

Response: Medicare Advantage Organizations (MAOs) are required to submit to CMS a detailed description of the benefits provided for each individual market plan they offer. MAOs are also required to submit to CMS a bid for each of these plan benefit packages which includes detailed pricing experience, assumptions and projections. MAOs negotiate with individual employers to provide Medicare Advantage plans that exclusively enroll their retirees. To facilitate the offering of such employer plans, CMS has waived the requirement for MAOs to submit plan benefit package information and unique bids for each of the plans that they offer to employers. Under this approach, MAOs may submit a single composite benefit package and bid for EGWPs and are allowed to customize that benefit package and bid pricing for each of the various

arrangements they negotiate with employers. Associated with the waiver of having a financial bid for each benefit package, CMS has also waived requirements related to the uniformity of premiums and provided waivers that permit negotiation and customization of benefit packages throughout the year rather than being limited by specific benefit packages that have been submitted with bids; using this flexibility, MAOs offering EGWPs (and employers that directly offer an EGWP) can - throughout the year – vary benefits from the composite bid that is currently submitted in order to offer enhanced or customized supplemental benefits.

This approach has reduced the administrative burden for MAO sponsors of EGWPs, but also means that CMS does not know how many EGWP plans any MAO offers, what specific benefits are provided in each of those plans, or the associated underlying costs. This lack of transparency has significantly impaired CMS' ability to comprehensively review and assess the reasonableness of the underlying actuarial assumptions and projections included in the bids submitted for EGWPs and to trace how federal funds, in the form of the capitation payments and the rebates, are spent for beneficiaries in specific EGWPs. This lack of transparency, combined with the fact that EGWPs do not compete in the open market, has resulted in EGWP bids that are systematically higher than bids for individual market MA plans. MedPAC has calculated that in 2012 margins were substantially higher for EGWPs (7.2%) than for other plans (4.4%). *See, e.g.*, MedPac, March 2015 Report to Congress; http://www.medpac.gov/documents/reports/chapter-13-the-medicare-advantage-program-status-report-(march-2015-report).pdf.

Given the lack of competition and transparency associated with EGWP bidding, we do not believe that the current policy of allowing MAOs to submit composite bids and benefit packages is sustainable. Instead of maintaining the current policy, we considered whether to revert to the statutory and regulatory requirement of requiring EGWP sponsors to submit to CMS for review and approval individual benefit packages and bids for each of their employer plans. However, we concluded that the administrative burden for MAOs and employers of such an approach, in addition to the significant challenges for CMS associated with expanding our review process to accommodate thousands of additional benefit packages and bids, would substantially hinder the offering of these plans.[3] As part of developing and submitting a financial bid for each plan benefit package, the MAO would have to commit to specific plan benefit packages at the time of the bid; the flexibility to modify benefits and customize plan offerings for employers would be limited compared to the flexibility provided under the composite bid waiver; changes after bid submission or mid-year would be more difficult. Using the statutory and regulatory bid

[3] This consideration of how requirements on CMS may contribute to hindering the offering of EGWPs is consistent with our past approach to exercising the authority under section 1853(i). 71 FR 22082 ("Specifically, because we do not receive and review these benefits we cannot appropriately oversee their provision and requiring submission of these benefits needs to be waived because we believe it would hinder the design of, offering, or enrollment in employer sponsored coverage.").

requirements would hinder the offering and design of MA plans by employers (either when offered under a contract with an MAO or offered directly). We, therefore, concluded that our proposed policy was the best framework for facilitating the offering of EGWPs and ensuring appropriate payments to such plans.

Section 1853(b) requires that CMS use the Advance Notice and Rate Announcement process for changes in Part C and D payment methodology; this proposal relates to the Part C payment methodology for EGWPs. Section 1853(b) requires us to provide advance notice of the proposed changes and to explain in the final Rate Announcement the assumptions and changes in methodology for payments to MA plans. We have complied with those requirements in proposing and finalizing this change in the methodology and assumptions for establishing the capitation rates (and rebate payments) for EGWPs. Moreover, not all waivers issued under section 1857(i) are in the MA regulations.[4] Indeed, when CMS implemented the EGWP waiver for Part D bidding to reduce administrative burden, CMS notified Part D sponsors of that waiver via an HPMS memo, stating in relevant part, "CMS believes that waiving the requirement to submit 2008 Part D bids will facilitate the offering of plans for employers and unions seeking to retain high quality coverage for their Medicare eligible retirees by avoiding the cost and administrative burden of submitting these bids."[5] The MA bid requirements are extensive and require significant documentation from actuaries, more so than is required in Part D bids; further, other flexibilities are associated with and flow from a waiver of the bidding requirements for EGWPs. CMS therefore believes that waiving the bidding requirements for Part C plans will have the similar effect of facilitating more offerings of these plan types in light of the significant amount of time and effort it would take to compile data and project all of the assumptions CMS requires throughout the bid submission and approval process for each plan benefit package.

Further, CMS has authority under sections 1857(i) and 1860D-22(b) of the Social Security Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. In this regard, CMS is confident that we are in full compliance with the statutory authority in both waiving the bid requirements and modifying the payment methodology to facilitate the offering of MA plans by employers or under contracts between employers and MAOs.

Comment: Several individual beneficiaries detailed personal experiences with their MA EGWPs, expressing concern for the potential losses of coverage and higher expenses that may result from this proposal.

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[4] See, e.g., Medicare Managed Care Manual Chapter 9 – Employer/Union Sponsored Group Health Plans; and https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/EGWP-Waivers.pdf.

[5] February 28, 2007 HPMS Memo, 2008 Employer Group Waiver Policy – Elimination of the Requirement for Entities Offering EGWPs to Submit Part D Bids.

Response: We appreciate these commenter's concerns and while each plan and beneficiary experience is distinct, we recognize that it is possible that some employers may choose to provide less supplemental coverage to retirees as a result of this policy change. However, this policy change will, for the first time, make transparent the amounts paid by CMS to insurers for beneficiaries enrolled in EGWPs. Employers, as a result, may be able to use this information to negotiate arrangements with insurers that retain, or perhaps even enhance, the value of the EGWP for their retirees.

Comment: A large portion of commenters asserted that the proposal presents significant operational challenges, especially with respect to timing. Under the proposal, payment rates for EGWPs would not be known until August, which they state is long after most negotiations between employers and EGWP sponsors must be concluded and too late for retirees to select plans. Several commenters indicated that contracts are already negotiated and planned for 2017. Some commenters indicated that they must determine final rates no later than June in order to develop and print open enrollment materials that are required to reach beneficiaries which will hinder or make impractical the ability of group sponsors to meet their obligations for communicating with their retirees and seriously compromise the ability of retirees to make informed decisions about their coverage. Moreover, commenters indicated, many EGWP group sponsors have obligations from different regulatory bodies and oversight boards that require prospective notice to their retirees before changes can be effective. Commenters expressed that MAOs may be in the situation of being unable to adjust either the benefits provided or premium charged to avoid significant financial losses caused by such a swiftly implemented and significant change. Each of these commenters urged CMS to consider alternative timelines from the proposed to prevent disruption of EGWP sponsors and beneficiaries with confusion and concern for members who have counted on and made decisions premised on being able to keep their health plans, claiming that these timing considerations alone would ultimately deter public and private employers' ability from providing EGWP coverage to their workforce.

Response: CMS appreciates the timing concerns raised by commenters and we are finalizing the proposal with modifications to address these concerns. In the Advance Notice, we proposed to calculate the bid-to-benchmark ratios for 2017 using non-EGWP bids and benchmarks for 2017. Under this proposed approach, CMS would have released EGWP rates in the August timeframe after completion of the 2017 bid review process. To address the timing concerns described above, however, we have calculated bid-to-benchmarks ratios for 2017 using 2016 bids and benchmarks and the resulting non-RPPO EGWP rates for each county are included at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html. The final RPPO EGWP rates will continue to be published in late summer when the final MA regional standardized A/B benchmarks reflecting the average bid component and the statutory component, i.e., the Regional Benchmarks, are published which is in keeping with the existing time line for all non-EGWP RPPOs. While the 2016 data are not as current as the data we proposed to use, we believe this revised approach appropriately prioritizes

the need to provide employers and insurers with information on payment rates in the Rate Announcement. Moreover, the bid-to-benchmark ratios have not fluctuated significantly over the past several years.

Comment: Several commenters expressed concern about the impact of the proposed payment changes on retiree benefits, such as EGWPs no longer being able to pay the Part B premium on behalf of enrollees and EGWPs potentially not being able to offer the supplemental benefits such as dental, vision and enhanced (non-Part D) drug benefits. Other commenters believe that the payment changes outweigh any administrative benefit as complex actuarial models will still need to be maintained to set group renewals and quotes, limiting any administrative benefit.

Response: While we appreciate the concerns raised by these commenters, we believe that there is sufficient funding under the methodology being finalized to sustain the offering of these benefits. Moreover, while some actuarial models may still need to be developed for internal plan purposes, the burden of meeting the June bid submission deadline will no longer need to be part of the consideration in the development of these models for these plan types, which we believe does lift the significant administrative burden. By contrast, the alternate proposal CMS considered that would have required MAOs to submit to CMS individual benefit packages and bids for each of their employer plans would have made meeting the June deadline an onerous prospect for MAOs offering EGWPs as well as created significant challenges for CMS associated with expanding our review process to accommodate thousands of additional benefit packages and bids, which would substantially hinder the offering of these plans. Further, as discussed above, by waiving the requirement to submit a financial bid for each plan benefit package, CMS is facilitating flexibility in the offering and design of EGWPs. MAOs will not be tied to specific EGWP plan benefit packages submitted as part of the MA bidding process and may customize benefit offerings throughout the year. We appreciate the concerns raised, however, and will continue to explore options for future policy development.

Comment: A few commenters suggested CMS permit EGWPs to separately reimburse members for their Part B premiums.

Response: The Social Security Administration (SSA) must be able to accurately track beneficiary payments of the Part B premium. Under current payment rules, if an MAO chooses to buy down their beneficiaries' Part B premiums, a fixed, standard amount for each beneficiary in their plan is determined through the bid process. This standard amount is then deducted for each of their beneficiaries from the monthly plan payments made from CMS to the MAO, which is then transmitted from CMS to SSA on a beneficiary level. There is no mechanism to permit the administration or collection of information directly from MA EGWPs to SSA to capture a payment of the Part B premium for their beneficiaries. As a result, this is not currently a feasible solution. We appreciate the concerns raised, however, and will continue to explore options for future implementation. It should be noted however, that very few (approximately 2%) MA EGWPs currently use rebate dollars to buy down any portion of the Part B premium for their

enrollees, so this is not expected to have a significant impact on beneficiaries enrolled in these plans. In addition, while an MAO may not buy down the Part B premium for MA EGWPs, they are not prohibited from offering other benefits or lower enrollee premiums in place of the Part B premium buydown. The elimination of the option to buy down the Part B premium for MA EGWPs does not affect the MA payments made to the MAOs.

Comment: A few commenters asserted that it seems to be unfair to lower reimbursement for these plans following a significant Medicare Part B premium increase in 2016 that disproportionately affected public employees who do not receive Social Security benefits, and further stated that the significant portion of their Part B-only individuals would not be eligible for individual MA plans unless they enrolled and paid the full Medicare Part A monthly premiums.

Response: We appreciate the concern raised by these commenters. We recognize that it is possible that some public employers may choose to provide less supplemental coverage to retirees as a result of this modification of payment methodology and policy. However, this policy change will, for the first time, make transparent the amounts paid by CMS to insurers for beneficiaries enrolled in EGWPs, which is currently not transparent to Employers given that MAOs submit highly aggregated bids which serve only as the starting point for their offerings to differing employers' with whom they contract under these offerings. Employers, as a result, may be able to use this information to negotiate arrangements with insurers that retain, or perhaps even enhance, the value of the EGWP for their retirees.

Comment: Many commenters stated their concern that the proposal will cause most insurers to abandon the employer group MA market, reduce coverage and/or increase premiums, which will lead to less choice for retirees and their former employers and discourage innovative plan design in these markets. Because this policy would disincentivize these plans, these commenters said, employers are likely to drop the EGWP coverage, and the burden shifts back to the government, with an increase of members on traditional Medicare. Several State and municipal organizations also noted that they may be forced to discontinue their retiree coverage or absorb price increases that would cause state and local budget difficulties.

Response: We appreciate the concerns but believe that there is sufficient funding under the methodology being finalized to sustain the offering of MA basic and supplemental benefits. We also believe that employers may be in a better position to negotiate under this methodology, because payment amounts would be standardized and known across competing plans. CMS does, however, recognize that, to the extent that CMS' payments to EGWPs are reduced and MAO margins remain the same, employers may pay higher premiums for current levels of supplemental coverage or may choose to reduce the supplemental coverage provided to employees under these plans.

Comment: Several commenters stated that CMS should keep the annual bidding process and not

proceed with the proposed payment methodology in 2017 as the bidding process takes into account claim experience, geographic location, and product coverage, but the proposal ignores the differences between employer and non-employer plans. Moreover, several commenters expressed concerns that this proposal would result in EGWP payments that are actuarially unsound. Many MAOs that submitted comments also stated that they build their EGWP bids based on true EGWP experience, so the bid amount requested has always reflected EGWP claims and therefore revenue requirements. To remove the EGWP bidding process and revert to a socialized bid would reduce the ability to maintain group MA business; further, the administrative savings from not bidding on group MA business versus individual business is not significant, especially for local players that sell EGWP policies primarily to small businesses.

Response: While we appreciate the perspective offered in these comments, CMS continues to believe that due to the nature of the unique agreements MA EGWPs enter into, EGWPs do not compete against other plans through the bidding process, and therefore have little incentive to submit lower MA bids to CMS under the current bidding rules. On the contrary, as noted in the Advance Notice, MedPAC has noted that the nature of the MA bid process and the ability to access federal funds creates incentives for these plans to bid as close to the benchmark as possible, in order to compete for employer business by lowering the costs imposed on employers. Under this new policy, MAOs offering EGWPs will now need to compete for employers to contract with them for these offerings on access, quality, customer service, and wrap-around benefits. Implementing this proposal will also result in savings to the Government. Further, as noted above, waiving the bidding requirement entirely and modifying the payment methodology for these plans helps ensure continued flexibility in plan design and the timing under which EGWP plan designs are finalized. We anticipate that these flexibilities and the increased amount of information available to employers will facilitate the offering of these plans in the future.

Comment: A few commenters stated that for MA EGWPs to attract employers, plans are frequently designed in ways that may lead to higher bids relative to the individual MA market. For example, MA EGWPs frequently cover larger geographic areas in order to accommodate large employers with retirees living in different parts of the country. Preferred Provider Organization (PPO) networks are much more commonly found in MA EGWPs than in the individual MA market as these benefit designs are both popular and valued in the employer market. Both broad networks and a larger geographic distribution of beneficiaries can lead to higher costs in coverage. Moreover, these plans offer coverage to beneficiaries in areas that are underserved by individual MA plans through extended service area options allowed under MA EGWPs waivers currently in place. The service area waivers allow for EGWPs to offer coverage in areas where a plan may not have a full network. However, they add to the cost of the product because, if enrollees use out-of-network providers with no contractual relationship with the plan, there is less opportunity to effectively engage in care coordination.

Response: We appreciate the concerns but, as noted above, believe that there is sufficient funding under the methodology being finalized to sustain the offering of these benefits. We also

believe that employers may be in a better position to negotiate under this methodology that waives the bidding requirements for EGWPs, because payment amounts would be standardized and known across competing plans. By removing the bidding requirements, MAOs will now need to compete for contracts with employers on access, quality, customer service, and wrap-around benefits.

Comment: A few commenters stated that while they recognize that there may be some problems with the current bid structure, they remain concerned that CMS has not fully analyzed the impact of this policy proposal or given full consideration of the rationale for higher bids from MA EGWPs. These commenters requested CMS to provide additional information on any current or ongoing analysis that has been conducted and encourages CMS to more widely solicit public comments on this policy proposal and analysis.

Response: We thank these commenters for their considered thoughts on this issue. However, we and MedPAC have monitored and analyzed this issue over the past several years and continue to observe consistently higher bids from EGWPs without explanation. In the 2012 Advance Notice, published on February 18, 2011, CMS raised these concerns publically, and specifically requested comment on the causes for the data relationships we and MedPAC were observing. We also stated in the 2012 Rate Announcement that we would be reviewing comments received for future policy development. We would reiterate, however, that the bidding approach that has been in effect through 2016 has hindered CMS's ability to analyze this issue fully in light of the fact that this bidding structure has not permitted CMS to know how many EGWP plans any MAO offers, what benefits are provided in each of those plans, or the associated underlying costs. This lack of transparency has significantly impaired CMS' ability to comprehensively review and assess the reasonableness of the underlying actuarial assumptions and projections included in the bids submitted for EGWPs and to trace how federal funds, in the form of the capitation payments and the rebates, are spent for beneficiaries in specific EGWPs.

Moreover, since the publication of the Advance Notice, CMS has provided the public with the estimated financial impact of the proposal via an HPMS memo released on March 7, 2016, which we are mitigating by implementing the policy with a transition. We appreciate the concerns raised, however, and will continue to analyze options for future policy development.

Comment: One commenter stated their belief that Medicare Supplement plans (Medigap) will benefit the most from this change, and well-managed Medicare Advantage plans will lose most of their EGWP membership.

Response: We appreciate the concerns but believe that there is sufficient funding under the methodology being finalized to sustain the offering of these MA plans.

Comment: A few commenters indicated that their particular areas of the country will be significantly more impacted than others given the benchmarks and bid-to-benchmark ratios that are anticipated to be applied to their payment rates, as well as the concentration of large group

employers and labor unions that offer retiree coverage in particular areas.

Response: The current bidding and payment methodology has disparate impacts on varying geographic areas today. By calculating the bid-to-benchmarks at a quartile level, then applying them to each county's rate, and taking into account double bonus counties and star ratings, we are accounting for a significant level of geographic variation in the payments in the methodology being finalized. In addition, under the approach being implemented for 2017, we have moderated the impact of the new policy by blending individual market plan and EGWP bids to calculate the bid-to-benchmark ratios.

Comment: Several commenters stated their belief that CMS's logic behind the proposal is flawed as the MA EGWP population's risk scores are less relevant to their costs than this proposal presumes, and instead it is more important to understand that in most cases, the benefits offered under these plans have been carefully negotiated as an integral part of the accrued retirement package for labor union and other large group employer workers. In some cases negotiated collective bargaining agreements require single employers to continue providing health care coverage to retirees. In addition, many are associated with Voluntary Employees' Beneficiary Associations (VEBAs) that provide health care benefits to retirees. In most cases these VEBAs were established and are maintained in accordance with the terms of class action or bankruptcy settlement agreements that were approved by federal district and/or bankruptcy courts.

Response: While we recognize that in certain circumstances the overall benefit package provided to retirees under an EGWP is the result of a collective bargaining or class action/bankruptcy agreement, the supplemental benefits provided under such an arrangement do not explain the higher bids that we have consistently observed from EGWPs. Buying down cost-sharing under Original Medicare is a supplemental benefit. Under the Medicare Advantage bidding process, all plans (both EGWPs and non EGWPs) submit a bid for providing the benefits covered under original Medicare. Despite bidding on the same package of basic benefits, on average, EGWP bids for A/B benefits have consistently been significantly higher than those submitted by non-EGWPs.

Comment: A few commenters also asserted that in the commercial market it is often true that administrative costs for employer-based products are less than individual products due to economies of scale. However, this is not the case for EGWP plans, especially in particular states, since CMS announced two years ago that they consider enhanced Part D EGWP benefits to be commercial coverage. As a result, certain state regulators consider EGWPs to be state-regulated products and have added a layer of regulation that has made them significantly more complex to administer than their individual counterparts.

Response: We appreciate these comments. We believe that they are in keeping with CMS's belief that waiving the requirement to submit 2017 Part C bids will facilitate the offering of Part C plans for employers and unions seeking to establish high quality coverage for their Medicare

eligible retirees by avoiding the cost and administrative burden of submitting complex bids to the federal government, particularly in light of these commenters' concerns about increased state oversight for those plans that offer both Medicare Advantage and Part D coverage.

Comment: Several commenters noted that EGWP bids tend to be higher than non-EGWP bids because EGWPs are predominately PPOs, rather than HMOs. They argue that when making an apples-to-apples comparison of EGWPs and non-EGWPs by plan type, the disparity in the bid-to-benchmark ratio shrinks significantly. These commenters argue that CMS's proposal will arbitrarily lower benchmarks for PPO products and will drive out PPO EGWPs from the marketplace. These commenters argue that the need to offer a broad network may be accounting for the rate difference, rather than the CMS assertion that the payments are subsidizing wrap-around coverage. According to the commenters, the current EGWP payment structure enables plans to recognize the impact of these various product characteristics and the impact of different cost structures between MA EGWP plans and individual market MA plans in their bids. The proposed change does not allow plans to reflect these differences in cost structures in MA EGWP specific bids and it shifts the MA EGWP funding to be based on individual plan costs (largely HMOs) despite the fact that MA EGWPs are largely PPO plans. Several of these commenters stated that if CMS should decide to proceed with the proposal that the bid to benchmark calculations be modified to account for the different ratio of HMO to PPO plans in EGWPs vs Non-EGWPs and to exclude D-SNPs from the calculations as they are not representative of the type of coverage an employer purchases, and are therefore irrelevant to the calculation.

Response: CMS recognizes that there are a larger number of MA EGWPs that are offered as PPO plans instead of HMO plans than in the individual MA market, where the inverse is true. In finalizing this policy, CMS considered whether such an adjustment would be appropriate to account for this differential in plan offerings between the two markets. However, in the course of reviewing the data, we determined that basing the MA EGWP payment rates on the small number of PPO plans in the individual MA market could introduce significant year-over-year instability in future EGWP payment rates.

Comment: One commenter indicated that retirees enrolled in MA EGWPs have a higher average age as compared to individual MA plans. This age difference may be a result of a greater propensity for EGWP plan retirees to stay in their same EGWP MA plan until death, since group retiree health insurance is generally supported by employer/union contributions toward the premium, which provides an incentive for retirees to maintain continuous coverage under the group plan, and "end of life" medical expenses in EGWP plans are higher than in individual plans.

Response: We appreciate that this commenter's concerns, however, the CMS-HCC risk adjustment model takes the age and health status of beneficiaries into account. Therefore, we would expect that if this were the case, risk scores for MA EGWPs would be higher on average

than those in the individual MA market. However, as we noted in the Advance Notice, CMS and MedPAC have analyzed the data and concluded that the inverse is true.

Comment: Many commenters noted that the proposal is complicated, the two week comment period did not provide plans sufficient time to fully understand its application and implementation, and CMS has not released enough information for stakeholders to fully evaluate the methodology and its financial impact. Moreover, several commenters suggested that while the Advance Notice is well-anticipated by companies in the health insurance industry, employers (including many state governments) and unions may not be aware of the publication or anticipate that it will have a significant impact on their finances or employee and retiree benefits.

Response: We appreciate that the comment period may be limited, however, section 1853(b) requires CMS to release and post the Rate Announcement on the first Monday in April and release the Advance Notice describing the proposals at least 45 days in advance. Similar proposals have been proposed for the past several years in the President's Budget, and MedPAC has made similar recommendations. So while we recognize that this policy was proposed for Part C implementation for the first time in the 2017 Advance Notice, the concepts behind the methodology being finalized have been proposed previously by the Administration. Moreover, in the 2012 Advance Notice, published on February 18, 2011, CMS raised these concerns publically, and specifically requested comment on the causes for the data relationships we and MedPAC were observing. We also stated in the 2012 Rate Announcement that we would be reviewing comments received for future policy development.

Comment: Commenters suggested that CMS needs to study the root cause of the differences in MA versus EGWP payment to identify the actual adjustments to policy that are required to increase payment equity.

Response: In the course of developing this policy, CMS considered requiring MA EGWPs to provide CMS with detailed information on the PBP provided to each employer group and class of retirees within that plan benefit package in order to delve deeper into the root causes of the differential bidding patterns. However, CMS concluded that it would impractical to require the submission and collection of data necessary to expand our review process to accommodate the large number of PBPs which could exceed 25,000 to 50,000 benefit packages depending on the number of unique plan variations MAOs offer to employers. It should be noted, that these figures are only a rough estimate, as under the bidding waivers in place through 2016 for MA EGWPs, CMS does not have sufficient data from submitted bids to know how many various benefit packages are currently being offered to employers by MAOs. Moreover, since retiree health benefits would be expected to vary among individual beneficiaries within a single Medicare plan on the basis of differing underlying union agreements or employment contracts, such data would likely need to be collected at the beneficiary level, rather than at the plan level. The burden of such expanded data collection and submission and review was determined to be unduly excessive for both plan sponsors and CMS.

Comment: A few commenters detailed several distinctions between MA EGWPs and MA non-EGWPs such as improved patient outcomes due to better coordination of care programs, the ability to better coordinate between vendors providing more comprehensive case management for their beneficiaries, flexible pricing and plan design, consistency in coverage during the transition from employment coverage to retirement coverage and improved customer service. Other commenters indicated that MA EGWPs and MA non-EGWPs are distinct as EGWPs serve a separate purpose, i.e., providing a vehicle to provide comprehensive medical coverage, integrating fee-for-service Medicare benefits with employer or union-funded supplemental employee/retiree benefits. Unlike individual-market MA plans, employer-plan sponsors select a limited number of EGWP options from which retirees can choose to enroll.

Response: We thank commenters for these observations and acknowledge that there are distinctions between EGWP and non-EGWP plans. However, we do not believe our proposal will inhibit the ability of employers and insurers to take advantage of these distinctions. Nor do we believe that these distinctions explain the higher bids that we have observed from EGWPs.

Comment: Many commenters argued that this proposal is too blunt to administer fairly and that the bidding process takes into account claim experience, geographic location, and product coverage fluctuations that cannot be accounted for with an administratively-set payment amount. A few other commenters noted that that MA EGWP bids serve an important administrative function as they enable CMS to correctly administer Part D and the retiree drug subsidy. The MA EGWP bids allow CMS to verify that groups receive at least actuarially equivalent benefits to what the MA plan offers its individual members. Commenters stated that the process helps ensure that any rebates from the bid savings are used to reduce premiums or enrich benefits. These commenters also encourage CMS to further discuss how CMS will oversee group premiums and benefit offerings if group bids are eliminated and there are no longer the group bid margin proximity rules. Without group bids, there may be uncertainty as to how MA plans will be regulated by CMS for their group business.

Response: We thank these commenters for their considered thoughts on this issue. We appreciate the concerns raised, and will continue to explore options for future policy development. We would also note that this policy is only waiving the MA EGWP bidding (BPT) requirements and detailing their alternative payment methodology. MA EGWPs will continue to submit the plan benefit package (PBP) and formulary in accordance with the rules for 2017.

Comment: A few commenters requested that we clarify whether the bid-to-benchmark ratios will be calculated on an individual bid basis for a particular county or will be tied to the weighted average bid-to-benchmark results for individual bids submitted nationally, whether the benchmarks that will be used will have the qualifying county adjustments included, and whether SNPs are part of the individual bid-to-benchmark ratio calculation. Others inquired as to why CMS doesn't collect employer group membership in the individual bids to better calculate an

organization's employer group ISAR and employer group risk scores to make the calculation of employer group payments based on individual bids more accurate and actuarially sound.

Response: As described in the Advance Notice and finalized as described herein, the bid-to-benchmark ratios are a weighted average at the quartile level which will result in four percentages – one for each quartile. The percentages are then applied to the county ratebook to each of the published 5%, 3.5%, and 0% county ratebook rates, which include adjustments for bonus counties. SNPs are included in the calculations to determine the bid-to-benchmark ratios. In developing the policy, CMS considered collecting a limited dataset from MA EGWPs such as projected risk scores based on the plan's service area; however, collecting even this limited data was determined to be contrary to the goal of reducing administrative burden on offering these plans, as some level of detail in support of the projections would need to be submitted to and evaluated by CMS to verify it's actuarial accuracy.

Comment: One commenter stated that they do not feel it is appropriate to apply the risk score to the county rebate amount as that is different than how the payment is made for individual plans.

Response: Under current bidding rules, rebate dollars resulting from an A/B bid below the benchmark are risk adjusted within the bid to determine the per-member-per month rebate amount CMS will pay to the MAO. CMS believes that both the A/B portion of the payment and the rebate portion of the payment should continue to be risk adjusted and, given the lack of bid submissions, we are therefore incorporating that step into the payment process in the methodology being finalized.

Comment: A few commenters indicated confusion regarding how this new methodology would interact with prior bid instructions related to margin requirements and consistency between underwriting assumptions and the bid. They requested clarification as to whether these requirements and others requirements previously included in the bid instructions would still be in place under this new methodology.

Response: Given that EGWPs will no longer submit bids to CMS, the bid review requirements related to margins will no longer be applicable to EGWPs. The instructions for the MA Bid Pricing Tools will be updated accordingly.

Comment: One commenter requested clarification regarding how the methodology will adjust individual bid-to-benchmark ratios for the Extended Service Area Waiver approved for EGWP plans, will the ISARs used to develop the individual bid-to-benchmark ratios be normalized to a 1.0 risk score, and how members in ESRD, Hospice, and MSP status would be treated under the proposed methodology.

Response: Under the finalized payment methodology, the MA EGWP payment will be based on the beneficiary's county code. CMS will calculate a bid-to-benchmark ratio for counties in each FFS quartile and the applicable bid-to-benchmark ratio for each county will be used to calculate

a standard EGWP payment for that county. The ISAR-adjusted bid and benchmarks are both standardized numbers in the bid pricing tool, so they are already at a 1.0 risk score. We are not applying a normalization adjustment in the bid-to-benchmark calculation. As a result, the payment for all EGWPs with the same quality Star Rating in a county will be the same, regardless of other counties the EGWP might include in its total service area. Plans will continue to be paid using the ESRD ratebook for their ESRD beneficiaries. MSP status is a payment adjustment to the risk score so the risk score applied to the county payment rate will reflect the MSP adjustment factor if applicable. Under current payment rules, beneficiaries in MA plans that elect Hospice currently only receive a rebate payment from CMS. If the rebate is $0.00 then these plans do not receive a payment. As discussed in the Advance Notice, specific rebate amounts will no longer be identifiable under the payment methodology being implemented, therefore, beginning in 2017, all MA EGWPs will receive $0.00 payment for each of their members that elect Hospice. We appreciate the concerns raised, however, and will continue to explore options for future policy development.

Comment: One commenter requested clarification surrounding the plan benefit package submission requirements for MA EGWPs, and further asked if these plans will need to upload a formulary that represents the "leanest" option that they would make available to EGWP plans.

Response: This methodology is only waiving the MA EGWP bidding (BPT) requirements and detailing their alternative payment methodology. Therefore, MA EGWPs will continue to submit the plan benefit package and formulary in accordance with the rules for 2017.

Comment: A few commenters suggested that the MA EGWP proposal represents a step backwards from the movement towards value based payment and improved models of care. They indicated that employers would drop EGWP coverage in favor of Medicare "wraparound" products, thereby increasing costs to the government, and retirees would lose access to care coordination programs that would possibly reverse gains in health status and outcomes. Commenters stated that this proposal could cause regression of the quality improvements made through the Star ratings program.

Response: We thank commenters for these observations, however, we do not believe our proposal will inhibit the ability of employers and insurers to take advantage of alternative payment models. In fact, we believe that employers may be in a better position to negotiate payment arrangements under this methodology to waive the bidding requirements for EGWPs, because payment amounts would be standardized and known across competing plans. By removing the bidding requirements, MAOs will now need to compete for employer contracts primarily on access, quality, customer service, and wrap-around benefits.

Comment: A few commenters expressed concerns about the impact on beneficiaries in Puerto Rico should this policy be finalized, stating that the economic situation in Puerto Rico and the government debt crisis preclude any further investment in these types of retirement plans, which

have significant actuarial deficits. For example, teachers in Puerto Rico decided a long time ago not to participate in the Social Security Program and their retirement fund is in a major crisis. Having their EGWP MA Plan provides beneficiaries with some relief. However, additional contributions to these MA EGWP retirement plans is not possible in the current economic times.

Response: We appreciate the concerns expressed by these commenters, but believe that the impact on Puerto Rico is minimal and that there is sufficient funding under the methodology being finalized to maintain the offering of sustainable benefits in Puerto Rico.

Comment: A significant majority of commenters requested that CMS reconsider and withdraw the proposal entirely.

Response: While we understand the concerns raised, we have explained throughout this section why we are finalizing the proposal with modifications. The waivers of bidding requirements and the modified payment methodology being finalized will eliminate potential burdens and hindrances on offering EGWPs associated with the MA requirement that each plan benefit package be associated with a financial bid while simultaneously resulting in savings to the Government by providing a more equitable payment methodology for MA EGWPs. Further, we note that CMS has previously waived bidding requirements for Part D for EGWPs and set payment amounts for Part D plans based on the competitive bids submitted for non-EGWP Part D plans; here CMS is finalizing a similar waiver and payment policy for EGWP Part C plans beginning with 2017.

Section G. CMS-HCC Risk Adjustment Model for CY 2017

Comment: Many commenters strongly support CMS' proposal to update the CMS-HCC model by separating the community model segment into six subgroups based on dual eligibility status. Many commenters support implementation of the new model without delay to improve and stabilize the payment structure for full-benefit dual eligible beneficiaries. A few commenters noted that the proposed changes would improve the sustainability of D-SNPs and MMPs and create a more equitable risk-adjustment system. One commenter thanked CMS for not including a clinical revision of the hierarchical condition categories (HCCs) as part of the model revision and supports CMS' proposal to use the same disease interactions across the 6-segment community model with the addition of the disease interaction for the disabled segment, as this promotes consistency across the segments.

Response: CMS appreciates the support.

Comment: Many commenters urged CMS not to implement the proposed model in 2017, or requested a phase in of the new model. These commenters are concerned that the proposed model changes will reduce overall revenue to the MA program through a net MA funding reduction of 0.6% and introduce disruptions to benefit designs. One commenter noted that coefficients for certain HCCs decrease under the proposed 2017 model compared to the 2014

model. Another commenter raised concerns that the changes CMS proposes to the *partial-benefit* dual eligible model could have the unintended consequences of reducing enrollment in Medicare Savings Programs (MSPs). A few commenters suggested implementing the new model in Puerto Rico alone as a pilot.

Response: CMS is proceeding with the implementation of the new model, which will pay more accurately for beneficiaries, regardless of their dual status, and reduce incentives for plans to avoid enrolling full benefit dual beneficiaries. Overall, the net impact on plan payments will vary based on the composition of plans' enrolled populations and disease profiles of beneficiaries within those populations.

Comment: A number of commenters expressed concern that the impact on MA payment of the revised model was greater than the -0.6% that CMS estimated and will lead to instability in the MA program. Several commenters requested more information regarding how CMS calculated the model impact. These commenters stated that the effects of the proposed model, combined with the Part C normalization factor, will result in additional and possibly unintended material differences on payment risk scores for CY 2017.

Response: We acknowledge the commenters' concerns and note that there was a technical error in the calculation of the model denominator used to create the model relative factors. This error resulted in model relative factors (and, therefore, the raw risk scores) that are 1.8% too low. This error directly affected the historical risk scores used in determining the normalization factor, which, as a result, was also too low.

Although the corrected model factors are 1.8% higher, our calculation of the industry level model impact is the same. To determine the industry level model impact, we compared the current model (2014 CMS-HCC model) to the revised CMS-HCC model. In order to isolate the model revision impact, we developed updated denominators for the two models based on the same year. The model denominators that were developed for the purpose of model impacts both had the same error, resulting in the same comparison once the error was fixed on both sides. We do note that the risk scores produced under the new model posted on HPMS should have been 1.8% higher.

Comment: A few commenters appreciated the transparency and early information regarding the proposed model in the Request for Comment in October 2015, but requested additional information, including details of how the changed model will operate, raw risk scores under the 2014 and proposed 2017 models, and analyses on impacts that outline how the negative 0.6% national impact was calculated. Some commenters also suggested that CMS allow plans the opportunity to study the proposal and the revised risk scores under the new model beyond the time period allowed for comment following release of the Advance Notice. A few commenters recommended additional analyses of the model before implementation while a few commenters urged CMS to monitor the results of the model changes. One commenter recommended that an

independent analysis be conducted by an external research organization to analyze the accuracy of the implemented risk adjustment model and to provide recommendations on areas for improvement, followed by a stakeholder process and at least a 60-day comment period.

Response: CMS has made efforts to release more information and at earlier times, than the statutory deadlines require, by, for example, releasing research findings four months prior to the publication of the Advance Notice through a Request for Comments, sharing plan-level risk scores (calculated under both the current and the proposed model) a month before the publication of the Notice; and CMS' plan to share operational details earlier than usual. We will continue to engage with stakeholders as we implement the model.

Comment: CMS received comments in support of maintaining the PACE CMS-HCC Risk Adjustment Model. One commenter recommended that CMS evaluate the impact of updating the PACE model by applying distinct risk factors for full, partial, and non-dual eligible enrollees; and also consider recalibrating the PACE model, which is currently calibrated with 2006/2007 data.

Response: CMS appreciates the support. We did not propose to make changes to the risk adjustment model that we use for PACE organizations and will continue to use the existing model for 2017. This model is described in the 2011 Advance Notice and Rate Announcement. We will consider these comments for future years.

Comment: A few commenters recommended providing transitional relief to plans receiving negative payment adjustments. For example, one plan recommended that CMS implement a one-time retroactive adjustment to plans serving high proportions of dual beneficiaries to compensate for prior underpayments based on duals served.

Response: CMS is continually working to improve our method for risk adjusting payments and can legally only make changes to future years.

Comment: Many commenters expressed concern that CMS is only focusing on dual eligible beneficiaries and that the new model will hurt plans with low enrollment of full-dual eligible beneficiaries. These commenters made suggestions about how CMS could make revisions to the risk adjustment model to improve the prediction of costs for full duals, while maintaining the current risk score level for non-duals. They stated that a "one-size fits all" approach does not work and that CMS should instead create proposals to address the needs of specific populations and geographic regions rather than broadly applying a policy to the entire Medicare program. A few commenters recommended that CMS implement the model only for dual-SNPs while retaining the current model for non-SNPs and institutional plans. One commenter stated that CMS should make an upward adjustment to the non-dual eligible categories to ensure that the revised model does not unfairly penalize non-dual plans. Several commenters that commended CMS for focusing on vulnerable populations believe this focus should not result in overall

funding reductions across the MA population. One commenter recommended that CMS revise the model only to reflect the costs between full and partial dual eligible beneficiaries. The commenter stated that CMS should refrain from adjusting the currently successful model for non-dual eligible beneficiaries. One commenter noted that the model change is not revenue neutral and that it is not clear if CMS has the authority to make model changes that are not revenue neutral to the MA population. A few commenters recommended that CMS institute a "hold harmless" that allows plans to receive the largest of their risk score calculated under the 2014 and 2017 models or alternatively institute a budget neutrality adjustment to assure that the overall payment for the MA population is not decreased.

Response: CMS believes that the 2017 model improves payment accuracy and results in more payment equity across plans. After extensive research, CMS has demonstrated that the current model underpredicts for full benefit duals, while overpredicting for both partial benefit duals and for non-duals. Further, it is evident that diagnoses are inadequate to fully predict the costs; in other words, beneficiaries with similar clinical profiles have different costs, and these costs differences are related to beneficiaries' dual status. Whether dual status is predictive of costs because it is a proxy for income level or because the status is indicative of price sensitivity, or a combination of both, is an open question. It is clear that dual status, as a supplemental predictor to diagnoses, is predictive of cost.

Regardless of how we better predict costs for any population of beneficiaries, CMS would need to redenominate the model to retain an average 1.0 risk score. When we redenominate the model, all the relative factors will change in relationship to the 1.0 average risk score. For example, simply increasing the Medicaid factors in the model, in order to better predict aggregate costs for full benefit duals, would have the effect of decreasing the risk scores for non-duals, relative to average. CMS sets this 1.0 risk score for the FFS population since Medicare Advantage payment rates are statutorily tied to FFS. In setting the 1.0 for the risk scores we use for payment, we mirror our approach of setting the average FFS risk score to 1.0 in the ratebook in order to be consistent with the rates. Therefore, we did not propose and are not making any changes to the model in order to retain the average MA risk score at the same level that it was under the current model. The change in the aggregate MA risk score is almost entirely due to the different distribution of duals compared to that in FFS (a small portion of the impact is due to updating the underlying data in the model by three years). Given that we believe that this revision improves the predictive ability of the model, we believe that it is appropriate to allow MA risk scores to change in response to the revised model. Finally, section 1853 does not require that risk adjustment be revenue neutral for MA plans.

Comment: Some commenters stated that revising the model will increase instability in the MA program. A few commenters highlighted their concern that the 2017 revision to the CMS-HCC model follows a series of recent major changes, including the clinical revision of the CMS-HCC model in 2014, introduction of encounter data as a source of risk scores, and conversion from

ICD-9 to ICD-10, to the model and risk adjustment methodology in the previous few years. One commenter recommended that CMS implement annual bounds to changes in the factors to prohibit overly significant changes in any one year and possible errors in predictive rates. Another commenter suggested that CMS refrain from making changes to the risk adjustment model more often than every two years.

Response: We appreciate commenters' concerns about stability and the impact of multiple changes happening in plan payment in the last few years. We note that the model that we implemented in 2014 was phased in over three years, and that we haven't changed the HCCs with the revisions to the model for 2017. Similarly, the implementation of ICD-10 has been planned for many years. There has been strong interest expressed, and CMS agrees, to continually look for ways to improve the predictive accuracy of the risk adjustment model. We believe, that if we identify a way to make an improvement to the model, we should do so.

Comment: Several commenters questioned CMS' decision to use FFS data to estimate the risk model changes in MA. One commenter stated that the proposed changes in the 2017 Advance Notice ignore the lack of any measure of quality or care management in the FFS spending data used as the basis for the risk adjustment model. Several commenters also recommended that CMS use MA data instead of FFS data for model calibration.

Response: CMS recognizes that FFS utilization and costs may not represent the experience in Medicare Advantage plans and our goal is to eventually calibrate the CMS-HCC risk adjustment model on MA data. We note that the aggregate dollars that a plan sponsor needs, in order to provide Parts A and B benefits to their enrolled beneficiaries, is determined in the plan bid. The purpose of the model is not to establish the total amount paid to the plan, but the relative expected costs of the beneficiaries enrolled in the plan. To the extent that the relative costs of diseases in the model differ for an MA plan from FFS, then the model may not perfectly predict that plan's costs. This will always be the case for any specific plan, since the model predicts expected relative costs, on average, across a population. Because we have used FFS data to calibrate our risk adjustment models since we first instituted risk adjusted payments to plans, we believe that it is a suitable alternative for determining the relative costs until we have sufficient experience using complete encounter data to develop the risk adjustment model.

Comment: Numerous commenters supported the inclusion of the Psychiatric HCC x Substance Abuse HCC disease interaction for the disabled segments of the community model.

Response: CMS appreciates the support.

Comment: A few commenters who support the proposed changes to the model expressed concerns about the omission of chronic conditions, such as CKD stages 1, 2, and 3 and diabetic neuropathy, as well as mental health conditions, including dementia, and mental health and substance abuse interaction terms from the model. Some commenters believe that CMS should

focus more on chronic conditions. One commenter noted that if CMS is concerned about MAOs coding dementia at greater levels in an effort to serve enrollees, the agency should review the data to determine whether or not such coding is appropriate. Another commenter noted that the revised model inappropriately cuts payments for chronic conditions regardless of dual status.

Response: CMS decides whether to include a condition category in the model after balancing several considerations, including each category's ability to predict costs for Medicare Parts A and B benefits, whether the diagnostic classifications measure disease burden, and whether diagnosis codes that are subject to discretionary or inappropriate coding should be excluded. CMS understands the clinical significance of the conditions recommended for inclusion in the model by commenters, including the importance of appropriately managing patients to slow the progression of kidney disease and that the treatment of dementia can be costly. Further, we understand that including these conditions in the model would potentially increase the risk scores of beneficiaries who have been diagnosed with them. Our concern regarding dementia and chronic kidney diseases focuses on the diagnosis and coding of these conditions relative to FFS and, in the case of dementia, the broad clinical definitions that have been developed in order to identify the disease. While we fully support these efforts to identify and treat dementia, we are concerned that the broad clinical definition may result in dementia being coded at greater levels in MA relative to FFS, resulting in overstatement of the risk of such beneficiaries and leading to inaccurate payment. Such concerns do not revolve around whether the coding is accurate, but rather whether it is different than in FFS. Although not all conditions are included in the CMS-HCC model, the model still predicts beneficiaries' expected costs for all A and B benefits, including costs associated with chronic and mental health conditions. Given the goal of managed care organizations, we expect plans will appropriately manage chronic conditions and mental health conditions for their beneficiaries, irrespective of model refinements.

Comment: A commenter requested clarification on whether or not the initial reason for Medicare entitlement will carry with a beneficiary for the duration of his/her time in the program, or whether every beneficiary over the age of 65 – regardless of disability status – will be classified as aged for purposes of the model segment.

Response: CMS is not changing how we handle the determination of aged versus disabled or the use of original reason for entitlement in the calculation of risk scores. For risk adjustment, all beneficiaries aged 65 and over are considered aged; if an aged beneficiary was originally entitled due to disability, they are treated as aged and originally disabled. We continue to use originally disabled factors for beneficiaries who are aged and were originally eligible for Medicare due to disability. These factors, like the other factors in the model, are additive. Non-aged beneficiaries will be classified as disabled for the purposes of determining interaction terms (if applicable) and, for beneficiaries in the community, which model segment to use for risk score calculation.

Comment: Some commenters recommended that CMS examine factors, other than dual status, which may further improve the model to help predict costs more accurately. These factors

include social determinants of health, functional status, lower risk deciles, and beneficiaries with high health costs.

Response: Medicaid data is a readily available and comprehensive data source that provides information about a status that serves well as a predictor of Medicare costs. While CMS has found that Medicaid status improves the ability of the model to predict costs, we welcome suggestions from stakeholders regarding other potential predictors of Medicare expenditures that are easily accessible and available to be used in both calibrating the risk adjustment model and calculating risk scores for all Medicare beneficiaries.

Comment: One commenter stated CMS ignores the fact that cost differences between full-benefit and partial-benefit duals reflect different utilization incentives for the two populations rather than true differences in clinical health care needs and costs. A few commenters encourage CMS to study QMBs independently to understand if adding them as an additional category of enrollees would further improve the accuracy of the model.

A few commenters questioned whether there exists sufficient consistency across states to ensure parity in the risk score model calculation. One commenter asked CMS to consider whether the definitions of the dual status categories, which are often decided at the state level, are consistent with how CMS proposed to stratify beneficiaries in developing the model. Another commenter stated that if the model is going to be implemented, CMS should either include dual code 01 as full dual or incorporate an adjustment factor by state (or groups of similarly situated states) to reflect the variation in the predictive ratios from state to state caused by the varying state eligibility requirements for QMB Plus and SLMB Plus status. A few commenters suggested the need for strong oversight and quality assurance work with state based Medicaid data. One commenter proposed enhancements to the current reporting systems requiring all states to report a minimum set of data upon which a status determination can be made or alternatively, CMS should consider a system similar to that already in use in the Extra Help program in Medicare Part D. Another commenter urged CMS to consider adjusting the proposed individual condition and demographic coefficients so that all dual coefficients (full/partial & aged/disabled) are equal to, or higher than their non-dual counterparts.

Response: We recognize that there are state-by-state differences in eligibility criteria that will result in different classifications for some beneficiaries who might be determined to be a partial benefit dual in some states and a full benefit dual in other states. However, as noted elsewhere in this Announcement, CMS believes that using Medicaid data, in general and to differentiate dual eligible subgroups (i.e., full benefit or partial benefit dual status) improves the accuracy of the model and better predicts costs for key subgroups of beneficiaries. Further, CMS does not have other data that would inform CMS about different income levels of Medicaid eligible beneficiaries, so we are unable to explore whether subsetting the Medicare population in other ways based on income would improve payment accuracy. Without the ability to test whether

other subsetting arrangements would improve the model, we also have insufficient information for assessing whether differing State Medicaid eligibility criteria are a reasonable basis for state-specific adjustments. As we reported in the October 2015 HPMS memo and in the 2017 Advance Notice, our analyses showed that the current CMS-HCC model overpredicts for partial benefit dual beneficiaries by 7.2% (disabled) and 12.3% (aged). Further, MedPAC has reported a similar finding, which indicates that CMS has been overpaying for partial dual beneficiaries. We also note that the model underpredicts for full benefit duals by approximately 5% (disabled) and 11% (aged). The differences between how well the current model predicts for full and partial benefit duals are sizable, and CMS believes that improving the prediction of the model is imperative.

We note that partial benefit dual risk scores are notably higher than non-dual risk scores. As we shared in the 2017 Advance Notice, our analyses show that the cost and disease patterns of the non-dual, full benefit dual, and partial benefit dual, and the aged versus disabled segments were distinct, both within the dual types (e.g., full benefit dual aged versus full benefit dual disabled) and between the dual types (e.g., full benefit dual disabled versus partial benefit dual disabled). Furthermore, the differences in cost patterns among these subgroups varied significantly both overall and by HCC disease category. In other words, predicting costs separately for each of these dual subgroups, even when using the same diagnoses, produced unique sets of coefficients. For example, the partial benefit duals are not just less expensive than full benefit duals (and more expensive that non-duals), but they have different clinical profiles and cost patterns. In the case of some conditions, the coefficients for partial benefit duals are higher than those for full benefit duals, reflecting the different clinical profiles.

Comment: One commenter requested that CMS establish a demonstration for C-SNPs, where they would be provided waivers to existing payment methods and regulatory policy.

Response: Thank you for your comment.

Comment: Many commenters stated that the new model is complicated and introduces significant operational and administrative challenges for both CMS and plans. One commenter stated that plans will have much more difficultly using six models to predict future risk scores and prepare accurate bids, which may create unnecessary volatility in benefit designs, member premiums, and cost sharing as forecasting CMS payments becomes far more complex. A few commenters were specifically concerned about dual eligibility determination and asked CMS to take into account the challenges involved with obtaining accurate and timely monthly data from states on dual status. These commenters asked CMS to consider developing a process for applying retroactive changes, if necessary. One commenter recommends that CMS clearly track payment adjustments and allow for the possibility that payment adjustments resulting from Medicaid retroactive status and delays in state reporting could occur after the final risk scores are run.

Response: We appreciate the challenges facing plans in order to implement this new model. CMS is in the process of developing technical specifications for how we would implement the proposed model and plan to release information regarding the operational implementation after the CY 2017 Rate Announcement has been published.

Comment: A few commenters indicated the need for a special adjustment to account for non-dual beneficiaries in Puerto Rico who would otherwise be considered partial benefit duals in a non-Territory state. Commenters suggested that the two components of this adjustment would be: 1) an estimate of the proportion of partial duals within the non-dual group in PR, which can be based off of the Puerto Rico Community Survey data or the proportion of partial duals estimated using the 10 states with the highest poverty levels, and 2) applying a factor to the non-dual population in Puerto Rico to account for the partial dual risk.

Response: CMS is not making this adjustment. If CMS were to make an adjustment to the risk scores of non-duals in Puerto Rico, to account for what the risk scores of some beneficiaries would be if Puerto Rico had implemented the QMB and SLMB eligibility categories, we would need to make an adjustment to both the risk scores used in payment and the risk scores used to standardize the ratebook. Since adjusting the risk scores in the ratebook would make the rates lower, CMS has determined that an adjustment for non-dual beneficiaries in Puerto Rico would not improve payments for Puerto Rico.

Comment: A number of commenters are concerned by the large drop in revenue for the Institutional segment of the model. Plans are requesting more information to explain why the recalibration of data (updates to the risk adjustment relative factors and coefficients) are having such a significant negative effect on plan payments. A few commenters recommended that CMS postpone or not implement the implementation of the revised model for the LTI segment until further analyses are conducted.

Response: As noted in the Advance Notice, in addition to the model revision to improve the predictive power of the model for dual eligibles, the entire CMS-HCC model, including the long term institution (LTI) segment, was recalibrated with more recent data years. We acknowledge commenters' concerns and have investigated the drivers of the decrease in the risk scores for the Institutional segment of the model. We observed that the actual average cost for beneficiaries in LTI status decreased by 8.6% when we compared 2010-2011 data against 2013-2014 data. Because the overall costs of beneficiaries in the community has increased slightly, the relative costs of LTI beneficiaries, relative to the average Medicare beneficiary, have also decreased. Specifically, the data year update accounts for the change in LTI risk scores, not the model revision, and given the changes in the actual LTI costs, the decrease in LTI risk scores would have occurred even if we only had recalibrated the existing model. Our research indicates that the decrease in LTI risk scores is mostly driven by decreased expenditures for SNFs, home health organizations, and DMEs in 2014 compared to 2011. Furthermore, we found that

utilization rates for ER visits, hospital stays, and SNF stays for this population were lower in 2014 than in 2011.

Comment: A few commenters encouraged CMS to review new enrollee scores utilizing the six community segments and develop separate rates for members in these membership groups. One commenter was concerned about the accuracy of the current "default" risk scores and the effect that imposing the new risk adjustment model will have on already inaccurate default risk scores. This commenter recommended that CMS should use current year data, supplemented with prior year data, to establish risk scores for members that age into Medicare to more accurately reflect member risk in the first year of Medicare eligibility or alternatively, increase the assumed morbidity in the age/gender risk score weights to more accurately reflect plan liability for these members.

Response: New enrollee risk scores are scores that CMS uses when a beneficiary does not have adequate diagnoses to calculate a full risk score (operationalized as having fewer than 12 months of Part B in the data collection year). Because prior year data is insufficient to predict risk in the payment year for these beneficiaries, CMS uses a combination of age-sex, Medicaid, and originally disabled factors to determine the risk score of a new enrollee. The new enrollee model is calibrated to individually predict for each age-sex/Medicaid/originally disabled combination, and the beneficiaries in the model sample are limited to those with less than 12 months of Part B in the data collection year so that predicted costs are reflective of the new enrollee population. Medicaid status has always been assessed in the payment year for new enrollees. CMS did analyze the effect of using separate factors for full benefit duals and partial benefit duals and has determined that predictive ability of the new enrollee risk scores does not improve with separate factors for partial and full dual benefit beneficiaries. Therefore, CMS is not making any changes to the new enrollee segment of the model.

Section H. Medicare Advantage Coding Pattern Adjustment

Comment: Many commenters were pleased that CMS is not going above the statutory minimum.

Response: CMS appreciates the support of the commenters.

Comment: We received several comments regarding the coding intensity adjustment level. Several commenters felt that the coding intensity adjustment should be lower. A few of these commenters expressed concerns that the cumulative impact of coding adjustment and other changes in 2017 may present a risk to the ongoing viability of some MA plans. In contrast, a few commenters requested that the adjustment be higher than the statutory minimum, expressing concern that CMS may not be fully adjusting for the differing coding trends.

Additionally, a few commenters indicated that coding patterns in MA are heterogeneous and that applying an across the board adjustment is inequitable. One commenter suggested that CMS should apply a coding adjuster to plans that code poorly instead of those that code well. Another

commenter proposed a segmented approach such that a low coding factor is applied to lower coding plans while a larger factor is applied to high coding plans.

Response: CMS determines the MA coding pattern adjustment using the model to be used in the payment year so that the impact on trends in coding differences of any model change are taken into account. While CMS understands the commenters' concerns, we have extensively analyzed the MA data and determined that the optimal way to apply the adjustment is to do so uniformly and industry wide using the statutory minimum adjustment level.

Comment: One commenter suggested that the coding adjustment factor be reduced or eliminated for C-SNPs. The commenter stated that SNPs serve beneficiaries who have specified chronic conditions and are high risk, and they provide more high-touch care to their members so it is impossible to compare C-SNP coding intensity to FFS, given the concentration of chronically ill patients in these [MA] products. The commenter also believes that the flexibility afforded to CMS under the CMMI demonstration authority gives CMS the ability to test the reduction or elimination of the coding pattern adjustment for C-SNPs without modifying the adjustment factor for any other plans (i.e., in a non-budget neutral way).

Response: MA coding adjustment is a methodological adjustment to risk scores to improve payment accuracy given differential coding patterns in MA and FFS. CMS measures the differences in coding patterns between MA and FFS by observing the year-over-year growth in disease scores for beneficiaries who remain in MA or in FFS over time. Therefore, our MA coding adjustment factor reflects differences in coding patterns over time, not levels of risk scores.

Comment: A few commenters noted that CMS incorrectly implied that any observed coding differentials between the FFS and MA populations are driven by inappropriate coding on the part of MA plans and urged CMS to recognize that higher coding does not necessarily equate to wrong coding. One commenter urged CMS to consider the interaction between the adjustment for coding intensity and those that may result from RADV audits and ensure that MA plans and providers are not over-penalized.

Response: As we have noted in previous Advance Notices and Rate Announcements, we are not assuming that MA coding is inaccurate in calculating the MA coding pattern adjustment factor. Rather, we are adjusting for the impact on risk scores of coding patterns that differ from FFS coding, the basis of the CMS-HCC model and the Part C normalization factor. RADV audits, on the other hand, have the purpose of validating that diagnosis codes submitted for risk adjustment are documented in the medical record and, therefore, are correctly reported for the beneficiary in question.

Comment: A few commenters thought that it was inappropriate to apply the coding pattern adjustment to encounter data-based risk scores and that coding adjustment should apply only to the RAPS-based portion of payment.

Response: CMS will continue to apply the MA coding difference factor to risk scores as long as we calibrate our CMS-HCC model solely on FFS data. Per the statute, we will apply this adjustment until we implement "risk adjustment using Medicare Advantage diagnostic, cost, and use data," meaning until we have recalibrated the model using MA encounter data. We also note that because the encounter data system accepts diagnoses obtained through chart review, MAOs will be able to submit the same diagnoses that they have been submitting into the RAPS. Given that the encounter data system does not change the definition of acceptable diagnoses or limit their submission, CMS anticipates that the risk scores calculated using encounter data will reflect the same coding trend as those calculated with RAPS-based diagnoses. CMS will monitor the impact of using encounter data-based diagnoses on risk scores and risk score trends.

Comment: A few commenters requested that CMS take the effect of ICD-10 on coding and reduce the MA coding adjustment factor.

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). In addition, we remind commenters that plans have until at least January 31st after the payment year to submit accurate risk adjustment data (which includes both submissions to the RAPS and the Encounter Data Processing System). Given the extended period providers and plans have had to transition to ICD-10 and the extended period of time plans have to submit and correct diagnosis codes, we do not believe an adjustment to the MA coding pattern adjustment factor is warranted.

Comment: One commenter noted that any policy changes that would have a significant impact on MA plan payment should be implemented only after being published in the Federal Register and considered under notice and comment conducted under the APA and the PRA.

Response: Per statute, the MA coding adjustment is to be made as part of the risk adjustment methodology established under section 1853(a)(3) of the Social Security Act. Section 1853(b)(2) provides that CMS "shall provide for notice to [MA] organizations of proposed *changes* to be made in the *methodology*. . .used in previous [year] and shall provide [MA] organizations an opportunity to comment on such proposed *changes."* (Emphasis added.) Section 1853(b)(1) in turn provides for a final notice in which the "risk and other factors to be used in adjusting" payment will be published. When section 1853(a)(3) was first implemented in 2000 with the initial risk adjustment methodology developed by CMS, the initial methodology was implemented through this section 1853(b) notice and comment process. All subsequent changes to the risk adjustment methodology, have all been implemented through the section 1853(b) notice process. We believe that in specifying in section 1853(b) a detailed process for providing MA organizations with "notice" and an "opportunity to comment" on "changes" in the MA payment "methodology," Congress was specifying that this process was to be used to implement such changes, and that in its judgment this process gives MA organization a sufficient opportunity for input on changes affecting their payments. This belief is buttressed by the fact

that Congress has on several occasions ratified in statute methodologies that CMS established through this 1853(b) process (e.g., the initial phase in of risk adjustment and the plan to phase out budget neutrality). Thus, we believe that the Advance Notice and Announcement process is the appropriate vehicle for implementing and updating the MA coding adjustment factor.

Section I. Normalization Factors

Comment: Many commenters questioned the accuracy of the normalization factors and subsequent impact provided by CMS in the 2017 Advance Notice.

Response: As mentioned in Section I, "CMS-HCC Risk Adjustment Model for CY 2017," CMS has discovered a technical error in the calculation of the denominator used to create relative factors for the revised CMS-HCC model. While the proposed normalization calculation methodology was applied correctly, the historical risk scores used to calculate the normalization factor were incorrect; specifically, due to the technical error in the model relative values discussed in Section G above, the risk scores were too low and resulted in a predicted payment year risk score that was too low. Please see the table below for updated historical FFS risk scores using the revised CMS-HCC model as well as the original scores from the 2014 CMS-HCC model for comparison.

Table III-1. Historical Risk Scores under the 2014 and the 2017 CMS-HCC Models

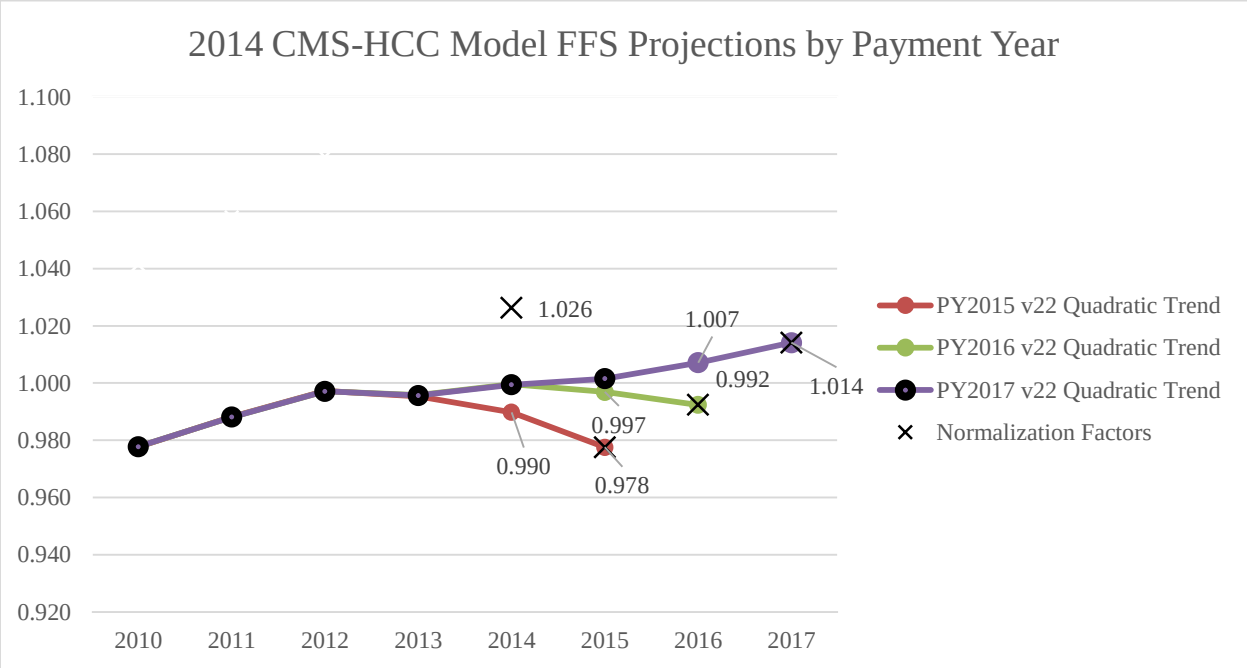
Year	FFS Risk Scores 2014 CMS-HCC Model	FFS Risk Scores 2017 CMS-HCC Model
2011	0.988	0.990
2012	0.997	0.998
2013	0.996	0.996
2014	0.999	1.000
2015	1.002	1.001

Comment: Some commenters asked that CMS change the methodology used to calculate the normalization factors. Commenters expressed concern that the quadratic functional form was not the best method for predicting future risk scores either because the influence of the aging baby boomer population on the trend has failed to materialize as expected or because there is not enough data to accurately predict future risk scores. Commenters suggested several alternatives for projecting normalization, including changes in methodology, such as a return to a linear function or a logistic growth function, or including additional years when applying a quadratic function.

Response: In response to comments, CMS has decided to increase the number of years included in the historical data used to calculate the normalization factor from four to five. CMS understands that baby boomers aging into Medicare is resulting in FFS risk scores increasing at a slower, less predictable, rate. The addition of an extra data point will better capture the variation

in FFS risk scores over time and further CMS' objective of better predicting the average FFS risk score for Payment Year 2017. We are not changing our methodology and will continue to use a quadratic equation to estimate a trend in risk scores and calculate the normalization factor for the payment year.

As some commenters observed, the normalization factors have been increasing over the past two years at a greater rate than might otherwise be expected. The increases in the normalization factors are the result of adding more recent years' risk scores to the historical data used to calculate each year's normalization factor. In 2013, FFS risk scores decreased. Since 2013, FFS risk scores have been increasing (although at a slower rate than before 2013). In other words, when we projected the Payment Year 2015 risk score using historical data ending in 2013, the projection reflected a downward trend that later turned out to be incorrect (i.e., the PY2015 normalization factor was too low). Similarly, the PY2016 normalization factor, although reflecting an upward movement in the historical data when we added the 2014 risk score, was also too low, although by less than the PY2015 normalization factor. The normalization factor for PY 2017 would have increased further if we had not increased the number of years included in the regression model in response to comment. These trends in risk scores and normalization factors can be seen in the graph of 2014 CMS-HCC model FFS risk scores below. The PY2017 normalization factor shown is the factor we would have used had we not implemented a revised CMS-HCC model or increased the number of historical years used when calculating normalization factor for PY2017.



*Black markers indicate actual risk score values

Comment: Many commenters requested that CMS provide a detailed explanation of the FFS normalization factor calculation for 2017.

Response: When CMS updates a risk adjustment model, dollar coefficients from the model are divided by average per capita FFS expenditure in the denominator year to create relative factors. Once a model is implemented, the average risk score in FFS is 1.0 in the denominator year. The revised CMS-HCC model has a 2015 denominator. If risk scores are calculated for any year other than the denominator year, those risk scores will not be 1.0. In order to keep the average FFS risk score 1.0 in the payment year, CMS calculates what we call a normalization factor that projects a FFS risk score trend to the payment year using historical FFS risk score data (see table above). Each payment model has a normalization factor that is updated in each payment year. A normalization factor for one year cannot be used with risk scores from another year or another model.

For the last several years, CMS has been using a quadratic function to predict future FFS normalization values. This function has the form:

$$FFS\ Risk\ Score\ (Normalization\ Factor) = Intercept + \beta_1 \times (Year) + \beta_2 \times (Year^2)$$
$$For\ PY2017, Year = 2017$$

The intercept and parameter estimates (β) are derived from an ordinary least squares (OLS) regression where FFS risk scores are regressed against year and year squared for five years of data.

Comment: Some commenters stated that the current methodology is not appropriate for the ESRD model. Several commenters also expressed concern about the significant impact of the Part D normalization factor. Both factors increase from 2016 to 2017. For Part D, commenters were concerned that the change in normalization factors would increase beneficiary premiums.

Response: For the Part D and ESRD models, CMS observes a similar pattern of under normalization in PY2015 as with the CMS-HCC model and, therefore, a larger than expected increase in normalization factors for PY2016 and PY2017, as more recent data leads to more accurate predictions in these years. As with the Part C normalization factor, and also in response to comments that we add an additional data year to more accurately explain variation in observed risk scores, CMS has decided to add an additional year of data to the calculation of the normalization factors in PY2017 for the ESRD Dialysis, Part D, and PACE/ESRD Functioning Graft payment models. Below are the updated normalization factors, along with the historical data used to calculate them.

Table III-2. PY2017 Normalization factors

Year	Revised CMS-HCC model	PACE/ESRD Functioning Graft CMS-HCC model	ESRD CMS-HCC Model	RxHCC model
2010				0.987
2011	0.990	1.031	0.956	0.996
2012	0.998	1.042	0.972	1.002
2013	0.996	1.043	0.974	0.995
2014	1.000	1.048	0.981	1.000
2015	1.001	1.052	0.989	
PY 2017 Normalization factor	0.998	1.051	0.994	0.976

*Please note that the Part C normalization factors use 2011-2015 data, while the RxHCC normalization factor uses 2010 – 2014 data.

Section J. Frailty Adjustment for PACE organizations and FIDE SNPs

Comment: Most commenters supported maintaining the current PACE frailty factors as well as the use of updated frailty factors to determine frailty scores for FIDE-SNPs.

Response: CMS appreciates the support.

Comment: A few commenters requested that the requirements for eligibility to receive frailty adjustments be expanded to include other plan types, such as I-SNPs and C-SNPs. Several commenters suggested that frailty factors should be applied to all frail beneficiaries, not just those beneficiaries enrolled in PACE plans or qualifying FIDE SNPs.

Response: Under the statute, CMS must use the same payment methodology for all MA plans, including Special Needs Plans (SNPs), except in specific cases. Section 1853(a)(1)(B)(iv) permits CMS to make frailty-adjusted payments only to certain dual SNPs – those with fully integrated, capitated contracts with States for Medicaid benefits, including long term care, and which have similar average levels of frailty as the PACE program. Thus, CMS cannot make frailty payments to any SNP that does not meet the statutory criteria without implementing frailty payments program-wide. If CMS were to apply a frailty adjustment to all MA plans, we would do so in a manner that does not increase aggregate MA payment. Specifically, the frailty model is calibrated to result in an average frailty score of 0.0. Thus, some enrollees would have a negative adjustment. Please reference the 2008 Advance Notice, published February 16, 2007, for more discussion on this topic. We also note that CMS has previously 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," 18 published March 2011, at

https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Evaluation_Risk_Adj_Model_2011.pdf for more information).

Comment: One commenter recommended that CMS base its frailty scores for comparison to PACE on the proportion of FIDE SNP members meeting PACE level of care requirements as assessed through State-approved assessment mechanisms used for nursing home and community based waiver level of care determinations.

Response: CMS calculates frailty scores using data obtained in a similar manner to the data used to calibrate the frailty model. CMS' frailty model is calibrated and frailty scores are calculated using data obtained from commonly-fielded surveys (the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey of FFS beneficiaries and the Health Outcome Survey of plan enrollees) to assess the average frailty of a plan or contract. Specifically, CMS uses limitations on activities of daily living (ADLs) obtained from written surveys that are completed by the beneficiary (please reference page 6 of the 2008 Advance Notice for a discussion of this source of the ADL data used to calibrate the frailty model). If CMS were to use ADL data from provider or plan sources, the frailty scores would be overstated. Further, because ADL data are collected via survey, we only collect the data for a subset of a plan's membership and it is, therefore, not possible to pay frailty calculated at an individual level for all enrollees in a plan. CMS believes the HOS and HOS-M survey currently provide the best estimate of a plan's frailty score because those surveys can be sampled at the PBP level and are standardized, unlike the state level assessments, which can vary from one state to the next.

See Table III-3 for the 2017 payment factors for all qualifying FIDE SNPs.

Table III-3. FIDE SNP Frailty Factors for CY 2017

ADL	Non-Medicaid	Medicaid
0	−0.083	−0.093
1-2	0.124	0.105
3-4	0.248	0.243
5-6	0.248	0.420

Section K. Encounter Data as a Diagnosis Source for 2017

Comment: While a number of commenters support the continued incorporation of diagnoses from encounter data into risk score calculations, many expressed concern that moving to a 50/50 blend of the RAPS/FFS and EDS/FFS risk scores is too aggressive at this time. There was a variety of recommendations for the blend of risk scores that ranged from maintaining the Payment Year 2016 blend of 90% of RAPS/FFS-based risk scores and 10% of encounter data/FFS-based risks scores to a more gradual increase in the transition blend. Several commenters suggested using a blend of 70% of the RAPS/FFS-based risk scores and 30% of the encounter data/FFS-based risk scores. Some commenters felt that, since the final encounter data

filtering logic and the related MAO-004 reports were only recently released, they have not had sufficient time to understand the impacts and how to operationalize the reports. In addition, there was concern expressed regarding the ability to accurately reflect the filtering impacts in the bid for Payment Year 2017, given that the impact of the blend for Payment Year 2016 will not be known for a while. A few commenters were concerned with complications in submitting encounters from capitated provider groups and the burden encounter data collection places on capitated provider groups. Some commenters raised concerns about the completeness, stability, and reliability of encounter data given problems with system edits. Some commenters thought the timing of an increased blend would be problematic given the unknown impact of ICD-10 on diagnosis reporting and risk scores. Finally, many commenters noted that CMS has not evaluated impacts of encounter data on risk scores nor conducted statistical analysis to ensure data accuracy and reliability.

Response: CMS appreciates the feedback and understands the challenges regarding the use of encounter data for risk adjustment. As many of the commenters noted, CMS has been and continues to work in good faith with submitters on technical and operational issues to address encounter data acceptance, completeness, and quality. CMS is also working closely with health plans to respond to their questions and make changes, where needed, to address the issues cited with the MAO-004 reports.

CMS's goal is to transition entirely from using diagnoses submitted to RAPS to using diagnoses from encounter data and we intend to continue transitioning away from a reliance on RAPS data for calculating risk scores. However, for 2017 payment, CMS will proceed with a blend percentage for the encounter data/FFS-based risk score of 25%, as opposed to the 50% blend that was proposed. Specifically, for Payment Year 2017, we will calculate a risk score using diagnoses submitted to RAPS and FFS diagnoses, and another risk score using diagnoses filtered from encounter data and FFS diagnoses. We will sum 75% of the RAPS/FFS-based risk score with 25% of the encounter data/FFS-based risk score. The blended scores will have the same normalization factor and the same MA coding adjustment.

The policies adopted through this Announcement apply to PY2017 (2016 dates of service), which will have a submission deadline no earlier than January, 2018. We note that encounter data submission rates have steadily increased while error rates have steadily decreased. CMS expects this trend to continue to improve as more experience is gained and for the data to stabilize by the time this blend would be in effect. CMS has also worked continuously with the plan community to understand other submission and operational issues through industry and individual plan level discussions, and will continue to do so. Given this, CMS plans to increase the weighting of encounter data-based risk scores over the next couple of years by moving to a risk score incorporating 50% of the encounter data/FFS-based risk score in 2018, a risk score incorporating 75% of the encounter data/FFS-based risk score for 2019, and a risk score of 100% encounter data/FFS-based risk score in 2020.

Comment**:** Some commenters supported the proposed 50/50 blend. Two commenters encouraged a more aggressive approach by going to risk scores based on 100% encounter data, stating that health plans have had sufficient time to acclimate to the EDS submission requirements and that, since these data inherently requires a richer level of data submission than RAPS, transition to this data source should result in greater overall payment accuracy. The commenter also noted that maintaining two separate data submission processes was burdensome to both health plans and CMS.

Response**:** CMS appreciates the support of the commenters.

Comment: A few commenters supported the proposal to continue the same method of calculating risk scores as used for the 2016 payment year for PACE plans.

Response: CMS appreciates the support of the commenters and is finalizing this as proposed.

Attachment IV. Responses to Public Comments on Part D Payment Policy

Section A. Update of the RxHCC Model

Comment: Most commenters expressed support for CMS's decision to not adjust the hepatitis C coefficient downward, and encouraged CMS's commitment to maintaining payment accuracy by making adjustments as treatment patterns evolve.

Response: CMS appreciates the support.

Comment: Some commenters suggested CMS consider making the hepatitis C coefficient "concurrent" in the RxHCC model going forward in order to more accurately capture costs.

Response: CMS's objective in using a prospective model is to identify chronic, predictable conditions, not acute events. Thus, the Part D risk adjustment model is not designed to predict costs based on diseases that are primarily diagnosed, treated and cured in the same year. Making a single factor concurrent would over-emphasize the cost attributed to that condition, and reduce the costs attributed to the other, prospective factors.

Comment: Some commenters suggested that CMS should continue to review drug costs and treatment patterns for other diseases and consider similar adjustments to other coefficients, so long as changes are based on appropriate actuarial and related data analytics.

Response: CMS appreciates this recommendation and will take it into consideration.

Comment: One commenter requested that CMS consider doing an analysis on the accuracy of the Medicare Part D RxHCC model for dual eligible and to share that analysis with states.

Response: CMS appreciates the request and will take it into consideration. However, the Part D risk adjustment model is currently segmented by low income status. The risk scores from these segments take into account the additional cost of low income beneficiaries.

Comment: Some commenters questioned whether CMS intended to leave blank the rows for NonAged_RXHCC 164 and NonAged_RXHCC 165 in Table 5 in the institutional segment.

Response: Yes, CMS intended to leave blank rows for NonAged_RXHCC 164 and NonAged_RXHCC 165 in Table 5 in the institutional segment. These interaction terms are technically included in the calibration of the Part D model but the predicted amounts are either negative or statistically no different from zero. To avoid confusion, we are removing these interaction terms from the final table of RxHCC factors.

Section B. Encounter Data as a Diagnosis Source for 2017

See Section K for comments and responses related to this issue.

Section C. Part D Risk Sharing

Comment: We received two comments in support of the decision not to make any changes to the Part D Risk sharing parameters and the analytical approach taken to reach this decision. One commenter added that staying consistent in this manner will allow for more accurate bids.

Response: CMS appreciates the support.

Section D. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy in 2017

Comment: A few commenters asked for CMS to change how the out-of-pocket threshold is updated each year, asking specifically for a change in how the parameter is indexed to better align with the growth in drug costs.

Response: Pursuant to section 1860D-2(b)(4)(i)(IV) of the Act, for each of years 2016 through 2019, the out-of-pocket threshold increase is the lesser of the annual percentage increase or the July CPI plus two percentage points. CMS does not have the authority to modify the parameter indexing methodology.

Comment: Several commenters expressed concern about the underlying drug cost trends driving the annual Part D benefit parameter updates. One commenter stated that brand name prescription drug price increases are continuing to accelerate while the effects of the "generic patent cliff" are beginning to subside. The commenter added that it is noteworthy that the growth rate for the Medicare Part D out-of-pocket cap is constrained through 2019 due to the Affordable Care Act. The commenter stated that, although Part D enrollees are protected now, they will soon face the full impact of benefit parameter changes that could increase their out-of-pocket liability by hundreds of dollars per year. The commenter strongly urged CMS to monitor Medicare Part D spending trends and their subsequent impact on enrollees.

Response: CMS appreciates the concerns of commenters and will continue monitoring Part D spending trends and their impact on enrollees.

Comment: One commenter noted that it is crucial that Part D sponsors have flexibility to use clinically-based tools and techniques to promote greater affordability in the program in response to the threat provided by the influx of high-cost drugs into the Part D market.

Response: While we appreciate the concerns of commenters and will continue to work with the industry to monitor Part D spending trends and manage their impact on enrollees, CMS must update the parameters for the defined standard Part D prescription drug benefit and promote affordability in a manner consistent with the statutorily prescribed methodology.

Comment: One commenter stated that, while Hepatitis C treatment costs present significant costs for plans and should be captured in the risk adjustment model, they should not be permitted

to have a significant and pervasive impact on Part D benefit parameters. The commenter requested CMS to consider alternative ways to derive benefit parameter increases, since the cost increases for Hepatitis C patients only impacts the extreme right tail of the claim distribution and have minimal bearing on the claim distribution pattern for approximately 99 percent of the Part D population.

Response: CMS again appreciates the concerns of commenters, but is required by statute to update the parameters for the defined standard Part D benefit by the annual percentage increase in average expenditures for covered Part D drugs per eligible beneficiary.

Comment: One commenter noted that the maximum copay thresholds for each tier of drug for individuals that qualify for the low-income subsidy have remained largely unchanged. The commenter suggests that CMS develop an indexing system where the cost sharing is tied to the cost of prescription drugs.

Response: While we appreciate the concerns of commenters and will continue monitoring Part D spending trends and their impact on enrollees, CMS must update the parameters for the low-income subsidy in a manner consistent with the statutorily prescribed methodology.

Section E. Part D Calendar Year Employer Group Waiver Plans

Comment: The majority of commenters expressed support for the proposal to pay CY EGWPs prospective reinsurance, with several indicating that through this proposal CMS has provided calendar year EGWPs with much needed cash flow relief from the effect of the rapid increases in the cost of specialty drugs experienced by all prescription drug plans over the past few years.

Response: We appreciate the support.

Comment: A few commenters requested that the amount paid be more plan specific instead of an average. While a few other commenters were uncertain as to whether the prospective payment amount would be based on a plan specific average or on a national average.

Response: The $26.50 prospective payment is the national average paid to Calendar Year EGWPs for payment year 2014. CMS considered incorporating a plan or contract specific methodology in the course of developing the proposal, but ultimately decided against that approach due to anticipated operational and administrative challenges for both CMS and plans. Moreover, the intent of the policy is not to pay more or less than actual incurred reinsurance, but to provide additional cash flow to these plans during the course of the benefit year until the actual incurred reinsurance costs are ultimately reconciled, which may not take place for as long as eleven months following the end of a calendar year.

Comment: A few commenters were unsure of the timing of the payments, the administration of the prospective payments, and the impact of the prospective payments on the regular adjustment process that occurs in normal plan year reconciliation, and requested clarifying details.

Response: Beginning in Calendar Year 2017, CMS will pay $26.50 per member per month in prospective reinsurance to each Part D Calendar Year EGWP as part of the monthly prospective payments currently made to these Contracts. Part D EGWPs will still be subject to reconciliation. Incurred actual reinsurance reconciliation calculations will remain intact as they exist today, except that the prospective reinsurance payments will be reconciled to actual incurred reinsurance costs during the normal annual reconciliation process. In the event that the prospective reinsurance payment amount for a plan for a year exceeds the actual incurred reinsurance amount calculated during reconciliation for a plan for a year, the difference between the prospective reinsurance payment and the actual incurred reinsurance amount calculated during reconciliation will be recouped by CMS. In the event that the prospective reinsurance payment amount for a plan for a year is less than the actual incurred reinsurance amount calculated during reconciliation for a plan for a year, the difference between the prospective reinsurance payment and the actual incurred reinsurance amount will be paid to the plan in accordance with current reconciliation processes. The reinsurance reconciliation rules as summarized above for CY Part D EGWPs will be applied the same way that the reinsurance reconciliation rules currently apply to non-EGWP plans that submit reinsurance estimates in their bid submissions, upon which they are paid prospectively, but which are ultimately reconciled to actual incurred reinsurance costs during the normal reconciliation process.

Comment: Two commenters opposed the policy expressing that paying a prospective reinsurance amount could cause confusion for the impacted plans and lead to an expectation of reduced premiums while, in fact, their payments will ultimately be reconciled annually. The commenters suggested that CMS either develop a prospective reinsurance payment for all CY EGWPs that is not reconciled, or continue the current practice of reconciling reinsurance payments without paying a prospective payment.

Response: Although CMS appreciates the commenters' concerns, we believe that our detailed responses to the comments we received on the policy sufficiently allay their concerns. Our responses provide more explicit detail surrounding the payment flow details, giving particular emphasis to the fact that the EGWP policy does not increase or decrease the amount any given Part D EGWP will ultimately be paid for their actual incurred reinsurance for any given payment year. The prospective amount paid in reinsurance will be reconciled to actual incurred reconciliation costs during the normal annual reconciliation process.

Comment: One commenter requested that CMS reconsider using the 2014 proposed values as metrics for prospective payments given significant drug pricing and payment differences that will have occurred between 2014 and 2017. The commenter asserted that basing prospective payments on 2014 will not accurately compare the current status of providing benefits in the program and will lead to frequent and potentially costly adjustments for the 2017 plan year.

Response: The reconciliation data for 2014 contains the most recent actual total reinsurance amount available for publication in the 2017 Advance Notice/Rate Announcement. CMS is

proposing this methodology as it is based on the most currently available actual Part D CY EGWP experience. The 2015 reinsurance reconciliation amounts will not be known until approximately November of 2016, which means CMS and plans will not know the amounts until near the beginning of the benefit year, which we believe would lead to unnecessary confusion in the payment process. In addition, given that these plans currently receive $0.00 in prospective reinsurance, we believe that providing the average amount of $26.50 per member per month is a reasonable and conservative amount to pay in order to accomplish our goal of providing additional cash flow throughout the year to facilitate the sustainable offering of these plans, while limiting the probability of needing to take back a large amount of prospective reinsurance payments in the annual reconciliation process when the prospective payments are reconciled to actual incurred reinsurance.

Comment: One commenter requested confirmation that the reinsurance amounts for plans without additional coverage in the coverage gap will not be different than for plans with additional coverage in the coverage gap.

Response: The reinsurance amounts will not be different for plans with and without additional coverage in the coverage gap. The reinsurance reconciliation rules as summarized herein for CY Part D EGWPs will be applied the same way that the reinsurance reconciliation rules currently apply to non-EGWP plans that submit reinsurance estimates in their bid submissions, upon which they are paid prospectively, but which are ultimately reconciled to actual incurred reinsurance costs during the normal reconciliation process.

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 2016	Prior year revisions	Annual percentage increase for 2017
API: Applied to all parameters but (1) and (2)	6.99%	4.45%	11.75%
July CPI (all items, U.S. city average): Applied to (1)	1.13%	−1.26%	−0.15%
September CPI (all items, U.S. city average): Applied to (2)	1.67%	−1.46%	0.18%

Part D Benefit Parameters

	2016	2017
Standard Benefit		
Deductible	$360	$400
Initial Coverage Limit	$3,310	$3,700
Out-of-Pocket Threshold	$4,850	$4,950
Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (3)	$7,062.50	$7,425.00
Estimated Total Covered Part D Spending for Applicable Beneficiaries (4)	$7,515.22	$8,071.16
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit		
Generic/Preferred Multi-Source Drug	$2.95	$3.30
Other	$7.40	$8.25
Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals (6)		
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 (5) (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 (6)	$1.20	$1.20
Other (6)	$3.60	$3.70
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	$2.95	$3.30
Other	$7.40	$8.25
Above Out-of-Pocket Threshold	$0.00	$0.00
Full Subsidy-Non-FBDE Individuals		

	2016	2017
Applied or eligible for QMB/SLMB/QI or SSI and income at or below 135% FPL and resources ≤ $8,780 (individuals) or ≤ $13,930 (couples) (7) (category code 1)		
Deductible	$0.00	$0.00
Maximum Copayments up to Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.95	$3.30
Other	$7.40	$8.25
Maximum Copayments above Out-of-Pocket Threshold	$0.00	$0.00
Partial Subsidy		
Applied and income below 150% FPL and resources below $13,640 (individual) or $27,250 (couples) (7) (category code 4)		
Deductible (6)	$74.00	$82.00
Coinsurance up to Out-of-Pocket Threshold	15%	15%
Maximum Copayments above Out-of-Pocket Threshold		
Generic/Preferred Multi-Source Drug	$2.95	$3.30
Other	$7.40	$8.25
Retiree Drug Subsidy Amounts		
Cost Threshold	$360	$400
Cost Limit	$7,400	$8,250

(1) Pursuant to section 1860D-2(b)(4)(B)(i)(IV) of the Act, for each of years 2016 through 2019, the Out-of-Pocket Threshold increase is the lesser of the annual percentage increase or the July CPI plus two percentage points.

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

(3) 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.

(4) 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 PDE records.

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

(6) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2016 values of $73.79, $1.21, and $3.64, respectively.

(7) These resource limit figures will be updated for contract year 2017.

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

Section 1860D-2(b)(6) of the Act defines the API 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 $360 in 2016 and rounded to the nearest multiple of $5.

Initial Coverage Limit: From $3,310 in 2016 and rounded to the nearest multiple of $10.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From $2.95 per generic or preferred drug that is a multi-source drug, and $7.40 for all other drugs in 2016, and rounded to the nearest multiple of $0.05.

Maximum Copayments up to the Out-of-Pocket Threshold for Certain Low Income Full Subsidy Eligible Enrollees: From $2.95 per generic or preferred drug that is a multi-source drug, and $7.40 for all other drugs in 2016, and rounded to the nearest multiple of $0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From $74[6] in 2016 and rounded to the nearest $1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From $2.95 per generic or preferred drug that is a multi-source drug, and $7.40 for all other drugs in 2016, and rounded to the nearest multiple of $0.05.

Section B. Annual Percentage Increase in Consumer Price Index (CPI)

Section 1860D-14(a)(4) of the Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments up to the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 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,

[6] Consistent with the statutory requirements of section 1860D-14(a)(4)(B) of the Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2016 value of $73.79.

and $3.60 for all other drugs in 2016[7], and rounded to the nearest multiple of $0.05 and $0.10, respectively.

Additionally, section 1860D-2(b)(4) of the Act requires that the "annual percentage increase" applied to the out-of-pocket threshold in 2017 is CPI+2%, which is the lesser of API and CPI+2%. The change in CPI in this case is measured over the 12-month period ending in July of the previous year, as required by statute. The threshold is increased from $4,850 in 2016 and rounded to the nearest multiple of $50.

Section C. Calculation Methodology

Annual Percentage Increase in Average Expenditures for Part D Drugs per Eligible Beneficiary (API)

For contract years 2007 and 2008, the APIs, as defined in section 1860D-2(b)(6) of the 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 contract year 2009, the APIs are based on Part D program data. For the 2017 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{August\ 2015 – July\ 2016}{August\ 2014 – July\ 2015} = \frac{\$3{,}615.90}{\$3{,}379.72} = 1.0699$$

In the formula, the average per capita cost for August 2014 – July 2015 ($3,379.72) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2015 – July 2016 ($3,615.90) is calculated based on actual Part D PDE data incurred from August 2015 – December 2015 and projected through July 2016.

The 2017 benefit parameters reflect the 2016 annual percentage trend as well as an update for revision to prior year estimates for API. Based on updated NHE prescription drug per capita costs and PDE data, the annual percentage increases are now estimated as summarized by Table V-2.

[7] Consistent with the statutory requirements of section 1860D-14(a)(4)(A) of the Act, the copayments are increased from the unrounded 2016 values of $1.21per generic or preferred drug that is a multi-source drug, and $3.64 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	**4.17%**	**4.69%**
2010	**3.07%**	**3.14%**
2011	**2.48%**	**2.36%**
2012	**2.45%**	**2.16%**
2013	**1.95%**	**2.53%**
2014	**−2.72%**	**−3.13%**
2015	**9.18%**	**10.03%**
2016	**6.37%**	**9.91%**

Accordingly, the 2017 benefit parameters reflect a multiplicative update of 4.45 percent for prior year revisions. In summary, the 2016 parameters outlined in Section A are updated by 11.75 percent for 2017, as summarized by Table V-3.

Table V-3. Annual Percentage Increase

Annual percentage trend for July 2016	6.99%
Prior year revisions	4.45%
Annual percentage increase for 2017	11.75%

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

Annual Percentage Increase in Consumer Price Index, September (September CPI)

To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in September 2016 includes an estimate of the September 2016 CPI based on projections from the President's FY2017 Budget.

The September 2015 value is from the Bureau of Labor Statistics. The annual percentage trend in the September CPI for contract year 2017 is calculated as follows:

$$\frac{\text{Projected September 2016 CPI}}{\text{Actual September 2015 CPI}} \; or \; \frac{241.918}{237.945} = 1.0167$$

(Source: President's FY2017 Budget and Bureau of Labor Statistics, Department of Labor)

The 2017 benefit parameters reflect the 2016 annual percentage trend in the September CPI of 1.67 percent, as well as a revision to the prior estimate for the 2015 CPI increase over the 12 month period ending in September 2015. Based on the actual reported CPI for September 2015, the September 2015 CPI increase is now estimated to be −0.04 percent. Accordingly, the 2017 update reflects a −1.46 percent multiplicative correction for the revision to last year's estimate. In summary, the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes not exceeding 100 percent of the Federal poverty line are updated by 0.18 percent for 2017, as summarized by Table V-4.

Table V-4. Cumulative Annual Percentage Increase in September CPI

Annual percentage trend for September 2016	1.67%
Prior year revisions	−1.46%
Annual percentage increase for 2017	0.18%

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

Annual Percentage Increase in Consumer Price Index, July (July CPI)

As is the case when calculating the annual CPI trend as of September 2016, the methodology to calculate the annual percentage increase in the CPI for the 12 month period ending in July 2016 includes an estimate of the July 2016 CPI based on projections from the President's FY2017 Budget.

The July 2015 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2017 is calculated as follows:

$$\frac{\text{Projected July 2016 CPI}}{\text{Actual July 2015 CPI}} \; or \; \frac{241.344}{238.654} = 1.0113$$

(Source: President's FY2017 Budget and Bureau of Labor Statistics, Department of Labor)

The 2017 benefit parameters reflect the 2016 annual percentage trend in the July CPI of 1.13 percent as well as a revision to the prior estimate for the 2015 CPI increase. Based on the actual reported CPI for July 2015, the CPI increase over the 12 month period ending in July 2015 is estimated to be 0.17 percent. The prior year revision here reflects the difference between this

actual 0.17 percent increase in CPI observed in July 2015 and the 2015 CPI increase estimate from the CY 2016 Rate Announcement, which erroneously used September instead of July CPI values. Accordingly, the 2017 update reflects a -1.26 percent multiplicative correction for the revision to last year's estimate.

In summary, the cumulative annual percentage increase in July CPI for 2017 is -0.15 percent, as summarized by Table V-5. This value plus two percentage points is less than the 11.75 percent cumulative API for 2017 described above. Thus, the out-of-pocket threshold will be increased by 1.85 percent for 2017.

Table V-5. Cumulative Annual Percentage Increase in July CPI

Annual percentage trend for July 2016	1.13%
Prior year revisions	−1.26%
Annual percentage increase for 2017	−0.15%

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

Section D. Retiree Drug Subsidy Amounts

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are also updated using the API, as defined previously in this document. The updated cost threshold is rounded the nearest multiple of $5 and the updated cost limit is rounded to the nearest multiple of $50. The cost threshold and cost limit are defined as $320 and $6,600, respectively, for plans that end in 2015, and, as $360 and $7,400, respectively, for plans that end in 2016. For 2017, the cost threshold is $400 and the cost limit is $8,250.

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

For 2017, the total covered Part D spending at out-of-pocket threshold for applicable beneficiaries is $8,071.16. The figure is calculated given the following basic assumptions:

- 100 percent beneficiary cost sharing in the deductible phase.
- 25 percent beneficiary cost sharing in the initial coverage phase and in the coverage gap.
- 51 percent beneficiary cost sharing for non-applicable (generic) drugs purchased in the coverage gap phase of the benefit.
- 90 percent cost sharing for the ingredient cost and sales tax for applicable (brand) drugs purchased in the coverage gap phase of the benefit – 40 percent beneficiary coinsurance and 50 percent coverage gap discount program discount.
- 40 percent cost sharing for the dispensing and vaccine administration fees for applicable (brand) drugs purchased in the coverage gap phase of the benefit.

In this estimate, it is also assumed that the dispensing and vaccine administration fees account for 0.11 percent of the gross covered brand drug costs used by non-LIS beneficiaries in the coverage gap. Therefore, a 60 percent reduction in cost sharing for dispensing and vaccine administration fees results in an overall reduction of 0.05 percent to 89.95 percent in cost sharing for applicable (brand) drugs in the coverage gap.

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

$$\text{ICL} + \frac{\text{100\% beneficiary cost sharing in the gap}}{\text{weighted gap coinsurance factor}} \quad or \quad 3{,}700 + \frac{\$3{,}725.00}{85.218\%} = \$8{,}071.16$$

- ICL is the Initial Coverage Limit equal to $3,700
- One hundred percent beneficiary cost sharing in the gap is the estimated total drug spending in the gap assuming 100 percent coinsurance.
- One hundred percent cost sharing in the gap is calculated as follows:

  OOP threshold − OOP costs up to the ICL *or* $4,950 − $1,225.00 = $3,725.00

- Weighted gap coinsurance factor is calculated as follows:

  (Brand GDCB % for non-LIS × 89.95% gap cost sharing for applicable drugs) + (Generic GDCB % for non-LIS × 51% gap cost sharing for non-applicable drugs)

  or

  (87.9% × 89.95%) + (12.1% × 51%) = 85.218%

- Brand GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries (i.e., non-LIS) attributable to applicable (brand) drugs, as reported on the 2015 PDEs.
- Gap cost sharing for applicable drugs is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for applicable (brand) drugs in the coverage gap, where:

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

  or

  89.95% = [(99.89% × 90%) + (0.11% × 40%)]

- Generic GDCB % for non-LIS is the percentage of gross covered drug costs below the out-of-pocket threshold for applicable beneficiaries (i.e., non-LIS) attributable to non-applicable (generic) drugs as reported on the 2015 PDEs.
- Gap cost sharing for non-applicable drugs is the coinsurance incurred by applicable beneficiaries (i.e., non-LIS) for non-applicable (generic) drugs in the coverage gap.

Attachment VI. CMS-HCC and RxHCC Risk Adjustment Factors

Table VI-1. 2017 CMS-HCC Model Relative Factors for Community and Institutional Beneficiaries

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
Female								
0-34 Years		–	0.244	–	0.318	–	0.344	1.031
35-44 Years		–	0.303	–	0.306	–	0.383	0.999
45-54 Years		–	0.322	–	0.338	–	0.374	1.007
55-59 Years		–	0.350	–	0.388	–	0.371	0.986
60-64 Years		–	0.411	–	0.449	–	0.395	1.028
65-69 Years		0.312	–	0.425	–	0.341	–	1.200
70-74 Years		0.374	–	0.511	–	0.406	–	1.092
75-79 Years		0.448	–	0.611	–	0.484	–	0.995
80-84 Years		0.537	–	0.739	–	0.552	–	0.860
85-89 Years		0.664	–	0.917	–	0.678	–	0.749
90-94 Years		0.797	–	1.037	–	0.817	–	0.626
95 Years or Over		0.816	–	1.094	–	0.913	–	0.456
Male								
0-34 Years		–	0.155	–	0.225	–	0.330	1.049
35-44 Years		–	0.190	–	0.204	–	0.267	1.074
45-54 Years		–	0.221	–	0.281	–	0.300	1.008
55-59 Years		–	0.271	–	0.372	–	0.307	1.055
60-64 Years		–	0.303	–	0.486	–	0.343	1.039
65-69 Years		0.300	–	0.492	–	0.334	–	1.269
70-74 Years		0.379	–	0.582	–	0.409	–	1.323
75-79 Years		0.466	–	0.692	–	0.491	–	1.331
80-84 Years		0.561	–	0.816	–	0.546	–	1.189
85-89 Years		0.694	–	1.009	–	0.679	–	1.129

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
90-94 Years		0.857	-	1.186	-	0.822	-	0.964
95 Years or Over		0.976	-	1.268	-	1.038	-	0.781
Medicaid and Originally Disabled								
Medicaid		-	-	-	-	-	-	0.062
Originally Disabled, Female		0.244	-	0.172	-	0.126	-	-
Originally Disabled, Male		0.152	-	0.192	-	0.105	-	-
Disease Coefficients	**Description Label**							
HCC1	HIV/AIDS	0.312	0.288	0.585	0.500	0.550	0.232	1.747
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.455	0.532	0.596	0.811	0.409	0.417	0.346
HCC6	Opportunistic Infections	0.435	0.704	0.548	0.919	0.482	0.765	0.580
HCC8	Metastatic Cancer and Acute Leukemia	2.625	2.644	2.542	2.767	2.442	2.582	1.143
HCC9	Lung and Other Severe Cancers	0.970	0.927	0.973	1.025	0.955	0.879	0.727
HCC10	Lymphoma and Other Cancers	0.677	0.656	0.713	0.761	0.667	0.577	0.401
HCC11	Colorectal, Bladder, and Other Cancers	0.301	0.352	0.332	0.361	0.325	0.400	0.293
HCC12	Breast, Prostate, and Other Cancers and Tumors	0.146	0.202	0.159	0.190	0.152	0.182	0.199
HCC17	Diabetes with Acute Complications	0.318	0.371	0.346	0.431	0.354	0.423	0.441
HCC18	Diabetes with Chronic Complications	0.318	0.371	0.346	0.431	0.354	0.423	0.441
HCC19	Diabetes without Complication	0.104	0.128	0.097	0.160	0.098	0.136	0.160
HCC21	Protein-Calorie Malnutrition	0.545	0.753	0.752	0.845	0.562	0.709	0.260
HCC22	Morbid Obesity	0.273	0.227	0.410	0.373	0.244	0.242	0.511
HCC23	Other Significant Endocrine and Metabolic Disorders	0.228	0.444	0.228	0.353	0.193	0.351	0.337
HCC27	End-Stage Liver Disease	0.962	1.110	1.242	1.349	0.889	0.963	0.962
HCC28	Cirrhosis of Liver	0.390	0.394	0.342	0.491	0.460	0.324	0.390
HCC29	Chronic Hepatitis	0.165	0.267	0.038	0.400	0.263	0.324	0.390
HCC33	Intestinal Obstruction/Perforation	0.246	0.524	0.369	0.503	0.324	0.510	0.335

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC34	Chronic Pancreatitis	0.276	0.678	0.333	0.875	0.412	0.849	0.241
HCC35	Inflammatory Bowel Disease	0.294	0.483	0.334	0.613	0.209	0.496	0.244
HCC39	Bone/Joint/Muscle Infections/Necrosis	0.425	0.474	0.552	0.713	0.418	0.491	0.345
HCC40	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.423	0.377	0.370	0.345	0.390	0.290	0.329
HCC46	Severe Hematological Disorders	1.388	3.188	1.219	4.256	1.226	3.529	0.680
HCC47	Disorders of Immunity	0.625	0.848	0.529	0.589	0.449	0.690	0.529
HCC48	Coagulation Defects and Other Specified Hematological Disorders	0.221	0.339	0.268	0.378	0.225	0.382	0.151
HCC54	Drug/Alcohol Psychosis	0.383	0.569	0.706	0.919	0.388	0.613	0.102
HCC55	Drug/Alcohol Dependence	0.383	0.285	0.522	0.366	0.377	0.286	0.102
HCC57	Schizophrenia	0.608	0.395	0.612	0.432	0.547	0.366	0.271
HCC58	Major Depressive, Bipolar, and Paranoid Disorders	0.395	0.209	0.444	0.178	0.413	0.163	0.271
HCC70	Quadriplegia	1.314	1.053	1.098	1.056	1.274	1.328	0.497
HCC71	Paraplegia	1.007	0.704	0.920	1.019	0.958	0.908	0.467
HCC72	Spinal Cord Disorders/Injuries	0.528	0.456	0.552	0.407	0.556	0.384	0.229
HCC73	Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.970	1.082	1.230	1.219	0.570	0.814	0.224
HCC74	Cerebral Palsy	0.280	0.132	-	-	0.158	0.052	-
HCC75	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	0.457	0.528	0.436	0.465	0.364	0.331	0.369
HCC76	Muscular Dystrophy	0.505	0.457	0.553	0.512	0.429	0.168	0.104
HCC77	Multiple Sclerosis	0.441	0.540	0.687	0.794	0.407	0.459	-
HCC78	Parkinson's and Huntington's Diseases	0.674	0.585	0.751	0.516	0.629	0.394	0.145
HCC79	Seizure Disorders and Convulsions	0.309	0.227	0.357	0.195	0.349	0.245	0.088
HCC80	Coma, Brain Compression/Anoxic Damage	0.584	0.302	0.946	0.324	0.508	0.155	0.042

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC82	Respirator Dependence/Tracheostomy Status	1.055	1.024	2.304	1.575	0.914	0.676	1.631
HCC83	Respiratory Arrest	0.658	0.781	1.033	0.484	0.704	0.429	0.727
HCC84	Cardio-Respiratory Failure and Shock	0.302	0.578	0.471	0.484	0.301	0.429	0.297
HCC85	Congestive Heart Failure	0.323	0.412	0.355	0.415	0.320	0.367	0.191
HCC86	Acute Myocardial Infarction	0.233	0.306	0.473	0.618	0.280	0.438	0.497
HCC87	Unstable Angina and Other Acute Ischemic Heart Disease	0.218	0.306	0.336	0.618	0.280	0.438	0.497
HCC88	Angina Pectoris	0.140	0.121	0.068	0.205	0.175	0.220	0.497
HCC96	Specified Heart Arrhythmias	0.268	0.284	0.369	0.377	0.283	0.258	0.224
HCC99	Cerebral Hemorrhage	0.263	0.282	0.474	0.690	0.278	0.280	0.114
HCC100	Ischemic or Unspecified Stroke	0.263	0.195	0.474	0.357	0.270	0.232	0.114
HCC103	Hemiplegia/Hemiparesis	0.538	0.324	0.548	0.435	0.603	0.401	0.031
HCC104	Monoplegia, Other Paralytic Syndromes	0.395	0.258	0.374	0.381	0.559	0.401	0.031
HCC106	Atherosclerosis of the Extremities with Ulceration or Gangrene	1.461	1.506	1.744	1.740	1.452	1.601	0.884
HCC107	Vascular Disease with Complications	0.400	0.486	0.540	0.756	0.443	0.549	0.321
HCC108	Vascular Disease	0.298	0.333	0.324	0.319	0.316	0.326	0.094
HCC110	Cystic Fibrosis	0.620	2.538	0.985	3.365	0.358	2.861	0.305
HCC111	Chronic Obstructive Pulmonary Disease	0.328	0.262	0.422	0.354	0.358	0.293	0.305
HCC112	Fibrosis of Lung and Other Chronic Lung Disorders	0.209	0.262	0.134	0.322	0.172	0.174	0.057
HCC114	Aspiration and Specified Bacterial Pneumonias	0.599	0.530	0.707	0.490	0.666	0.373	0.067
HCC115	Pneumococcal Pneumonia, Empyema, Lung Abscess	0.221	0.128	0.162	0.049	0.302	0.220	0.067
HCC122	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.217	0.171	0.223	0.284	0.276	0.195	0.460
HCC124	Exudative Macular Degeneration	0.499	0.385	0.278	0.090	0.336	0.115	0.228
HCC134	Dialysis Status	0.422	0.500	0.672	0.637	0.435	0.512	0.462
HCC135	Acute Renal Failure	0.422	0.500	0.672	0.637	0.435	0.512	0.462

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
HCC136	Chronic Kidney Disease, Stage 5	0.237	0.141	0.244	0.167	0.184	0.147	0.436
HCC137	Chronic Kidney Disease, Severe (Stage 4)	0.237	0.141	0.244	0.079	0.184	0.035	0.202
HCC157	Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone	2.163	2.203	2.879	2.626	2.274	2.655	0.924
HCC158	Pressure Ulcer of Skin with Full Thickness Skin Loss	1.204	1.393	1.576	1.559	1.074	1.237	0.295
HCC161	Chronic Ulcer of Skin, Except Pressure	0.535	0.636	0.757	0.631	0.586	0.620	0.294
HCC162	Severe Skin Burn or Condition	0.321	0.348	0.003	0.537	0.525	0.119	0.076
HCC166	Severe Head Injury	0.584	0.302	0.946	0.324	1.065	0.155	0.042
HCC167	Major Head Injury	0.191	0.044	0.274	0.171	0.133	0.049	-
HCC169	Vertebral Fractures without Spinal Cord Injury	0.495	0.456	0.552	0.407	0.516	0.384	0.209
HCC170	Hip Fracture/Dislocation	0.418	0.513	0.520	0.668	0.383	0.484	-
HCC173	Traumatic Amputations and Complications	0.266	0.340	0.412	0.383	0.233	0.232	0.267
HCC176	Complications of Specified Implanted Device or Graft	0.597	0.871	0.721	1.156	0.584	0.876	0.502
HCC186	Major Organ Transplant or Replacement Status	1.000	0.618	0.816	1.075	0.795	0.655	0.962
HCC188	Artificial Openings for Feeding or Elimination	0.571	0.785	0.775	0.870	0.579	0.867	0.500
HCC189	Amputation Status, Lower Limb/Amputation Complications	0.588	0.455	0.787	1.065	0.737	0.696	0.407
Disease Interactions								
HCC47_gCancer	Immune Disorders*Cancer Group	0.893	0.675	0.815	0.652	0.776	0.808	-
HCC85_gDiabetesMellit	Congestive Heart Failure*Diabetes Group	0.154	0.096	0.205	0.160	0.178	0.139	0.154
HCC85_gCopdCF	Congestive Heart Failure*Chronic Obstructive Pulmonary Disease Group	0.190	0.174	0.240	0.217	0.186	0.181	0.164
HCC85_gRenal	Congestive Heart Failure*Renal Group	0.270	0.493	0.271	0.711	0.299	0.609	-

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
gRespDepandArre_gCopdCF	Cardiorespiratory Failure Group*Chronic Obstructive Pulmonary Disease Group	0.336	0.256	0.564	0.524	0.460	0.449	0.423
HCC85_HCC96	Congestive Heart Failure*Specified Heart Arrhythmias	0.105	0.285	0.200	0.405	0.116	0.318	-
gSubstanceAbuse_gPsychiatric	Substance Abuse Group*Psychiatric Group	-	0.191	-	0.233	-	0.230	-
SEPSIS_PRESSURE_ULCER	Sepsis*Pressure Ulcer	-	-	-	-	-	-	0.252
SEPSIS_ARTIF_OPENINGS	Sepsis*Artificial Openings for Feeding or Elimination	-	-	-	-	-	-	0.568
ART_OPENINGS_PRESSURE_ULCER	Artificial Openings for Feeding or Elimination*Pressure Ulcer	-	-	-	-	-	-	0.331
gCopdCF_ASP_SPEC_BACT_PNEUM	Chronic Obstructive Pulmonary Disease*Aspiration and Specified Bacterial Pneumonias	-	-	-	-	-	-	0.254
ASP_SPEC_BACT_PNEUM_PRES_ULC	Aspiration and Specified Bacterial Pneumonias*Pressure Ulcer	-	-	-	-	-	-	0.366
SEPSIS_ASP_SPEC_BACT_PNEUM	Sepsis*Aspiration and Specified Bacterial Pneumonias	-	-	-	-	-	-	0.321
SCHIZOPHRENIA_gCopdCF	Schizophrenia*Chronic Obstructive Pulmonary Disease	-	-	-	-	-	-	0.363
SCHIZOPHRENIA_CHF	Schizophrenia*Congestive Heart Failure	-	-	-	-	-	-	0.173
SCHIZOPHRENIA_SEIZURES	Schizophrenia*Seizure Disorders and Convulsions	-	-	-	-	-	-	0.483
Disabled/Disease Interactions								
DISABLED_HCC85	Disabled, Congestive Heart Failure	-	-	-	-	-	-	0.321
DISABLED_PRESSURE_ULCER	Disabled, Pressure Ulcer	-	-	-	-	-	-	0.608
DISABLED_HCC161	Disabled, Chronic Ulcer of the Skin, Except Pressure Ulcer	-	-	-	-	-	-	0.369
DISABLED_HCC39	Disabled, Bone/Joint Muscle Infections/Necrosis	-	-	-	-	-	-	0.567
DISABLED_HCC77	Disabled, Multiple Sclerosis	-	-	-	-	-	-	0.425

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
DISABLED_HCC6	Disabled, Opportunistic Infections	-	-	-	-	-	-	0.277

NOTES:

1. The denominator is $9,185.29
2. In the "disease interactions" and "disabled interactions," the variables are defined as follows:
   Immune Disorders = HCC 47
   Cancer = HCCs 8-12
   Congestive Heart Failure = HCC 85
   Diabetes = HCCs 17-19
   Chronic Obstructive Pulmonary Disease = HCCs 110-112
   Renal = HCCs 134 – 137
   Cardiorespiratory Failure = HCCs 82-84
   Specified Heart Arrhythmias = HCC 96
   Substance Abuse = HCCs 54-55
   Psychiatric = HCCs 57-58
   Sepsis = HCC 2
   Pressure Ulcer = HCCs 157-158
   Artificial Openings for Feeding or Elimination = HCC 188
   Aspiration and Specified Bacterial Pneumonias = HCC 114
   Schizophrenia = HCC 57
   Seizure Disorders and Convulsions = HCC 79
   Chronic Ulcer of Skin, except Pressure = HCC 161
   Bone/Joint/Muscle Infections/Necrosis = HCC 39
   Multiple Sclerosis = HCC 77
   Opportunistic Infections = HCC 6

   SOURCE: RTI International analysis of 2013-2014 Medicare 100% data and RTI International analysis of 2013-2014 Medicare 100% institutional sample.

Table VI-2. 2017 CMS-HCC Model Relative Factors for Aged and Disabled New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.664	0.985	-	-
35-44 Years	0.936	1.221	-	-
45-54 Years	1.035	1.337	-	-
55-59 Years	1.004	1.342	-	-
60-64 Years	1.122	1.438	-	-
65 Years	0.522	1.059	1.130	1.566
66 Years	0.516	0.946	1.167	1.619
67 Years	0.544	0.946	1.167	1.619
68 Years	0.581	0.946	1.167	1.619
69 Years	0.605	0.946	1.167	1.619
70-74 Years	0.674	0.975	1.167	1.619
75-79 Years	0.892	1.092	1.167	1.619
80-84 Years	1.066	1.395	1.167	1.619
85-89 Years	1.324	1.458	1.167	1.619
90-94 Years	1.324	1.678	1.167	1.619
95 Years or Over	1.324	1.678	1.167	1.619
Male				
0-34 Years	0.456	0.766	-	-
35-44 Years	0.665	1.095	-	-
45-54 Years	0.834	1.357	-	-
55-59 Years	0.889	1.422	-	-
60-64 Years	0.923	1.582	-	-
65 Years	0.514	1.201	0.790	1.613
66 Years	0.533	1.208	0.957	1.613
67 Years	0.575	1.208	1.005	2.202
68 Years	0.641	1.208	1.074	2.202
69 Years	0.671	1.311	1.398	2.202
70-74 Years	0.776	1.311	1.398	2.202
75-79 Years	1.040	1.361	1.398	2.202
80-84 Years	1.270	1.603	1.398	2.202
85-89 Years	1.511	1.850	1.398	2.202
90-94 Years	1.511	1.850	1.398	2.202
95 Years or Over	1.511	1.850	1.398	2.202

NOTES:

1. The denominator is $9,185.29
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.

SOURCE: RTI International analysis of 2013-2014 100% Medicare data.

Table VI-3. 2017 CMS-HCC Model Relative Factors for New Enrollees in Chronic Condition Special Needs Plans (C-SNPs)

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	1.136	1.633	-	-
35-44 Years	1.409	1.868	-	-
45-54 Years	1.507	2.068	-	-
55-59 Years	1.618	2.123	-	-
60-64 Years	1.689	2.177	-	-
65 Years	1.003	1.546	1.747	2.161
66 Years	0.997	1.546	1.785	2.214
67 Years	1.063	1.569	1.805	2.272
68 Years	1.100	1.569	1.805	2.272
69 Years	1.123	1.569	1.805	2.272
70-74 Years	1.269	1.776	1.932	2.415
75-79 Years	1.480	1.973	2.096	2.576
80-84 Years	1.687	2.162	2.252	2.844
85-89 Years	1.920	2.381	2.252	2.844
90-94 Years	1.920	2.602	2.252	2.844
95 Years or Over	1.920	2.602	2.252	2.844
Male				
0-34 Years	1.045	1.329	-	-
35-44 Years	1.254	1.658	-	-
45-54 Years	1.503	1.954	-	-
55-59 Years	1.630	2.091	-	-
60-64 Years	1.670	2.187	-	-
65 Years	0.971	1.478	1.655	2.224
66 Years	0.989	1.485	1.691	2.224
67 Years	1.015	1.600	1.705	2.360
68 Years	1.082	1.600	1.734	2.360
69 Years	1.111	1.703	1.780	2.360
70-74 Years	1.302	1.898	1.874	2.356
75-79 Years	1.522	2.080	2.000	2.582
80-84 Years	1.758	2.229	2.254	2.582
85-89 Years	2.047	2.544	2.254	2.582
90-94 Years	2.047	2.544	2.254	2.582
95 Years or Over	2.047	2.544	2.254	2.582

NOTES:

1. The denominator is $9,185.29
2. For payment purposes, a new enrollee is a beneficiary who did not have 12 months of Part B eligibility in the data collection year. CMS-HCC new enrollee models are not based on diagnoses, but include factors for different age and gender combinations by Medicaid and the original reason for Medicare entitlement.
3. The relative factors in this table were calculated by estimating the incremental amount to the standard new enrollee risk model needed to predict the risk scores of continuing enrollees in C-SNPs.

SOURCE: RTI International analysis of 2013-2014 100% Medicare data.

Table VI-4. Disease Hierarchies for the 2017 CMS-HCC Model

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

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

Table VI-5. RxHCC Model Relative Factors for Continuing Enrollees

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
Female						
0-34 Years		-	0.290	-	0.423	1.918
35-44 Years		-	0.477	-	0.637	1.886
45-54 Years		-	0.563	-	0.735	1.682
55-59 Years		-	0.543	-	0.710	1.556
60-64 Years		-	0.504	-	0.645	1.414
65-69 Years		0.264	-	0.407	-	1.491
70-74 Years		0.264	-	0.396	-	1.382
75-79 Years		0.251	-	0.385	-	1.285
80-84 Years		0.237	-	0.357	-	1.197
85-89 Years		0.221	-	0.328	-	1.113
90-94 Years		0.183	-	0.268	-	1.002
95 Years or Over		0.126	-	0.178	-	0.813
Male						
0-34 Years		-	0.227	-	0.470	1.660
35-44 Years		-	0.382	-	0.606	1.791
45-54 Years		-	0.498	-	0.660	1.618
55-59 Years		-	0.519	-	0.649	1.450
60-64 Years		-	0.478	-	0.595	1.334
65-69 Years		0.274	-	0.351	-	1.332
70-74 Years		0.279	-	0.353	-	1.275
75-79 Years		0.246	-	0.347	-	1.218
80-84 Years		0.188	-	0.317	-	1.167
85-89 Years		0.149	-	0.289	-	1.098
90-94 Years		0.093	-	0.260	-	1.021
95 Years or Over		0.071	-	0.216	-	0.864
Originally Disabled Interactions with Sex						
Originally Disabled_Female		0.101	-	0.180	-	0.066
Originally Disabled_Male		-	-	0.127	-	0.066
Disease Coefficients	**Description Label**					
RXHCC1	HIV/AIDS	2.913	3.350	3.437	3.881	2.206
RXHCC5	Opportunistic Infections	0.221	0.011	0.145	0.148	0.160
RXHCC15	Chronic Myeloid Leukemia	6.271	6.682	7.000	8.912	4.011
RXHCC16	Multiple Myeloma and Other Neoplastic Disorders	3.405	3.628	2.791	3.246	1.044

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	1.435	1.390	1.346	1.385	0.421
RXHCC18	Lung, Kidney, and Other Cancers	0.255	0.281	0.280	0.287	0.050
RXHCC19	Breast and Other Cancers and Tumors	0.087	0.029	0.078	0.085	0.050
RXHCC30	Diabetes with Complications	0.396	0.437	0.461	0.608	0.431
RXHCC31	Diabetes without Complication	0.263	0.259	0.300	0.354	0.299
RXHCC40	Specified Hereditary Metabolic/Immune Disorders	2.785	11.019	2.945	9.727	0.138
RXHCC41	Pituitary, Adrenal Gland, and Other Endocrine and Metabolic Disorders	0.111	0.179	0.052	0.183	0.064
RXHCC42	Thyroid Disorders	0.095	0.160	0.092	0.155	0.065
RXHCC43	Morbid Obesity	0.067	-	0.066	0.068	0.169
RXHCC45	Disorders of Lipoid Metabolism	0.054	0.038	0.094	0.126	0.063
RXHCC54	Chronic Viral Hepatitis C	1.921	2.461	1.713	1.989	0.508
RXHCC55	Chronic Viral Hepatitis, Except Hepatitis C	0.322	0.396	0.860	0.586	0.251
RXHCC65	Chronic Pancreatitis	0.239	0.238	0.148	0.163	0.143
RXHCC66	Pancreatic Disorders and Intestinal Malabsorption, Except Pancreatitis	0.094	0.238	0.084	0.163	0.106
RXHCC67	Inflammatory Bowel Disease	0.470	0.403	0.388	0.718	0.205
RXHCC68	Esophageal Reflux and Other Disorders of Esophagus	0.098	0.074	0.151	0.170	0.076
RXHCC80	Aseptic Necrosis of Bone	0.162	0.201	0.149	0.135	0.108
RXHCC82	Psoriatic Arthropathy and Systemic Sclerosis	0.720	0.792	1.116	1.802	0.538
RXHCC83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	0.318	0.383	0.406	0.710	0.172
RXHCC84	Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies	0.202	0.331	0.233	0.341	0.107
RXHCC87	Osteoporosis, Vertebral and Pathological Fractures	0.054	0.152	0.121	0.195	-
RXHCC95	Sickle Cell Anemia	0.085	0.185	0.070	0.777	0.482
RXHCC96	Myelodysplastic Syndromes and Myelofibrosis	0.738	0.883	0.653	0.682	0.518
RXHCC97	Immune Disorders	0.428	0.448	0.484	0.403	0.377
RXHCC98	Aplastic Anemia and Other Significant Blood Disorders	0.085	0.180	0.070	0.228	0.039
RXHCC111	Alzheimer`s Disease	0.475	0.206	0.180	0.093	-

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC112	Dementia, Except Alzheimer`s Disease	0.198	0.094	0.040	-	-
RXHCC130	Schizophrenia	0.291	0.336	0.457	0.756	0.203
RXHCC131	Bipolar Disorders	0.291	0.319	0.317	0.509	0.203
RXHCC132	Major Depression	0.154	0.269	0.185	0.364	0.189
RXHCC133	Specified Anxiety, Personality, and Behavior Disorders	0.154	0.239	0.179	0.362	0.106
RXHCC134	Depression	0.150	0.191	0.140	0.227	0.106
RXHCC135	Anxiety Disorders	0.060	0.112	0.092	0.197	0.101
RXHCC145	Autism	0.154	0.239	0.374	0.410	0.106
RXHCC146	Profound or Severe Intellectual Disability/Developmental Disorder	0.026	0.114	0.374	0.309	-
RXHCC147	Moderate Intellectual Disability/Developmental Disorder	0.026	-	0.224	0.172	-
RXHCC148	Mild or Unspecified Intellectual Disability/Developmental Disorder	-	-	0.098	0.030	-
RXHCC156	Myasthenia Gravis, Amyotrophic Lateral Sclerosis and Other Motor Neuron Disease	0.316	0.632	0.323	0.542	0.142
RXHCC157	Spinal Cord Disorders	0.138	0.161	0.082	0.059	0.074
RXHCC159	Inflammatory and Toxic Neuropathy	0.212	0.421	0.219	0.388	0.088
RXHCC160	Multiple Sclerosis	1.904	3.250	1.807	3.809	0.856
RXHCC161	Parkinson`s and Huntington`s Diseases	0.496	0.716	0.313	0.430	0.208
RXHCC163	Intractable Epilepsy	0.293	0.494	0.260	0.899	0.078
RXHCC164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	0.112	0.046	0.034	0.139	-
RXHCC165	Convulsions	0.062	-	0.034	0.087	-
RXHCC166	Migraine Headaches	0.142	0.257	0.126	0.150	0.126
RXHCC168	Trigeminal and Postherpetic Neuralgia	0.133	0.260	0.149	0.181	0.185
RXHCC185	Primary Pulmonary Hypertension	0.621	1.784	0.570	1.468	0.229
RXHCC186	Congestive Heart Failure	0.176	0.120	0.230	0.136	0.135
RXHCC187	Hypertension	0.141	0.078	0.204	0.109	0.065
RXHCC188	Coronary Artery Disease	0.130	0.035	0.142	-	0.012
RXHCC193	Atrial Arrhythmias	0.230	0.097	0.098	0.014	0.068

Continuing Enrollees (CE) RxHCC Model Segments

Variable	Disease Group	Community, Non-Low Income, Age≥65	Community, Non-Low Income, Age<65	Community, Low Income, Age≥65	Community, Low Income, Age<65	Institutional
RXHCC206	Cerebrovascular Disease, Except Hemorrhage or Aneurysm	0.052	-	0.039	-	-
RXHCC207	Spastic Hemiplegia	0.174	0.167	0.067	0.193	-
RXHCC215	Venous Thromboembolism	0.111	0.151	0.069	0.115	0.039
RXHCC216	Peripheral Vascular Disease	-	-	0.037	-	-
RXHCC225	Cystic Fibrosis	0.365	3.541	0.352	3.683	0.775
RXHCC226	Chronic Obstructive Pulmonary Disease and Asthma	0.311	0.144	0.352	0.249	0.200
RXHCC227	Pulmonary Fibrosis and Other Chronic Lung Disorders	0.159	0.144	0.128	0.249	0.029
RXHCC241	Diabetic Retinopathy	0.260	0.202	0.191	0.119	0.151
RXHCC243	Open-Angle Glaucoma	0.266	0.199	0.306	0.260	0.222
RXHCC260	Kidney Transplant Status	0.328	0.070	0.407	0.393	0.201
RXHCC261	Dialysis Status	0.183	0.274	0.389	0.757	0.301
RXHCC262	Chronic Kidney Disease Stage 5	0.086	0.030	0.091	0.033	0.065
RXHCC263	Chronic Kidney Disease Stage 4	0.086	0.030	0.086	0.033	0.065
RXHCC311	Chronic Ulcer of Skin, Except Pressure	0.143	0.131	0.071	0.090	0.048
RXHCC314	Pemphigus	0.271	1.212	0.203	0.193	0.048
RXHCC316	Psoriasis, Except with Arthropathy	0.188	0.219	0.345	0.630	0.228
RXHCC355	Narcolepsy and Cataplexy	0.780	1.325	0.641	1.302	0.350
RXHCC395	Lung Transplant Status	1.126	0.954	1.169	1.160	0.639
RXHCC396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	1.098	0.954	1.169	1.160	0.457
RXHCC397	Pancreas Transplant Status	0.251	0.070	0.407	0.393	0.201
Non-Aged Disease Interactions						
NonAged_RXHCC1	NonAged * HIV/AIDS	-	-	-	-	1.009
NonAged_RXHCC130	NonAged * Schizophrenia	-	-	-	-	0.268
NonAged_RXHCC131	NonAged * Bipolar Disorders	-	-	-	-	0.268
NonAged_RXHCC132	NonAged * Major Depression	-	-	-	-	0.206
NonAged_RXHCC133	NonAged * Specified Anxiety, Personality, and Behavior Disorders	-	-	-	-	0.130
NonAged_RXHCC134	NonAged * Depression	-	-	-	-	0.122
NonAged_RXHCC135	NonAged * Anxiety Disorders	-	-	-	-	0.049
NonAged_RXHCC145	NonAged * Autism	-	-	-	-	0.130
NonAged_RXHCC160	NonAged * Multiple Sclerosis	-	-	-	-	1.227
NonAged_RXHCC163	NonAged * Intractable Epilepsy	-	-	-	-	0.111

Note: The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
Source: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	0.653	0.653	-	-
35-44 Years	1.074	1.100	-	-
45-54 Years	1.290	1.536	-	-
55-59 Years	1.228	1.732	-	-
60-64 Years	1.227	1.898	-	-
65 Years	0.562	1.756	1.163	1.756
66 Years	0.616	1.756	1.111	1.756
67 Years	0.623	1.756	1.111	1.756
68 Years	0.645	1.756	1.111	1.756
69 Years	0.669	1.756	1.111	1.756
70-74 Years	0.688	1.756	1.100	1.756
75-79 Years	0.687	1.756	0.687	1.756
80-84 Years	0.643	1.756	0.643	1.756
85-89 Years	0.537	1.756	0.537	1.756
90-94 Years	0.317	1.756	0.317	1.756
95 Years or Over	0.317	1.756	0.317	1.756
Male				
0-34 Years	0.427	0.714	-	-
35-44 Years	0.803	0.885	-	-
45-54 Years	1.091	1.493	-	-
55-59 Years	1.152	1.493	-	-
60-64 Years	1.110	1.836	-	-
65 Years	0.595	1.773	0.961	1.773
66 Years	0.657	1.773	0.925	1.773
67 Years	0.668	1.773	0.925	1.773
68 Years	0.686	1.773	0.925	1.773
69 Years	0.714	1.773	0.925	1.773
70-74 Years	0.745	1.773	0.762	1.773
75-79 Years	0.737	1.773	0.737	1.773
80-84 Years	0.657	1.773	0.657	1.773
85-89 Years	0.545	1.773	0.545	1.773
90-94 Years	0.332	1.773	0.332	1.773
95 Years or Over	0.332	1.773	0.332	1.773

Notes:

1. The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD, Not Originally Disabled	Concurrently ESRD, Not Originally Disabled	Originally Disabled, Not Concurrently ESRD	Originally Disabled, Concurrently ESRD
Female				
0-34 Years	1.003	2.079	-	-
35-44 Years	1.494	2.079	-	-
45-54 Years	1.538	2.170	-	-
55-59 Years	1.428	2.224	-	-
60-64 Years	1.325	2.081	-	-
65 Years	0.924	2.084	1.186	2.084
66 Years	0.600	2.084	0.906	2.084
67 Years	0.600	2.084	0.906	2.084
68 Years	0.600	2.084	0.906	2.084
69 Years	0.600	2.084	0.906	2.084
70-74 Years	0.616	2.084	0.749	2.084
75-79 Years	0.683	2.084	0.683	2.084
80-84 Years	0.683	2.084	0.683	2.084
85-89 Years	0.683	2.084	0.683	2.084
90-94 Years	0.534	2.084	0.534	2.084
95 Years or Over	0.534	2.084	0.534	2.084
Male				
0-34 Years	0.869	2.154	-	-
35-44 Years	1.265	2.125	-	-
45-54 Years	1.390	2.131	-	-
55-59 Years	1.251	1.968	-	-
60-64 Years	1.161	1.847	-	-
65 Years	0.831	1.921	0.978	1.921
66 Years	0.507	1.921	0.569	1.921
67 Years	0.507	1.921	0.569	1.921
68 Years	0.507	1.921	0.569	1.921
69 Years	0.507	1.921	0.569	1.921
70-74 Years	0.523	1.921	0.612	1.921
75-79 Years	0.536	1.921	0.536	1.921
80-84 Years	0.559	1.921	0.559	1.921
85-89 Years	0.487	1.921	0.487	1.921
90-94 Years	0.362	1.921	0.362	1.921
95 Years or Over	0.362	1.921	0.362	1.921

Notes:

1. The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. Originally Disabled is defined as originally entitled to Medicare by disability only (OREC = 1).
3. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

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

Variable	Not Concurrently ESRD	Concurrently ESRD
Female		
0-34 Years	2.353	2.767
35-44 Years	2.353	2.767
45-54 Years	2.405	2.767
55-59 Years	2.400	2.767
60-64 Years	2.137	2.767
65 Years	2.280	2.767
66 Years	1.970	2.767
67 Years	1.970	2.767
68 Years	1.970	2.767
69 Years	1.970	2.767
70-74 Years	1.820	2.767
75-79 Years	1.545	2.767
80-84 Years	1.514	2.767
85-89 Years	1.321	2.767
90-94 Years	1.082	2.767
95 Years or Over	1.082	2.767
Male		
0-34 Years	2.290	2.614
35-44 Years	2.692	2.614
45-54 Years	2.340	2.614
55-59 Years	2.124	2.614
60-64 Years	2.011	2.614
65 Years	2.002	2.614
66 Years	1.889	2.614
67 Years	1.889	2.614
68 Years	1.889	2.614
69 Years	1.889	2.614
70-74 Years	1.791	2.614
75-79 Years	1.676	2.614
80-84 Years	1.467	2.614
85-89 Years	1.343	2.614
90-94 Years	1.343	2.614
95 Years or Over	1.343	2.614

Notes:

1. The Part D Denominator used to calculate relative factors is $1,014.31. This Part D Denominator is based on the combined PDP and MA-PD populations.
2. For new enrollees, the concurrent ESRD marker is defined as at least one month in the payment year of ESRD status—dialysis, transplant, or post-graft.

Source: RTI Analysis of 100% 2014 PDE, 2013 Carrier NCH, 2013 Inpatient SAF, 2013 Outpatient SAF, 2014 HPMS, 2014 CME, 2013-2014 Denominator, Part D Intermediate File, and 2013 Medicare Advantage Diagnoses File.

Table VI-9. List of Disease Hierarchies for RxHCC Model

Rx Hierarchical Condition Category (RxHCC)	If the Disease Group is listed in this column…	…Then drop the Disease Group(s) listed in this column
	Rx Hierarchical Condition Category (RxHCC) LABEL	
15	Chronic Myeloid Leukemia	16 ,17 ,18 ,19 ,96 ,98
16	Multiple Myeloma and Other Neoplastic Disorders	17 ,18 ,19 ,96 ,98
17	Secondary Cancers of Bone, Lung, Brain, and Other Specified Sites; Liver Cancer	18 ,19
18	Lung, Kidney, and Other Cancers	19
30	Diabetes with Complications	31
54	Chronic Viral Hepatitis C	55
65	Chronic Pancreatitis	66
82	Psoriatic Arthropathy and Systemic Sclerosis	83 ,84 ,316
83	Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	84
95	Sickle Cell Anemia	98
96	Myelodysplastic Syndromes and Myelofibrosis	98
111	Alzheimer's Disease	112
130	Schizophrenia	131 ,132 ,133 ,134 ,135 ,145 ,146 ,147 ,148
131	Bipolar Disorders	132 ,133 ,134 ,135
132	Major Depression	133 ,134 ,135
133	Specified Anxiety, Personality, and Behavior Disorders	134 ,135
134	Depression	135
145	Autism	133 ,134 ,135 ,146 ,147 ,148
146	Profound or Severe Intellectual Disability/Developmental Disorder	147 ,148
147	Moderate Intellectual Disability/Developmental Disorder	148
163	Intractable Epilepsy	164 ,165
164	Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy	165
185	Primary Pulmonary Hypertension	186 ,187
186	Congestive Heart Failure	187
225	Cystic Fibrosis	226 ,227
226	Chronic Obstructive Pulmonary Disease and Asthma	227
260	Kidney Transplant Status	261 ,262 ,263 ,397
261	Dialysis Status	262 ,263
262	Chronic Kidney Disease Stage 5	263
395	Lung Transplant Status	396 ,397
396	Major Organ Transplant Status, Except Lung, Kidney, and Pancreas	397

How Payments are made with a Disease Hierarchy: EXAMPLE: If a beneficiary triggers Disease Groups 163 (Intractable Epilepsy) and 164 (Epilepsy and Other Seizure Disorders, Except Intractable Epilepsy), then DG 164 will be dropped. In other words, payment will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the organization's payment will be based on DG 163 rather than DG 164.

Source: RTI International.

Attachment VII: CY 2017 Final Call Letter

CY 2017 Call Letter
Table of Contents

How to Use This Call Letter

The 2017 Call Letter contains information on the Part C and Part D programs that Medicare Advantage Organizations (MAOs), Part D sponsors, and Medicare-Medicaid Plans (MMPs) need to take into consideration in preparing their 2017 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: 1) improvement in quality of care for individuals, 2) promotion of alternative payment models, 3) program integrity and beneficiary/tax-payer value, and 4) improvement in beneficiary experience. This year, to achieve these outcomes, CMS's Call Letter activities follow four major themes: improving bid review, decreasing costs, promoting creative benefit designs, and improving beneficiary protections.

If you have questions concerning this Call Letter, please contact: Wanda Pigatt-Canty at Wanda.Pigatt-Canty@cms.hhs.gov (Part C issues), Lucia Patrone at Lucia.Patrone@cms.hhs.gov (Part D issues) and mmcocapsmodel@cms.hhs.gov (MMP 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 Medicare Advantage (MA), Medicare Advantage-Prescription Drug) (MA-PD), Prescription Drug Plan (PDP), Medicare-Medicaid Plan (MMP), and cost-based plans. The calendar provides important operational dates for all organizations such as the date bids are due to CMS, the date that organizations must inform CMS of their contract non-renewal, and dates for beneficiary mailings.

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
January 12, 2016	Release of Contract Year CY 2017 Initial and Service Area Applications for MA/MA-PD/PDP, SNP, EGWP, 1876 Cost Plan Expansions	✓	✓	✓	
January 12, 2016	MOC Renewal Submission period begins for SNP and MMP MOCs with approvals ending at the end of CY 2016	✓			✓
January 12 & 14, 2016	Industry Training and Technical Assistance for CY 2017 Model of Care (MOC) Submissions	✓			✓
January 13 & 20, 2016	Industry training on 2017 Applications	✓	✓	✓	
January 15, 2016	Deadline for D-SNPs meeting a high level of integration, as determined by CMS, to submit a request to CMS to offer additional supplemental benefits	✓			
February 17, 2016	CY 2017 Initial and Service Area Expansion Application for MA/MA-PD/PDP, SNP, EGWP, 1876 Cost Plan Expansion are due in HPMS by 8pm EST	✓	✓	✓	
February 17, 2016	MOC Renewals Submissions for SNP and MMP MOCs with approvals ending at the end of CY 2016 are due in HPMS by 8pm EST.	✓			✓
Late February, 2016	Submission of meaningful use HITECH attestation for qualifying MA Employer Plans and MA-affiliated hospitals	✓			
Early-Mid February, 2016	D-SNPs that requested to offer additional supplemental benefits are notified by CMS as to whether they meet required qualifications	✓			
February 2016	CMS notifies MA, MA-PDs and PDPs regarding non-renewal of their contract(s) for CY 2017 due to consistently low star ratings	✓	✓		
February 2016	CMS releases guidance concerning updates to Parent Organization designations in HPMS	✓	✓	✓	✓
March 17, 2016	Parent Organization Update requests from sponsors due to CMS (instructional memo released in February 2016)	✓	✓	✓	✓
Mid-Late March, 2016	Release of CY 2017 Formulary Training Video and 2017 Formulary Reference File (FRF)	✓	✓	✓	✓
March 25, 2016	Release of the Fiscal Soundness Module in HPMS	✓	✓	✓	✓
March/April, 2016	CMS coordinates with MAOs and PDP Sponsors to resolve low enrollment issues for CY 2017	✓	✓	✓	

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early April, 2016	CY 2017 Out Of Pocket Cost (OOPC) model and OOPC estimates for each plan made available to MAOs, 1876 Cost Plans submitting MA conversion bids, and Part D sponsors for download from the CMS website. Information will assist plans in meeting meaningful difference and Total Beneficiary Cost (TBC) requirements prior to bid submission	✓	✓	✓	
Early April, 2016	Information about renewal options for contract year 2017 (including HPMS crosswalk charts) provided to plans	✓	✓		
April 2016	Summary of Benefits guidance released	✓	✓	✓	
April 2016	Conference call with industry to discuss the 2017 Call Letter	✓	✓	✓	✓
April 4, 2016	Release of the 2017 Final Announcement of Medicare Advantage Capitation Rates and MA and Part D Payment Policies released, including the CY 2017 Call Letter	✓	✓	✓	✓
April 6, 2016	Industry training on CY 2017 Formulary Submission	✓	✓	✓	✓
April 8, 2016	Release of the 2017 Plan Benefit Package (PBP) online training module	✓	✓	✓	✓
April 8, 2016	Release of the 2017 Plan Creation Module, PBP, and Bid Pricing Tool (BPT) software in HPMS	✓	✓	✓	✓
April 8, 2016	Deadline for upload of Provider Specific Plan (PSP) full network	✓	✓	✓	
April 11, 2016	Deadline for MAOs to submit requests for full contract consolidations for CY 2017	✓		✓	
Mid-April, 2016	Release of HPMS Memo: Contract Year 2017 Medicare Advantage Bid Review and Operations Guidance	✓			
April 18, 2016	Release of the 2017 Medication Therapy Management (MTM) Program Submission in HPMS		✓		✓
April 20, 2016	Industry training dedicated to Annual Part D Formulary and Benefit Compliance Training	✓	✓	✓	✓
Mid-Late April, 2016	MAOs submit plan requests for tiering of medical benefits and justifications to CMS for review and consideration	✓			
Late April, 2016	Total Beneficiary Cost data for CY 2017 Bid Preparation Release	✓			
May, 2016	Final ANOC/EOC, LIS rider, Part D EOB, formularies, transition notice, provider directory, pharmacy directory, and MMP models for 2017 available for all organizations	✓	✓	✓	✓
May 1, 2016	MA, MA-PD and PDP plans to notify CMS of 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. This will allow CMS to make the required changes in HPMS to facilitate the correct upload of bids in June	✓	✓	✓	

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
May 2, 2016	Deadline for submission of CY 2017 MTM Programs from all sponsors offering Part D including Medicare-Medicaid Plans (except those participating in the Enhanced MTM Model test) (11:59pm PDT)		✓		✓
May 5, 2016	2016 Medicare Advantage & Prescription Drug Plan Spring Conference & Webcast	✓	✓	✓	✓
May 6, 2016	Release of the 2017 Bid Upload Functionality in HPMS	✓	✓	✓	✓
May 6, 2016	Release of 2017 Actuarial Certification Module in HPMS	✓	✓	✓	
May 16, 2016	Release of 2017 Formulary Submission Module in HPMS	✓	✓	✓	✓
May 18, 2016	Deadline for submission of CY 2017 MTM Program attestations from all sponsors offering Part D including Medicare-Medicaid Plans (except those participating in the Enhanced MTM Model test) (11:59pm PDT)		✓		✓
Mid-Late May, 2016	Release of CY 2017 Formulary Reference File Update	✓	✓	✓	✓
May 27, 2016	Plans/Part D sponsors begin to upload agent/broker compensation information in HPMS	✓	✓	✓	✓
May 27, 2016	Release of the 2017 Marketing Module in HPMS. Plans/Part D sponsors begin to submit 2017 marketing materials	✓	✓	✓	✓
Late May/Early June, 2016	Release of the 2017 Medicare Marketing Guidelines in HPMS	✓	✓	✓	✓
Late May, 2016	CMS sends qualification determinations to applicants based on review of the 2017 applications for new contracts or service area expansions	✓	✓		
May 31, 2016	Release of CY 2015 Medical Loss Ratio (MLR) Report software in HPMS	✓	✓		
June 2016	Release of state-specific marketing guidance for MMPs.				✓
June 1, 2016	Release of the 2015 DIR Submission Module in HPMS	✓	✓	✓	✓
June 6, 2016	Deadline for submission of CY 2017 bids (including Service Area Verification) 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 2017 Medicare Plan Finder to submit PBPs (11:59 p.m. PDT) Deadline for submission of CY 2017 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 a CY 2017 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 2017	✓	✓	✓	✓ *Non-bid related items only*

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Early June to Early September, 2016	CMS completes review and approval of 2017 bid data. Plans/Part D sponsors submit attestations, contracts, initial actuarial certifications, and final actuarial certifications	✓	✓	✓	
June 7-10, 2016	Window for submitting first round of crosswalk exception requests through HPMS	✓	✓	✓	
June 10, 2016	Deadline for submission of CY 2017 Supplemental Formulary files, Free First Fill file, Partial Gap file, Excluded Drug file, Over the Counter (OTC) drug file, Home Infusion file, and Non-Extended Day Supply file through HPMS (11:59 a.m. EDT)	✓	✓	✓	✓
June 10, 2016	Deadline for submission of Medicare Advantage Value Based Insurance Design (VBID) file *(Only applicable to Medicare Advantage Plans that have been preapproved for Part D VBID benefits)* (11:59 a.m. EDT)	✓	✓		
June 10, 2016	Deadline for submission of Additional Demonstration Drug (ADD) file *(Medicare-Medicaid Plans Only)* (11:59 a.m. EDT)				✓
June 10, 2016	Deadline for upload of Provider Specific Plan (PSP) specific networks	✓	✓	✓	
June 16, 2016	2016 MA and PDP Audit and Enforcement Conference and Webcast	✓	✓	✓	✓
Late June, 2016	CMS sends an acknowledgement letter to all MA, MA-PD, MMP, PDP and Medicare cost-based plans that are non-renewing or reducing their service area	✓	✓	✓	✓
Early July, 2016	2017 Plan Finder pricing test submissions begin	✓	✓	✓	✓
July 1, 2016	Deadline for D-SNPs to upload required State Medicaid Agency Contract and Contract Matrix to HPMS	✓			
July 1, 2016	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, 2016	Plans' deadline to submit non-model Low Income Subsidy (LIS) riders to the appropriate Regional Office for review.	✓			
Mid July 2016	Release of CY 2017 FRF Update in advance of the Limited Formulary Update Window	✓	✓	✓	✓
Mid-Late July, 2016	CY 2017 Limited Formulary Update Window	✓	✓	✓	✓
Late July, 2016	Submission deadline for agent/broker compensation information via HPMS	✓	✓	✓	✓
Mid-Late July 2016	Second window for submitting HPMS crosswalk exceptions	✓	✓	✓	
Late July / Early August, 2016	CMS releases the 2017 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, 2016	Rebate reallocation period begins after release of the above bid amounts	✓	✓	✓	

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
No Later Than July 29, 2016	CMS informs currently contracted organizations of its decision to not renew a contract for 2017	✓	✓	✓	
August 1, 2016	Plans expected to submit model Low Income Subsidy (LIS) riders in HPMS	✓	✓	✓	
August 16, 2016	Deadline for organizations to complete the plan connectivity data in HPMS to ensure timely approval of contracts.	✓	✓	✓	✓
August 18-22, 2016	CY 2017 preview of the 2017 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs)	✓	✓		✓
August 24-26, 2016	First CY 2017 Medicare Plan Finder (MPF) Preview and Out- of-Pocket Cost (OOPC) Preview in HPMS	✓	✓	✓	✓ *MPF only*
August 31, 2016	2017 MTM Program Annual Review completed		✓		✓
Late August 2016	Contracting Materials submitted to CMS	✓	✓	✓	
End of August/Early September 2016	Plan preview periods of Part C & D Star Ratings in HPMS	✓	✓	✓	
September 1, 2016	Deadline for submission of detailed operational information on soft and/or hard formulary-level cumulative morphine equivalent dose (MED) opioid point of sale (POS) edit(s).	✓	✓	✓	✓
Early September 2016	CMS begins accepting plan correction requests upon contract approval	✓	✓	✓	
Mid- September 2016	All 2017 contracts fully executed (signed by both parties: Part C/Part D Sponsor and CMS)	✓	✓	✓	
Mid-September 2016	Release of the non-renewal /service area reduction models	✓	✓	✓	✓
September 6-9, 2016	Second CY 2017Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS	✓	✓	✓	✓ *MPF only*
September 16 -30, 2016	CMS mails the 2017 *Medicare & You* handbook to Medicare beneficiaries	✓	✓	✓	✓
Late September, 2016	D-SNPs that requested review for FIDE SNP determination notified as to whether they meet required qualifications	✓			
September 21, 2016	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.	✓	✓	✓	

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
September 30, 2016	The following documents are due to current enrollees by September 30, 2016: • Standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) for all MA, MA-PD, PDP, and cost-based plans (including those not offering Part D and those that do offer Part D). • Standardized ANOC with the Summary of Benefits for D-SNPs and MMPs that choose to separate the ANOC from the EOC. • Abridged or comprehensive formularies • LIS rider • Pharmacy/Provider directories • The multi-language insert should be sent with the ANOC/EOC and the SB. The documents identified above are the only CY 2017 documents permitted to be sent prior to October 1, 2016	✓	✓	✓	✓
October 1, 2016	Organizations may begin marketing their CY 2017 plan benefits. Note: Once an organization begins marketing CY 2017 plans, the organization must cease marketing CY 2016 plans through mass media or direct mail marketing (except for age-in mailings). Organizations may still provide CY 2016 materials upon request, conduct one-on-one sales appointments, and process enrollment applications	✓	✓	✓	✓
October 1, 2016	Tentative date for 2017 plan and drug benefit data to be displayed on Medicare Plan Finder on Medicare.gov (not applicable to EGWPs)	✓	✓	✓	✓
October 2, 2016	The final personalized beneficiary non-renewal notification letter must be received by PDP, MA plan, MA-PD plan, 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, 2016	✓	✓	✓	
October 13, 2016	Part C & D Star Ratings go live on medicare.gov on or around October 13, 2016	✓	✓	✓	
October 15, 2016	Part D sponsors must post PA and ST criteria on their websites for the 2017 contract year		✓		✓
October 15, 2016	2017 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)	✓	✓		✓

2017*Note: The dates listed under Part C include MA and MA-PD plans. The dates listed under Part D also apply to MA and cost-based plans offering a Part D benefit.		***Part C**	***Part D**	**Cost**	**MMP**
Mid October, 2016	Release of the online CY 2018 Notice of Intent to Apply for a New Contract or a Contract Expansion (MA, MA-PD, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs)	✓	✓	✓	✓
November 4, 2016	Release of CY 2015 MLR Report Upload Functionality in HPMS	✓	✓		
November 14, 2016	Notices of Intent to Apply (NOIA) for CY 2018 due for MA and MA-PD plans, MMP, PDPs, and "800 series" EGWPs and Direct Contract EGWPs.	✓	✓		✓
Early November, 2016	First display of Plan Finder data for sponsors/MA organizations that submitted a plan correction request after bid approval	✓	✓	✓	✓
Late November, 2016	Part C & D display measures data are posted in HPMS for plan preview	✓	✓	✓	
November – December, 2016	CMS issues "close out" information and instructions to MA plans, MA-PD plans, MMPs, PDPs, and cost-based plans that are non- renewing or reducing service areas	✓	✓		✓
December 1, 2016	Cost-based plans must publish notice of non-renewal, as per §417.494 of Title 42 of the CFR.			✓	
December 2, 2016	Deadline for submission of CY 2015 MLR Reports (11:59 PT)	✓	✓		
December 5, 2016	Release of CY 2015 MLR Attestation Module in HPMS	✓	✓		
December 7, 2016	End of the Annual Election Period	✓	✓		✓
December 9, 2016	Deadline for submission of CY 2015 MLR Attestations (11:59 PT)	✓	✓		
Mid December, 2016	Part C & D display measures data on cms.gov updated	✓	✓	✓	
December 31, 2016	Deadline for MMPs that separated the ANOC from the EOC to provide the EOC to enrollees				✓
2017					
January 1, 2017	Plan Benefit Period Begins	✓	✓	✓	✓
January 1 – February 14, 2017	Annual 45-Day Medicare Advantage Disenrollment Period (MADP)	✓			
Early January 2017	Release of CY 2018 MAO/MA-PD/MMP/PDP/SAE/EGWP applications	✓	✓		✓
Mid-January, 2017	Industry training on CY 2018 applications	✓	✓	✓	✓
Mid-February 2017	Applications due for CY 2018	✓	✓	✓	✓

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 MA, MA-PD, PDPs and cost-based plans are due the first Monday in June and shall be in a form and manner specified by the Secretary. Therefore, for CY 2017, the bid submission deadline is June 6, 2016 at 11:59 PM Pacific Daylight Time.

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

- Plan Benefit Package (PBP) and Bid Pricing Tool (BPT)
- Service Area Verification (SAV)
- Plan Crosswalk (if applicable)
- Formulary Submission (if offering a Part D plan with a formulary)
- Formulary Crosswalk (if offering a Part D plan with a formulary)
- Substantiation (supporting documentation for bid pricing) including cost-sharing justification that supports benefit designs which use a coinsurance or copayment amount for which CMS does not have an established amount (if applicable) for MA plans as described in the "Part C Cost Sharing Standards" of this Call Letter.

MA, MA-PD, PDP, and cost-based plans are responsible for confirming that complete and accurate bids are submitted by the June deadline. Consistent with past years, CMS reminds organizations that all required components of an organization's bid must be submitted by the deadline in order for the bid to be considered complete. If any of the required components are not submitted by the deadline, the bid submission will be considered incomplete and not 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) 2016 Bid Upload Functionality in HPMS," dated May 8, 2015).

The Health Plan Management System (HPMS) Bid Upload functionality, which is made available to organizations in May, allows organizations to submit each required bid component well in advance of the deadline. The Bid Upload functionality includes reporting tools that track those components that were successfully submitted and those that are still outstanding. CMS expects organizations to take advantage of these resources and make certain that all components of their bid are submitted successfully and accurately by the submission deadline.

All organizations are expected to contact CMS about any technical upload or validation errors well in advance of the bid submission deadline. CMS will not accept late submissions unless they are the result of a technical issue beyond the organization's control, in what is expected to

be very rare and unique circumstances. All organizations should make sure that appropriate personnel are available both before and after the bid submission deadline to address any ongoing bid upload and/or validation issues that might prevent the bid from proceeding to desk review.

Inaccurate Submissions

CMS reminds organizations that it will only approve a Part D bid under 42 CFR §423.272(b) if the organization offering the plan's bid complies with all applicable Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations. In addition, all Part C bids under §422.254 (a)(3) must be complete, timely, and accurate or CMS has the authority to impose sanctions or may choose not to renew the contract. See also §§ 422.256 and 423.265. Bids that contain inaccurate information and/or fail to meet established thresholds may, among other things, result in an unnecessary diversion of CMS and organizations' time and resources and call into question an organization's ability and intention to fully comply with Part C and D requirements.

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

- An MA-PD bid 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 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.

Organizations and sponsors that submit clearly inaccurate bids on June 6, 2016 and organizations that resubmit bids prior to approval to change or correct items, such as rebate reallocation and fail to meet Part C and D requirements, and/or established thresholds, will receive a compliance notice in the form of a letter and/or a corrective action plan. In addition, organizations and sponsors that submit inaccurate bids may not be allowed to revise their bids to correct inaccuracies, and the bids may be denied. Organizations and sponsors should engage in sufficient due diligence to make certain their bids are accurate before submission.

Plan Corrections

As required by 42 CFR §§422.254, 423.265(c)(3) and 423.505(k)(4), submission of the final actuarial certification serves as documentation that the final bid submission has been verified and is complete and accurate at the time of submission. A request by an organization or sponsor for a plan correction indicates the presence of inaccuracies and/or the incompleteness of a bid and

calls into question an organization's or sponsor'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 organization or sponsor until the plan correction window in September. The plan correction window will be open from early September to late September 2016. The only changes to the PBP that will be allowed during the plan correction period are those that modify the PBP data to align with the BPT. No changes to the BPT are permitted during the plan correction period.

In advance of the bid submission deadline, CMS will provide organizations and sponsors the guidance and tools necessary for a complete and accurate bid submission. These tools will include a Medicare Plan Finder (MPF) summary table report that will be released in HPMS in 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. Organizations and sponsors are encouraged to use this time prior to the submission deadline to verify their bid will not require a plan correction. Organizations and sponsors submitting plan corrections will receive a compliance action and will be suppressed in MPF until the first MPF update in November. In addition, CMS may issue more severe compliance actions such as warning letters and corrective action plans to organizations/sponsors that have demonstrated a consistent pattern of bid submission errors over multiple contract years and/or previously received a compliance notice for CY 2016.

We received comments expressing concern about organizations and sponsors receiving compliance actions for simple data input errors. CMS reminds organizations and sponsors that they should take this opportunity to conduct quality assurance activities prior to bid submission.

Contracting Organizations with Ratings of Fewer Than Three Stars in Three Consecutive Years – Timeline for Application of Termination Authority

CMS may, under our regulatory authority at 42 C.F.R. §§ 422.510(a)(4)(xi) and 423.509(a)(4)(x), terminate the contracts of organizations that have failed to achieve a rating of three stars or better on their Part C or Part D performance in three consecutive years. Since CMS announced through rulemaking in 2012 that we would consider consistently low Star Ratings as a basis for terminating a Part C or Part D contract, a significant number of organizations have taken steps to improve the performance of their poor performing contracts. In other instances, organizations have non-renewed low-rated contracts or consolidated their operations into different, higher-rated contracts. As a result, the overall quality of Medicare plan options available to beneficiaries continues to improve.

In the CY 2016 final Call Letter, CMS announced that contracts that earned their third consecutive Part C or Part D rating of less than three stars with the release of the 2016 ratings in the fall of 2015 would receive non-renewal notices from CMS in February 2016 with an

effective date of December 31, 2016, at 11:59 pm EST. We also announced that we would not calculate or publish 2017 Star Ratings associated with the non-renewed contracts.

CMS advises MAOs and PDP sponsors that we will conduct future star rating-based terminations according to a similar timeline. That is, CMS will issue contract non-renewal notices in February of each year, with an effective date of December 31st of the same year, to all contracts that meet the criteria for a Star Rating-based termination with the release of the set of Star Ratings issued in October of the preceding year. In March, following the issuance of the non-renewal notices, beneficiaries enrolled in plans offered under the non-renewed contracts will receive notices advising them that they will need to choose a new plan during the next annual election period to continue their Part C and Part D plan enrollment without interruption during the following benefit year. CMS may stay the issuance of non-renewal and beneficiary notices in instances where the organization that holds the contract eligible for non-renewal is prepared to complete a consolidation of that contract into a higher-rated contract during the bid cycle for the upcoming plan year. In that situation, CMS will allow the organization to complete the contract consolidation process during the bid submission and review cycle, but we will retain the right to issue the notices at the conclusion of the review cycle should the organization fail to complete the consolidation process. Finally, CMS will not calculate or publish Star Ratings for non-renewed contracts during the year in which CMS issues the non-renewal notice, so terminated contracts should not expect there to be an opportunity for CMS to reverse its determination based on the contract's improved Star Rating performance during its last year of operation.

Enhancements to the 2017 Star Ratings and Beyond

One of CMS' most important strategic goals is to improve the quality of care and health status of Medicare beneficiaries. For the 2017 Star Ratings, CMS continues to enhance the Star Ratings methodology to further align with our policy goals. Our priorities include enhancing the measures and methodology to reflect the true performance of organizations and sponsors, ensuring stability due to the link to payment, and providing advance notice of future proposals. In this document, we describe enhancements for the 2017 Star Ratings and beyond. CMS is not adding any new measures for 2017 Star Ratings. Except as noted below, the methodology will remain the same as the 2016 Star Ratings.

For reference, the list of measures and a description of the methodology for the 2016 Star Ratings are included in the Technical Notes available on the CMS webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

The cut points to determine star assignments 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 2017 using the most current data available.

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

We appreciate the feedback we received on the 2017 Request for Comments and the draft Call Letter. In addition to noting some of the more significant comments below, summaries of comments to the draft Call Letter and responses are included in Appendix 4 to this final Call Letter.

Changes to Measures for 2017

CMS' general policies regarding specification changes to Star Ratings measures include the following:

- If a specification change to an existing measure is announced in advance of the measurement period, the measure remains in the Star Ratings, it will not be moved to the display page.
- If the change announced during the measurement period significantly expands the denominator or population covered by the measure, the measure is moved to the display page for at least one year.
- If the change announced during the measurement period does not significantly impact the numerator or denominator of the measure, the measure will continue to be included in the Star Ratings (e.g., when during the measurement period additional codes are added that would increase the number of numerator hits for a measure).

The methodology for the following measures is being modified:

- **Improvement measures (Part C & D).** While the methodology for incorporating measures into the calculation of the two improvement measures (one each for Part C and D) remains the same as in prior years, we have updated the measures used for each improvement measure to account for measures with at least two years of data. Refer to Appendix 3 for updates to the measures to be used to calculate the 2017 improvement measures. If a contract's CAHPS measure score moved to very low reliability with the exclusion of enrollees with less than 6 months of continuous enrollment for the 2015 survey administration, then the 2014 CAHPS measure score (used in 2015 Star Ratings) will be used instead as the baseline for the 2017 improvement calculation for that measure. If the contract has missing 2015 CAHPS data due to very low reliability, we would use the 2014 CAHPS data only if there is a significant improvement from 2014 to 2016. This policy should affect very few contracts but will hold contracts harmless from missing data.

- **Appeals Timeliness/Reviewing Appeals Decisions measures (Part C) and Appeals Upheld measure (Part D).** Currently, these measures include cases that are reopened and

decided by April 1 of the following contract year. In some instances, appeals filed in the 4th quarter of the year and then subsequently reopened may not be determined by the IRE by April 1. We will modify these measure specifications so that if a reopening occurs and is decided prior to May 1, 2016, the reopened decision will be used. Reopenings decided on or after May 1, 2016 will not be reflected in these data, and the original decision result will be used.

- **Transition from ICD-9 to ICD-10 (Part C & D).** The measure stewards, such as the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), have reviewed their measure specifications with diagnosis-related requirements to transition from ICD-9 to ICD-10.

  NCQA has incorporated the ICD-10 codes in the 2016 Healthcare Effectiveness Data and Information Set (HEDIS). During the period that spans the use of both ICD-9 and ICD-10 codes due to look-back periods for some measures, both ICD-9 and ICD-10 codes will be used.

- **Appeals Upheld measure (Part D).** This measure shows how often the IRE decided the drug plan's denial of an appeal was appropriate. For the 2016 Star Rating Upheld measure, we excluded appeal cases for beneficiaries enrolled in hospice at any point during 2014. As noted in the 2016 Call Letter, this exclusion was only necessary for the 2016 measure as it was based on 2014 data that may have been affected by hospice policy changes in 2014. CMS hospice policy has not changed since 2014, so it is no longer necessary to exclude hospice appeal cases. This exclusion will not be continued for the 2017 Star Rating Appeals Upheld measure.

- **Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D).** We will add a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score since exclusions are applied to the plan-reported MTM data.

  The CMR rate measure is an initial measure of the delivery of MTM services, and we continue to look forward to the development and endorsement of outcomes-based MTM measures as potential companion measures to the current MTM Star Rating. More information is provided later in this section about the Center for Medicare and Medicaid Innovation's Part D Enhanced MTM Model. Lastly, we will be implementing additional data integrity checks (discussed later in this section) to safeguard against inappropriate attempts to bias the data used for this measure.

- **Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating).** Based on PQA specification change, the measure will exclude from the denominator those

patients with one or more claims for sacubitril/valsartan. This exclusion will be applied for the 2017 Star Ratings.

Removal of Measures from Star Ratings

1. **Improving Bladder Control (Part C).** This measure, collected through the Health Outcomes Survey (HOS), assesses the percentage of beneficiaries with urine leakage who discussed their problem with their provider and received treatment for the issue. 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 a problem. This action will remove a potential bias towards only sampling patients who were treated unsuccessfully. Second, NCQA changed the treatment indicator to assess whether treatment was discussed, as opposed to it being 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 the degree to which urinary incontinence impacts beneficiaries' quality of life. Data from this outcome indicator will be analyzed further before any new measure (or measure specification change) is proposed as part of the Star Ratings. CMS will request further input on this measure in the 2018 Request for Comments.

   These changes required revising the underlying survey questions in HOS. The revised questions were first collected in 2015. As a result of these changes, this measure will not be reported in the 2017 Star Ratings. The revised measure will be reported on the 2017 display page. The 2016 display measure uses data from the old questions.

2. **High Risk Medication (Part D).** The High Risk Medication (HRM) measure calculates the percent of Medicare Part D beneficiaries 65 and older who received two or more prescription fills for the same HRM drug with a high risk of serious side effects in the elderly. The measure is endorsed by the PQA and National Quality Forum (NQF), and the HRM rate is calculated using the PQA specifications and medication list based on American Geriatrics Society (AGS) recommendations. The AGS recently released the 2015 update of the Beers Criteria, which serve as the foundation for the AGS recommendations.

   In the draft 2017 Call Letter, CMS proposed to remove the HRM measure from the Star Ratings and move it to the display measures for 2017. This proposal was based on a number of factors. While the AGS states that the criteria may be used as both an educational tool and quality measure, it also states that the intent is not to apply the criteria in a punitive manner (i.e., penalizing prescribers that are trying to do the best for their patients). Specifically, the addition of a drug to the HRM list is not a contraindication to use, rather an encouragement to avoid use in the senior population without consideration of risks and benefits based on individual patient characteristics. This is a very difficult decisional balance to evaluate in a

plan that does not have access to full clinical information. As the measure can be calculated only by using prescription drug event (PDE) data, medications cannot be included on the HRM List that have risks conditional on clinical factors that cannot be measured using PDE data alone. As a result, some "Avoid" medications are included in the measure, while others are not. This may create unintended consequences including the inappropriate encouragement of certain non-HRM medications, which may not be the best choice for an individual beneficiary's clinical circumstance.

Based on feedback to the draft 2017 Call Letter (see Appendix 4 for summary of Star Ratings comments and responses) and concerns that a change was being made after the measurement period in which efforts by Part D sponsors were invested, the HRM measure will remain in the Star Ratings for 2017 (based on 2015 data) and move to the display page for 2018 (based on 2016 data). We will continue to provide HRM measure reports to Part D sponsors on a monthly basis through the Patient Safety Analysis website, and we will continue to identify outliers.

The PQA recently made two changes to the HRM measure specifications. First, any patient with a hospice indicator at any point during the measurement year will be excluded from the denominator calculation. We will implement this change immediately for the 2017 Star Rating measure based on 2015 data. Second, the PQA revised the criteria to calculate the average dose for doxepin, reserpine, and digoxin. We will implement this change for the 2018 measure based on 2016 data. Any additional updates endorsed by the PQA by the 2017 formulary and bid deadlines in May and June 2016 may be considered for adoption in the 2019 measures (using 2017 data).

Our initial analysis of HRM found that after controlling for contract effects and dual eligible or low income subsidy status, there is a significant association between dual eligible/low income status and HRM use. This association remains after further controlling for age, sex, and race/ethnicity. However, because it is under direct provider control and should not be affected by non-clinical beneficiary characteristics, the HRM measure was not one of the measures adjusted for socio-economic status (SES) (discussed later in this Call Letter). We recommend that the measure developers further review this measure to better understand the associations.

Avoiding potentially inappropriate medications in older adults remains important for quality of care for Medicare beneficiaries**.** HRM will be reconsidered for the Star Ratings again in the future once analyses and specification changes, if any, are completed by the PQA. Any changes will be proposed or implemented with sufficient lead time.

Data Integrity

It is essential that the data used for CMS' Star Ratings are accurate and reliable. CMS' policy is to reduce a contract's measure rating to 1 star if it is determined that biased or erroneous data have been submitted. This would include cases where CMS finds mishandling of data, inappropriate processing, or implementation of incorrect practices by the organization/sponsor have resulted in biased or erroneous data. Examples would include, but are not limited to: a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract's failure to adhere to Plan Finder or PDE data requirements; a contract's errors in processing coverage determinations/exceptions or organization determinations found through program audits or other reviews; compliance actions due to errors in operational areas that would directly impact the data reported or processed for specific measures; or a contract's failure to pass Part C and D Reporting Requirements Data Validation related to organization/sponsor-reported data for specific measures. Sponsors should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications are posted on http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx. Information about Data Validation of Reporting Requirements data is posted on https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.

CMS has taken several steps in the past years to protect the integrity of the data; however, we continue to identify new vulnerabilities where inaccurate or biased data could exist. We also must safeguard against the Star Ratings Program creating perverse incentives for sponsors. CMS is piloting program audit protocols in 2016, including Part D sponsors' MTM programs (discussed later in the Call Letter). Findings identified during pilots of these new MTM audit protocols would not be applied to Star Ratings. Once the protocols are finalized, we would review and apply any relevant MTM program audit findings that could demonstrate systemic failures by sponsors that resulted in biased MTM data, outside of the Data Validation (DV) results. CMS is concerned about sponsor activities that may not be detected by DV standards, such as attempts to restrict eligibility from their approved MTM programs, encouraging beneficiaries to opt-out of MTM programs within the first 60-days, or reporting CMRs that do not meet CMS' definition per guidance.

DV standards primarily focus on compliance with CMS' reporting requirements, and CMS considers failing to meet these standards to represent systemic issues that would result in biased data. DV element-level failures can indicate that incomplete or inaccurate data were reported for use in Star Ratings. It is possible for a sponsor to receive a passing score for a section, but have specific element-level failures that directly impact the validity of their measure. For example, if the DV found a sponsor's errors in the numbers of beneficiaries enrolled in the MTM or receiving a CMR, regardless of the overall MTM DV score, CMS would still have concerns about the accuracy of the sponsor's CMR numerator and denominator.

CMS may perform additional audits or reviews to ensure the validity of data for specific contracts. Without rigorous validation of Star Ratings data, there is risk that CMS will reward contracts with falsely high ratings.

Impact of Socio-economic and Disability Status on Star Ratings

A key goal of the MA and Part D programs is to achieve greater value and quality for all beneficiaries; therefore, an important corollary is that we do not distort quality signals in our measures or mask true differences in quality of care. CMS continuously reviews the Star Ratings methodology to improve the process, incentivize plans, and provide information that is a true reflection of the performance and experience of the enrollees. The policies implemented must result in high quality of care and improved health outcomes for all of our beneficiaries, while acknowledging the unique challenges of serving traditionally underserved subsets of the population.

A number of MA organizations and PDP sponsors believe that enrollment of a high percentage of dual eligible (DE) enrollees and/or enrollees who receive a low income subsidy (LIS) limits their plans' ability to achieve high MA or Part D Star Ratings. CMS has responded to the concern from our stakeholders by comprehensively gathering information to determine if the Star Ratings are sensitive to the LIS/DE and disability status of a contract's enrollees. If adjustments are to be made to address this issue, they must be data driven. For example, if a disparity is due to challenges in serving disabled beneficiaries, rather than in serving LIS/DE beneficiaries, then the adjustment should clearly focus on the disability status of beneficiaries. Similarly, unless our methods are transparent and open to input from a breadth of sources, MA organizations and Part D sponsors will not be able to easily translate our findings into actionable quality improvement steps.

With support from our contractors, CMS has undertaken research to provide scientific evidence as to whether MA organizations or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. In 2014, we issued a Request for Information to gather information directly from organizations to supplement the data that CMS collects, as we believe that plans and sponsors are uniquely positioned to provide both qualitative and quantitative information that is not available from other sources. In February and September 2015, we released details on the findings of our research.[8] We have also reviewed reports about the impact of socio-economic status (SES) on quality ratings, such as the report published by the National Quality Forum (NQF) posted at www.qualityforum.org/risk_adjustment_ses.aspx and both the Medicare Payment Advisory Commission's (MedPAC) *Report to the Congress: Medicare Payment Policy* posted at http://www.medpac.gov/documents/reports/mar2015_entirereport_revised.pdf and their recent

[8] The February release can be found at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html.
The September release can be found at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf.

presentation released on September 10th entitled *Factors Affecting Variation in Medicare Advantage Plan Star Ratings* posted at http://www.medpac.gov/documents/september-2015-meeting-presentation-factors-affecting-variation-in-medicare-advantage-plan-star-ratings.pdf. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, P.L. 113-185) instructs the Office of the Assistant Secretary for Planning and Evaluation (ASPE) to conduct a study that examines the effect of individuals' SES on quality measures, resource use, and other measures for individuals under the Medicare program and report its findings to Congress by October 2016. In addition, ASPE will issue a report to Congress by October 2019 on the impact of SES on quality and resource use in Medicare using measures (e.g., education and health literacy) from other data sources. Because ASPE's research agenda aligns closely with our goals, we will continue to work collaboratively with ASPE and other governmental agencies to broaden and expand the focus of the issue.

CMS has also engaged NCQA and the PQA to examine their measure specifications used in the Star Ratings Program to determine if re-specification is warranted. The majority of measures used for the Star Ratings Program are consensus-based. Measure specifications can be changed only by the measure steward (the owner and developer of the measure). Thus, measure scores cannot be adjusted for differences in enrollee case-mix unless required by the measure specification. Measure re-specification is a multi-year process. For example, NCQA has a standard process for reviewing any measure and determining whether a measure requires re-specification. NCQA's re-evaluation process is designed to ensure any resulting measure updates abide by desirable attributes of relevance, scientific soundness, and feasibility. Relevance describes the extent to which the measure captures information important to different groups, e.g., consumers, purchasers, policymakers. To determine relevance, NCQA assesses issues such as health importance, financial importance, and potential for improvement among entities being measured. Scientific soundness captures the extent to which the measure adheres to clinical evidence and whether the measure is valid, reliable, and precise. Feasibility captures the extent to which a measure can be collected at reasonable cost and without undue burden. To determine feasibility, NCQA also assesses whether a measure is precisely specified and can be audited. The overall process for assessing the value of re-specification emphasizes multi-stakeholder input, use of evidence-based guidelines and data, and wide public input.

CMS Research

As stated in the 2016 final Call Letter, CMS believed additional research into the nature of the differential performance on a subset of measures was necessary before any interim or permanent changes in the Star Ratings measurements could be developed and implemented. Of the 32 measures included in Star Ratings for Part C and 15 measures for Part D, 8 measures for Part C and 2 measures for Part D were already case-mix adjusted in some way. CMS further excluded measures that should not be affected by the enrollee's SES or disability status. These exclusions for example include the HRM measures (for reasons described in an earlier section) and complaints measures. That is, a measure was *excluded* from analysis if the measure was already

case-mix adjusted for SES (i.e., CAHPS and HOS measures), if the focus of the measurement was not a beneficiary-level issue but rather a plan- or provider-level issue (e.g., appeals, call center, Part D price accuracy, HRM), if the measure was scheduled to be retired or revised, or if the measure was applicable to only Special Needs Plans (SNPs) (i.e., SNP Care Management, Care for Older Adults measures). These exclusions resulted in a remainder of 16 measures.

The 16 clinical quality measures that comprised the subset of the Star Ratings measures examined included: adult BMI assessment, rheumatoid arthritis management, breast cancer screening, controlling blood pressure, diabetes care – blood sugar controlled, diabetes care – eye exam, diabetes care – kidney disease monitoring, colorectal cancer screening, osteoporosis management in women who had a fracture, plan all-cause readmissions, annual flu vaccine, monitoring physical activity, reducing the risk of falling, medication adherence for diabetes medications, medication adherence for hypertension, and medication adherence for cholesterol.

After the publication of the 2016 Final Call Letter, CMS further examined LIS/DE differences ("effects") and their magnitude. Due to the considerable overlap between LIS/DE beneficiaries and disabled beneficiaries, the research was expanded to consider the possible role of disability status. The research considered the association between the performance on Star Ratings measures and enrollment of LIS/DE/disabled beneficiaries, and the variability across contracts of differences in performance on each measure to gain a better understanding of LIS/DE differences revealed in the preliminary research.

The methodology employed permitted the estimation of within-contract differences associated with LIS/DE and/or disability. Within-contract differences are differences that may exist between subgroups of enrollees in the same contract (e.g., if LIS/DE enrollees within a contract have a different mean or average performance on a measure than non-LIS/DE enrollees in the same contract). These differences may be favorable or unfavorable for LIS/DE and/or disabled beneficiaries. Between-contract differences in performance associated with LIS/DE and/or disability status ("between-contract LIS/DE and/or disability disparities") are the possible additional differences in performance between contracts associated with the contract's proportion of LIS/DE and disabled enrollees that remain after accounting for within-contract disparities by LIS/DE and disability status. If LIS/DE and/or disabled beneficiaries are more or less likely than other beneficiaries to be enrolled in lower-quality contracts, then between-contract disparities may represent true differences between contracts in quality. Because of this possibility, between-contract disparities may not be appropriate for adjustment due to the risk of masking true differences in quality. Adjusting for within-contract disparities is an approach aligned with the consensus reflected in the NQF report on sociodemographic adjustment, which states that, "…*only the within-unit effects are adjusted for in a risk adjustment procedure because these are the ones that are related specifically to patient characteristics rather than differences across units*" (National Quality Forum, 2014). Our research focused on measuring within-contract differences in performance for LIS/DE and/or disabled compared to non-LIS/DE and non-disabled beneficiaries.

Our additional research findings were consistent with the preliminary results shared in the 2016 Final Call Letter. The research to date has provided scientific evidence that there exists a within-contract LIS/DE and disability effect for a subset of the Star Ratings measures. The size of the effect differs across measures and is not exclusively negative.

CMS is firmly committed to building the foundation for a long-term solution that appropriately addresses the issue at hand and aligns with our policy goals. Any policy response must delineate the two distinct aspects of the LIS/DE and/or disability issue - quality and payment. The Star Ratings Program focuses on accurately measuring the quality of care provided, so any response must focus on enhancing the ability to measure actual quality differences among contracts. To address the LIS/DE and disability issue we must accurately address any sensitivity of the ratings to the composition of the beneficiaries enrolled in a contract at the basic building block of the rating system, the measure. CMS has encouraged the measure stewards to examine our findings and undertake an independent evaluation of the measures' specifications to determine if measure re-specification is warranted. Additionally, the payment response focuses on payment accuracy for beneficiaries with different dual statuses, differentiated by aged or disabled status, by improving the predictive performance of the CMS-HCC risk-adjustment model to take into account the unique cost patterns of each of these subgroups of beneficiaries. CMS proposed revisions to the CMS-HCC risk adjustment models for Payment Year 2017 elsewhere in the Advance Notice. Information about the payment methodology for 2017 can be found in the CY 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies.

Interim Analytical Adjustments

Background: While the measure stewards undertake a comprehensive review of their measures used in the Star Ratings Program and ASPE continues its work under the IMPACT Act, CMS explored interim analytical adjustments to address the LIS/DE and disability effect in the near term. We recognize that the interim response needs to be both transparent and feasible to implement pending any changes to measure specifications that may be made by the measure stewards. In addition, the integrity of the Star Ratings and the core of its methodology must be maintained. Further, the adjustment must not result in unnecessary complexity and burden to plans and sponsors. CMS sought to develop methods to afford plans and sponsors the time needed to validate their data and not impinge on the time allotted for the plan preview period. Plans must feel confident in their ability to understand the methodology and reproduce their overall and summary ratings.

As noted in the "Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond" released on November 12, 2015[9], CMS in concert with ASPE developed two options

[9] The Request for Comment can be found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf

for interim analytical adjustments to address the LIS/DE and disability effect: (1) a Categorical Adjustment Index (CAI) and (2) Indirect Standardization (IS). The proposed methods were explained more fully during the User Call on December 3, 2015.[10] The proposals align with the goals of making adjustments that reflect the actual magnitude of the differences observed in the data, providing valid quality ratings to facilitate consumer choice, and providing incentives for MA and Part D quality improvement. The Categorical Adjustment Index (CAI) is a factor that would be added to or subtracted from a contract's overall and/or summary Star Rating to adjust for the average within-contract disparity; the adjustment factor varies by a contract's proportion of LIS/DE and disabled status beneficiaries. The CAI approximates the effect of case-mix adjustment of contract performance scores for DE/LIS and disabled status. MA contracts would have up to three adjustments – one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). PDPs would have one adjustment for the Part D summary rating. As described in the Request for Comments, Indirect Standardization (IS), the alternative proposal for adjustment, would have been applied to the same subset of the individual measures that are adjusted for the determination of the CAI. The focus of the adjustment is the within-contract LIS/DE and/or disability status difference in the measure scores while allowing for the existence of true differences in quality by contract. The standardization would employ the current year's measure scores.

The overall reaction to the proposed analytical adjustments presented in "The Request for Comments" was mixed. There were a limited number of comments addressing the measure set for adjustment. The comments related to the measure set ranged from a general agreement to the subset of 7 measures selected, to expansion of the adjusted measure set, to the 16 measures researched by CMS to the inclusion of all measure used in the Star Ratings Program regardless of whether they were already adjusted or not. Many respondents did not express a preference for either proposed interim analytical adjustment approach. Of those who did provide a preference, the majority preferred CAI instead of IS, citing its similarity to CAHPS, greater transparency, ease of understanding, the ability to have the CAI factors in advance of the plan preview, and more flexibility and accuracy of the method. Many commenters expressed concern about the large volume of data needing validation if the IS method were implemented and its impact on the plan preview period. Many commenters urged CMS to provide simulations such that contracts could have a better understanding of the impact on their ratings.

After careful review and consideration of the "Request for Comments," CMS included the CAI adjustment in the draft 2017 Call Letter for further consideration. In addition, using the 2016 Star Ratings data, CMS simulated the change in the distribution of ratings to the overall and Part C and D summary Star Ratings for MA organizations and Part D summary Star Rating for PDP contracts after the application of both proposed interim analytical adjustments and released

[10] The User Call slides can be found at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Potential-Options-for-SES-and-Disability-Adjustments_120315.pdf.

summaries of the results of the simulations in the draft Call Letter.[11] The simulations results did not include contracts that exclusively serve Puerto Rico. The simulation results for Puerto Rico and a discussion of the LIS Indicator were presented in a separate section. Contracts were able to review their simulation results under each of the proposed analytical adjustments in HPMS beginning on February 22, 2016.

For the simulations, the measures selected for adjustment were determined by our research and included the measures that had the greatest differences in outcomes between LIS/DE and/or disability beneficiaries and non-LIS/DE and/or non-disabled beneficiaries within the same contracts. The primary basis for the selection of the subset of measures for adjustment was the research conducted using the 2012 measurement period that examined the variability of the within-contract differences for measures that had a median absolute difference between LIS/DE and non-LIS/DE beneficiaries of 5% or more and/or no contracts that had the LIS/DE subgroup outperform the non-LIS/DE subgroup within a contract. For PDPs, the research showed that the median absolute difference in performance between LIS/DE and non-LIS/DE enrollees was greater than 5% for Medication Adherence for Hypertension. It was slightly smaller for MA-PDs, but to apply consistent adjustments across MA-PDs and PDPs it is included for adjustment for both delivery systems. Appendix 5 provides the summary statistics of the minimum, median, and maximum for the within-contract variation for the LIS/DE differences revealed in our research per measure for MA and PDP contracts. The measures selected for adjustment included the following six Part C measures for MA (MA-only, MA-PD) and 1876 contracts: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, and Reducing the Risk of Falling. In addition, Medication Adherence for Hypertension (RAS antagonists) was adjusted for MA-PDs and PDPs.

The simulations resulted in less movement, in the overall and summary Star Ratings, with the application of the CAI compared to IS. The CAI values were modest negative adjustments for contracts that had low percentages of dual/disabled enrollees and larger positive adjustments for contracts with higher percentages of LIS/DE and disabled enrollees. By design, the values of the CAI are monotonic and thus, contracts with a larger percentage of vulnerable beneficiaries would realize more positive adjustments. The values of the CAI values thus align with the findings of our research and reflect the actual magnitude of the differences observed in our research. The changes in the Star Ratings that resulted due to the application of IS were not as consistent with the research findings. The application of IS affected some contracts in an unexpected direction, such that some contracts with high LIS/DE and disabled proportions received a negative adjustment, while some contracts with low enrollments of vulnerable beneficiaries experienced gains to their Star Ratings. The simulations confirmed that, based on the 2016 Star Ratings, the analytical adjustment using CAI tends to increase the ratings for contracts with higher

[11] The draft Call Letter which includes the simulations is posted at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2017Advance.html.

proportions of LIS/DE and disabled beneficiaries, while the IS analytical adjustment did not seem to do so as specifically and to the same degree as did the CAI.

CMS appreciates the views and opinions contained within the responses to the draft Call Letter. We have listened carefully to the concerns of our multiple stakeholders in both the development and decision for the response to these concerns for the final Call Letter. We hold steadfast to our goal of providing the highest quality of care to our beneficiaries and incentivizing plans to do so. We are grateful for the positive feedback that commended our examination of the issue at-hand. Many commenters applauded CMS for the transparency in our processes and the multi-pronged approach to developing a response that both aligned with our goals and reflected the magnitude of the issue revealed in our research.

There was overwhelming support in response to the draft Call Letter for moving forward with implementing the CAI analytical adjustment for the 2017 Star Ratings. While some commenters expressed hesitation to implementing an interim solution, CMS believes that it is a necessary first step for building the foundation for a long-term solution. CMS will implement the CAI beginning with the 2017 Star Ratings. We will continue to work closely with our HHS partners and look forward to our continued collaboration with ASPE as they too are examining the same issue on a broader scale. The Star Ratings measure stewards will continue to examine their measures for possible re-specification and CMS will continue to support and encourage them to do so.

While the measure stewards continue their examination of the measure specification and ASPE completes their studies and formulates recommendations, the CAI will be considered annually as an interim adjustment.[12] The CAI methodology is such that it does not impact the core of the Star Ratings methodology and thus, it affords CMS the ability to be nimble and reactive to changes in the landscape in a timely fashion. The CAI methodology is flexible and allows modification. Annually, CMS will request comments as to the subset of measures to be included for adjustment. We welcome comments throughout the year on all aspects of the Star Ratings Program and encourage our multiple stakeholders to provide suggestions for enhancement to the Star Ratings Program. As stated in the draft 2017 Call Letter, the rating year's CAI values will be published in the final Call Letter each year during the period while the interim solution is applied. The CAI values will be determined using the previous rating year's measurement period which allows the release of the values well in advance of the first preview period. In addition, the Medicare Part C & D Star Rating Technical Notes[13] (Technical Notes) will provide the CAI values along with the details of the methodology. Since 2017 is the initial year of implementation, the details of the methodology are included in this 2017 final Call Letter.

[12] If ASPE makes recommendations that modify the Star Ratings methodology, CMS will provide contracts with simulations for review and comment.

[13] The Technical Notes are posted at http://go.cms.gov/partcanddstarratings.

Categorical Adjustment Index Methodology

This section provides the details of the methodology that was employed to determine the 2017 CAI values for the overall and summary Star Ratings.

As discussed previously, the CAI is a factor that would be added to or subtracted from a contract's overall and/or summary Star Rating to adjust for the average within-contract disparity. Contracts are categorized based on their percentages of LIS/DE and disabled beneficiaries, and the CAI value will be the same for all contracts within each final adjustment category. The CAI values will be determined using the prior year's Star Rating data. For the 2017 Star Ratings, the CAI values were based on the reportable values for the 2016 Star Ratings year using data from all contracts that meet reporting requirements. The CAI calculation for the PDPs is performed separately and employs the PDP specific cut points. The percentages of LIS/DE and disabled per contract will be determined using Medicare enrollment data from CY 2015. If a beneficiary was designated as a full or partial dual (Medicare and Medicaid) at any time during 2015 and/or if during the application process, the beneficiary was deemed LIS eligible, the individual will be categorized as LIS/DE. Disability status will be based on the original reason for entitlement for Medicare. The percentages for LIS/DE and disability percentages will be provided to contracts during plan preview. (This year, LIS/DE and disability percentages were provided with the simulation results.)

The CAI values will be available and released in the final Call Letter each year while the interim solution is applied. The values for the index will be presented and applied using 6 decimal places. The CAI methodology, the list of the measures adjusted for the determination of the CAI values, and all applicable rounding rules will be detailed and available in the Technical Notes for the applicable year.

MA plans will have up to three mutually exclusive and independent adjustments – one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). PDPs will have one adjustment for the Part D summary rating.

For 2017, the measures selected for adjustment are: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, and Reducing the Risk of Falling. In addition, Medication Adherence for Hypertension (RAS antagonists) would be adjusted for MA-PDs and PDPs.

The adjusted measure scores used in the calculation of the CAI values will be determined from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores by LIS/DE and disability status for MA or PDP contracts, without masking potential differences in quality across contracts. The regression models used for adjustment quantify the relationship between the measure score of interest and LIS/DE and disability status, controlling for between-contract differences using contract fixed effects.

The approach employed to determine the adjusted measure scores approximates case-mix adjustment in a patient-level, logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status, similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case-mix adjustment, the only adjusters are LIS/DE and disability status. Measure scores are adjusted first, and then the adjusted measure score is converted to a measure-level Star Rating using the measure thresholds for the given Star Ratings year. The purpose of the adjusted measure scores is to calculate the values of the CAI and not for contract-level information. Therefore, the adjusted measures scores will not be displayed nor shared with contracts; only measure scores that are calculated following the measure specification are displayed for public use. (As noted previously, only the measure steward has the authority to change a measure specification.) The unadjusted measure score cut points are employed in the conversion from a score to a star and are done in order to compare changes in measure stars using adjusted measure scores relative to unadjusted measure scores. The use of the unadjusted measure thresholds for the conversion is justified given the CAI is applied to the unadjusted overall and summary Star Ratings. Since the CAI will be added to or subtracted from the unadjusted overall Star Rating, the reward factor (formerly known as the I-factor) would be based on unadjusted scores. The Part C and D Improvement measures will use unadjusted measure scores for both years being compared.

Once all measures selected for adjustment have been converted to measure-level star ratings, the CAI values are determined using the following methodology:

(1) Contracts are divided into an initial set of categories based on some combination of a contract's percentages of enrolled LIS/DE and disabled beneficiaries. As done in the simulations, for the overall Star Rating and the Part C summary Star Rating, 50 initial categories are formed corresponding to the 10 deciles of LIS/DE and the 5 quintiles for disability. For the Part D summary Star Rating adjustment for PDPs, the initial categories consist of the 16 combinations of LIS/DE quartile and disability quartile.

The number of initial categories employed in this first step of the methodology will be determined based on the distribution of the composition of the contracts' enrollees. Each initial category does not need to contain the same number of contracts. It is possible that some initial categories will have only a small number of contracts or perhaps no contracts based on the distribution of the contracts' percentages for LIS/DE and disabled beneficiaries. Alternative initial groupings may be considered if numerous cells are underpopulated.

(2A) The adjusted overall and summary Star Ratings per contract are calculated using the adjusted measure-level stars of the measures selected for adjustment instead of the unadjusted measure-level stars.

(2B) The unadjusted overall and summary Star Ratings per contract are calculated using the unadjusted measure-level stars of the measures.

For the 7 measures that were selected for adjustment, the aggregated summary measure-level scores were derived from the patient-level data. The summary measure-level scores for the 7 selected measures may differ slightly from the summary scores submitted by the contract. The unit of analysis for the calculation of the CAI values for the subset of measures selected for adjustment must be consistent and is necessary for apple-to-apple comparisons.

(3) For each contract and each rating type, the difference between the adjusted overall or summary Star Rating and the corresponding unadjusted Star Rating is computed.

(4) Within each of the initial categories, the mean difference between the adjusted overall or summary Star Rating and the corresponding unadjusted Star Rating is determined.

(5) The mean differences for the initial categories in step (4) are examined and categories are then combined into final adjustment groups to ensure at least 20 MA contracts or 10 PDPs in each category and attain monotonicity with increasing percentages of LIS/DE and disability.

The initial categories will be collapsed to form the final adjustment categories in a manner that enforces monotonicity. In other words, initial categories are combined such that, as the percentages of LIS/DE or disabled beneficiaries within a category increases and the other dimension does not decrease, the adjustment (value of the CAI) increases. The final adjustment categories will be created with a minimum number of 20 contracts per each final MA adjustment group and 10 contracts per each final PDP adjustment group. The guideline for the number of contracts per final adjustment group is designed to maintain the stability of the estimates. If possible, final adjustment categories will be collapsed such that CAI values differ by at least 0.01 units in at least one of the two dimensions (LIS/DE and disability). (It may not always be possible to have final CAI category values differing by at least 0.01 units in at least one dimension given the goal of imposing monotonicity across both the DE/LIS and disability dimensions.)

(6) Using the contracts that fall within each of the final adjustment groups, the mean difference between the adjusted overall or summary Star Rating and the corresponding unadjusted Star Rating is computed per group.

(7) The set of mean differences for each Star-Rating-specific final adjustment group found in Step (6) is the CAI value set.

(8) For each contract, the final adjusted overall and/or summary Star Ratings are computed by adding the corresponding CAI value for the final adjustment category that the contract falls within based on the contract's percentages of LIS/DE and disabled beneficiaries to a contract's unadjusted overall and/or summary Star Rating[14]. (There are separate CAI values for the overall,

[14] The CAI value can be either positive or negative. A positive CAI value will result in an increase of the HPMS posted score after the application of the CAI value. A negative CAI value will result in a decrease of the HPMS posted rating after the application of the CAI value.

Part C, and Part D summary Star Ratings.) The adjusted overall and summary Star Ratings will be posted on Plan Finder and HPMS.

The CAI is applied outside of the specification and is applied to each contract's current year overall and/or summary Star Ratings. The measure specification for every measure used in the Star Ratings Program remains unchanged by the CAI adjustment. Each contract within a given final adjustment group receives the same adjustment to its overall and/or summary Star Rating.

The application of the CAI value for a contract will be carried out rounded to 6 decimal places for both the unadjusted and adjusted Star Ratings. Rounding will take place after the application of the CAI value and the rounding rules for the HPMS posted values as detailed in the Technical Notes will be employed. All Star Ratings are displayed to the nearest half-star.

For the 2017 Star Rating year, the CAI will be applied to the overall and summary scores that will be calculated as they have been in past using summary scores. In 2017, the rating-specific adjustment factor that will be applied to contracts' overall and summary Star Ratings will be determined using the plan proportion of LIS/DE and disabled beneficiaries from the 2015 enrollment data.

2017 Categorical Adjustment Index Values

The values of the 2017 CAI values are below. The upper limit for each category is not included in that category, but rather the next higher category. For example, if a contract's percentage of LIS/DE beneficiaries is 8.94%, the contract's LIS/DE decile will be 2. The exceptions for the upper limit exclusion for a class are the tenth decile for LIS/DE and the fifth quintile for disabled.

Tables 1 and 2 provide the range of the percentages that correspond to the LIS/DE deciles and disability quintiles for the categorization of MA contracts for the CAI for the overall Star Rating.

Table 1: Categorization of MA Contracts into LIS/DE Deciles for the Overall Rating

LIS/DE Decile	Percentage of Contract's LIS/DE Beneficiaries
1	0.00% to less than 8.94%
2	8.94% to less than 12.60%
3	12.60% to less than 15.70%
4	15.70% to less than 19.00%
5	19.00% to less than 23.90%
6	23.90% to less than 30.37%
7	30.37% to less than 46.30%
8	46.30% to less than 73.90%
9	73.90% to less than 99.00%
10	99.00% to 100.00%

Table 2: Categorization of MA Contracts into Disability Quintiles for the Overall Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
1	0.00% to less than 9.00%
2	9.00% to less than 13.10%
3	13.10% to less than 18.86%
4	18.86% to less than 26.50%
5	26.50% to 100.00%

Table 3 provides the description of each of the final adjustment categories for the overall Star Rating for MA contracts and the associated values of the CAI for each final adjustment category.

Table 3: Final Adjustment Categories and CAI Values for the Overall Rating

Final Adjustment Category	%LIS/DE Decile	%Disability Quintile	CAI Value
1	1	1	−0.015566
2	2-9 1-6	1 2	−0.006181
3	1-5 6	3-5 3	0.002408
4	7-8	2-3	0.013514
5	10 9 6-8	1-4 2-4 4	0.024680
6	6-8	5	0.028531
7	9	5	0.054610
8	10	5	0.081245

Tables 4 and 5 provide the range of the percentages that correspond to the LIS/DE deciles and disability quintiles for the initial categories for the determination of the CAI values for the Part C Summary.

Table 4: Categorization of MA Contracts into LIS/DE Deciles for the Part C Summary Rating

LIS/DE Decile	Percentage of Contract's LIS/DE Beneficiaries
1	0.00% to less than 8.72%
2	8.72% to less than 12.38%
3	12.38% to less than 15.56%
4	15.56% to less than 18.81%
5	18.81% to less than 23.56%
6	23.56% to less than 29.84%
7	29.84% to less than 45.43%
8	45.43% to less than 71.92%
9	71.92% to less than 99.01%
10	99.01% to 100.00%

Table 5: Categorization of MA Contracts into Disability Quintiles for the Part C Summary Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
1	0.00% to less than 8.81%
2	8.81% to less than 12.69%
3	12.69% to less than 18.69%
4	18.69% to less than 26.30%
5	26.30% to 100.00%

Table 6 provides the description of each of the final adjustment categories for the Part C summary rating and the associated value of the CAI for each final adjustment category.

Table 6: Final Adjustment Categories and CAI Values for the Part C Summary Rating

Final Adjustment Category	%LIS/DE Decile	%Disability Quintile	CAI Value
1	1	1	−0.017914
2	2-8 1-6	1 2	−0.002435
3	1-5 6	3-5 3	0.005340
4	7-8	2-3	0.010543
5	9-10 6-10	1-3 4	0.014127
6	6-8	5	0.020904
7	9	5	0.032875
8	10	5	0.046083

Tables 7 and 8 below provide the range of the percentages that correspond to the LIS/DE deciles and the disability quintiles for the initial categories for the determination of the CAI values for the Part D summary rating for MA-PDs.

Table 7: Categorization of MA-PD Contracts into LIS/DE Deciles for the Part D Summary Rating

LIS/DE Decile	Percentage of Contract's LIS/DE Beneficiaries
1	0.00% to less than 8.94%
2	8.94% to less than 13.01%
3	13.01% to less than 16.11%
4	16.11% to less than 20.43%
5	20.43% to less than 26.25%
6	26.25% to less than 32.62%
7	32.62% to less than 47.87%
8	47.87% to less than 78.88%
9	78.88% to less than 99.60%
10	99.60% to 100.00%

Table 8: Categorization of MA-PD Contracts into Disability Quintiles for the Part D Summary Rating

Disability Quintile	Percentage of Contract's Disabled Beneficiaries
1	0.00% to less than 9.39%
2	9.39% to less than 13.58%
3	13.58% to less than 19.95%
4	19.95% to less than 29.71%
5	29.71% to 100.00%

Table 9 provides the description of each of the final adjustment categories for the Part D summary rating for MA-PDs and the associated values of the CAI for each final adjustment category.

Table 9: Final Adjustment Categories and CAI Values for the Part D Summary Rating for MA-PDs

Final Adjustment Category	%LIS/DE Deciles	%Disability Quintiles	CAI Value
1	1-5	1-2	−0.007435
2	1-5	3-5	−0.002020
3	6-10	1-3	0.000944
4	6-10	4	0.027383
5	6-8	5	0.052087
6	9	5	0.088059
7	10	5	0.091937

Tables 10 and 11 provide the range of the percentages that correspond to the LIS/DE and disability quartiles for the initial categories for the determination of the CAI values for the Part D summary rating for PDPs. Quartiles are used for both dimensions (LIS/DE and disability) due to the limited number of PDPs as compared to MA contracts.

Table 10: Categorization of PDP Contracts into LIS/DE Quartiles for the Part D Summary Rating

LIS/DE Quartile	Percentage of Contract's LIS/DE Beneficiaries
1	0.00% to less than 3.79%
2	3.79% to less than 11.41%
3	11.41% to less than 49.43%
4	49.43% to 100.00%

Table 11: Categorization of PDP Contracts into Disability Quartiles for the Part D Summary Rating

Disability Quartile	Percentage of Contract's Disabled Beneficiaries
1	0.00% to less than 5.37%
2	5.37% to less than 9.98%
3	9.98% to less than 28.32%
4	28.32% to 100.00%

Table 12 provides the description of each of the final adjustment categories for the Part D summary rating for PDPs and the associated value of the CAI per final adjustment category.

Please note that the CAI values for the Part D summary rating for PDPs are different from the CAI values for the Part D summary rating for MA contracts.

Categories were chosen to enforce monotonicity and to yield a minimum of 10 contracts per final adjustment category. There are three final adjustment categories for PDPs for the Part D summary rating.

Table 12: Final Adjustment Categories and CAI Values for the Part D Summary Rating for PDPs

Final Adjustment Category	%LIS/DE Quartiles	%Disability Quartiles	CAI Value
1	1-2 3-4	1-4 1-2	−0.108739
2	3 4	3-4 3	−0.022527
3	4	4	0.127092

Additional response to address lack of an LIS indicator for enrollees in Puerto Rico
Under statute, aspects of the Medicare and Medicaid programs are implemented differently in Puerto Rico. We are cognizant of the particular challenges in not only Puerto Rico, but in all territories without LIS and propose an additional analytical adjustment for contracts serving these areas exclusively to address the fact that the Part D LIS is not available there.

Notably, Puerto Rican beneficiaries are not eligible for LIS, which is an important element of the methodology for the analytical adjustment. (Beneficiaries in the 50 states and DC are eligible for LIS if their income is less than 150% of the Federal Poverty Level (FPL) and they meet the applicable resource requirement.) In the draft Call Letter, CMS proposed implementing an additional adjustment to make the proposed CAI analytical adjustment equitable for contracts in Puerto Rico. The additional adjustment would be used to identify beneficiaries in Puerto Rico's contracts whose incomes would result in an LIS designation in the 50 states and DC. Although LIS in the states depends on both income and resources, a data source for resource information for PR enrollees is not available.

Representatives of and advocates for Puerto Rico and MA organizations have expressed additional concerns about the sensitivity of the Star Ratings in responses to the 2016 draft Call Letter and the Request for Comments released in 2015. CMS responded in the 2017 draft Call Letter by proposing two additional provisions in the 2017 Star Ratings to specifically address

these concerns. CMS proposed for contracts that are solely serving beneficiaries in Puerto Rico: (1) the use of an LIS indicator that would be used in conjunction with the CAI analytical adjustment, and (2) a differentiated weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings.

In order to determine the LIS indicator for contracts in Puerto Rico, CMS must use a data source that is readily available at this time. For the 2017 Star Ratings, CMS proposed employing the contract-specific proportion of DE beneficiaries in Puerto Rico calculated using the rating year enrollment data and the overall mean proportion of beneficiaries at or below 150% of the FPL in Puerto Rico based on the American Community Survey (ACS). The data source for the LIS indicator must provide valid, reliable estimates for use in the Star Ratings. We are cognizant of the statutory differences in the implementation of the Medicaid Program in Puerto Rico including the eligibility for DE status that is limited to a lower percentage of the FPL than in the states due to the cap on the Federal Medical Assistance Percentage (FMAP) in the territories.

The contract-level modified LIS/DE proportion for Puerto Rico was proposed to be developed from two sources of information: (1) the overall proportion of beneficiaries in Puerto Rico with incomes less than 150% of the FPL and (2) each contract's proportion of DE beneficiaries using the most current data available. A linear regression model using the most recent data would be developed to predict the percentage of LIS/DE in a contract using the percentage of DE using MA contracts in the 10 states with the highest poverty.[15] The parameters from the model would then be used to estimate the percentage LIS/DE for each Puerto Rican contract (i.e., contracts with a service area only in Puerto Rico) from the contract-specific proportion DE. These estimates then would be adjusted to reflect the higher overall level of poverty in Puerto Rico by using data from the ACS. Using the model developed, each contract's proportion of DE beneficiaries in Puerto Rico would have a corresponding proportion of LIS to create a contract-level measure of LIS/DE percentage to be used in the CAI.

CMS also recognizes the additional challenge unique to Puerto Rico related to the medication adherence measures in the Star Ratings Program. It has been shown that beneficiaries' out-of-pocket costs may adversely affect medication adherence, which presents an additional barrier for Puerto Rican contracts serving beneficiaries whose incomes would result in an LIS designation in the states. In the past, CMS has considered reducing the weights for the Medication Adherence measures, but in general such changes were not supported, and ultimately CMS decided not to move forward with these proposals.

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[15] The preliminary modelling suggested employing the 50 states and the District of Columbia results in very high accuracy in predicting contract-level LIS from contract-level DE. There is an insignificant impact on the model coefficients when restricting the data source to the lower-income subsets of states. CMS is moving forward using the percentage of DE using MA contracts in the 10 states with the highest poverty to create a contract-level measure of LIS/DE percentage to be used in the CAI. The states used for the development of the model are: Mississippi, New Mexico, Louisiana, Arkansas, Georgia, DC, Kentucky, Alabama, Arizona, and South Carolina. The list of states would be updated each year in the Technical Notes.

We commend the Puerto Rican contracts on their improved performance overall across the 2016 Star Ratings and in particular the Part D Medication Adherence measures. This year, CMS proposed an additional option to the LIS/DE adjustment noted above, one that is similar to a previous proposal, but limited to MAO and PDP contracts that operate solely in Puerto Rico or other non-continental territories in order to address the unique challenges of improving medication adherence in those areas. For the 2017 Star Ratings, CMS proposed to reduce the weights of the three Part D Medication Adherence measures to zero for the calculation of the overall and summary ratings, and retain the values and the associated weight of the three adherence measures for the calculation of the improvement factor.

The summary of the simulations provided in February 2016 in the CY 2017 draft Call Letter and the individual contract simulations provided through HPMS used only income, not resource, information to simulate the LIS indicator as described above. The value for the LIS indicator in Puerto Rico (determined through modeling) was used in the application of the CAI analytical adjustment for the overall and summary Star Ratings.[16] Using both the LIS indicator and CAI for contracts in Puerto Rico resulted in one contract realizing an increase in its overall Star Rating by half a star. (With IS, one contract would have experienced a decline in its overall Rating by half a star). There were no changes in the Part C or Part D summary ratings for Puerto Rican contracts for the CAI simulation. (For the IS simulation, one MA Puerto Rican contract would experience a decline by half a star in its Part C summary rating and another MA contract would experience a decline by half a star in its Part D summary rating.)

The simulations of the down weighting of the adherence measures for Puerto Rico resulted in four MA-PDs increasing by a half-star in its overall rating, independent of making an SES adjustment. With the down weighting of the adherence measures, one PDP increased one star in its Part D summary rating.

Overall, the draft Call Letter commenters expressed appreciation for acknowledging the unique challenges of Puerto Rico contacts and widespread support for the estimated LIS indicator and, the reduction in the weights for the three Part D adherence measures. Based on these comments, CMS will implement the interim estimates for the LIS indicator using modelling based on the 10 states with the highest level of poverty for the 2017 Star Ratings. In addition, for the 2017 ratings year, CMS will employ the data source as outlined in the draft Call Letter (i.e., the ACS) instead of waiting for the availability of a different data source. CMS has explored other sources of data for use in determining the LIS indicator for the upcoming rating year, but at this time no other source has been identified. We continue to encourage stakeholders in Puerto Rico to provide data appropriate for determining the LIS indicator.

[16] Currently, none of the territories, except Puerto Rico, have contracts that serve exclusively beneficiaries within the territory. The proposed changes discussed in this section will also apply to other territories without the LIS if those contracts serve exclusively beneficiaries in the territory.

CMS will also move forward to reduce the weights of the three Part D Medication Adherence measures to zero for the calculation of the overall and summary ratings for contacts operating solely in Puerto Rico. Further, to continue to create incentives to improve medication adherences in Puerto Rico, CMS will retain the adherence measures in the determination of the improvement measure.

2017 CMS Display Measures

Display measures on CMS.gov are not part of the Star Ratings. These may include measures that have been transitioned from the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed for informational purposes. Similar to the process used in 2016, organizations and sponsors will have the opportunity to preview their data for the display measures prior to release on CMS' website. Data for measures moved to the display page will continue to be collected and monitored; poor scores on display measures may reveal underlying compliance and performance issues that are subject to enforcement actions by CMS. It is expected that all 2016 display measures will continue to be shown on CMS.gov in 2017. CMS will continue to provide advance notice regarding measures considered for implementation as future Star Ratings measures. Other display measures may be provided as information only. Below are a number of revised or new measures for the 2017 display page.

1. **Timely Receipt of Case Files for Appeals (Part D) & Timely Effectuation of Appeals (Part D).** For the 2016 display measures, the data time frame for both measures was January 1, 2015 – June 30, 2015. CMS will change the data time frame from the first six months of the current year to January 1 – December 31 of the previous year. For example, the 2017 display measures will be based on IRE data from January 1, 2015-December 31, 2015. This change will allow the appeal display measures to match the same timeframe used for the Part D Appeal Star Ratings measures.

2. **Medication Reconciliation Post Discharge (Part C)**. The Medication Reconciliation Post-Discharge (MRP) measure assesses the percentage of discharges from acute or non-acute inpatient facilities for members 66 years of age and older for whom medications were reconciled within 30 days of discharge. This measure has been collected in SNP HEDIS since 2008. NCQA made two changes: 1) expanded the coverage on this measure from Medicare SNPs only to all MA plans; and 2) expanded the age range to members 18 years and older. Both of these changes for HEDIS 2016 are seen as important steps to measure the quality of care coordination post-discharge for MA beneficiaries as well as ensuring patient safety. CMS will include this measure on the 2017 display page and in the 2018 Star Ratings. Please refer to the NCQA HEDIS 2016 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications.

3. **Hospitalizations for Potentially Preventable Complications (Part C).** NCQA added to HEDIS 2016 a risk-adjusted measure of hospitalization for ambulatory care sensitive

conditions based on the NQF-endorsed Prevention Quality Indicators (PQI), developed by AHRQ. This measure assesses the rate of hospitalization for complications of chronic and acute ambulatory care-sensitive conditions. The measure is therefore an important indicator of care coordination. CMS will include this measure on the 2017 display page and in the 2018 Star Ratings unless there are data issues with the initial data collection. Please refer to the NCQA HEDIS 2016 Technical Specifications for Health Plans Volume 2 for measure construction and technical specifications.

4. **Statin Therapy for Patients with Cardiovascular Disease (Part C).** NCQA has added two sets of statin therapy measures to HEDIS aligned with the 2013 ACC/AHA blood cholesterol guidelines. These measures are focused on two of the major statin benefit groups described in the guidelines: patients with clinical atherosclerotic cardiovascular disease and patients with diabetes. Since some of these HEDIS measures overlap with the measures developed by the PQA, CMS will include only one of the HEDIS measures on the 2017 display page where it will remain for two years. After gaining experience with the new treatment guidelines and metric, we plan to include this measure in the 2019 Star Ratings. This measure focuses on statin therapy for patients with cardiovascular disease. It is the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year.

5. **Asthma Measures (Part C).** NCQA has expanded its asthma measures to include older adults. HEDIS 2016 includes two measures for older adults. Medication Management for People with Asthma is the percentage of members 5 to 85 years of age who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period (i.e., first prescription date through end of measurement year). The Asthma Medication Ratio is the percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. CMS has shared all comments received with NCQA and will continue to monitor the development of these measures. CMS will include these on the 2017 and 2018 display page and will consider these for inclusion in Star Ratings for future years.

6. **Statin Use in Persons with Diabetes (SUPD) (Part D).** This new PQA-endorsed measure, Statin Use in Persons with Diabetes (SUPD), calculates the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period. Beneficiaries in hospice according to the Enrollment Database (EDB) will be excluded from the denominator of the SUPD measure for the entire year. Part D sponsors have received year of service 2015 SUPD measure reports on a monthly basis through the Patient Safety Analysis website, and we will add the SUPD measure to the 2017 display page (using 2015 data) where it will remain for two

years. After gaining experience with the new treatment guidelines and metric, we plan to add the SUPD measure to the 2019 Star Ratings (using 2017 data).

Lastly, in January 2015, the PQA's Quality Metrics Expert Panel (QMEP) considered whether beneficiaries taking proprotein convertase subtilisin/kexin type 9 (PCSK-9) inhibitors should be excluded from the measure denominator. At this time, the QMEP decided not to exclude beneficiaries taking PCSK-9 inhibitors from SUPD measure denominator. It is our understanding that the PQA will review the measure specifications again when more information is available about this new therapeutic class.

Forecasting to 2018 and Beyond

The following describes changes to existing measures and potential new measures. CMS will also monitor any additional measures developed by NCQA or PQA for potential incorporation into the Star Ratings for 2018 or later.

New Measures

The section above describes a number of new measures under consideration for the 2018 Star Ratings that will be reported as 2017 display measures. The following are additional measures under consideration for the Star Ratings or display measures for 2018 and beyond.

1. **Care Coordination Measures (Part C).** Effective care coordination contributes to improved health outcomes. CMS believes that 5-star contracts perform well on our Star Ratings measures because they understand how to effectively coordinate care for their enrollees. Our assumption about plan care coordination activities, however, is based largely on anecdote and discussions with high performing plans, as well as on data we collect from CAHPS surveys, which reflect enrollees' experiences with the care they receive.

   CMS is working to expand efforts in this area. To identify potential new care coordination measures, CMS has awarded two contracts to conduct targeted research, extensive literature reviews, and data analysis, and to engage in discussions with expert panels and high performing plans. As part of this effort, the contractors are using various data sources such as administrative data, encounter data, Part D data and medical record reviews. We are considering whether the measures should be focused on subgroups of MA enrollees or all MA enrollees. We are also considering the activities that best represent care coordination, such as ensuring seamless transitions across settings, appropriate follow up after inpatient and emergency department visits, communication across providers, and comprehensive assessments, as well as the relationship between the plan and provider in care coordination activities. CMS continues to welcome comments on measures that could be developed using MA encounter data. We will provide updates to the industry as this work progresses.

2. **Depression Measures (Part C).** NCQA has adapted a provider-level depression outcome measure developed by Minnesota Community Measurement for use in HEDIS. Depression Remission or Response in Adolescents and Adults (DRR) uses a patient-reported outcome measure, the PHQ-9 tool, to assess whether patients with depression have achieved remission or have an improvement in their symptoms. The measure assesses the percentage of individuals age 12 and older with depression and an elevated PHQ-9 score (greater than 9) who achieve a PHQ-9 score of less than 5 at six months or have a 50% reduction in their PHQ-9 score. This measure also uses a new data collection methodology for HEDIS, relying on data coming from electronic clinical data systems (e.g., EHRs, clinical registries, case management records). If approved, the new measure would be published in HEDIS 2017. CMS shared with NCQA comments received as part of our Request for Comments and draft Call Letter on this topic and will continue to monitor the development of this measure.

3. **Appropriate Pain Management (Part C).** NCQA is exploring opportunities to develop a new measure(s) focusing on appropriate pain management. The intent is to assess the quality of pain management and treatment. There is no definite timeline established for the development of this measure.

4. **Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D).** In the 2016 Call Letter, we noted that three opioid overutilization measures were in development by the PQA. We further stated that if these measures were endorsed by the PQA prior to the 2017 bid deadline in June 2016 that we may adopt them as future display measures or alternatively use them in the Overutilization Monitoring System (OMS). The measures were endorsed by the PQA in May 2015.

   PQA's three opioid measures examine multi-provider, high dosage opioid use among individuals 18 years and older without cancer and not in hospice care.

   Measure 1 (Opioid High Dosage): The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine equivalent dose (MED) for 90 consecutive days or longer.

   Measure 2 (Multiple Prescribers and Multiple Pharmacies): The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

   Measure 3 (Multi-Provider, High Dosage): The proportion (XX out of 1,000) of individuals without cancer or hospice receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine equivalent dose (MED) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

We tested the measures using the PQA specifications. We will develop new patient safety reports for the three opioid overutilization measures to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website, similar to the other patient safety measures. The website also includes the OMS. The reports will allow sponsors to track their performance over time and allow for contract level trending and outlier analyses. Reports will be distributed beginning with 2016 dates of service. After at least one year to gain experience with the measures we will add these three measures to the 2019 Part D display page (using 2017 data). We are not adding these measures to the Star Ratings at this time due to concerns (1) about the current lack of consensus clinical guidelines for the use of opioids to treat chronic, non-cancer pain and potential exceptions due to medical necessity and (2) pending additional analysis on diagnosis data sources, such as newly available encounter data for Medicare Part C and resolving timing issues of RAPS file updates, which are used to identify exclusions for certain cancer conditions.

These measures were developed and endorsed by the PQA prior to publication of the CDC Guideline for Prescribing Opioids for Chronic Pain. We encourage the PQA to review the CDC Guideline and consider potential updates to the measure specifications as applicable.

Additionally, NCQA is adapting the three opioid overuse measures developed by the PQA for potential use in HEDIS.

5. **Antipsychotic Use in Persons with Dementia (APD) (Part D).** CMS has been particularly concerned with the unnecessary use of antipsychotic drugs in nursing homes and, as a result, has pursued strategies to increase awareness of antipsychotic use in long term care settings. In 2013, we began to calculate a general atypical antipsychotic utilization rate, called *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes*, for inclusion in the Part D display measures. The average rates decreased from approximately 24.0% in 2011 to 21.4% in 2013.

   There continues to be increased attention on this important issue. The United States Government Accountability Office (GAO) released a report[17] in January 2015 describing the inappropriate use of antipsychotics in Part D beneficiaries with dementia, in both community (i.e., outside of nursing homes) and long-stay nursing home residents during 2012, with recommendations for CMS to address this problem. The GAO conducted this study due to concerns raised regarding the use of antipsychotic drugs to address the behavioral symptoms associated with dementia, the FDA's boxed warning that these drugs may cause an increased risk of death when used by older adults with dementia, and because the drugs are not approved for this use.

[17] Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings. http://www.gao.gov/products/*GAO-15-211*. *GAO-15-211*: Published: Jan 30, 2015. Publicly Released: March 2, 2015.

In addition, the PQA endorsed the measure, *Antipsychotic Use in Persons with Dementia (APD).* This provides CMS with a new measure developed through a consensus process to monitor the inappropriate use of antipsychotics in both the nursing home and community settings across Medicare Part D plans.

We tested this measure based on the PQA specifications. We calculated the APD measure rate in aggregate for all contracts, MA-PDs, and PDPs, and at the individual contract level, for all beneficiaries, community-only residents (never a nursing home resident), and both short-term and long-term nursing home residents that met the inclusion and exclusion criteria. Beneficiaries were identified as long-stay nursing home residents if they had stays greater than 100 cumulative days in a nursing home during the year based data in the Long Term Care Minimum Data Set (MDS). Each beneficiary was counted in only one category for the entire measurement period within a contract and not considered separately for time spent in different settings (e.g., a beneficiary who experienced both short-term and long-term nursing home stays was included only in the long-term category).

To identify the numerator and denominator populations, we used diagnosis data obtained from inpatient (IP), outpatient (OP), and carrier claims from the Common Working File (CWF) and RxHCCs from the RAPS. OP and Carrier claims are available for PDP contracts only. We also adjusted rates based on the number of months beneficiaries are enrolled in each Part D contract (i.e., member-years adjustment).

We conducted reliability testing using mixed effect logistic regression with varying intercept. The testing results indicate that the rate variations at the contract level are statistically significant, providing evidence that the measure is reliable.

A report, Antipsychotic Use in Part D Enrollees with Dementia, which summarizes the testing results, is posted on CMS.gov at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Antipsychotic-Use-in-Part-D-Enrollees-with-Dementia-v12092015.pdf.

We will develop new patient safety APD measure reports to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website beginning with year of service 2016. We will add the overall APD measure plus breakout rates for community-only residents, short-term nursing home residents, and long-term nursing home residents to the 2018 Part D display measure set (using 2016 data) to continue to draw attention to the inappropriate use of antipsychotics in persons with dementia without an appropriate mental health diagnosis in both the community and nursing home settings. The APD measure will replace the *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes* display measure. However, we do not propose adding this measure to the Star Ratings pending additional research on diagnosis data sources, such as newly available encounter data for Medicare Part C and resolving timing issues of RAPS file updates.

Changes to Existing Star Ratings and Display Measures and Potential Future Changes

1. **Colorectal Cancer Screening (Part C Star Rating)**. The Colorectal Cancer Screening (COL) measure assesses the percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer. This measure is based on the U.S. Preventive Services Task Force (USPSTF) guideline on colorectal cancer screening in adults age 50-75. NCQA is monitoring updates to the guideline as the USPSTF has recently released a draft recommendation statement. NCQA will consider revisions to the COL measure once the USPSTF final recommendation statement is published. It is anticipated that the final release of recommendations will not occur until late 2016.

2. **Fall Risk Management (Part C Star Rating).** The Fall Risk Management (FRM) measure, collected through the Health Outcomes Survey, consists of the following two indicators: 1) *Discussing Fall Risk* assesses the percentage of Medicare members 75 years of age and older or 65-74 years of age with a balance or walking problem or fall in the past 12 months who discussed falls or problems with balance or walking with their current practitioner; and 2) *Managing Fall Risk* assesses the percentage of Medicare members 65 years of age and older who had a fall or had problems with balance or walking in the past 12 months and received fall risk intervention from their current practitioner (defined as suggesting use of a cane or walker, a vision or hearing test, physical therapy or exercise, or taking of a postural blood pressure). NCQA is currently re-evaluating this measure to align with the most current U.S. Preventive Services Task Force (USPSTF) guidelines. NCQA is proposing to 1) revise the denominator in the *Discussing Fall Risk* indicator to include all Medicare members age 65 and older and 2) revise the numerator for the *Managing Fall Risk* indicator to include plan members who report having had an intervention. The survey question will list examples of interventions to prompt survey respondents to recall if they received any fall risk management intervention from their provider. These proposed changes, if approved, would be published in HEDIS 2017 or HEDIS 2018.

3. **Pneumococcal Vaccination Status for Older Adults (Part C Display).** The Pneumococcal Vaccination Status for Older Adults (PNU) measure, collected through the Medicare CAHPS survey, assesses the percentage of Medicare members 65 years of age and older who have ever received a pneumococcal vaccination. In 2014, The Advisory Committee on Immunization Practices (ACIP) released new recommendations that all adults 65 years of age and older should receive sequential administration of both PCV13 and PPSV23. NCQA is considering changes to the measure to align with the most current guidelines. Specifically, they are evaluating the feasibility of developing a new measure of pneumococcal vaccination based on alternative data sources, such as administrative claims, state immunization registries and electronic health records. In the meantime they recommend the following wording changes to the existing CAHPS measure: "Have you ever had one or more pneumonia shots? Two shots are usually given in a person's lifetime and these are different from a flu shot. It is

also called the pneumococcal vaccine." Pending OMB approval the new wording will be utilized for 2017 CAHPS implementation. This measure is on the CMS display page.

4. **CAHPS measures (Part C & D).** Patient experience surveys such as CAHPS focus on how patients experienced or perceived key aspects of their care, not how satisfied they were with their care. CAHPS surveys follow scientific principles in survey design and development. The surveys are designed to reliably assess the experiences of a large sample of patients. They use standardized questions and data collection protocols to ensure that information can be compared across health care settings. CAHPS surveys are developed with broad stakeholder input, including a public solicitation of measures and a technical expert panel, and the opportunity for anyone to comment on the surveys through multiple public comment periods through the Federal Register.

   The current MA & PDP CAHPS Survey includes the core CAHPS 4.0 Health Plan Survey. CMS conducted an experiment in 2015 to understand how CAHPS measures differ between 4.0 and 5.0, and based on the results we will update the survey for future years to reflect AHRQ's CAHPS 5.0 Health Plan Survey. The findings from the experiment suggest that these changes are associated with a small increase in scores for several evaluative MA measures. These small increases did not significantly differ across contracts. Since there are no longer fixed thresholds for Star Ratings and they are based on the actual distribution of scores, there should be no shifts in Star Ratings due to transition to the version 5.0 instrument compared to what would have been the case with 4.0. Every contract would have the same expected Star Rating whether version 4.0 or 5.0 is used, and the correlation between this year's Star Ratings and next year's Star Ratings should be the same regardless of whether 4.0 or 5.0 is used next year.

   The 5.0 update applies recent improvements in survey design that resulted from development and testing of the Clinician & Group Surveys. The 5.0 version of the CAHPS Health Plan Survey incorporates some minor changes into the wording of core items, and a change in the placement of one core item that also resulted in the deletion of a screener item.

   The following are the changes in the 5.0 version of the Health Plan Survey:

   - **The items about access to urgent and non-urgent appointment items** were modified to ask respondents if they were able to get an appointment as soon as they needed, as opposed to as soon as they *thought* they needed. Non-urgent appointments are described as *a check-up or routine care* rather than *health care.* In addition, the phrase*, "…not counting the times you needed care right away"* was deleted from these questions. These revisions simplify the items and make them consistent with questions in other CAHPS surveys.

   - **The item about how often it was easy to get appointments with specialists** was revised to ask respondents if they got an appointment to see a specialist as soon as

they needed. This revision makes the item consistent with other CAHPS items that ask about access to care.

- **The item about how often it was easy to get care, tests, or treatment** was moved from the Your Health Plan section to the Your Health Care in the Last 6 Months section, because respondents had difficulty attributing this item to the health plan.

- **The screener item about getting care, tests, or treatment through the health plan** was deleted because the subsequent question was moved to an earlier section of the survey and no longer required a screener.

These changes would take effect for the 2017 CAHPS survey administration (used for 2018 Star Ratings) based on OMB approval. We will use the following standard for deciding that a specification change has occurred for a CAHPS measure in connection with the modification of the wording to decide whether to exclude the measure from the improvement measure calculation: (1) at least one item within the measure changed in wording, had a wording change in its screener, or had a wording change in the immediately preceding item, and (2) the measure score in version 5.0 was significantly different from the measure score in version 4.0 in the 5.0 experiment. Three MA measures meet this standard: Getting Care Quickly, Customer Service, and Care Coordination. Thus, these three measures will be excluded from the Part C improvement measure for the 2018 Star Ratings.

We are also considering changing the sampling for CAHPS in future years when a contract is listed in HPMS as a consolidation between July of the prior year and January of the current year when the CAHPS sample is drawn. The sampling frame for the surviving contract would include the enrollees for all members of all contracts involved if two or more contracts consolidate under the same parent organization. We will continue to study this and will give advance notice before making any changes to the methodology.

CMS provides translations of the MA & PDP CAHPS Survey in Spanish and Chinese. All translations are the product of translation and review by native speakers of the target languages and have had multiple rounds of qualitative testing with Medicare beneficiaries with characteristics similar to the MA & PDP CAHPS population. By providing survey translations, CMS promotes standardization by assuring that questions are presented similarly to beneficiaries across and within languages, which also promotes comparability of the results across vendors and contracts. The survey administration protocol for MA & PDP CAHPS does not permit "live," "individual," or "real-time" translation of the survey by an interpreter as such an approach does not promote comparability of data, and there is no mechanism for assuring the accuracy and consistency of the translation. The MA & PDP CAHPS protocol does allow for the use of proxy respondents in cases where a respondent is unable to complete the survey.

We note that CMS applies standards of reliability to CAHPS results, directly and through significance testing. Contract measures with interunit reliability (IUR) less than 0.60 are flagged as Very Low Reliability and are excluded from use in public reports or incentive payments. Those with IUR less than 0.72 are flagged as low reliability (up to 12% of the entire number of participating contracts) and limited use is made of those data, requiring stronger supporting evidence to classify a contract as different from average. The number of contracts falling below this criterion varies by measure from a few percent of contracts to about half. Tests of significance also play a role in CAHPS analyses, and these automatically adjust for the precision of available data. Finally, CMS offers contracts the option of augmenting their CAHPS sample sizes if they wish to obtain more precise overall results and/or perform subgroup analyses with larger samples. CMS reminds sponsors that the case-mix coefficients for the CAHPS Star Ratings measures are available in the Star Ratings Technical Notes each year.

We received several comments requesting that CMS shorten the MA CAHPS survey. CMS is committed to shortening the 2017 MA CAHPS survey by removing some questions that are not used in current Star Ratings measures.

5. **MPF Price Accuracy (Part D Star Rating).** CMS plans to make a few updates to this measure for the 2018 Star Ratings. The first change is related to the method by which claims are excluded from the measure. Currently, the measure is limited to claims filled for a 30-day supply at pharmacies reported by sponsors as retail only or retail and limited access only in their MPF Pharmacy Cost files. That is, claims that are not filled for exactly a 30-day supply, or claims filled for 60 and 90 days' supply are excluded. Additionally, claims filled by retail pharmacies that are also long term care, mail order, or home infusion pharmacies are excluded. These restrictions result in the exclusion of many PDEs, thus potentially biasing the reliability of the measure.

   We plan to include claims with 28-34 day supply, as we believe it would be appropriate to compare their PDE costs to MPF's fixed display of 1 month pricing. We also plan to include 60-62 and 90-93 day supply claims for a more comprehensive evaluation of PDE claims. Beginning with CY 2015 MPF submissions, plans must provide brand and generic dispensing fees for 60 and 90 day supply claims in the Pharmacy Cost file. CMS can use these data, along with 60 and 90 day supply Pricing File data, to compare MPF and PDE costs.

   Additionally, we plan to use the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims. CMS began requiring pharmacies to populate the Pharmacy Service Type field on all PDEs at the end of February 2013. We recommend expanding the retail claims identification process to include all PDEs that are from retail pharmacies according to the Pharmacy Cost data and have a Pharmacy Service Type of either Community/Retail or Managed Care Organization (MCO). Although

some sponsors cited concern about the accuracy of these data as reported by pharmacists, Part D sponsors are ultimately responsible for the accuracy of their submitted PDE to CMS. According to PDE requirements, CMS expects "…sponsors and their network pharmacies to develop and implement controls to improve the accuracy of this information during 2013…" This methodology change would increase the number of PDEs eligible for inclusion in the Price Accuracy Scores while continuing to identify only retail claims.

We plan to make changes to the methodology by which price accuracy is calculated. The current methodology measures the magnitude, but not the frequency, of a contract's PDE prices being higher than the MPF prices. A contract's accuracy score can be significantly impacted by high price PDEs. As a result, contracts with divergent accurate price reporting and/or consistency can receive the same Price Accuracy Score. CMS is interested in modifying the methodology to factor in both how much and how often PDE prices exceeded the prices reflected on the MPF. The frequency of inaccuracy by a contract would be the percent of claims where the PDE price is greater than the MPF price. The numerator is the number of claims where the PDE price is greater than MPF price, and the denominator is the total number of claims. This ratio is then subtracted from 1 and multiplied by 100 to calculate the Claim Percentage Score, with 100 as the best possible score and 0 as the worst possible score. The contract's accuracy score would be a composite of the Price Accuracy Score and the Claim Percentage Score.

By capturing the frequency of inaccuracy as well as the magnitude, the measure would better depict the reliability of a contract's MPF advertised prices. CMS is aware that while the MPF display is updated every two weeks, real time pricing, at the point of sale, can change as often as every day. Some sponsors have expressed concern that in order to perform well in the Price Accuracy measure, they cannot offer lower prices at point of sale in real time than the prices are displayed on MPF. We note that PDEs priced lower than MPF displayed pricing do not lower a contract's score in this measure.

CMS' simulation of this proposal found little change in the range of contracts' accuracy scores. Other options we explored include measuring the magnitude of inaccuracy as a percentage cost difference, instead of the current measure's use of absolute cost difference. Testing however found this method may overstate small differences between PDE and MPF costs for low-cost claims. For example, when using percentage cost differences, a claim with a $2.00 PDE price and a $1.00 MPF price would be considered equally overpriced as a claim with a $200.00 PDE price and a $100.00 MPF price.

We plan to implement these changes for the 2018 Star Ratings (using 2016 PDE and MPF data). We believe the changes will greatly improve the Price Accuracy Scores, making them a more comprehensive assessment of contracts' price reporting for Part D beneficiaries. For consistency, we will also implement these changes for the 2018 display measure, Plan Submitted Higher Prices for Display on MPF.

6. **Drug-Drug Interactions (DDI) (Part D Display).** The PQA-endorsed DDI measure is currently a Part D display measure. This measure 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 has conducted an extensive review of the drug-drug pairs included in the DDI measure. They engaged a DDI expert panel convened by the University of Arizona on PQA's behalf, which completed the review, including a comparison to the DDI list developed for the Office of the National Coordinator for Health Information Technology (ONC). The Expert Panel's recommendations were reviewed by the PQA's Measure Update Panel for consideration by the PQA's Quality Metrics Expert Panel (QMEP). Next, the PQA will test the DDI measure specifications because there will be extensive changes. We will closely monitor any updates to this measure, test updated specifications when available, and propose changes in the future for the Part D display measure and patient safety reporting.

7. **Center for Medicare and Medicaid Innovation Model Tests.** We note that some stakeholders (and commenters to the Request for Comments and draft Call Letter) have expressed concern regarding the potential for the improvements in quality resulting from the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced MTM Model test to adversely influence the Star Ratings of contracts ineligible to participate (or that include some PBPs ineligible to participate). CMS' goal is to not penalize participants or non-participants in either model.

   As the model tests are implemented, we will closely monitor performance trends of participating plans across individual measures and determine if any changes are warranted.

   For the MA-VBID Model test, CMS is considering the exclusion of some of the model-participants' data when calculating measure-level cut points.

   The Part D plans participating in the Part D Enhanced MTM Model test will be waived from the MTM requirements under Section 1860D–4(c)(2) and 42 CFR 423.153(d) and the Part D Reporting Requirements for MTM. However, Part D sponsors will not be waived from establishing MTM programs in compliance with current requirements and reporting data for the remaining plans under each Part D contract. Therefore, the MTM Program CMR Completion Rates will be calculated using available plan-reported data from the remaining plans under the Part D contract.

   Some stakeholders in response to the Request for Comments and draft Call Letter expressed concern that Enhanced MTM Model participants will sometimes be significantly advantaged or disadvantaged by the removal of the participating PBPs from the calculation of the CMR completion rate measure at the contract level, and have suggested the elimination of this measure for PDP contracts with model-participating plans. Some alternative possible options

are to establish different cut points for model participants or to case-mix adjust scores for the purpose of determining cut points. We are aware that the national scope of many PDP contracts must be taken into consideration in evaluating options for addressing potential differences in performance between participating and non-participating plans. Commenters requested that CMS engage stakeholders and provide information as these potential adjustments are developed. CMS will continue to consider how to address any potential differences in performance between participating and non-participating plans, taking these comments into consideration.

Measurement and Methodological Enhancements

CMS is committed to continuing to improve the Part C and D Star Ratings by identifying new measures and methodological enhancements. Feedback or recommendations can help CMS' continuing analyses, as well as our collaboration with measurement development entities such as NCQA and PQA.

As announced in the March 8, 2016 HPMS memo, CMS is suspending the reduction in the overall and summary Star Ratings of contracts that are under sanction, while CMS re-evaluates the impact of sanctions, audits, and CMPs on the Star Ratings[18]. CMS plans to describe our proposals in the Request for Comments in fall 2016.

Based on feedback received from the Star Ratings Request for Comments in fall 2015 and the CY 2017 draft Call Letter concerning our methodology for the Call Center Monitoring measure, beginning in 2017 CMS will allow the interpreter an extra 60 seconds to address an introductory question that is asked prior to three specific plan benefit questions. This will affect the 2018 Star Ratings.

CMS would like to clarify that the Call Center Monitoring tasks are described in the annual memos issued via HPMS each year, which ask plans to update all phone numbers in HPMS. Specifically, CMS informs health plans that "[t]he **Timeliness Study** measures Medicare Part C and Part D *current enrollee* beneficiary call center phone lines and pharmacy technical help desk lines to determine average hold times and disconnect rates" and "The **Accuracy and Accessibility Study** measures plan sponsors' Medicare Part C and Medicare Part D *prospective enrollee beneficiary call center phone lines* to determine (1) the availability of interpreters for individuals, (2) TTY functionality, and (3) the accuracy of plan information provided by customer service representatives (CSRs) in all languages." The same description is used in any compliance action issued. The pharmacy technical assistance line, or what is labeled as "pharmacy" in the monitoring results or compliance actions, refers to the requirement found at 42 C.F.R. § 423.128(d)(1). The Medicare Marketing Guidelines, at Appendix 3, clarifies the

[18] Prior to the suspension of this policy, contracts under an enrollment sanction were automatically assigned 2.5 stars for their highest rating. If a contract under sanction already had 2.5 stars or lower for their high rating, it received a 1-star reduction. Contracts were evaluated and adjusted for enrollment sanctions at two periods each year.

requirement as, "Part D Sponsors must operate a toll-free pharmacy technical help call center or make available call support to respond to inquiries *from pharmacies and providers* regarding the beneficiary's Medicare prescription drug benefit; *inquiries may pertain to operational areas such as claims processing, benefit coverage, claims submission, and claims payment."* The pharmacy technical assistance line listed in HPMS must be the toll-free number that pharmacies and providers would use to inquire about issues like claims submission or claims processing, and it is not intended to be the number a beneficiary would call. The Part D current enrollee or prospective member lines are the numbers intended for use by a current or prospective beneficiary.

Finally, we note that CMS has a rigorous Quality Assurance and Audit process over the test call process that involves multiple layers of review before, during and after each monitoring period. We encourage plans/sponsors to request and review their raw call data to validate the results. CMS believes that validation of the information by plans/sponsors is an important tool in our overall review of the monitoring contractor's performance, and we encourage plans/sponsors to contact CMS via CallCenterMonitoring@cms.hhs.gov if they believe an error occurred.

Medicare Parts C & D Program Audits

Proposed Release Date for the 2017 Part C and Part D Program Audit Protocols

Each year, the Medicare Parts C & D Oversight & Enforcement Group (MOEG) releases the Part C and Part D audit protocols to the industry in an effort to be as transparent as possible about our audit approach. We remain committed to continuous improvement in the development of our audit processes and protocols, and value the input and feedback of all sponsors and stakeholders. We have received feedback previously that sponsors would appreciate our audit protocols being released well in advance of the audit year, to allow more time to implement the new protocols and prepare for audits.

In the draft Call Letter, we indicated that beginning with the 2017 audit protocols, we would release the following year's protocols by the end of July, instead of mid-to-late fall. In other words, the 2017 protocols will be released in July of 2016. This release date should allow sponsors sufficient time to program their systems to pull accurate audit universes, conduct self-assessments, and prepare for an audit.

We noted, however, that this approach would delay our ability to incorporate sponsor's feedback on protocols until the following year's versions were released; so, feedback gathered on 2016 protocols would be incorporated into the 2018 protocols. We received multiple comments from sponsors, and all were very supportive of publishing audit protocols earlier. However, many sponsors raised concerns with the lag time that would occur with respect to incorporating feedback from the industry. We received many suggestions, including issuing interim updates to protocols in between annual releases, but most sponsors suggested we post protocols in draft, allow time for comment and then publish them in final. However, our earlier proposal failed to

consider the time to get changes to protocols approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). When protocols are going through the PRA approval process, they are published in the Federal Register for a 60 day and then subsequent 30 day comment periods. We will solicit sponsor feedback on our protocols during this more formal process. Audit protocols will be submitted to OMB annually, allowing sponsors an opportunity to provide feedback and have that feedback considered for incorporation each year. We will continue to work to issue audit protocols early in the year.

This new release cycle will have a particular impact on the two audit protocols that are being piloted in 2016, the Medication Therapy Management (MTM) and Provider Network Adequacy (PNA) protocols.

As stated in the draft Call Letter, we gather feedback from sponsors who take part in an audit with pilot protocols and use their feedback and experience to evaluate if updates and changes are needed to our pilot protocols prior to finalizing them. Since we will begin the process of finalizing the 2017 protocols only a few months into the 2016 pilot audit period, we do not believe that we will have gathered enough feedback on the pilot protocols prior to the July release date. Therefore, we are extending the pilot of these protocols into 2017 in order to allow time to gather feedback and determine if revisions are needed to the pilot audit protocols. Therefore, these protocols will be subject to a separate release cycle for 2016 and 2017.

As a reminder, sponsors subject to pilot protocols do not receive a score for the pilot, nor does it factor into their overall audit score. Finally, the results from the pilot audit protocol do not appear in the final audit report.

We would also like to acknowledge that the Provider Network Adequacy protocol will not be administered as a normal audit protocol and will not happen in conjunction with the remainder of our program audits. As mentioned in Section II of this document, wide scale monitoring efforts are underway with respect to network adequacy and provider directory. MOEG, in coordination with the Medicare Parts C & D Contract Administration Group (MCAG) are taking a comprehensive approach to monitor, audit and validate compliance with these requirements. Therefore, MOEG will be using the results of MCAG's provider directory monitoring each year to audit and validate correction of any deficiencies identified throughout the year. Those organizations that fail to correct and come into compliance with these requirements may be subject to possible enforcement action, including civil money penalties or enrollment sanctions.

Medicare Parts C & D Enforcement Actions

Civil Money Penalty (CMP) Calculation Methodology

When CMS makes a determination that a plan sponsor's operational deficiencies adversely affected or had the substantial likelihood of adversely affecting enrollees, the agency imposes Civil Money Penalties (CMPs) in accordance with Subpart O of 42 C.F.R. §§ 422 and 423. As

noted in the draft Call Letter and reflected again in comments to the draft Call Letter, a number of plan sponsors and industry groups have requested more information on the approach CMS uses to determine CMP amounts and how the impact of certain deficiencies are factored into a given CMP. In response to this interest, CMS plans to release a memo describing our interpretation of the applicable rules in a CMP Methodology by 2017, but will provide an opportunity for industry to comment before finalizing. This CMP methodology may be modified and republished on an as needed basis.

Compliance and Enforcement Actions Related to Part D Auto-Forwards

Part D plan sponsors are required to have procedures for making timely coverage determinations and redeterminations and for notifying enrollees of those decisions within the required adjudication timeframes. If notice of the decision is not provided within the required timeframe, the case must be automatically forwarded to the Part D Independent Review Entity (IRE). While all auto-forwarded cases represent non-compliance with CMS requirements for timely processing, of particular concern to CMS are plan sponsors with inordinately high levels of cases that are auto-forwarded throughout the plan year due to the plan sponsor's failure to meet the required adjudication timeframes. The requirements related to auto-forwarding untimely cases from the sponsor to the Part D IRE are set forth at 42 CFR Part 423, Subpart M and in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

As stated in the draft Call Letter, the volume of cases auto-forwarded to the IRE has been significant and sustained over the past several years. CMS has been monitoring auto-forward rates with the expectation that there would be a meaningful reduction of this volume over time as Part D plan sponsors gained program experience. In 2017, CMS will continue to increase the level and severity of the compliance and enforcement actions imposed on plans that substantially fail to comply with adjudication requirements for coverage determinations and redeterminations.

We received a number of comments asking CMS to clarify what thresholds will be used in determining whether a sponsor is considered an outlier. CMS will use data to determine which plan sponsors are outliers with respect to untimely decisions and the corresponding rate at which cases are auto-forwarded to the Part D IRE per 10,000 enrollees. This outlier threshold will be established each year and will be based on a quarterly auto-forward rate per 10,000 enrollees. This outlier threshold will be in alignment with the Star Ratings auto-forward measure 2-star cut-point (for the 2016 Star Ratings this annual cut-point was 38.5 - 66.8).

Pursuant to § 423.752(c)(1)(i), CMS has the authority to impose CMPs on sponsors that substantially fail to comply with the requirements related to coverage determinations, appeals and grievances in accordance with § 423.509(a)(4)(ii). A plan sponsor's inordinately high auto-forward rate is evidence of substantial failure to comply with the requirements to notify enrollees of coverage determination and redetermination decisions within the required timeframes. These failures adversely affect (or have the substantial likelihood of adversely affecting) beneficiaries

by causing inappropriate delays in accessing needed prescription drugs and/or financial hardship to beneficiaries.

Enforcement Actions Related to One Third Financial Audit Findings

Sections 1857(d)(1) and 1860D-12(b)(c) of the Social Security Act require the HHS Secretary to provide for the annual audit of the financial records of at least one-third of the Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs). The one-third financial audit program is designed to examine the health plans' financial records, internal controls over payment disbursements, Medicare utilization and costs, and the computation of Part C & D bids. As stated in the draft Call Letter, instances of noncompliance from these audits have identified significant financial errors, disallowed costs, and internal control weaknesses. While sponsors are required to put a corrective action in place and rectify their deficiencies, certain findings with adverse beneficiary impact, such as incorrect or increased cost-sharing or copayments for beneficiaries, warrant further enforcement actions. As a result, for audits conducted in 2017 (based on CY 2015) CMS will begin to consider findings and observations of noncompliance from the one-third financial audits for potential enforcement actions, in accordance with 42 CFR §§422.752(c)(i) and 423.752(c)(i). We received comments requesting further information about what criteria will be used in determining potential enforcement actions. Therefore, information related to these actions will be shared in advance with the industry.

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 CY 2016 Call Letter, CMS indicated its intention to partner with private payers to test innovations in health plan design for CMS beneficiaries.

Since the CY 2016 Call Letter, CMS has announced the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) Model tests, both scheduled to begin on January 1, 2017. These model tests are described below.

We received suggestions for potential model tests for CMS to conduct under Innovation Center authority, and a request that CMS include both participants and non-participants in model test learning. CMS appreciates these suggestions, and looks forward to continuing to engage stakeholders in the model test development and learning processes.

Medicare Advantage Value-Based Insurance Design Model Test

The MA-VBID Model test is an opportunity for MAOs to offer mandatory supplemental benefits or reduced cost sharing to enrollees with CMS-specified chronic conditions, focused on the services that are of highest clinical value to them. Only those MAOs approved by CMS to

participate in the model may do so, and only within PBPs accepted into the model test. The model will test whether these interventions can improve health outcomes and lower expenditures for Medicare Advantage enrollees and for the Medicare program. CMS is conducting the model test in seven states, and the application period for joining the model in CY 2017 closed in January 2016.

We received comments supportive of the MA-VBID model test, with suggestions for improvement in future model years, and will take these suggestions into account. Two commenters requested that CMS allow participating MAOs to offer supplemental non-covered benefits contingent on participation in disease management or related programs for the clinically-targeted enrollee population. CMS views this type of intervention as being within the flexibility offered by the model test's Request for Applications, and MAOs wishing to offer innovative approaches to VBID should make appropriate proposals to CMS for our consideration in future application cycles.

Part D Enhanced MTM Model

The Part D Enhanced MTM Model will test whether providing Part D sponsors with additional payment incentives and regulatory flexibilities will engender enhancements in the MTM program, leading to improved therapeutic outcomes, while reducing net Medicare expenditures. The model is an opportunity for stand-alone basic Part D plans to right-size their investments in MTM services, identify and implement innovative strategies to optimize medication use, improve coordination of care between plans and providers, and strengthen system linkages.

Standalone PDP basic plans that have applied and been approved to participate in the CMS Innovation Center's Enhanced MTM Model will offer MTM programs subject to the terms and conditions of the model test in the five selected Part D regions. All other Part D plans, including any ineligible plans offered by the PDP sponsors of participating plans, will remain subject to the current regulatory requirements for MTM programs and must include those costs in their 2017 Part D bids. None of the waivers or funding available to model-participating plans is applicable to the other ineligible plans offered by those PDP sponsors. A participating plan sponsor may use lessons learned from model beneficiary and provider engagement and intervention strategies to increase participation within its mandatory MTM programs in other plans, to the extent allowable outside of the model. For more information, please visit: https://innovation.cms.gov/initiatives/enhancedmtm/.

We received comments generally supportive of the Enhanced MTM model test, with several comments requesting continued robust stakeholder engagement on the model. CMS will take these comments into consideration as the model progresses. Three commenters suggested that CMS modify the Enhanced MTM model to allow drug manufacturers to participate in the development of new MTM strategies. The Enhanced MTM model is designed to test PDP Sponsor-driven approaches to improving medication usage among at-risk enrollees. The model

test does not permit collaboration with drug manufacturers. However CMS will continue to evaluate all avenues to improve medication usage and health outcomes in considering future model tests.

Section II – Part C

Guidance on the Future of Provider Directory Requirements and Best Practices

CMS wants to further emphasize the importance of providing accurate provider directories to MA enrollees. Inaccurate provider directories can impede access to care and bring into question the adequacy and validity of the MAO's network as a whole. In concert with previously released guidance, our focus remains making sure provider directories are accurate for Medicare beneficiaries and their caregivers who rely on them to make informed decisions regarding their health care choices.

CMS is aware of pilot programs being tested by some MAOs to use new technology to simplify the process of updating provider directories for physicians and other network participants. We are supportive of industry efforts to improve provider directories and encourage MAOs and providers to continue to work collaboratively to develop more effective and efficient methods of maintaining accurate provide directories. We see great potential with the use of technologies that capitalize on machine readable information. To foster the development of such technologies, we urge both industry and provider community to strive to provide data, including provider information on network participation, in a machine readable format. CMS has purposefully not prescribed the means by which MAOs must update their provider directories in order to allow innovation in this area such as updating provider directories by gathering a digital representation of provider participation and contact information directly from a provider's web page.

We received comments on the critical role that providers play in ensuring provider directory accuracy. CMS agrees that a component of accuracy relies on providers keeping plans abreast of changes. CMS has taken this into account in our Medicare Marketing Guidelines (MMG) regarding quarterly provider outreach and updating any identified errors within 30 days of receipt. We continue to encourage the industry and the provider community to work collaboratively to address this important matter.

Preliminary data gathered by CMS, as well as continued stakeholder concerns, has intensified our concerns with provider directory accuracy. We will continue to aggressively identify and pursue instances of non-compliance by using a host of oversight methods. For example, with contractor support, we have developed a comprehensive process for monitoring provider directory accuracy, which is currently underway. The data collected through our monitoring activities could drive additional reviews of network adequacy, as well as future monitoring

and/or audit-based activities. Moreover, identified areas of non-compliance may be subject to compliance and/or enforcement actions, including civil money penalties or enrollment sanctions.

We received a number of comments regarding the provider directory monitoring activities currently underway. Commenters urged CMS to share our methodology for the reviews as well as to provide preliminary data to MAOs prior to taking any compliance and/or enforcement action. We will share the methodology in an upcoming HPMS memo. We will also provide preliminary data related to the monitoring to MAOs prior to taking any action. Additionally, some commenters requested leniency from CMS as MAOs work to improve accuracy of provider directories. While we acknowledge the industry's efforts thus far, our focus remains on overall directory accuracy, which is a long-standing Medicare Advantage requirement. We will continue along the path of issuing compliance and enforcement actions when necessary.

CMS also remains committed to making provider directory requirements across CMS programs consistent. As such, the MA program is taking steps to harmonize the requirements and provide organizations that operate across multiple CMS programs consistency in the application of provider directory requirements.

Currently among MA, QHPs and the Medicaid managed care programs, MA provides the least prescriptive provider directory requirements. (See 42 C.F.R. §422.111(b)(3)(i) and explained in sections 60.4 and 100.4 of the Medicare Marketing Guidelines (https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2016-Medicare-Marketing-Guidelines-Updated.pdf). The MA program also has the fewest data elements required for its provider directory. In addition, both Medicaid and the QHPs have moved toward some level of machine readability for online provider directory content (see 45 C.F.R. 156.230(c) with additional guidance provided via Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces; and Proposed Medicaid Final Rule CMS–2390–P, 42 C.F.R. 438.10(h)(4)), while MA has not. The Office of Management and Budget (OMB) defines "machine readable" as a format in a standard computer language (not English text) that can be read automatically by a web browser or computer system.

We received a number of comments in support of harmonizing the provider directory requirements across CMS programs. We received mixed comments regarding the additional data elements that were identified. We will continue to review and consider additional data elements in the future. As this is only a best practice at this time, we will share this information with our counterparts who work on the QHPs and Medicaid requirements.

Regulatory updates to § 422.111 would generally be needed to require MA organizations to issue provider directories that include the additional elements. CMS intends to propose such revisions in the future and encourages the inclusion of the elements listed below in provider directory requirements as a best practice and urges MAOs to incorporate them into their production of such directories in advance of future rulemaking.

The following are the provider directory data elements we believe are appropriate to use in current MAOs' provider directories:

- Machine readable content
- Provider medical group
- Provider institutional affiliation
- Non-English languages spoken by provider
- Provider website address
- Accessibility for people with physical disabilities

We received a number of comments regarding machine readability, with commenters requesting additional information and some requesting CMS select a standard for machine readability. Since machine readability is currently a best practice for Medicare Advantage, CMS urges the industry to look to the guidance provided by the QHPs and Medicaid to strengthen oversight processes, as well as to identify a standardized format for machine readable information.

We recognize that MAO customer service call centers use a variety of approaches to address calls from enrollees who need assistance in locating a provider that is accepting new patients. We also understand that there is no single approach that can be used for all calls or situations. To further augment the customer service experience, we are encouraging MAOs institute the best practice of incorporating a "warm transfer" policy to their customer service call when practical. For enrollees calling to request help finding a provider that is accepting new patients, the CSR would close the call by calling the provider's office, establishing the need(s) of the enrollee, and transferring the enrollee to the provider's office to complete the appointment process. When determining if a warm transfer should be used, the MAO should guard against steering by providing the enrollee with choices of providers and to provide any needed materials/resources to aid in provider selection, the MAO should consider the time of the call and the likelihood of the provider's office being available, and most importantly, the MAO should determine if the enrollee would like to be transferred to the providers office.

Overview of CY 2017 Benefits and Bid Review

Portions of this guidance apply to cost-based plans and MA plans (including EGWPs, Dual-Eligible Special Needs Plans (D-SNPs), Chronic Care Special Needs Plans (C-SNPs), and Institutional Special Needs Plans (I-SNPs)). We currently do not evaluate whether employer group plans, D-SNPs, and 1876 Cost Plans are duplicative under §422.256(b)(4), also referred to as the "meaningful difference" evaluation. Similarly, employer group plans and 1876 Cost Plans are not evaluated for low enrollment under §422.506(b)(1)(iv) and (b)(2). CMS reserves the right to review employer group plans for low enrollment and/or meaningful difference in future years.

Medicare-Medicaid Plans in Capitated Financial Alignment Demonstrations are not subject to the review criteria summarized in the table below and benefits and benefit review guidance for these plans will be provided separately.

CMS makes 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 6, 2016 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 at any time prior to final approval will receive a compliance notice, even if the organization is allowed to correct the deficiency. The severity of compliance notice may depend on the type and/or severity of errors.

IMPORTANT NOTE: As indicated in the Rate Announcement, CMS has adopted the proposal to waive MA employer bidding requirements beginning in CY 2017. Although this change affects CMS' ability to evaluate the PMPM Actuarial Equivalent Cost Sharing discussed in this section, MA employer plans continue to be subject to all unwaived MA requirements regardless of whether they are evaluated as part of bid review or reviewed in connection with other oversight. Employer plans will not be submitting a Bid Pricing Tool (BPT), but must submit a Plan Benefit Package (PBP) in accordance with CMS requirements (consistent with past years) and make a good faith effort in projecting CY 2017 member months for each plan and place the amount in Section A-2 of the PBP. Please see "Plan Benefit Package (PBP) Updates and Guidance" of this Call Letter for additional information.

The following chart displays key MA bid review criteria and identifies which criteria are used in reviewing the bids of the plan types identified in the column headings.

Table 13. 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] Section 1876 Cost Plans and MA 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)).

CMS has made changes to service category cost sharing amounts, PMPM Actuarial Equivalence factors, and Total Beneficiary Cost (TBC) requirements for CY 2017 and have provided these changes in each applicable section below. Consistent with past years, 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 the benefits review requirements.

Plans with Low Enrollment

At the end of March, CMS sent affected MAOs a list of non-SNP plans that have fewer than 500 enrollees or fewer than 100 enrollees for SNP plans and that have been in existence for three or more years [as of March 2016 (three annual election periods)]. The notification represents CMS' decision not to renew such plans under 42 CFR §422.506(b)(1)(iv) and (b)(2). The list did not include plans with low enrollment that CMS determines are located in service areas that do not

have a sufficient number of competing options of the same plan type (such that the low enrollment plan still represents a viable plan option for enrollees).

Through return e-mail, MAOs must either (1) confirm that each of the low enrollment plans identified by CMS will be eliminated or consolidated with another of the organization's plans for CY 2017, or (2) provide a justification for renewal. If CMS does not find a unique or compelling reason that the low enrollment plan is a viable independent option for enrollees, CMS will instruct the organization to eliminate or consolidate the plan. Instructions and the timeframe for submitting business cases and the information required in those submissions were included with the list of low enrollment plans sent to the MAO.

Note: These requirements do not apply to Section 1876 cost plans, employer plans, or MA Medical Savings Account (MSA) plans.

CMS recognizes there may be certain factors, such as the specific populations served and geographic location of the plan, that lead to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because they focus on a subset of enrollees with certain medical conditions. CMS will consider this information when evaluating whether specific plans should be non-renewed based on insufficient enrollment. MAOs should follow CMS renewal/non-renewal guidance (see the Medicare Managed Care Manual: section 150 of Chapter 4, and/or section 60.2 of Chapter 16B) to determine whether a low enrollment plan may be consolidated with another plan(s). CMS will continue to evaluate and implement low enrollment requirements on an annual basis.

CMS received comments expressing concerns about applying low enrollment restrictions to employer plans in the future. Although CMS does not intend to apply low enrollment criteria to employer plans in CY 2017, we will consider in the future how to apply the applicable standard (that the "plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option") to employer plans and whether to take enforcement action in that context.

Meaningful Difference (Substantially Duplicative Plan Offerings)

Pursuant to §422.254(a)(4), MAOs offering more than one plan in a given service area must guarantee the plans are substantially different so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs. For CY 2017, 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. For CY 2017, benefits and the reduction in cost sharing that are offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the meaningful difference evaluation. Documentation and instructions for the OOPC model are available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html.

CMS considers HMO and HMO-POS as one plan type, unless the HMO-POS plan covers all Parts A and B services outside the network, in which case the HMO-POS plan is considered meaningfully different from the HMO plan. Consistent with CY 2016, this standard for evaluating meaningful difference will not include geographic or provider limitations on the out-of-network benefits. However, CMS in future years may consider HMO-POS plans meaningfully different only if the plans do not place geographic or provider limitations on the out-of-network benefits.

We received several comments recommending that CMS not move forward with further restrictions on HMO-POS plans in the future. CMS will take these comments into consideration as part of our ability to interpret and apply the meaningful difference regulatory requirement in the future.

For CY 2017, CMS will evaluate meaningful differences among CY 2017 non-employer and non-cost contractor plans offered by the same MAO, in the same county and, under the same contract, 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). We currently do not apply the meaningful difference evaluation to D-SNPs.

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. CMS considers 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.

CMS is considering whether to conduct this evaluation at either the legal entity or parent organization level in future years. We received several comments recommending that CMS not move forward with this approach in future years due to the potential restrictions it could place on organizations and the benefits offered to the enrollees. CMS will take these comments into

consideration as part of our ability to interpret and apply the meaningful difference regulatory requirement in the future.

Note that plan characteristics such as premium, variations in provider networks, and/or serving different populations are not considered meaningfully different characteristics. Commenters requested CMS to consider allowing premium and/or provider network differences as part of their meaningful difference evaluation. We will continue to consider these comments, but will maintain our current position. Premium is excluded from the criteria because the regulatory meaningful difference requirement is intended to be an objective measure of benefits between two plans; the inclusion of premium would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity. Provider network differences have also been excluded from our criteria because having a provider in one plan and not the other is not a change in benefit coverage. In addition, plan providers can change throughout the year (e.g., terminate their provider contract or close their practice to new members), so it is not necessarily accurate or transparent to a beneficiary making a plan choice for the year.

CMS expects MAOs to submit CY 2017 plan bids that meet the meaningful difference standards, but will not prescribe how the MAOs should redesign benefit packages to achieve the differences. Furthermore, MAOs will have access to the necessary tools to calculate OOPC estimates for each plan prior to bid submission. CMS will not approve plan bids that do not meet these standards.

CMS notes that meaningful difference will be evaluated based on the "as submitted formulary" prior to rebate reallocation, and "first approved formulary" following rebate reallocation. MAOs must follow the CY 2017 renewal/non-renewal guidance in the Final Call Letter to determine if their plans may be consolidated with other plans.

NOTE: Please see Plan Benefit Package (PBP) and policy updates below for changes to PBP that may impact the OOPC model and could potentially affect the meaningful difference evaluation for certain plans.

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 standard. A plan's TBC is the sum of the 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 confirm enrollees 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). For CY

2017, benefits and cost sharing that are offered as part of the Value-Based Insurance Design (VBID) model test will not be included in the TBC evaluation. The MA plans that are participating in the VBID model test will be evaluated under the TBC calculation, including plan premium and non-VBID benefits and cost sharing.

Under §422.254, CMS reserves the right to further examine and request changes to a plan bid even if a plan's TBC is within the required amount. This approach not only protects enrollees from significant increases in cost sharing or decreases in benefits, but also confirms enrollees have access to viable and sustainable MA plan offerings.

CMS has focused on sharing information with and providing transparency to the MAOs as it relates to the TBC year-to-year evaluation. CMS proposed to modify the payment adjustment in a different way than indicated in the CY 2016 Final Call Letter. Rather than "discounting" the plan-specific payment adjustment (including a coding intensity component), CMS proposed to eliminate the coding intensity adjustment factor. Since most of the Affordable Care Act (ACA) payment changes have been implemented, it is our expectation that MAOs are better positioned to share payment changes and provide affordable and effective benefits for beneficiaries. Going forward, the payment adjustment in the TBC calculation will account for changes in county benchmarks, quality bonus payment, and/or rebate percentages.

CMS received comments from several organizations opposed to this change in interpretation and implementation because future coding intensity and other rate pressures are unknown and could result in unanticipated revenue pressure. Some commenters suggested CMS should keep the coding intensity adjustment and also include an adjustment for changes in the risk score model to provide greater flexibility in modifying benefits. Other comments supported our proposal since most of the ACA payment changes have been implemented and MAOs should be positioned to share in payment changes. We appreciate the comments and will move forward with eliminating the coding intensity adjustment factor as part of our TBC analysis for CY 2017.

Other comments suggested giving consideration to indexing the TBC change amount to account for annual medical inflation and that Institutional SNPs may warrant special consideration in applying the TBC evaluation. We will give consideration to these suggestions as policy and guidance is developed for CY 2018.

In addition, we received comments concerned about expectations related to the Health Insurance Providers Fee moratorium as bids are prepared for CY 2017 and its year-to-year impact on the TBC evaluation. Consistent with past years, MAOs must address requirements implemented under the ACA, 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 the benefits review requirements.

CMS will continue to incorporate the technical and payment adjustments described below and expect organizations to address other factors, such as coding intensity changes, risk adjustment model changes and payment of the health insurance provider's fee independently of our TBC requirement. As such, plans are expected to anticipate and manage changes in payment and other environmental factors to minimize changes in benefit and cost sharing over time. CMS also reminds MAOs that the Office of the Actuary extends flexibility on margin requirements so MAOs can satisfy the TBC requirement.

In mid-April 2016, as in past years, CMS will provide plan specific CY 2016 TBC values and the following adjustments that are incorporated in the TBC calculation to account for changes from one year to the next:

- Technical Adjustments: (1) annual changes in OOPC model software and (2) maximum Part B premium buy-down amount change in the bid pricing tool, if applicable (no change for CY 2017).

- Payment Adjustments: (1) county benchmark, and (2) quality bonus payment and/or rebate percentages.

CMS will maintain the TBC change threshold at $32.00 PMPM for CY 2017. A plan experiencing a net increase in adjustments must have an effective TBC change amount below the $32.00 PMPM threshold to avoid denial of the bid under section 1854(a)(5)(C)(ii). Conversely, a plan experiencing a net decrease in adjustments may have an effective TBC change amount above the $32.00 PMPM threshold. In an effort to support plans that improve quality compensation and experience large payment adjustments, along with holding plans accountable for lower quality, CMS will apply the TBC evaluation as follows.

For CY 2017, the TBC change evaluation will be treated differently for the following specific situations:

- Plans with an increase in quality bonus payment and/or rebate percentage, and an overall payment adjustment amount greater than $32.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $32 PMPM) plus applicable technical adjustments.

- Plans with a decrease in quality bonus payments and/or rebate percentage, and an overall payment adjustment amount less than -$32.00 PMPM will have a TBC change threshold of $64.00 PMPM (i.e., 2 times TBC change limit of $32.00 PMPM) plus applicable technical adjustments. That is, plans would not be allowed to make changes that result in greater than $64.00 worth of decreased benefits or increased premiums.

- Plans with a star rating below 3.0 and an overall payment adjustment amount less than −$32.00 PMPM will have a TBC change threshold of $64.00 PMPM (i.e., 2 times TBC

change limit of $32.00) plus applicable technical adjustments.

- Plans not accounted for in the three specific situations above will be evaluated at the $32 PMPM limit, similar to last year.

CMS received feedback subsequent to last year's Call Letter suggesting that CMS make changes to the TBC evaluation for Special Needs Plans for End Stage Renal Disease (ESRD), which are subject to larger increases and/or decreases in payment amounts. To moderate potentially large payment changes and provide MAOs with the ability to maintain benefit stability year-to-year, while helping provide protection for this vulnerable beneficiary population, CMS proposed this year to apply limits to the payment adjustment for ESRD plans as described below:

- Plans with an increase in the overall payment adjustment amount greater than $32.00 PMPM will have a TBC change threshold of $0.00 PMPM (i.e., −1 times the TBC change limit of $32 PMPM) plus applicable technical adjustments.

- Plans with a decrease in the overall payment adjustment amount less than -$32.00 PMPM will have a TBC change threshold of $64.00 PMPM (i.e., 2 times TBC change limit of $32.00 PMPM) plus applicable technical adjustments. That is, plans would not be allowed to make changes that result in greater than $64.00 worth of decreased benefits or increased premiums.

We received comments acknowledging CMS's efforts to address the TBC challenges facing ESRD plans, but expressing concern that the proposed changes may not go far enough in managing the potential impact of ESRD payment changes. Some commenters recommended a separate TBC evaluation for ESRD plans. We understand that organizations may have concerns related to this limitation when payments are decreasing, but are finalizing this guidance for CY 2017. CMS will monitor and evaluate potential modifications for CY 2018.

Consistent with the CY 2016 Final Call Letter, CMS proposed that each individual plan being consolidated into another plan must meet the TBC requirement on its own merit. For CY 2017, CMS will be moving forward with this interpretation and implementation; therefore, organizations consolidating multiple plans into a single plan will no longer be permitted to use the enrollment-weighted average TBC change of the consolidating plans.

We received comments from several organizations expressing concerns because multiple plans may need to be consolidated due to organizational or marketplace changes, as well as CMS pressures. Commenters pointed out that if plans were unable to meet this requirement, it could result in disruption for beneficiaries. CMS is finalizing this approach for CY 2017 as it affords greater protection for beneficiaries and enrollees in non-renewing plans will be able to actively select another MA plan from the same or competing organization based on CMS non-renewal guidance.

NOTE: Please see policy updates below for changes to the PBP that will impact the OOPC model and may potentially affect the TBC evaluation for certain plans.

Maximum Out-of-Pocket (MOOP) Limits

As codified at 42 CFR §422.100(f)(4) and (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.

Table 14 below displays the CY 2017 mandatory and voluntary MOOP amounts and the combined (catastrophic) MOOP amount limits applicable to Local PPOs and Regional PPOs. 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. We chose to display the possible ranges of the MOOP amount within each plan type 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 14. CY 2017 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

We received a comment requesting clarification as to whether PPOs are permitted to offer a combined MOOP amount within the mandatory range, while having an in-network MOOP amount within the voluntary range. Although we will take this comment under consideration for the future, CMS's current policy is that the in-network MOOP amount dictates the combined MOOP range for PPOs. The MOOP ranges stated in the Call Letter above are accurate.

As explained in the CY 2012 Call Letter, MOOP limits are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The mandatory MOOP amount represented approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, five percent of Original Medicare beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments and coinsurance. The voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Original Medicare out-of-pocket costs.

The Office of the Actuary conducts an annual analysis to help CMS determine the proposed MOOP amount. Since the MOOP requirement was finalized in §422.100(f)(4) and (5), a strict application of the 95th and 85th percentile would have resulted in MOOP limits fluctuating up and down year-to-year. CMS has exercised discretion to maintain stable MOOP limits from year-to-year, if the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages, and does not discourage the adoption of the lower voluntary MOOP amount if the limit increases one year and then decreases the next. CMS expects to increase MOOP limits if a consistent pattern of increasing costs emerges over a period of time.

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 make certain 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. D-SNPs have the flexibility to establish $0 as the MOOP amount, thereby guaranteeing there is no cost sharing for plan enrollees, including those who are liable for Medicare cost sharing. Otherwise, if the D-SNP does charge cost sharing for Medicare covered or non-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.

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

IMPORTANT NOTE: As indicated in the Rate Announcement, CMS has adopted the proposal to waive MA employer bidding requirements beginning in CY 2017. Although this change affects CMS' ability to evaluate the PMPM Actuarial Equivalent Cost Sharing discussed in this

section, MA employer plans continue to be subject to all unwaived MA regulatory requirements whether they are evaluated as part of bid review or reviewed in connection with other oversight.

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. See 42 CFR §422.254(b)(4). CMS will apply this requirement separately to the following service categories for CY 2017: Inpatient, Skilled Nursing Facility (SNF), 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 2017.

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 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 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 15. 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)*** [1]	**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	1.382	$34.97	$0.00	Pass
SNF	$10.83	$58.19	$9.89	1.069	$10.58	$0.25	Fail
DME	$3.00	$11.37	$2.65	1	$2.65	$0.35	Fail
Part B-Rx	$0.06	$1.42	$0.33	1	$0.33	$0.00	Pass

[1] 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.

Part C Cost Sharing Standards

For CY 2017, CMS will continue the 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 16 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 in violation of other applicable standards. CY 2017 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. Inpatient standards have been updated to reflect estimated changes in Original Medicare cost for CY 2017.

Table 16. CY 2017 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	$4,177
Inpatient - 10 days	1a	$2,471	$1,977
Inpatient - 6 days	1a	$2,251	$1,801
Mental Health Inpatient - 60 days	1b	$2,606	$2,085
Mental Health Inpatient - 15 days	1b	$1,988	$1,590
Skilled Nursing Facility – First 20 Days[1]	2a	$20/day	$0/day
Skilled Nursing Facility – Days 21 through 100[2]	2a	$164.50/day	$164.50/day
Emergency Care/Post Stabilization Care	4a	$75	$75
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
Dialysis Services	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 plan level deductible amount and/or out-of-network providers.

[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.

MAOs with benefit designs that use 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 documentation with their initial bid that clearly demonstrates how the coinsurance or copayment amount satisfies CMS service category requirements. This documentation must be submitted under the "cost sharing justification upload" section in the Bid Submission module of HPMS (Navigation Path: Plan Bids > Bid Submission > CY 2017 > Substantiation > Select Applicable Contract Number). CMS annually evaluates available Medicare data and other information to apply MA requirements in accordance with applicable law. Organizations are afforded the flexibility to design their benefits as they see fit so long as they satisfy Medicare coverage requirements.

As indicated in the table above, for SNF days 1 through 20, CMS will reduce the cost sharing limit for CY 2017 voluntary MOOP plans from $40 per day to $20 per day for beneficiary protection. In addition, we also intend to reduce the cost sharing limit from $20 per day to $0 per day for CY 2018 MA plans so that SNF cost sharing will align with Original Medicare for both voluntary and mandatory MOOP. We received comments from organizations in support of this change because it aligns with Original Medicare and helps vulnerable beneficiaries experiencing health care challenges, while other commenters expressed concerns about limiting benefit flexibility. CMS appreciates these comments and is finalizing the change for CY 2017 and expects to make the proposed change for CY 2018.

CMS has traditionally afforded MAOs greater flexibility in establishing Parts A and B cost sharing by adopting a lower, voluntary maximum out-of-pocket (MOOP) limit than is available to plans that adopt a higher, mandatory MOOP limit. The number of MA plans with voluntary MOOPs has decreased significantly over the past several years which may call into question the value of allowing cost sharing flexibility and serve to minimize the impact of changes made to this policy.

CMS requested comments about whether current cost sharing flexibility should still be available to voluntary MOOP plans, and suggestions about other incentives to encourage MAOs to offer plans with a lower voluntary MOOP for enrollees. For example, flexibilities to highlight voluntary MOOP plans in marketing materials or a special indicator or priority sorting on Medicare Plan Finder. These types of marketing-related incentives may encourage plans and brokers to educate beneficiaries on the MOOP and its value to their overall financial protection should they experience large medical expenses during a plan year.

Most commenters recommended that CMS continue to provide benefit flexibility so that organizations would be encouraged to offer voluntary MOOP plans and also provided helpful suggestions. For example, expanding the benefit flexibility to other categories, modifying both the voluntary and mandatory MOOP amounts, providing potential marketing and/or preferential treatment on Medicare Plan Finder. Some commenters supported efforts to limit high cost

sharing, but did not want plans to be discouraged from offering plans with lower MOOP amounts which affords greater beneficiary protection.

We appreciate these comments and expect to continue cost sharing flexibility for voluntary MOOP plans. CMS will consider expanding benefit flexibility to additional service categories, adjusting MOOP amounts, and providing additional marketing and Medicare Plan Finder incentives. However, the difference in cost sharing limits between a voluntary MOOP and mandatory MOOP plan may be reduced somewhat to balance concerns about potentially discriminatory benefit designs.

We received comments about increasing the limits for certain services (e.g., emergency care), decreasing limits for certain services (e.g., physical therapy and speech-language pathology services), and publishing limits for services that CMS communicated with organizations about potentially high cost sharing (e.g., cardiac and pulmonary rehabilitation services). We also received a comment expressing concern about having separate categories for mental health and non-mental health benefits in the plan benefit package (PBP) and separate service category cost sharing requirements.

MA 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 §422.100(j)). Although CMS has not established a specific service category cost sharing limit for all possible services in the Call Letter, MA plans may not pay less than 50% of the contracted (or Medicare allowable) rate and cost sharing for services cannot exceed 50% of the total MA plan financial liability for the benefit. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Original Medicare service category cannot exceed 50% of the average contracted rate of that service (Medicare Managed Care Manual, Chapter 4, Section 50.1). Organizations typically have much lower cost sharing for enrollees than this requirement due to effective managed care principles, effective negotiations between organizations and providers, and competition.

MAOs are not permitted to design "benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services" (42 CFR §422.100(f)(2)). CMS evaluates bid and marketplace data to identify areas of concern, conducts research, and may add service category cost sharing limits in the future based on these analyses. For example, cardiac and pulmonary rehabilitation services are areas of concern that we continue to monitor, and we will ask MA organizations to provide justification for cost sharing above the following amounts for CY 2017 benefit designs as part of bid review:

- Cardiac Rehabilitation Services: $50
- Intensive Cardiac Rehabilitation Services: $100

- Pulmonary Rehabilitation Services: $30

CMS recognizes that mental health services may have a different cost structure than non-mental health services which is reflected in the plan benefit package (PBP) by having different categories. PBP documentation defines the differences between these categories and organizations have the flexibility to use reasonable methods to distinguish between mental health and non-mental health services.

Part C Optional Supplemental Benefits

As part of our evaluation whether the bid and benefits are not discriminatory against enrollees with specific (or high cost) health needs, CMS will continue to review non-employer bid submissions to verify enrollees electing optional supplemental benefits are receiving reasonable value. As in CY 2016, CMS considers a plan to be not discriminatory when the total value of all optional supplemental benefits offered to non-employer plans under each contract meets the following thresholds: (a) the enrollment-weighted contract-level projected gain/loss margin, as measured by a percent of premium, is no greater than 15% and (b) the sum of the enrollment-weighted contract-level projected gain/loss margin and non-benefit expenses, as measured by a percent of premium, is no greater than 30%.

CMS understands 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.

Plan Benefit Package (PBP) Updates and Guidance

Projected Member Months

As indicated in the Rate Announcement, CMS has adopted the proposal to waive MA employer bidding requirements beginning in CY 2017. Employer plans will not be submitting a MA or Part D Bid Pricing Tool (BPT), but must complete and submit a Plan Benefit Package (PBP) in accordance with CMS requirements (consistent with past years). Organizations should make a good faith effort in projecting CY 2017 member months for each plan and place the amount in Section A-2 of the PBP. The following question must be completed for all MA and 1876 Cost Plan organizations that do not submit a Bid Pricing Tool (BPT): "Indicate CY 2017 total projected member months for this plan."

Medical Services Performed in Multiple Health Care Settings

In our continuing effort to avoid duplication of medical services entered in the PBP, CMS is offering additional guidance on how to place services that can be performed in different health care settings (e.g., physician office, outpatient hospital, and free standing facility) in the appropriate service category and correctly complete data entry within the PBP.

The outpatient hospital service category in the PBP has historically included a variety of services that may have their own dedicated PBP category. By including the same service in multiple locations throughout the PBP, we are concerned that marketing materials may be confusing and that CMS cost sharing requirements could be compromised. Based on the out-of-pocket cost (OOPC) model methodology, including services with zero cost sharing for the minimum amount in a multiple service category will reduce the estimated out-of-pocket costs used by beneficiaries in comparing plans on Medicare Plan Finder and adversely affect CMS bid review for meaningful difference and Total Beneficiary Cost (TBC).

Our goal is to ultimately have PBP service categories reflect cost sharing for services provided in different places of service. For example, Cardiac and Pulmonary Rehabilitation Services can be administered in a number of health care settings including outpatient hospitals, free- standing facilities, or a physician's office. Instead of having these services appear in multiple PBP service categories, we expect cost sharing for these services to appear only in PBP Service Category 3 (Cardiac and Pulmonary Rehabilitation Services). The minimum/maximum data fields allow plans to reflect the varying cost sharing associated with different places of service, when needed. The note for this service category will describe the cost sharing associated with the various places of service and must be consistent with the data entry. Cardiac and Pulmonary Rehabilitation Services in any other section of the PBP will not satisfy CMS requirements and the organization will be asked to correct its bid submission.

Another area of particular concern is Medicare-covered preventive services. All Medicare-covered zero dollar cost sharing preventive services must be included in PBP Service Category 14a and must not be included in any other service category (i.e., those benefits that are rated as A or B by the United States Preventive Services Task Force). For example, we do not expect to see a zero in the minimum data field in 9a (Outpatient hospital services) with a note that explains the zero dollar amount is for preventive services. All of the zero dollar Medicare-covered preventive services are to be placed in 14a only.

For CY 2016, plans were required to reflect cost sharing for the service categories listed in the table below appropriately within each designated service category:

PBP Sec. B	Service Category
3	Cardiac and Pulmonary Rehabilitation Services
7a	Primary Care Physician Services
7d	Physician Specialist Services excluding Psychiatric Services
7f	Podiatry Services
9d	Outpatient Blood Services
11b	Prosthetics/Medical Supplies
12	Dialysis Services
14a	Medicare-Covered Zero Cost-Sharing Preventive Services
15	Medicare Part B Rx Drugs and Home Infusion Drugs

In addition to the service categories listed above, plans must enter cost sharing for the service categories shown in the table below appropriately within each designated service category for CY 2017. These services should not be referenced in any other service category. We anticipate these changes will improve transparency and streamline the data entry so the cost sharing associated with those PBP service categories below reflects the services provided across a variety of healthcare settings.

PBP Sec. B	Service Category
7c	Occupational Therapy Services
7g	Other Health Care Professional Services
7i	Physical therapy and Speech Language Pathology Services
8a	Outpatient Diagnostic Procedures and Tests and Lab Services
8b	Outpatient Diagnostic and Therapeutic Radiological Services
9a	Outpatient Hospital Services
9b	Ambulatory Surgical Center Services (ASC)

CMS received several comments regarding PBP category B9a. One organization suggested this service category be eliminated, while another commenter requested examples of services that

may be included in this category. Examples of services we expect to be identified under B9a in the PBP include observation, outpatient palliative care, and outpatient surgical services (i.e., outpatient surgical services not provided in an Ambulatory Surgical Center as defined by Original Medicare). We will continue to evaluate opportunities to streamline data entry and avoid duplication in the PBP in the future.

We also received a comment requesting clarification on a service that may be related to more than one PBP category during the same patient encounter. We do not expect a service to take place in more than one service category during a patient encounter. For additional guidance related to professional and facility fees being charged by providers during a patient encounter, please refer to the section titled "Cost Sharing/Bundling and Facility."

Medicare-Covered Preventive Services

In previous years, MAOs were able to include non-zero dollar Medicare-covered preventive services in multiple service categories. CMS is modifying the PBP to rename B14a from "Medicare-covered Preventive Services" to "Medicare-covered Zero Dollar Preventive Services," and will create a new service category where all other Medicare-covered preventive services and any cost sharing (if applicable) can be identified clearly. This new services category will be B14e "Other Medicare-Covered Preventive Services," and will replace B14e "Diabetes Self-Management Training." PBP service category B14e "Other Medicare-Covered Preventive Services" will include cost sharing fields for the glaucoma screening benefit, diabetes self-management training, as well as up to five other optional Medicare-covered preventive services for which a copayment may be required that can be entered by the MAO.

CMS received comments requesting examples of preventive services that may be included in the B14a and B14e PBP service categories. Preventive services included in the B14a PBP service category, are subject to §422.100(k), which requires coverage of preventive services by MA plans without cost sharing, based on coverage under Original Medicare without cost sharing because of a grade A or B recommendation by the US Preventive Services Task Force (USPSTF) and are listed at §410.152(l). As noted in the 2011 final rule [76 FR 21475 (April 15, 2011)], §422.100(k) is designed to require zero cost-sharing for services within the scope of §1833(a)(1)(Y), which requires that the preventive service be graded A or B by USPSTF. Please note that services not graded A or B by USPSTF and/or not covered without cost sharing by Original Medicare are appropriate for the B14e service category.

We also received a comment recommending inclusion of information regarding Advance Care Planning coverage in the Call Letter. Advance Care Planning is a Medicare covered benefit, and as such, is required to be covered by MA plans.

Policy Updates

Tiered Cost Sharing of Medical Benefits

MAOs may choose to tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data. In addition to other standards for this plan design that are provided in the Medicare Managed Care Manual, Chapter 4, the tiered cost sharing must be applied so that all plan enrollees are charged the same cost sharing amount for any specific provider and all providers are available and accessible to all enrollees in the plan. CMS reminds organizations that they may not exclude any members from being eligible to access tiered providers.

We received comments expressing concern about the criteria the plans are using to select tiered providers, and about beneficiaries being challenged to navigate plans that tier medical benefits in order to have access to the most appropriate physicians and hospitals. Organizations are permitted to define their tiering approach based on their own efficiency and quality data. In addition, organizations are required to satisfy all MA provider contracting and benefit requirements, as well as communicate benefits in a clear and transparent manner through marketing materials.

CMS received comments requesting further clarification on tiering requirements and the tiering request submission process. For CY 2017, MAOs will be submitting tiering requests through an electronic mailbox. Organizations must submit the benefit design to CMS prior to bid submission to help make sure benefits are acceptable and communications are transparent for beneficiaries. Organizations also are permitted to modify proposed cost sharing amounts in their actual bid submission. Further details regarding the process will be provided in an HPMS memorandum in mid-April.

Cost Sharing /Bundling and Facility

As discussed in the draft Call Letter, CMS wants to make sure that cost sharing requirements are transparent to MA enrollees and Medicare beneficiaries who are considering enrolling in MA. We look to MA plans to present enrollee cost sharing so that it is simple and easy to understand.

Specifically, MA plans should not unbundle Medicare services and charge multiple cost sharing for services. For example, we are aware that in some cases an enrollee may receive a service in a facility setting that includes an additional facility fee that does not apply when the service is furnished in a physician's office. While MA plans may have higher copays based on place of service, the enrollee's entire cost sharing responsibility should be apparent and included in a single copayment or coinsurance. This approach makes it easier for enrollees to understand and anticipate the cost sharing they will incur prior to receiving services. Our policy to provide as much transparency as possible about MA benefits and enrollee cost sharing, is long-standing and is consistent with MA disclosure requirements at 42 CFR section 422.111(b)(2) which require

that MA plans clearly and accurately disclose benefits and cost sharing. Accordingly, in situations where there is a difference in cost sharing based on place of service, charges such as "facility fees," should be combined (bundled) into the cost sharing amount for that particular place of service and clearly reflected as a total copayment in appropriate materials distributed to beneficiaries. Our goal is not to prevent appropriate cost sharing, but to ensure that cost sharing is transparent.

We received several comments on this issue, a number of which were supportive and a few that asked for additional clarification and examples. Our expectation is that an MA enrollee will see the actual and complete cost sharing for a particular service fully and clearly disclosed in the members' Evidence of Coverage (EOC) document, in Medicare Plan Finder, and in plan materials. We have encountered instances where it was not readily apparent in plan disclosure documents that the member would be charged cost sharing for a particular service furnished in a specific place of service in addition to a separate facility fee. To avoid the enrollee confusion caused by charging multiple cost share amount for a single service we are clarifying that we expect MAOs to charge a single cost sharing amount to enrollees that combines all cost sharing associated with a particular service.

Interoperability-MA Plans and Contracted Providers

Background

Interoperability is the ability of systems to exchange and use electronic health information from other systems without special effort on the part of the user.[19] The health care industry is moving towards interoperability because it promotes more effective exchange of health information, seamless care transitions, improved care coordination and enrollee health outcomes and enables providers and communities to deliver smarter, safer and more efficient care.

We believe that commercial payers as well as the Medicaid program have taken steps to promote interoperability across provider settings, and align with Office of the National Coordinator for Health Information Technology (ONC) standards for meaningful use and certified electronic health records (EHRs). CMS issued a final rule on October 16, 2015 requiring eligible professionals to utilize certified technology to promote health information exchange as part of the Medicare and Medicaid EHR Incentive Program. This is a broader effort, however, to support delivery system reform and quality initiatives focused on patient outcomes.

In addition, §13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), requires that our contracts require MAOs to utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under §3004 of the Public Health Services Act, as amended by §13101 of the ARRA.

[19]Institute of Electrical and Electronic Engineers- http://www.ieee.org/200Bindex.html?WT.mc_id=mn_ieee.

In alignment with the referenced legislation and Medicaid, CMS is currently exploring how best to encourage the adoption of technology that supports interoperability between MAOs and their contracted providers, and the need for rulemaking to require such adoption. In the draft Call Letter, CMS sought comment from the industry regarding their experience with these activities, including barriers to successful adoption.

We received several comments regarding experience with the adoption of technology supporting interoperability between MAOs and contracted providers. Most of the comments received were supportive of interoperability and recognized the benefits of sharing information and having a more complete and informed view of enrollees. Commenters outlined the barriers to adopting the necessary technology and made recommendations. We appreciate the comments received on this topic and will take them into consideration as we consider future policy-making, especially with respect to providers participating in alternative payment models. In addition, CMS will continue to gain insight from the industry and other stakeholders, into the complexities of adopting technology that supports interoperability.

Alternative Payment Models (APMs)

Alternative Payment Models (APMs) are provider payment structures that incentivize health care quality, emphasize value over volume, and improve care coordination activities. To help promote the transformation of our health care delivery system away from rewarding volume over value, the Administration has set a goal to have 30 percent of Medicare fee-for-service payments made tied to APMs by the end of 2016 and 50 percent by the end of 2018. The Administration announced that an estimated 30 percent of Medicare payments are tied to alternative payment models as of January 2016.

In the Contract Year (CY) 2016 Call Letter, CMS indicated that we would reach out to MAOs to gain a better understanding of their use of provider incentives and value based contracting for physician services. Subsequently, CMS had conversations with a number of MAOs concerning their use of APMs. As a result of the high level of interest in the use of APMs and the long term Administration payment goals, CMS has added APM questions to the Part C reporting requirements. Specifically, CMS will ask MAOs to report on the proportion of payments made to providers based on the HHS developed four categories of value based payment: fee-for-service with no link to quality; fee-for-service with a link to quality; alternative payment models built on fee-for-service architecture; and population-based payment.

In order to maintain consistency with HHS goals of increasing the proportion of payment made based on quality and value, CMS will continue to support MAOs' efforts to improve cost efficiency, reduce costs, and improve health outcomes through the use of APMs. In order to better support the continued implementation, growth, and sustainability of these models in MA, in the draft Call Letter, CMS sought comments from the industry regarding challenges and concerns associated with the use of APMs in MA.

We received many comments from physician groups, beneficiary advocates, MAOs, and other stakeholders, expressing support for CMS's efforts in this area. Some MAOs asked that CMS further clarify and define the HHS categories of value based payment. For further information concerning these categories, we ask that plans refer to the LAN APM Definitional Framework White Paper at https://hcp-lan.org/workproducts/apm-whitepaper.pdf.

Connecting Beneficiaries to Care

As a reminder, MA beneficiaries are entitled to an introductory "Welcome to Medicare" preventive visit within their first twelve months in Medicare. Each year thereafter, MA beneficiaries are then entitled to an Annual Wellness Visit (AWV). CMS recognizes the importance of yearly preventive visits to drive quality improvement in the care beneficiaries receive and will continue to look at ways in which MAOs can further engage beneficiaries and connect them to preventive and needed care.

Counseling and Related Support Services

Recognizing that Alzheimer's disease and related dementias pose a serious and growing threat to Medicare beneficiaries and their families, CMS encourages MAOs to offer enrollees who are diagnosed with Alzheimer's or other related dementias innovative supplemental benefits that could enable their enrollees to remain in the community. Such benefits would provide a defined set of counseling and related supports to the enrollee or to the enrollee together with their informal (non-paid) caregivers. In designing their supplemental benefits, MAOs can take advantage of a variety of resources, including those provided by the Alzheimer's Association, and learning from models such as the New York University Caregiver Intervention (NYUCI) and the Department of Veterans' Affairs Resources for Enhancing Alzheimer's Caregivers Health (REACH) program.

Prohibition on Billing Medicare-Medicaid Enrollees for Medicare Cost-Sharing

We remind all Medicare Advantage (MA) plans of their obligation to protect dual eligible beneficiaries from incurring liability for Medicare cost-sharing. In July 2015, CMS released a study finding that confusion and inappropriate balance billing persist notwithstanding laws prohibiting Medicare cost-sharing charges for QMB beneficiaries, Access to Care Issues Among Qualified Medicare Beneficiaries (QMB) ("Access to Care") https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf. These findings underscore the need to re-educate providers, plans, and beneficiaries about proper billing practices for dual eligible enrollees.

Under 42 CFR §422.504(g)(1)(iii), all MAOs --without exception-- must educate providers about balance billing protections applicable to dual eligible enrollees. Federal law bars Medicare

providers from collecting Medicare Part A and Medicare Part B deductibles, coinsurance, or copayments from those enrolled in the Qualified Medicare Beneficiaries (QMB) program, a dual eligible program which exempts individuals from Medicare cost-sharing liability. (See Section 1902(n)(3)(B) of the Social Security Act, as modified by 4714 of the Balanced Budget Act of 1997). Balance billing prohibitions may likewise apply to other dual eligible beneficiaries in MA plans if the State Medicaid Program holds these individuals harmless for Part A and Part B cost sharing. See 42 CFR §422.504(g)(1)(iii). For more information about dual eligible categories and benefits, please visit: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/medicare_beneficiaries_dual_eligibles_at_a_glance.pdf.

In contracts with providers, MAOs must specify these balance billing prohibitions and instruct providers to either accept the MA payment as payment in full or bill the State for applicable Medicare cost-sharing for enrollees that are eligible for both Medicare and Medicaid. MA plans can find information about an enrollee's dual eligible status in the Monthly Membership Detail Data File. (See Appendix F.12, # 85 Dual Status Code in *the Plan Communications User Guide Appendices* at https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html).

In addition, CMS encourages MAOs to take affirmative steps to address common points of confusion among providers regarding balance billing. For example, we urge MAOs to explain that all MA providers-- not only those that accept Medicaid-- must abide by the balance billing prohibitions. Further, CMS suggests that plans clarify that balance billing restrictions apply regardless of whether the State Medicaid Agency is liable to pay the full Medicare cost sharing amounts. (Federal law allows State Medicaid Programs to reduce or negate Medicare cost-sharing reimbursements for QMBs in certain circumstances. See Section 1902(n)(3)(B) of the Social Security Act, as modified by 4714 of the Balanced Budget Act of 1997).

Finally, to monitor provider compliance with balance billing rules and target provider outreach, CMS encourages MAOs to identify problem areas from plan grievance and CMS Complaint Tracking Module data. These steps will complement continued MAO efforts to remediate individual violations and clarify appropriate billing procedures.

We received several supportive comments regarding the draft Call Letter's reminder to MA plans of their obligations to protect dual eligible beneficiaries from balance billing by educating providers about billing prohibitions. Numerous commenters concurred that confusion and inappropriate billing still exist, agreed that provider contracts must specify applicable rules, and supported our recommendations that plans address common points of confusion and use grievance and Complaint Tracking Module data to monitor plan compliance. We thank commenters for these comments and note that we are adopting the draft language in its entirety.

Additionally, we received a number of requests seeking further information for providers and additional CMS recommendations to improve compliance. In response to commenters' request for clarification, we note that our interpretation of the applicable anti-discrimination provisions is that MA providers are prohibited from discriminating against patients based on their QMB status. (See Managed Care Manual, Ch. 4, Section 10.2.5). We will consider adding a policy clarification to future guidance in this regard. We point out that CMS has stepped up efforts to educate providers and beneficiaries about balance billing rules and is considering administrative options to help providers better identify QMB patients. Finally, CMS continues to explore further measures to address and track billing problems and to promote adherence to billing rules.

Medicare Advantage Organization Responsibilities for Clinical Trials

We want to remind MAOs of their responsibilities regarding clinical trials. These responsibilities are also specified in section 10.7 of Chapter 4 of the Medicare Managed Care Manual. While Original Medicare is generally responsible for payment of costs for most clinical trials, under National Coverage Determination (NCD) 310.1, MAOs are responsible for payment in the following instances:

- Category A and B investigational device exemption trials

  MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B investigational device exemption (IDE) studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A IDE studies and for routine care items and services, as well as the Category B device under study in Category B IDE studies.

  The local MAC(s) with jurisdiction over the MA plan's service area determines coverage of IDE studies.

- NCDs for clinical trials with coverage with evidence development

  In separate NCDs requiring coverage with evidence development (CED), original Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines, for each NCD, that the significant cost threshold is exceeded for that item or service (see 42 CFR §422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html). Billing instructions are issued for each NCD.

In the case of clinical trials that are paid for by Original Medicare under NCD 310.1, we require MAOs, to provide coverage for: (1) services to diagnose conditions covered by clinical trial

services, (2) most services furnished as follow-up care to clinical trial services and (3) services already covered by the MAO. Should an MA plan beneficiary choose to participate in a clinical trial, he or she may remain in his or her MA plan while paying Original Medicare costs for a qualifying clinical trial.[20]

We received one comment on this section during the public comment period. The commenter disagreed with CMS's current policy of paying on a fee-for-service basis for qualified clinical trials items and services provided to MA beneficiaries that are covered under the relevant NCDs on clinical trials. CMS is not revising its current clinical trial policy.

Dual-Eligible Special Needs Plans

We received broad support from commenters, including D-SNP sponsors, states, and beneficiary advocates, to take administrative steps that enhance CMS-state cooperation in managing the D-SNP program and improving the experience for dually-eligible beneficiaries enrolled in these plans. We are grateful for this support. Commenters provided helpful recommendations on how we could best operationalize the steps proposed in the draft Call Letter and suggested other actions we could take in this area. We are taking all those comments into consideration as we move forward.

In addition to the comments on the specific areas below, we received comments regarding four additional areas in which CMS should use its administrative flexibility: (1) the use of integrated model marketing materials; (2) translation requirements; (3) joint CMS and State oversight of D-SNPs; and (4) use of Medicare-Medicaid Plan (MMP) network adequacy standards and processes. Several commenters recommended that CMS expand the use of modified MMP member materials to other D-SNPs beyond those participating in the Minnesota Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience. CMS has received positive feedback from states and plans, including those in Minnesota, regarding integrated model materials, such as a Summary of Benefits, Annual Notice of Change, Evidence of Coverage/Member Handbook, List of Covered Drugs (formulary), and Provider and Pharmacy Directory, developed for both the Financial Alignment Initiative demonstrations as well as the Minnesota demonstration. The materials integrate Part C, Part D, and Medicaid benefits information and have been consumer tested. CMS will continue to explore the feasibility of allowing integrated D-SNPs to use these model material templates in lieu of the Medicare Advantage and Part D models.

Several commenters requested that CMS expand its translation requirements to encompass more materials and more languages than are currently required under the MA and Part D regulations and the Medicare Marketing Guidance. While changing the translation standard for Medicare health plans would require a regulation change, we will continue to explore other options for

[20] Clinical trials are covered under the Clinical Trials National Coverage Determination (NCD) (NCD manual, Pub. 100-3, Part 4, Section 310).

addressing the concerns about receipt of the Multilanguage Insert, as well as translation of additional materials than those currently required in the Medicare Marketing Guidelines pursuant to 42 CFR§ 422.2264(e) and § 423.2264(e). We also note that states can impose additional requirements regarding translation of member materials via their MIPPA contracting with D-SNPs. In addition, as outlined in 42 CFR § 422.111(h)(1)(iii) and § 423.128(d)(1)(iii), MAOs/Part D sponsors must provide interpreter service to all non-English speaking and limited English proficient beneficiaries regardless of the percentage of non-English speaking beneficiaries in the service area.

We received several comments requesting the collaborative contract oversight process and the network standards used in the Minnesota demonstration be extended to other integrated D-SNPs. CMS intends to continue to test the network standards that target the dual eligible population in the Minnesota demonstration before making a determination on using the standards for other integrated D-SNPs.

CMS will continue to evaluate how best to provide effective oversight in other states with integrated D-SNPs. We note that CMS has already established joint monitoring calls in one other state.

D-SNP Non-Renewals

We received broad support to notify states of pending nonrenewals, service area reductions, and terminations of integrated D-SNPs that deliver Medicaid benefits prior to the public release of this information in the fall, when D-SNPs and other MA plans must send their nonrenewal notices. Commenters stated that early notification would allow states to make preparations to minimize any disruption in the delivery of Medicaid benefits provided by nonrenewing integrated D-SNPs and to work with their contracted D-SNPs to ensure D-SNP messaging, including the required nonrenewal notice, accurately conveys the impact nonrenewal will have on the delivery of Medicaid benefits and the options Medicare-Medicaid enrollees have for their Medicaid coverage. We will work with states and plan sponsors as we develop procedures, including appropriate assurances of confidentiality when notifying states of pending nonrenewals of their contracted D-SNPs. In addition, we will work with stakeholders to improve the model nonrenewal notice for integrated D-SNPs that we piloted last year in Arizona.

D-SNP Model of Care

Beneficiary advocates, states, and D-SNP sponsors were generally supportive of a process for interested states to add specificity to existing elements that describe state requirements related to the management of Medicaid Long-Term Services and Supports (LTSS) to the CMS review criteria for model of care (MOC) employed by D-SNPs that deliver Medicaid LTSS. Similarly, we received support for allowing states to review MOCs against their requirements concurrent with NCQA's review of MOCs in HPMS. Taken together, these proposals would help the MOC review ensure that the D-SNP MOCs fully address state goals for the delivery of LTSS by their

contracted D-SNPs. We intend to work with stakeholders to ensure that this process does not create a more burdensome MOC review process for D-SNP sponsors.

While we intend to create a process that would allow states to share the results of their review with CMS, we reiterate that the joint review process would not change the current CMS requirements for review and approval of D-SNP MOCs by NCQA. We also note that states have the ability now through their D-SNP MIPPA contracts to require that the MOC address delivery of Medicaid benefits, in particular LTSS, and to require their contracted D-SNPs to revise their MOCs to meet state requirements. This process does not alter that ability but integrates the state and CMS process for review of the MOC for integrated D-SNPs.

Finally, we recognize that the review of MOCs at the contract level may require some changes to the way in which the MOC describes different care processes for different populations under the contract, particular when some D-SNPs under the same contract may deliver Medicaid LTSS while other D-SNPs do not. We will work with D-SNP sponsors so that the contract-level MOC can reflect the differing care needs of different populations under the contract.

Section III – Part D

Formulary Submissions

CY 2017 Formulary Submission Window

The CY 2017 HPMS formulary submission window will open this year on May 16, 2016 and close at 11:59 pm PDT on June 6, 2016. CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 6, 2016 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid and therefore a failure to submit and link a formulary to each plan that uses a formulary by the June 6th deadline will result in denial of that bid submission.

CY 2017 Formulary Reference File

CMS released the first CY 2017 Formulary Reference File (FRF) in March 2016. The March FRF release will be used in the production of the Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2016, in order to assist plan sponsors in satisfying meaningful difference and MA 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.

In May 2016, CMS is planning to provide a subsequent release of the 2017 FRF prior to the June 6th formulary submission deadline. We will aim to make the May FRF available earlier this year, although it will be released in mid to late-May in order to allow for sufficient time to evaluate and add new Part D drugs that become available in our datasets. Since the OOPC

model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2010 and 2011, new Part D drugs cannot be included in the OOPC model since they would not have appeared in the survey. Further, given the limited timeframe between the May release of the 2017 FRF and the June 6th deadline, CMS is unable to accommodate an updated version of the 2017 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS cautions plan sponsors that any newly added drugs on the May release of the 2017 FRF will not be included in the 2017 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 to the May release of the 2017 FRF, since additional limitations will be imposed on the summer formulary update window. While moving the summer formulary update window later in the year would result in more up-to-date formulary information, this benefit must be weighed against Part D sponsors' ability to print marketing materials by necessary deadlines. We will, however, investigate whether an additional HPMS formulary enhancement-only window is possible for CY 2017.

Part D sponsors are reminded that they may enhance their formularies by adding Part D drugs (with or without utilization management restrictions), reducing beneficiary cost-sharing, or removing utilization management edits between the summer update window and the first HPMS submission of the upcoming plan year. Consistent with section 60.5 of the Medicare Marketing Guidelines, these enhancements must be included in the Part D sponsor's marketing materials and must be submitted during the next available HPMS formulary submission window. Sponsors are encouraged to notify beneficiaries of formulary additions in a timely manner since in some cases, such as new generics, an earlier conversion could lead to better value for the beneficiary and potentially reduce program costs.

In an effort to better align plan sponsors' submission of quantity limits (QLs) with CMS' review, a new column will be added to the HPMS-posted FRF that indicates the unit for which sponsors must submit their QLs. While the vast majority of submitted QLs, such as those for solid oral dosage forms are straightforward, this additional information will be useful for products such as kits that contain prefilled syringes. The HPMS formulary submission will not be validated against this field. Rather, it will serve as a point of reference for CMS and Part D sponsors during the review of submitted QLs. Finally, we are evaluating the feasibility of including an informational column on the FRF that would periodically track price changes for FRF drugs.

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

Consistent with 42 CFR §423.153(b), CMS reminded sponsors in the 2015 Call Letter that they must establish utilization management controls, such as prior authorization (PA), in order to reduce costs and to prevent inappropriate utilization of prescribed medications under Part D. Currently, we permit Part D sponsors to implement point of sale (POS) PA edits to determine whether a drug is: 1) covered under Medicare Parts A or B; 2) being used for a Part D medically-accepted indication (MAI) (as defined in section 1860D-2(e)(4) of the Social Security Act); or 3) a drug, drug class, or has a 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., when used for cosmetic purposes or hair growth). While CMS allows sponsors to implement these PAs during transition (either for new enrollees into a plan or for current enrollees affected by formulary changes) to prevent Part D coverage for excluded drugs or for non-medically-accepted indications of Part D drugs, sponsors continue to be confused about which POS PA edits are permitted during transition. Section 30.4.8 of Chapter 6 of the Prescription Drug Benefit Manual (available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf) discusses edits for transition fills. The requirements for Part D sponsors to limit coverage to Part D drugs and Part D medically-accepted indications, assist in preventing over-utilization and under-utilization of prescribed medications, and utilize 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, POS PA edits for such purposes are appropriate even during transition.

The 2015 Call Letter encouraged sponsors to utilize PA for drugs that have a high likelihood of use for a non-medically-accepted indication. Section 10.6 of Chapter 6 of the Prescription Drug Benefit Manual discusses medically-accepted indication (available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf)

The 2015 Call Letter specified Transmucosal Immediate Release Fentanyl (TIRF) products and Cialis as examples of drugs that have a high likelihood of use for non-medically-accepted indications. Our guidance is focused on those drugs that pose the greatest risk for non-medically accepted indications, and, therefore, CMS does not expect to see POS PA edits during transition to determine the indication on most Part D drugs.

Coverage duration is a required component of criteria that are submitted to CMS as part of the formulary review process for PA approval. Sponsors often approve criteria for the duration of the plan year or for one calendar year from the initial approval date. Once a PA is approved, sponsors are not prohibited from utilizing "grandfathering" policies that allow beneficiaries to receive a drug from year to year without a requirement to satisfy the PA criteria in the future. In

general, policies that facilitate appropriate access to medications for beneficiaries with chronic conditions are looked upon favorably by CMS. However, if such policies are implemented for products that have significant safety concerns and the high potential for non-MAI use (e.g., TIRF drugs), we expect sponsors to periodically confirm that beneficiaries continue to use these drugs for medically-accepted indications. This confirmation can be accomplished by establishing limits to the "grandfathering" processes for these drugs or through robust retrospective drug utilization review processes. This expectation would also apply to cases where members are moving across plans or when a new PBM is being utilized, for example.

Medication Therapy Management (MTM)

Annual MTM Eligibility Cost Threshold

Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold. Per §423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries is specified as costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in §423.104(d)(5)(iv). The 2016 MTM program annual cost threshold is $3,507. The 2017 MTM program annual cost threshold is updated for 2017 using the annual percentage increase of 11.75%, as specified in the Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Therefore, the 2017 MTM program annual cost threshold is $3,919.

Annual MTM Submission and Approval Process

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: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html. The guidance memo for CY 2017 will be released approximately one month before the 2017 MTM program submission deadline. The CY 2017 guidance memo will include the MTM program submission template. Questions regarding the MTM submission process or policy may be sent via email to partd_mtm@cms.hhs.gov.

Annually, Part D plan sponsors must submit an MTM program description to CMS through the Health Plan Management System (HPMS) for review and approval. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year.

Due to enhancements to the HPMS MTM submission module and expanded guidance and submission instructions over the years, MTM program submissions have increasingly high rates of initial approval. Beginning with the CY 2017 submissions, we will implement a modified

annual MTM program review process and add attestations to the HPMS submission module as described below.

- All Part D sponsors will continue to submit an MTM program description through HPMS each year. Sponsors will continue to submit change requests throughout the year.
- Attestations of the Part D sponsor's compliance with Part D MTM program requirements will be added to the MTM submission module in HPMS. The attestation will be included in the CY 2017 guidance memo.
- Sponsors must attest to meeting the MTM program requirements during the annual submission. Sponsors must re-attest when they submit change requests. The MTM Attestation must be completed via HPMS by the Chief Executive Officer (CEO), Chief Operating Officer (COO), or the Chief Financial Officer (CFO).
- A subset of MTM program submissions will be comprehensively reviewed including:
    - Any new contracts;
    - Any contracts whose MTM submission failed initial review the prior year;
    - Any contracts that failed reporting requirements data validation or audit for MTM (when implemented);
    - Any contracts that scored less than 3 stars on the MTM comprehensive medication review completion rate measure; and
    - Any contracts selected based on a random sample of other program submissions.

The Annual Calendar in this Call Letter highlights key dates for the submission of MTM programs and attestations, as applicable. Of note, the attestation deadline is two weeks after the deadline for submission of CY 2017 MTM programs in HPMS. We will continue to monitor beneficiary complaints, validation results of plan-reported MTM data, and CMS program audits of MTM programs.

Submission Requirements for Enhanced MTM Model Participants

The CMS Center for Medicare and Medicaid Innovation announced the Part D Enhanced MTM Model, an opportunity for stand-alone basic Prescription Drug Plans (PDPs) in selected regions to offer innovative MTM programs, aimed at improving the quality of care while also reducing costs. More information about the model test is available at https://innovation.cms.gov/initiatives/enhancedmtm/.

The Enhanced MTM Model test will begin January 1, 2017 with a five-year performance period. CMS will test the model in 5 Part D regions: Region 7 (Virginia), Region 11 (Florida),

Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona). Eligible defined standard, actuarially equivalent, or basic alternative stand-alone PDPs in these regions, upon approval from CMS, can vary the intensity and types of MTM items and services based on beneficiary risk level and seek out a range of strategies to individualize beneficiary and prescriber outreach and engagement.

The current MTM requirements are waived for the PBPs approved to participate in the Enhanced MTM Model and data on participating PBPs must not be reported per the Part D Reporting Requirements under the current MTM program. This MTM data will instead be reported in accordance with model terms and conditions.

Plan sponsors with contracts that include PBPs that are not eligible to participate in the model must ensure that those non-participating plans comply with all standard MTM program requirements, including the submission of MTM program details in HPMS. More information will be provided in the CY 2017 guidance memo.

Part D Reporting Requirements for MTM

For monitoring purposes, Part D sponsors are responsible for reporting several data elements to CMS related to their MTM program per the Part D Reporting Requirements. Element X, "Topics discussed with the beneficiary during the comprehensive medication review (CMR), including the medication or care issue to be resolved or behavior to be encouraged," is suspended for the 2016 Part D Reporting Requirements until a more standardized set of data can be collected.

The industry, including the Pharmacy Quality Alliance (PQA) and the Academy of Managed Care Pharmacy (AMCP), is working on a framework to define drug therapy problems (DTPs). Once finalized by industry, sponsors should begin to develop the capacity to collect and report drug therapy problems using a standard framework and common terminology. Also, after industry development, we will consider proposing new MTM data elements for the Part D Reporting Requirements through the Paperwork Reduction Act (PRA) process as early as the 2018 Part D Reporting Requirements to capture drug therapy problems at the beneficiary-level using standard categories and definitions. This process allows for public comment.

Improving Clinical Decision-Making for Certain Part D Coverage Determinations

In the draft Call Letter, CMS solicited stakeholder feedback on potentially proposing regulatory changes that would permit Part D plans to extend the adjudication timeframe for certain coverage determination requests for drugs subject to prior authorization (PA) or step therapy (ST) where the plan has been unable to obtain needed clinical information from the prescriber and the adjudication timeframe has been impacted by a weekend or holiday. We received numerous comments from a range of stakeholders in response to our request, and thank all commenters for their helpful feedback. Almost all commenters were strongly supportive of our goal to ensure

that coverage determinations are made with the benefit of all information and clinical documentation necessary for making a correct and clinically sound decision as quickly as possible and, whenever possible, at the initial coverage determination level.

About half the comments we received were from Part D plan sponsors and PBMs. Most were in favor of longer timeframes, but many expressed concerns that the limitations we suggested would be confusing, as well as costly and difficult for plans to implement. Several plans and PBMs noted that the problem of prescribers not responding to requests for additional information is not limited to weekends and holidays, and a few stated that providing a short extension will not likely resolve the problem of non-responsive prescribers. Some commenters expressed concern that the Part D adjudication timeframes, even with a limited extension, would be too short to allow for written notice of the extension without causing significant confusion, since the written notice would be likely to arrive in the mail after the plan has rendered a decision and provided verbal notification to the enrollee. Commenters also noted that implementation of an extension for some types of coverage determinations, along with tolling of exception requests for prescriber supporting statements, would create additional implementation difficulties.

For the reasons described above, most plans and PBMs that supported implementation of extensions in Part D sought more expansive opportunities to extend the timeframes, including allowing both tolling and extensions, allowing extensions for all coverage determinations, eliminating the written notice requirement to the beneficiary, extending the adjudication timeframes for standard and/or expedited cases by adding 24 or 48 hours, or advocated changes that would allow tolling for all coverage determinations where the timeframe does not begin until all information is received. A few plans urged CMS to immediately proceed with proposed rulemaking that would provide longer timeframes.

Some plans and PBMs expressed concerns that CMS must ensure the use of extensions does not adversely affect beneficiary access, and a few recommended that extensions not be allowed for expedited requests. A few commenters believed that prescribers are more likely to respond to a denial notice than a request for information, suggesting that issuing the denial rather than delaying the decision may actually reduce any delay in accessing needed medications. One PBM recommended that CMS approach this issue by urging network MA-PD and Medicare-enrolled prescribers to be more accountable to beneficiaries when seeking coverage of a needed drug.

We received several comments from beneficiary and patient advocacy organizations, which were also in favor of informed decision-making, but expressed significant concerns about potential overuse of extensions and adverse impact on beneficiary health. These commenters agreed with CMS statements in the draft Call Letter that any extensions would have to be carefully limited to protect beneficiary access to drugs. Some commenters did not support extensions for expedited requests. Beneficiary advocates strongly supported testing a potential policy change through a pilot or demonstration that is open to stakeholder feedback in its design and includes benchmark testing.

Comments received from pharmacies and manufacturers were mixed, with some support for allowing sufficient time to obtain missing information and reduce rejected claim and appeals volumes, but they also urged CMS to establish clear rules and safeguards to avoid unnecessary delays and adverse impact on beneficiary health status. LTC pharmacies opposed extensions, noting existing payment issues due to their requirement to dispense; further delays would cause additional payment issues. Pharmaceutical manufacturers opposed extensions for expedited requests because of the risk of beneficiary harm.

We received comments from a few prescriber organizations. Prescribers are opposed to utilization management generally because they believe it does not improve quality of care and requires too much time and paperwork. Commenters expressed concern that delays in approval can delay or interrupt treatment and result in beneficiary harm. One commenter argued that plans would use extensions when they failed to conduct appropriate outreach to the prescriber.

After review of all comments submitted, CMS does not intend to move forward with any proposed regulatory changes for extensions in Part D at this time. As we stated in the draft Call Letter, we recognize the challenge posed by the short adjudication timeframes for plans to successfully obtain needed information from prescribers and provide a fully informed decision within the timeframe. However, we agree with the commenters who noted that written notice of the extension—an important beneficiary protection—would not be feasible, and that the limitations we suggested could be confusing for plans, beneficiaries and prescribers, and difficult for plans to implement and oversee effectively. We also agree with the numerous commenters who expressed concerns about making broader changes to adjudication timeframes, including a more expansive extension opportunity, given the more immediate need for access to drug therapy and that fact that coverage must be approved before the enrollee can access the drug.

Acknowledging the challenges inherent in existing timeframes, we also recognize the limitations we have in extending those timeframes while still complying with the statutory requirement for timely determinations that emphasize the health needs of the beneficiary. This is particularly true for expedited requests, where the prescriber or the plan has determined that taking additional time to render a decision could seriously jeopardize the life or health of the beneficiary. While retaining existing requirements, which do not allow extensions, may increase the likelihood that plans will have to deny requests to meet the timeframes, we believe that there is great value in the enrollee receiving the standardized denial notice that includes a written denial rationale and an explanation of the appeals process.

While we do not intend to move forward with any rulemaking to allow extensions in Part D, CMS will continue to explore how we might assist plans and PBMs in providing fully informed coverage determinations, limiting unnecessary denials, and avoiding delays that could potentially cause beneficiary harm. After consideration of the comments received on the draft Call Letter, we intend to direct our efforts on reducing the volume of coverage determination requests that are initially incomplete, including exploring how increased use of electronic health records and

other technology could make the information needed from prescribers more accessible outside of business hours; encouraging the increased use of e-prescribing and e-prior authorization to increase dissemination of plan formularies to prescribers at the point of care; and leveraging MA-PD plan contracting arrangements with network providers who are prescribing Part D drugs. CMS is currently developing additional subregulatory guidance to help ensure that Part D plan sponsors are consistently conducting appropriate outreach to prescribers to obtain missing information and make informed decisions within the existing Part D timeframes.

Some plans and PBMs who commented on this proposal included related plan data, e.g., rates of adverse coverage determinations based on missing information and rates of appeals of those denials. We want to particularly thank those commenters for providing this information as we continue to contemplate how we might improve clinical decision-making as early as possible in the coverage and appeals process.

Access to Preferred Cost-Sharing Pharmacies

In the CY 2016 Call Letter, CMS announced several steps we would take to address low access to preferred cost-sharing pharmacies (PCSPs). First, we announced that we would post information about 2016 PCSP access levels on the CMS website. Second, we announced that we would require plans who were outliers with respect to access to PCSPs to disclose that their plan's PCSP network offered lower access than other plans. Outliers were set at the bottom 10th percentile compared to all Part D plans in a given geographic type, using 2014 data. CMS required marketing materials to include specific disclaimer language for plans offering access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas. Finally, we announced that we would work with plans that were extreme outliers to address concerns about beneficiary access and marketing representations relating to preferred cost-sharing. We worked with several such plans to either improve access or develop targeted marketing strategies to ensure that beneficiaries selecting these plans were aware of their status as extreme outliers.

CMS is pleased to note that plans increased PCSP access dramatically for 2016. As shown in the table below, the bottom 10th percentile of plans in 2016 offer access within two miles to 71% of urban beneficiaries, compared to 40% in 2014.

Table 17. PCSP Access Rates for the Bottom 10th Percentile of Plans, 2014 through 2016

	2014	2015	2016	Convenient Access Standard for All Retail Pharmacies
Urban Access Rate	40%	62%	71%	90%
Suburban Access Rate	87%	92%	95%	90%
Rural Access Rate	77%	77%	82%	70%

Because we believe the current policy is increasing access to PCSPs, we do not plan to make significant changes for 2017. Specifically, we will not change the outlier thresholds for 2017 to reflect the higher access levels achieved for 2016.

Therefore, CMS will continue its PCSP policy as announced in the 2016 Call Letter and implemented for the 2016 plan year. Plans that provide PCSP pharmacy access within 2 miles of less than 40% of beneficiaries' residences in urban areas, within 5 miles of less than 87% of beneficiaries' residences in suburban areas, and within 15 miles of less than 70% of beneficiaries' residences in rural areas will be identified as outliers in 2017. Outlier plans will be required to disclose in marketing materials, including websites, that their plans' PCSP networks offer lower access. Contract Year 2016 disclaimer language was announced in the June 24, 2015 HPMS memo "Marketing Disclaimer Language for Plans with Limited Access to Preferred Cost-Sharing Pharmacies," and in the final "Medicare Marketing Guidelines" released on July 2, 2015. CMS continues to expect that plans will analyze their own 2016 and 2017 networks to determine whether they are below outlier thresholds. CMS will analyze preferred cost-sharing pharmacy access on a quarterly basis and will remind plans of their outlier status periodically.

CMS will also continue to work with extreme outliers to address concerns about beneficiary access and marketing representations related to preferred cost-sharing. CMS will notify these plans in or around April 2016 that we plan to address 2017 PCSP access issues with them during bid negotiations. In 2016, most plans identified as extreme outliers opted to improve access rather than develop marketing plans to better inform beneficiaries of low PCSP access. We anticipate plans will take similar steps during 2017 negotiations.

We will continue to publish information about PCSP access levels annually on the CMS website at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html. We will also explore the feasibility of incorporating this information into the Medicare Plan Finder in the future.
Sponsors that fail to include required marketing disclosure language and/or do not meet the terms of bid negotiation agreements will be subject to compliance and/or enforcement actions.

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. The benefit parameters for CY 2017 are set forth in Table 19 below.

Adjustments to the Minimum Meaningful Difference and specialty tier thresholds are described below. The other cost-sharing thresholds are established consistent with previous years methodology based on the 95th percentile of the CY 2016 Bid Data. For CY 2017, we will be maintaining the copayment cost-sharing thresholds without the inflation adjustment.

Tier Labeling and Composition

We again remind sponsors that we expect Drug Tier Labels to be representative of the drugs that make up that tier. However, we have received a number of plan sponsors' comments via the 2016 Call Letter and in response to the Request for Comments on Non-Defined Standard Plan Tier Models for CY 2017, solicited through a HPMS memo in June 2015, recommending that CMS provide a non-preferred drug tier option that will allow for a drug mix regardless of generic/brand status. Based on the comments received and as part of our continued efforts to provide tier label options that provide flexibility and transparency in benefit design, CMS included additional tier models for CY 2017 with a non-preferred drug tier option. The details of CY 2017 tier model options are included in the CY 2017 Plan Benefit Package Software and Formulary Submission PRA information collection request, now pending approval at the Office of Management and Budget, Office of Information and Regulatory Affairs. This information collection request is available on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html?DLPage=4&DLEntries=10&DLSort=1&DLSortDir=descending.

With the addition of a non-preferred drug tier, sponsors will have the option of selecting a non-preferred drug tier or non-preferred brand tier but not both. If sponsors continue to use a non-preferred brand tier, CMS will evaluate the brand/generic composition of that tier as part of the bid review process. Non-preferred brand tier outliers will be communicated for any plans that do not have a majority of brand drug products in that tier.

Table 18. 2015 Prescription Drug Event Data

2015 PDE Data	**Average of % Beneficiary Cost-Share**		
	Generic Drugs	**Brand Drugs**	**All Drugs**
Non-Preferred Brand Total	32.56%	20.77%	22.81%
Plan w/ Copay	**35.75%**	**19.90%**	**22.48%**
Plan w/ Coinsurance	**26.02%**	**22.72%**	**23.54%**

CMS review of preliminary 2015 prescription drug event data (PDE) (Table 18.) showed that beneficiaries pay a lower cost-share for generics in plans that have a coinsurance cost-sharing structure (26.02%) for their non-preferred brand tier than in plans that use a copay cost-sharing structure (35.75%). Overall, on average for all drugs on the non-preferred brand tier, there was no substantial difference in beneficiary cost-sharing between plans that use a copay cost-sharing structure and those that use coinsurance. However, based on industry comments received, it is our understanding that the new non-preferred drug tier likely will contain a greater proportion of generic drug products than the current non-preferred brand tier composition. While we appreciate that generic drug price increases are changing the paradigm, we also acknowledge that sponsors may include lower cost generics on the non-preferred drug tier in an effort to balance the brand/generic drug composition of the tier and maintain actuarial equivalence. As cost trends in the Part D program are increasingly driven by high cost drugs it is important that we consider policy impacts on beneficiaries with lower overall drug costs. In the draft Call Letter, we proposed that Part D sponsors consider the use of a coinsurance structure for the non-preferred drug tier instead of a copay. While the analysis outlined above in Table 18 demonstrated reduced cost-sharing for generics on non-preferred brand tiers with coinsurance cost structures, we did receive comments that suggest beneficiaries tend to prefer copay structures and that Part D sponsors would like to continue to have options in their benefit design. We recognize that there are advantages and disadvantages of copay/coinsurance cost-sharing structures, including the consistency that a copay structure offers to beneficiaries. As such, CMS will allow Part D sponsors the flexibility to determine what cost-sharing structure is most appropriate for their benefit design. We will expect, however, that sponsors evaluate, and be prepared to demonstrate if necessary, that the cost-sharing structure chosen provides a value for beneficiaries. During the first year of implementation and until further notice, CMS will conduct an outlier test for those Part D sponsors who choose a copay for the non-preferred drug tier, to determine if beneficiaries will receive a benefit for drugs on this tier at the proposed copay. Moving forward, we will continue to evaluate the type and level of cost-sharing that is most appropriate for this tier and that balances the Part D sponsor's ability to mix brand and generic drugs within a tier while maintaining transparency and a meaningful benefit offering for the beneficiaries who enroll in plans with non-preferred drug tiers.

A few commenters requested guidance on how to handle tiering exceptions for the non-preferred drug tier option. Sponsors should refer to existing tiering exception guidance, which can be found at 42 CFR §423.578(a) and in Chapter 18, section 30.2.1 of the Prescription Drug Benefit Manual. This guidance is applicable to this new tiering option. Tiering exceptions allow an enrollee to request coverage of a drug in a higher cost-sharing tier at the more favorable terms applicable to drugs in a lower cost-sharing tier provided certain conditions are met. The applicability of a tiering exception is generally not determined by the name of the tier (e.g., Preferred Generic, Non-Preferred Brand), but rather by the drugs included on that tier, the availability of therapeutically equivalent drugs on the plan sponsor's formulary, and a determination by the plan, based on the prescriber's supporting statement, that the drug in the

lower cost-sharing tier for the treatment of the enrollee's condition 1) would not be as effective as the requested drug in the higher cost-sharing tier and/or 2) would have adverse effects.

For purposes of determining whether coverage gap cost-sharing thresholds specified in Table 19 have been met, we will continue to rely on the FDA marketing status to identify formulary drugs as applicable or non-applicable. The maximum coinsurance of 60% applies to tiers that contain only applicable drugs. If non-applicable (i.e., generic) drugs or a combination of both generic and applicable drugs are on a tier, then the maximum coinsurance of 31% applies. 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.

Benefit Review

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 we will conduct the same cost-sharing analysis for the Select Care/Diabetic Drug Tiers, even though the maximum allowable coinsurance value is less than 25%. 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 the retail network.

Despite ACIP recommendations and Healthy People 2020 targets, adult immunization rates still remain low. We encourage Part D sponsors to consider offering $0 or low cost-sharing for vaccines to promote this important benefit. While the inclusion of a dedicated vaccine tier or a Select Care/Select Diabetes tier that contains vaccine products as part of a 5 or 6 tier formulary structure is not a requirement, sponsors who choose to offer one of these formulary tiers must set the cost-sharing at $0 for that tier. This policy is unchanged from CY 2016.

Over the last three years, we have seen a continuing decrease in the 95th percentile meaningful difference between basic and enhanced alternative (EA) plans which indicates there is a decreasing differential between basic and EA plan drug benefits. In order to continue to drive the participation of plans that provide distinct product offerings, CMS will use a meaningful difference threshold based on the 50th percentile for CY 2017 instead of the 95th percentile. As a result of the closing of the coverage gap, the change for CY 2017 to the 50th percentile is necessary to maintain an OOPC differential within the range of the original meaningful difference threshold. Specifically, the meaningful difference threshold will be based on the 50th percentile of the October CY 2016 Bid Data run through the CY 2016 OOPC MPF model which incorporates CY 2016 Formulary Data, 2010/11 MCBS Data, and FDA data for brand/generic

determinations related to coverage gap cost-sharing estimates. In contrast to the continuing decrease in the 95th percentile meaningful difference between basic and EA plans, we have seen a continuing increase in year over year meaningful difference between EA to EA plans. The increase in meaningful difference between EA to EA plans makes it more challenging for plan sponsors to offer second EA plans. For CY 2017, we will also use the 50th percentile, instead of the 95th percentile, to establish the meaningful difference threshold between EA to EA plans to lessen the impact of EA to EA differences year over year and help maintain stability in the program.

Therefore, in 2017 the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings will be $23 and the minimum monthly cost-sharing OOPC difference between enhanced PDP offerings will be $34. These values remain in close range of those established originally for this policy in 2012.As in the past, these meaningful difference requirements apply to all stand-alone PDPs, including those belonging to sponsors under a consolidation plan. We also 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**.**

In the CY 2012 Call Letter CMS explained that it does not believe that sponsors can demonstrate meaningful differences based on expected OOPCs between two stand-alone basic Part D benefit designs while maintaining both the statutory actuarial equivalence requirements and fulfilling the requirement to maintain cost effective drug utilization review programs. As we approach CY 2020 and the coverage gap closes, CMS believes that Part D sponsors will find it difficult to maintain three plans (a basic and at most two EA plans) that will meet the meaningful difference test between all plans when the coverage gap is closed. Therefore, CMS encourages plan sponsors to consider the impact of the coverage gap closing on their current and future plan offerings to minimize future beneficiary disruption. We expect that for CY 2017 our application of the meaningful difference standard will still allow us to approve up to 3 plan benefit packages (1 basic and at most, two enhanced plans).

The methodology for developing the CY 2017 out-of-pocket costs (OOPC) model is consistent with last year's methodology. For more information, please reference the HPMS memorandum dated December 18, 2015 titled "Medicare Plan Finder (MPF) Plan Version (V1) of Out-of-Pocket Cost (OOPC) Model for CY 2016 and Updated Total Beneficiary Costs (TBC) Data Released on HPMS." Customary updates for utilization data, as well as PBP and formulary data used for CY 2017 bid submissions, are also included in the 2017 model.

In the 2016 Call Letter, we proposed instituting a Total Beneficiary Cost (TBC) measure for PDPs, similar to what has been in place for MAOs. The proposed change was intended to meet CMS's goals of establishing a more transparent and predictable process that beneficiaries can use to select plans that meet their health care needs, while also being protected from high or unexpected cost-sharing. After completing analysis and engaging in discussions with

stakeholders, CMS will not implement for CY 2017 an out-of-pocket cost (OOPC) or market basket approach to set thresholds for increases in cost-sharing and premiums whereby we would deny Part D plan bids with significant increases, pursuant to our authority in Section 3209 of the Affordable Care Act. Instead CMS will calculate and publish the Part D TBC to support transparency related to the out-of-pocket beneficiary costs year over year.

Table 19. Benefit Parameters

	CY 2017 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$23
Enhanced Alternative Plan vs. Enhanced Alternative Plan	$34
Maximum Copay: Pre-ICL and Additional Cost- Sharing Reductions in the Gap (3 or more tiers)	S[2,3]
Preferred Generic Tier	<$20[4]
Generic Tier	$20
Preferred Brand/Brand Tier	$47
Non-Preferred Drug Tier	$100
Non-Preferred Brand Tier	$100
Injectable Tier	$100
Select Care/Diabetic Tiers[5]	$11
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S[2,3]
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable tier	33%
Select Care/Diabetic Tiers[5]	15%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs) [6]	S[3]
Preferred Generic Tier	31%
Generic Tier	31%
Preferred Brand/Brand Tier	60%
Non-Preferred Drug Tier	60%
Non-Preferred Brand Tier	60%
Injectable Tier	60%
Select Care/Diabetic Tiers[5]	60%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$670

[1]The Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold is based on the 50th percentile of the October CY 2016 Bid Data run through the CY 2016 OOPC MPF model which incorporates CY 2016 Formulary Data, 2010/11 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 threshold established annually by CMS.

[2] These thresholds are based on the 95th percentile of the CY 2016 Bid Data. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary.

[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] Cost-sharing for the Preferred Generic Tier need only be lower than that for the cost-sharing of the Generic Tier. There is not a separate maximum cost-share threshold for the Preferred Generic Tier.

[5] The Select Care Drug and Select Diabetic Drug Tiers must provide a meaningful benefit offering with low or $0 beneficiary cost-sharing for drugs targeting specific conditions (e.g., $0 tier for drugs related to diabetes and/or smoking cessation). The coinsurance threshold for these tiers is derived from an average expected copayment amount using PDE data for drugs submitted on preferred cost-sharing tiers. As noted earlier in this section, we continue to expect cost-sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be $0.

[6] 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 31% 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.

Specialty Tiers

Per 42 CFR 423.578 (a)(7), if a Part D plan sponsor maintains a formulary tier (the specialty tier) in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception. Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement. The current cost threshold of $600 was established in CY 2008.

In order to make sure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that meet the standards set forth in Section 30.2.4 of Chapter 6 of the Prescription Drug Benefit Manual. Part D sponsors offering prescription drug benefit plans with a specialty tier are limited to the defined standard cost-sharing of 25%, if the plan requires the standard deductible, and up to 33% cost-sharing if no deductible is required, or some percentage in-between dependent on a decreased deductible. In return Part D sponsors are shielded from tier exceptions for the most expensive drugs, and as a result would not need to increase their bids or their Part D premiums to maintain actuarial equivalence.

As noted in the CY 2016 Call Letter, we continue to evaluate the specialty tier eligibility cost threshold. The current $600 threshold repeatedly identified outlier prescription drug event (PDE) data – less than one percent of 30 day equivalent fills exceeded $600. However, initial analyses of 2015 PDE indicate that this percentage now slightly exceeds one percent. This, coupled with the significant increase in the cost of Part D drugs since the last adjustment to the specialty tier threshold, supports an increase in the specialty tier threshold for CY 2017. To

adjust the threshold, we propose applying the annual percentage increase used in the Part D benefit parameter updates to the existing threshold. Thus, for CY 2017, the specialty tier cost threshold will be $670. We may or may not increase the threshold on an annual basis moving forward. Annually, we will test the proposed increased threshold and continue to perform other analyses to assess whether threshold adjustments are necessary. To assist in future policy decisions, we will also conduct a series of analyses to investigate 1) whether the inclusion of Part D drugs on a specialty tier adversely affects drug utilization or enrollment decisions by certain types of beneficiaries, and 2) the impact of tiering exceptions for specialty tier drugs.

To support CMS's transparency initiatives, raise awareness, and educate beneficiaries on the cost of prescription drugs and their impact on the Part D program, CMS intends to add a hyperlink on the Medicare Plan Finder on Medicare.gov to the Medicare Drug Spending Dashboard, which is published on CMS.gov, and estimates implementation for 2017 Open Enrollment in fall 2016.

Generic Tier $0 Copay Plans

Since the program began in 2006, use of lower cost generic alternatives by Medicare Part D enrollees has been high and steadily increasing as single source drugs lose patent exclusivity. However, low-income subsidy (LIS) enrollees continue to have lower use of generics compared to enrollees without income subsidies. Lower generic use is often attributed to the small differential between generic and brand drug copays legislatively mandated for LIS enrollees. Changes in copay to increase cost differential between brand and generic drugs for LIS beneficiaries requires Congressional authority; however, lowering the generic copay does not and in 2012, 685 or 21.1% of plans offered generic-tier $0-copay plans. Of those 685 plans, 265 were PDP plans and 420 were MA-PD plans. We, therefore, explored the impact of enrollment in generic-tier $0 copay plans on generic substitution rates between both LIS and Non-LIS enrollees compared to enrollment in generic-tier non-$0 copay plans.

Using 2012 prescription drug event data, our analysis found that generic substitution rates (GSR) for generic-tier $0 copay plans were 1.2 to 3.0 percentage points higher than in non-$0 copay plans. This finding held true for both Enhanced PDP and MA-PD plans, and PDP Basic plans for both LIS and non-LIS Part D populations. Within MA-PD Basic plans, GSR was not statistically different for LIS or non-LIS populations, but there were very few MA-PD generic-tier $0 copay basic plans. The lack of basic MA-PD plans is attributed to policy that does not require MA plans to offer a basic plan if they offer an EA plan without a monthly supplemental Part D premium in the same service area. Overall, if Part D enrollment were shifted from generic-tier non-$0 into $0 copay plans, generic use could potentially increase. Even small increases in generic use could mean significant savings to beneficiaries and to the Medicare Part D program. However, our analysis is not without limitations. A complete description of the study is found here: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html. At this time, CMS is providing these results

as informational only and as an opportunity for further discussion on ways to increase generic use in Part D and in particular, the LIS population.

CMS has seen an increase in the number of plans with deductibles in 2016 compared to 2015. Some of these plans have a $0 cost-share for generic drugs but require the beneficiary to meet a deductible prior to receiving generic medications for free. One option available to Part D sponsors is to provide first dollar generic coverage for medications on the $0 generic copay tier by exempting the $0 cost-sharing tier from the deductible. CMS encourages plan sponsors to consider first dollar coverage for generic medications and other ways to increase generic use in the Part D program.

Part D Employer Group Waiver Plans (EGWPs)

Since January 1, 2014, supplemental benefits provided by employer group waiver plans (EGWPs) beyond the parameters of the defined standard benefit are always considered non-Medicare other health insurance (OHI). (See 77 Federal Register 22072 (April 12, 2012); and 80 Federal Register 7912 (February 12, 2015).) As a result of this change, we have continued to receive industry questions regarding the effect, if any, it had on other EGWP and Part D rules. The purpose of this guidance is to clarify CMS requirements for EGWPs with respect to some Part D rules involving plan design and formularies that consistently have been the focus of these and other inquiries.

Section 1860D-22(b) of the Social Security Act gives CMS the authority to waive or modify Part D requirements that hinder the design of, offering of, or enrollment in EGWPs. All Medicare Part D requirements apply unless explicitly waived or modified by CMS, and the waivers are only available to those EGWPs that meet the circumstances and conditions imposed as part of those waivers. See 42 CFR §423.458(c)(3) and (4). In general, Part D sponsors cannot offer EGWPs with combined benefits (i.e., Part D plus employer OHI) with lesser value than the basic Part D benefit nor establish benefit designs that substantially discourage enrollment by certain Part D eligible beneficiaries. EGWPs must follow Part D rules in cases in which the provision of employer OHI is inextricably intertwined with drugs offered under the Part D benefit such that the two cannot be separated as a practical matter. (See also January 25, 2013 HPMS memo including Insurance Standards Bulletin Series guidance: "Because the Affordable Care Act has increased basic Part D benefits in the coverage gap, as of 2013 there will be very few claims that do not contain some basic Part D benefits and would not ultimately be governed (as a practical matter) by the Part D regulations.")

As conditions of the waivers identified below, we remind Part D sponsors of EGWPs of the following: (Please note that other conditions may attach to these waivers.)

Waiver: Part D sponsors offering EGWPs are not required to submit the same bid packages in their entirety as are Part D sponsors of individual plans. Prescription Drug Benefit Manual (PDBM), Ch. 12, EGWPs, §20.9. (For details, see 2016 HPMS Memo entitled "Release of the

2016 Plan Benefit Package and Bid Pricing Tool Software and Related Technical Bidding Guidance for Part D Employer/Union-Only Group Waiver Plans" (April 10, 2015).

- EGWP benefits (meaning, the Part D benefits, taking into consideration employer OHI) must continue to meet the following applicable actuarial standards in 42 CFR §423.104(e):
    - Deductible is limited to no greater than defined standard deductible;
    - Total Benefit is at least actuarially equivalent to the basic Part D benefit; and
    - Catastrophic Benefit is at least actuarially equivalent to the basic Part D catastrophic benefit.

      See also PDBM, Ch. 12, EGWPs, §20.9.
- Part D sponsors of EGWPs should take into consideration the annual established copay and coinsurance tier maximum thresholds for Part D plans when designing their tiered benefits to ensure they are not discriminating and discouraging certain beneficiaries from enrolling in the EGWP. *See* 2012 final Call Letter, page 146 (April 4, 2011).

Waiver: EGWPs do not need to submit a unique formulary variation for each individual employer/union sponsored group health plan. PDBM, Ch. 12, EGWPs, §20.14.

- EGWPs that provide benefits with formularies will continue to:
    - Submit for CMS approval through the HPMS formulary module a base formulary, utilization management criteria, and transition policy that represent the minimum drug benefit upon which all other formulary variations in the same plan must be built. *See* 2015 final Call Letter, page 127 (April 7, 2014). In other words, EGWPs cannot provide a formulary benefit that is less than what is included in the base formulary.
        - Submit a base formulary which has the fewest drugs and the most restrictive UM that any EGWP formulary variation will offer. For EGWPs with multi-tiered formularies, submit the maximum number of tiers that will be offered by any EGWP formulary variation in that same 800 series plan and ensure each drug is placed on the tier where it has the highest possible cost-sharing of any formulary variation. *See* 2015 final Call Letter, page 127 (April 7, 2014).
        - Assign all EGWP 800 series Part D plans to a formulary through the formulary crosswalk process. *See* Release of the Contract Year (CY) 2016 Bid Upload Functionality in HPMS (May 8, 2015 HPMS memo).

- Only make enhancements to approved formularies (i.e., enrich formularies) that increase the value for any beneficiary who uses the drug(s). *See* 2015 final Call Letter, page 127 (April 7, 2014).

- Follow all applicable (that is, non-waived) CMS rules, including those found in PDBM, Chapter 6, Part D Drugs and Formulary Requirements, when restricting access (often referred to as making negative maintenance and non-maintenance changes) to drugs covered under the Part D benefit that appear in any EGWP formulary (whether base or enriched). EGWPs restrict access when they, for instance, remove drugs; increase cost-sharing; and impose or make more restrictive existing prior authorization or step therapy requirements or quantity limits. *See* PDBM, Ch. 12, EGWPs, §§10.1, 20.14. To provide further clarification, please note:

    - When required by the circumstances of the negative change, we would require EGWPs to, for instance, provide notice of the changes; exempt affected enrollees from the proposed change for the plan year; update formularies and other applicable beneficiary communications; and process enrollee requests for exceptions.

    - EGWPs making negative changes to drugs on the base formulary must request CMS approval through the HPMS negative change request (NCR) module. In contrast, when an EGWP adds drugs to enhance the base formulary, CMS does not require the sponsor to submit the additional drugs in HPMS for CMS approval. *See* PDBM, Ch. 12, EGWPs, §20.14. Subsequently, if an EGWP wanted to make a negative change to a drug that was not included in the base formulary, as a matter of operations, it would not be possible for the EGWP to submit a negative change request for that drug through HPMS. Therefore, while we continue to require EGWPs to follow all other applicable rules regarding negative changes to drugs included under the Part D benefit that appear on an enriched EGWP formulary, we do not require them to submit such changes to the HPMS NCR module.

Improving Drug Utilization Review Controls in Medicare Part D

In the final 2013 Call Letter and supplemental guidance, CMS described a medication safety approach by which sponsors are expected to reduce beneficiary overutilization of opioids and maintain access to needed medications.[21] In July 2013, CMS launched the Overutilization

[21] An excerpt from the Final 2013 Call Letter, the supplemental guidance and additional information about the OMS are available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html).

Monitoring System (OMS) to help oversee sponsors' compliance with this CMS overutilization guidance.

CMS continues to focus on and expect sponsors to further reduce opioid and acetaminophen (APAP) overutilization in the Medicare Part D program. In this section, we describe the results of Part D sponsors' implementation of improved drug utilization controls to prevent overutilization and improve medication use since January 2013, 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 policies described below to reduce the unsafe overutilization of medications by Part D beneficiaries and increase access to treatment.

- Timeliness of beneficiary-level opioid point of sale (POS) edit submissions to the Medicare Advantage and Prescription Drug System;
- Discontinuation of OMS APAP reporting through the OMS;
- Changes to the OMS opioid overutilization methodology;
- Formulary-level cumulative morphine equivalent dose (MED) POS edits;
- Soft opioid POS edit following initiation of buprenorphine -for the treatment of opioid use disorder;
- Access to medication-assisted treatment for opioid use disorder;
- Elimination of utilization management processes that may lead to inappropriate use of methadone in pain management.

In addition, the Enhancements to the 2017 Star Ratings and Beyond section of the 2017 Call Letter discusses implementation of three new PQA-endorsed opioid overutilization measures.

New Expectation for Entering Opioid Point of Sale Claims Edit Information in the Medicare Advantage and Prescription Drug System (MARx)

CMS enhanced MARx in February 2014 to automate the process by which sponsors notify other sponsors about their beneficiary-level opioid POS claim edit decisions. In accordance with current guidance, sponsors enter information in MARx when they have made a decision to implement a beneficiary-level opioid POS claim edit. MARx then alerts a new sponsor when a beneficiary identified in this manner by the previous sponsor enrolls in the new sponsor's plan. To facilitate data sharing between Part D sponsors, CMS has expected sponsors to submit POS edit notifications into MARx in a timely manner, which we are now specifying as within seven (7) business days of the date on the beneficiary's written advance notice. CMS also expects sponsors to submit implementations, terminations, and modifications of such POS edits within

seven (7) business days of the event. We encourage sponsors to use the MARx User Interface for faster submissions than the batch file process; instructions are available in the Medicare Advantage and Prescription Drug Plans Communications User Guide, which is available on the CMS webpage, https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Plan_Communications_User_Guide.html. As of March 10, 2016, CMS has received 2,693 contract-beneficiary-level opioid POS edit notifications through MARx for 2,520 unique beneficiaries.

Results of Overutilization Policy

Part D sponsors have had a significant impact on reducing overutilization of opioids and APAP. From 2011 through 2015, there was a 47% decrease or 13,753 fewer Medicare Part D beneficiaries identified as potential opioid overutilizers (i.e., beneficiaries with at least 90 consecutive days with greater than 120 mg MED daily with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims). This represents a 57% decrease in the share of beneficiaries using opioids who are identified as potential opioid overutilizers (see Table 20).

Table 20. OMS Part D Potential Opioid Overutilization Rates, 2011 – 2015*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Total Beneficiaries with at Least 90 Consecutive Days >120 mg MED Daily AND > 3 Prescribers & > 3 Pharmacies for Opioid Claims	Difference Year-to-Year	Share of Opioid Utilizers Flagged as Outliers	Difference in Share Year-to-Year
2011	31,483,841	10,049,914	31.9%	29,404		0.29%	
2013	37,842,632	11,794,908	31.2%	25,347	− 4,057 *47% decrease*	0.21%	−0.08% *57% decrease*
2014	39,982,962	12,308,735	30.8%	21,838	− 3,509	0.18%	−0.04%
2015	41,835,016	12,510,448	29.9%	15,651	− 6,187	0.13%	−0.05%

*Table 20 includes partial year inactive contracts, and hospice and cancer patients are excluded from utilizer and potential overutilizer counts. For these opioid utilization comparisons, CMS used OMS methodology and prescription drug event (PDE) TAP Data processed with cut-off dates in the early January of the following year.

The number of beneficiaries identified annually as potentially overutilizing APAP from 2011 to 2015, based on the CMS definition in the OMS, decreased by 94%, from 76,681 to 4,539 (see Table 21).

Table 21. OMS Part D Potential APAP Overutilization Rates, 2011-2015*

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing APAP	% Part D Enrollees Utilizing APAP	Total Beneficiaries with Daily APAP Dose Exceeding 4 g for 30 or More Days Within Any Six-month Period with at Least One Day Exceeding 4 g Within the Most Recent Calendar	Difference Year-to-Year	Share of APAP Utilizers Flagged as Outliers	Difference in Share Year-to-Year
2011	31,483,841	9,449,693	30.0%	76,581		0.81%	
2013	37,842,632	10,591,651	28.0%	26,122	−50,459	0.25%	−0.56%
2014	39,982,962	10,845,499	27.1%	6,286	−19,836	0.06%	−0.19%
2015	41,835,016	10,712,430	25.6%	4,539	−1,747	0.04%	−0.02%

*For these APAP utilization comparisons, CMS used OMS methodology and PDE TAP Data. For 2011, PDE TAP Data were processed through 13AUG2012; subsequent year analyses used PDE TAP data processed with cut-off dates in the early January of the following year.

Updates to Overutilization Policy for Contract Year (CY) 2017

Discontinuation of APAP Reporting through the OMS

Since the annual number of beneficiaries overutilizing APAP has decreased dramatically since 2011, we will discontinue the reporting of APAP overutilization tickets in the OMS beginning with the April 2016 OMS reports. However, we will continue to monitor APAP overuse through a new Patient Safety measure. The High APAP Daily Dose Rate will be defined as the number of APAP days exceeding a 4 g daily dose (DD) per 1,000 APAP user days, and will be reported for CY 2016 at the contract level for information purposes only. We will also identify outliers at the contract level, and will implement new outlier response requirements beginning in 2017 similar to the process used for other Patient Safety measures. The current Patient Safety outlier methodology can be found on the Patient Safety Website under Documentation › Help Documents › Outlier Threshold Reports. CMS thanks sponsors for their APAP utilization efforts, encourages continuation of these efforts, and reinforces that implementation of APAP safety edits based on FDA labelling do not require a formulary submission to CMS.

Opioids

Compliance Activities and Changes to the OMS Opioid Overutilization Methodology

Since the OMS was launched in July 2013, CMS has used the following criteria to identify beneficiaries who may potentially be overutilizing opioids:

> Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

In the 2015 Call Letter, we described our concern that some sponsors' internal criteria or processes to identify and address potential opioid overutilization may be insufficient. For the January 2014 OMS reports, 67% of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria (OMS response code BSC). CMS also announced that beginning January 2015, sponsors' internal opioid criteria for retrospective identification of egregious patterns of opioid overutilization and subsequent case management should be no less restrictive than 120 mg daily MED over at least 90 consecutive days.[22] Other criteria, such as the number of prescribers and pharmacies, could vary from CMS specifications. Sponsors may also vary the measurement period, and our understanding is that most sponsors look back 90 to 120 days.

Continued review of sponsors' responses to the OMS in 2015 suggested potential noncompliance with CMS guidance. In light of this, we performed additional outreach to assess compliance with CMS guidance by select Part D sponsors who were identified as outliers based on their APAP and opioid responses to the OMS. CMS contacted Part D sponsors at the parent organization level to obtain information about their overutilization criteria and case management programs, and for the sponsors to explain their responses to specific tickets received through the OMS. Overall, we found that sponsors were generally compliant with CMS guidelines.

Based on our analysis of the information from this effort, we identified opportunities to potentially modify the OMS opioid overutilization criteria in the future (as early as 2018) to reduce the number of tickets for which sponsors repetitively submit response codes BSC (No further review planned: Beneficiary did not meet the sponsor's internal criteria) and BOR (Beneficiary-level POS edit determined not necessary: Beneficiary's overutilization resolved).

Ideas include to:

- Shorten the measurement period from 12 months to 6 months; and
- Use average MED rather than a count of 90 consecutive days of high MED.

The revised 'Overutilization of Opioids' criteria would be:

> Use of opioids with an average daily MED exceeding 120 mg for an episode of at least 90 days with more than 3 prescribers and more than 3 pharmacies contributing to their

[22] Note: The OMS 'Overutilization of Opioids' criteria was developed and the compliance activities occurred prior to the recent publication of the CDC Guideline for Prescribing Opioids for Chronic Pain discussed later in the Call Letter. We will consider changes to the criteria based on the CDC Guideline for presentation in the 2018 Call Letter.

opioid claims, during the most recent 6 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice.

The average MED is calculated by summing each PDE's MED and dividing this sum by the duration of the opioid episode in days. An opioid episode consists of at least two opioid PDE fills. The episode duration is the number of days between the first and last opioid PDE's dispensing date during the measurement period plus the last PDE's days' supply plus 1 day (end-date). If the end-date is beyond the last day of the measurement period, the quantity is multiplied by the percent of the days' supply that occurs during the measurement period, and the end-date becomes the last calendar day of the measurement period.

By allowing gaps between prescription fills and days' supply in the calculation, the average MED per 90-day episode methodology may identify more beneficiaries who are chronic users of high opioid doses than the consecutive days method. Shortening the measurement period from 12 months to the most recent 6 months may better identify current potential overutilization and reduce the number of repeat cases reported by the OMS. We are analyzing the impact of these potential revisions in identifying beneficiaries who may potentially be overutilizing opioids.

In addition, CMS is investigating how prescribers are counted in the OMS opioid overutilization criteria. We are analyzing the feasibility of grouping NPIs (National Provider Identifiers) within a clinical practice as reported in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) rather than count unique NPIs, which would reduce false positives in the group practice setting. Suggestions include grouping based upon Tax ID number (TIN), Employer ID number (EIN), or primary location address. Identifying common clinical practice groups based on prescribers whose NPIs are associated only with one primary location TIN or a single EIN could prevent mismatching of prescribers who participate in multiple clinical practices. This conservative grouping methodology resulted in a 4.8% decrease in the number of beneficiaries potentially overutilizing opioids that would have been identified by the OMS in the October 2015 cycle.

We thank those commenters who offered suggestions on how to improve the metric and the grouping of NPIs. CMS plans to continue to investigate potential modification of this measure for implementation in 2018 based on experience from compliance activities, additional analyses, and the CDC guideline (as described further below).

Other findings and takeaways from our compliance activities include:

- Sponsors should review repeat OMS response replies. For example, instead of resubmitting the BSC response code repeatedly for the same case, sponsors may confirm medical necessity with the prescribers. The DMN (Determined Medically Necessary) response code triggers the OMS exception logic for one year.

- Although several morphine equivalent conversion factors exist, CMS encourages

sponsors to use the CDC morphine milligram equivalent (MME[23]) conversion factors within their opioid overutilization programs. The MME conversion table is available on the CMS webpage, Improving Drug Utilization Controls in Part D (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html), which contains information to help Part D sponsors create or revise their programs to address the unsafe use of opioid pain medications.

We thank the sponsors that participated in this outreach effort. We were not only able to assess potential non-compliance, but we gained information on ways to improve our guidance and overutilization methodology.

CMS' Expectation for Formulary-Level Cumulative Opioid POS Edits in CY 2017

Although the overutilization of opioids has decreased in Part D as discussed above, CMS has indicated on multiple occasions that we believe Part D sponsors should implement formulary-level cumulative opioid edits at POS to prospectively prevent opioid overutilization. Industry reaction had previously been that such edits were premature due their complexity. As described in the final 2016 Call Letter, we commenced a pilot project in 2015 to assess the feasibility and impact of such POS edits.

Through the pilot project, we noted that Part D sponsors demonstrated that they can effectively implement a soft or hard formulary-level cumulative opioid MED edit at POS while blocking the edit for beneficiaries with known exceptions. The sponsors evaluated their own data when developing edit specifications and exclusion criteria to identify potential opioid overutilization while maintaining access to opioids when needed for their enrollees. Formal complaints were not received from beneficiaries or providers. Additional information about the pilot project experience was described in the draft CY 2017 Call Letter.

- For CY 2017, we proposed that sponsors' implement both the soft and hard[24] cumulative MED POS edits. Soft edit claim rejections could be overridden at the pharmacy level by the pharmacist submitting appropriate NCPDP codes, and with respect to hard edit claim rejections, the rejected prescription drug claim would not be approved in the absence of a plan decision to override the edit. In the draft Call Letter, we proposed the following parameters for the POS edits: Soft edits that can be overridden at the pharmacy level when a prescription claim will result in the

[23] Note: CDC's terminology, morphine milligram equivalents (MME), is equal to morphine equivalent dose (MED) in milligrams as used by CMS. Often calculated as a daily dose.

[24]More information about soft and hard rejects and edits is available from the Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf, and 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 1/22/2015).

beneficiary's active or overlapping opioid prescriptions reaching or exceeding a certain daily cumulative MED threshold. This threshold may be set at 90 mg to 120 mg MED. The soft-edit rejection can be overridden by the pharmacist submitting appropriate NCPDP codes.

- Hard edits for daily cumulative MED threshold at or above 200 mg MED.

We also described methods to minimize false positives by accounting for known exceptions.

Commenters supported our original proposal for both types of edits, and some supported only soft or hard edits for CY 2017. Others expressed concern for potential delay of beneficiary access to needed medications, the short time between the final Call Letter and the formulary submission deadline, and the need for more time to develop, test, and implement the edits. Due to the comments received, we are revising our expectations for CY 2017 formulary-level cumulative opioid MED POS safety edits. For CY 2017, we expect sponsors to implement either a soft edit or a hard edit, or they may use both soft and hard edits as we originally proposed in the draft Call Letter, and work toward a hard edit at a minimum in 2018 using reasonable controls to limit false positives. We will review 2016 and 2017 experience with these edits to inform content in the CY 2018 Call Letter.

For CY 2017, we expect sponsors' Pharmacy and Therapeutics (P&T) committees to develop the specifications for their formulary-level cumulative MED POS edit(s) based on the opioid overutilization in their Part D plans, and reasonable numbers of targeted beneficiaries for plan oversight. We recommend that a soft opioid edit threshold should be set at levels no lower than 90 mg MED, and a hard opioid edit threshold should set no lower than 200 mg MED. We also expect sponsors to apply specifications to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management, or appeals processes. If sponsors decide to include a provider count criterion in the soft or hard edit specifications, we recommend two prescribers of the active opioid prescriptions as the threshold (at a minimum). We also do not recommend a consecutive high-MED days criterion because it would not prevent beneficiaries from reaching high opioid doses.

In order to allow more time to develop and test the full edit specifications, Part D sponsors will have until September 1, 2016 to submit the detailed operational information to CMS for review. The documentation must include information such as the type of edit(s), the MED level being utilized, exclusion criteria, and other screening information, as well as a written description of the program's mechanics, including the mechanism by which the edits will be resolved. This information must be submitted via e-mail to partdformularies@cms.hhs.gov with a subject line of "Cumulative MED – [applicable FID number]." A submission template will be provided to

Part D sponsors' formulary contacts at a later date. Finally, we wish to clarify the HPMS formulary submission requirements with respect to quantity limits. Opioids that have a quantity limit that is below any applicable FDA-approved maximum doses must be submitted as part of the HPMS formulary submission. However, if the only quantity restriction that will be applied at POS is a cumulative MED edit described in this section, a quantity limit does not need to be reflected on the HPMS formulary submission. The cumulative MED edit is considered to be a safety edit. This guidance updates that which is included in section 30.2.2.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. We are also clarifying that non-formulary opioids can be included in the cumulative MED editing even though they are not included on the formulary.

Concurrent Use of Opioids and Buprenorphine

As described in the 2016 Call Letter, we investigated the concurrent use of buprenorphine and opioids in Part D as a potential new measure for the OMS as informational only. Currently, the sublingual (SL) and buccal formulations of buprenorphine and buprenorphine-naloxone film or tablets are only approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorder and not for the treatment of pain. Because buprenorphine effectively blocks the analgesic properties of other opioids used to treat acute pain, it generally prevents the use of other opioids as an adjunctive treatment for pain syndromes.

An analysis of PDE data from April 1, 2014 through March 31, 2015 identified over 24,500 Medicare Part D beneficiaries with concurrent buprenorphine buccal and SL formulations and opioid use, including over 20% with 30 or more concurrent opioid days. CMS believes there are additional opportunities for improvements through drug utilization management. Therefore, we expect sponsors to implement a soft POS edit when an opioid prescription is presented following the initiation of buprenorphine for the treatment of opioid use disorder. CMS believes that a soft edit that only rejects the opioid prescription following the buprenorphine claim should not impede access to buprenorphine for the treatment of opioid use disorder. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims. At this time, we will not include a measure of concurrent use of opioids and buprenorphine in the OMS, but we will continue to monitor utilization trends. For additional guidance in the use of buprenorphine in the treatment of opioid use disorders refer to http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

Concurrent Use of Opioids and Benzodiazepines

CMS is also concerned with the concurrent use of opioids and benzodiazepines, and we want to raise public awareness of this important issue. The combination of opioids and benzodiazepines can exacerbate respiratory depression, the primary factor in fatal opioid overdose. The risk of opioid-related morbidity and mortality is increased in all patients, even those who do not show signs of aberrant drug behavior. In a 2015 study, investigators found that 49% of a study

population who died from a drug overdose while taking opioid analgesics were concurrently prescribed benzodiazepines.[25] Further, the CDC advises clinicians to avoid prescribing opioids and benzodiazepines concurrently whenever possible.[26]

We found through analysis of 2015 PDE data (as of March 2016) that almost 3.1 million beneficiaries were dispensed an opioid medication with at least one day overlap with a benzodiazepine medication, excluding beneficiaries enrolled in hospice or with a cancer diagnosis. This represents 24% of opioid users and 8% of Part D enrollees (non-hospice/non-cancer). Also, about one-third of beneficiaries concurrently utilizing opioids and benzodiazepines only had one event (most less than 30 days), whereas over two-thirds had more than one event of overlap usage. The top three opioid and benzodiazepine combinations by number of events in 2015 included hydrocodone-acetaminophen with alprazolam, lorazepam, or clonazepam. We encourage Part D sponsors to evaluate their claims data and use drug utilization management tools that are available to them as necessary to help address the concurrent use of these drug classes.

CMS will continue to monitor concurrent use of opioids and benzodiazepines among Medicare Part D enrollees. Also, we are aware that a measure concept, Double Threat: Concurrent Use of Opioids and Benzodiazepines, is in development by the PQA, which may be considered for future use in oversight or performance measurement.

Access to Medication-Assisted Treatment

Despite efforts such as those outlined above, opioid use disorder continues to be a significant public health concern. In October 2015, the President issued a Memorandum to Federal Departments and Agencies to identify barriers to medication-assisted treatment (MAT) for opioid use disorders and develop action plans to address these barriers. In response, CMS will use available vehicles to inform physicians, MA organizations and Part D sponsors about MAT coverage, including clarifying that MA plans have the same obligation to cover substance use disorder treatment as is available under Original Medicare and that Part D plans must ensure access to MAT that are covered under Medicare Part D.

Currently only buprenorphine, buprenorphine/naloxone, and naltrexone are covered Part D drugs when used for medication-assisted treatment (MAT) of opioid use disorder. It is critical that Medicare beneficiaries who are in need of these therapies have appropriate access to these drugs in Part D. Given the requirements imposed by the Drug Addiction Treatment Act of 2000 and Risk Evaluation and Mitigation Strategy for buprenorphine-containing products for MAT, Part D sponsors should not impose prior authorization criteria that simply duplicate these requirements. When prior authorizations are utilized, Part D sponsors must also carefully consider approval

[25] Park TW, Saitz R, Ganoczy D, et al. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. *BMJ* 2015;350:h2698.
[26] http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

durations so as to not subject beneficiaries who are in need of these therapies to unnecessary hurdles or lapses in treatment. Part D formulary and plan benefit designs that hinder access, either through overly restrictive utilization management strategies or high cost-sharing, will not be approved.

Under current statute, methadone, an FDA-approved medication for the treatment of opioid use disorder, is not covered by Part D for substance use disorder treatment because it does not meet the Part D requirement that it "may be dispensed only upon a prescription" since it must be dispensed in an opioid treatment program and cannot be dispensed upon a prescription at a pharmacy when used for this purpose. We appreciate comments submitted on whether or not this statutory requirement is a barrier to treatment. Absent a change in law, Medicare is unable to cover methadone for MAT under Medicare Part B or Part D. However, under Part C, MA organizations may cover methadone for MAT as a supplemental benefit.

A Note about the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain

The CDC prepared a guideline for opioid prescribing to assist primary care providers in delivering safer, more effective chronic pain management for patients with pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline, which was published on March 15, 2016, was developed through a rigorous scientific process using subject matter experts, the most recent scientific evidence, and public comment. Topics include 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use, including the use of opioids in patients age 65 and older. In the guideline, CDC identifies 50 mg MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing dosage to 90 MME per day. The guideline also presents tapering methodology for long-term, high opioid dose users, which may be useful to reduce high opioid doses. We encourage sponsors' P&T committees to carefully review and consider CDC's recommendations, and to share the CDC guideline with opioid prescribers. The CDC Guideline for Prescribing Opioids for Chronic Pain is available on the CDC website at http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

During 2016, we will consider potential revisions to CMS overutilization guidance and the OMS opioid overutilization methodology based on the CDC guideline, for presentation in the 2018 Call Letter. In addition, we will consider recommendations set forth in the guideline during the CY 2017 formulary and benefits review. For example, CDC notes that methadone has been associated with a disproportionately high number of overdose deaths relative to its prescribing frequency for pain management. As a result, the guideline states that methadone should not be used as a first line agent for pain management when an extended-release/long-acting opioid is indicated, and that only providers who are familiar with the complexities of methadone's pharmacokinetic and pharmacodynamics properties should prescribe it for pain. Part D sponsors should evaluate their utilization management strategies and eliminate processes that may lead to

inappropriate utilization of methadone in pain management. Submitted Part D benefit packages and formularies will be reviewed to ensure that methadone is not the sole preferred opioid analgesic within a plan design.

Point of Sale Pilot

In the draft Call Letter, CMS provided an overview of the Point of Sale (POS) pilot we conducted in 2015. We shared initial takeaways from the pilot and solicited feedback from stakeholders on: (1) how CMS and Part D plans might reduce the volume of rejected claims on the front end by resolving certain issues before the prescription arrives at the pharmacy; and (2) how plans might employ proactive processes to resolve certain POS issues without the enrollee having to request a coverage determination.

Most of the comments we received about the POS pilot were generally supportive of the project's goals to reduce rejected claims at the POS when possible, and explore ways to reduce unnecessary delays in access to needed drugs. Several commenters asked for clarification on any guidance CMS will provide for future changes to POS processes, including potential regulatory changes, and more information about the pilot findings. A few commenters asked for clarification on whether initiation of a proactive outreach approach starts the clock on a coverage determination, or whether denial notices would be required if proactive outreach does not result in authorization of the requested drug.

Overall, commenters expressed a range of concerns about potential policy changes in this area. Some commenters, while noting that the pilot was a positive step toward improving beneficiary access to needed drugs, also expressed concerns about the methodology, including the usefulness of findings without benchmark data for comparison and a lack of information about how the pilot may have impacted affected beneficiaries. Other commenters stated a belief that the pilot was too limited in scope to form the basis of a regulatory change, recommended seeking more industry feedback before introducing new requirements, and underscored the need to allow plans and PBMs sufficient time to make any necessary systems or process modifications before any required changes become effective. A few commenters voiced concerns that the proactive outreach developed and tested in the pilot represents an additional financial and operational burden on plan sponsors, and provided no added benefit to enrollees or the program. Comments related to implementation of a potential policy change varied: some commenters recommended that changes allow for flexibility, one commenter requested that CMS identify target drugs, and another commenter stated that any proposed changes should not circumvent the existing coverage and appeals process by creating a new flexible, informal process for plans/PBMs that would lack transparency and be difficult to oversee.

A number of commenters responded to our request to identify additional means to address POS issues, and we thank them for their responses. Commenters offered a variety of suggestions, including:

- CMS could develop additional guidance and requirements related to electronic prescribing (eRx) and electronic prior authorization (ePA), which the commenter believes will increase adoption of eRx and the more consistent use of a single standard for ePA;

- Part D plan sponsors could improve existing or implement new review of enrollee claims history to facilitate authorizations when appropriate;

- MA-PD plans could leverage existing provider contracting arrangements to make formularies more accessible to prescribers who are contracted with the plan; and

- CMS could consider how lessons learned from the POS Pilot might be applied to the Part D Enhanced MTM Model Test.

We received a few additional comments related to the Part D coverage and appeals process generally which were outside the scope of the POS pilot and will not be addressed in the Call Letter. We thank all commenters for sharing their feedback, ideas and concerns related to this project.

After analyzing the results of the pilot and the comments received in response to the draft Call Letter, we agree that additional exploration of these issues is warranted before proposing any regulatory changes, and CMS will not impose changes to operational requirements for the 2017 plan year. While we made sure to include a variety of organizations in the pilot—large and small plans, standalone Part D and MA-PD plans, and PBMs—all participants expressed concerns about the resources necessary to implement their varied proactive outreach processes on a larger scale, including the need to spend more time conducting outreach to prescribers to obtain necessary information than is generally needed during the coverage determination process. Participants and CMS have concerns about diverting plan resources from the coverage determination process to a proactive process to resolve POS issues where the enrollee has not requested a coverage decision and believe this approach may not provide the most benefit to enrollees.

While we appreciate commenters' concerns about the methodology of the pilot, we believe our flexible approach yielded robust and varied findings. By allowing participants to devise their own processes and select which drugs to target, we obtained information on where flexibility could maximize the benefit for enrollees and minimize any additional burden on plans, PBMs, and prescribers. This methodology also gave us insight into where we might target continued exploration of POS issues by seeing where varied organizations diverged in process design, drug selection, and ideas that went beyond the framework CMS initially devised. Additionally, one of the main reasons CMS conducted this pilot was to explore potential solutions to POS issues *without* the enrollee having to take action, and to more seamlessly address situations where beneficiary advocacy groups have advised CMS that enrollees can be confused by the coverage

determination process and uncertain about what action they should take when a pharmacy claim rejects under Part D.

Despite our concerns about the significant resources needed for, and potential limits of, a proactive process to resolve rejected claims, we identified multiple opportunities to address POS issues which CMS will continue to explore to develop best practices and potential future policy changes. These opportunities include developing additional guidance and exploring additional requirements related to eRx and ePA to increase adoption of these technologies, testing the use of "smart edits" where information is or could be made available in real-time to allow certain claims to favorably auto-adjudicate at the POS, and further exploring how certain rejected claims may be targeted for proactive outreach in concert with existing rejected claim review and MTM requirements. We agree with many commenters that additional research in these areas is advisable before suggesting best practices or implementing new requirements on a larger scale. We do, however, encourage Part D sponsors to continue to analyze POS access issues, and to identify methods for resolving POS edits whenever possible without the beneficiary having to take action, such as initiating or expanding rejected claims review processes. We also encourage Part D plans and PBMs to continue to share ideas and information, as well as questions and concerns with CMS, by sending an email to POSpilot@cms.hhs.gov.

On January 21, 2016, CMS hosted a conference call and invited the pilot participants to share information about their experiences in the pilot with other Part D plan sponsors, PBMs and interested stakeholders. Participants discussed how they identified target drugs, the processes they developed for outreach, challenges and successes of the process, resource allocation and comparison to the coverage determination process, and recommendations for any CMS policy changes, including ideas for increasing prescriber awareness of formulary information at the point of care. We have recently posted presentation materials, as well as the audio recording and transcript of that call on the CMS website at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html.

While CMS is not imposing any new operational requirements for 2017, we want to take this opportunity to remind MA-PD plans of the new requirements at 42 CFR §422.112(b)(7), which became effective January 1, 2016. MA-PD plans are required to coordinate all Medicare benefits administered by the plan for prescription drugs that may be provided under Part B or Part D by establishing and maintaining a process to ensure timely and accurate POS transactions, and to issue a decision and authorize or provide the benefit as appropriate under Part B or Part D when a party requests a coverage determination. CMS intends to develop additional subregulatory guidance for MA-PD plans related to our expectations for coordination of benefits when drug claims are rejected at the POS because of a B v. D prior authorization requirement.

Extended Days' Supply and First Fill Quantity Limits

Part D sponsors that offer an extended (2 or 3 month) days' supply are not required to uniformly apply this benefit across each tier. Sponsors must indicate in the plan benefit package (PBP) if an extended days' supply for a given tier applies across an entire tier, or applies only to a subset of drugs on a tier. Currently there is no process for sponsors to indicate which specific drugs on a partial extended days' supply tier qualify for extended days' supplies verses those drugs that do not.

In an effort to increase transparency, beginning in CY 2017, sponsors that indicate a partial extended days' supply tier within their PBP will be required to submit the specific drugs not available as extended days' supply as an HPMS supplemental file. This file ("Non-Extended Day Supply") includes the RXCUIs that will not be available as an extended days' supply during initial formulary submission and as necessary during formulary update window submissions. Detailed submission guidance will be provided during the formulary submission training at a later date.

Part D sponsors of EGWPs offering this option will not be required to provide a "Non-Extended Day Supply" supplemental file because they do not complete the Medicare Rx section of the PBP. We continue to require EGWPs to otherwise follow non-waived rules governing extended days' supply.

We understand many plans offer beneficiaries 2 or 3 month supplies of medications as a convenient and potentially cost saving option. However, consistent with good medical practice, it can often be appropriate for the prescriber to follow up sooner with a patient starting a new therapy. This is especially true in the case of complex therapies or drugs with a narrow therapeutic index or a high risk of side effects. With any multi-day fill there is the potential that a patient's dose may change or he or she discontinue therapy due to side effects, adverse reactions, or lack of clinical response. In these cases, the remaining amount of medication is often wasted. The potential for drug waste is especially pronounced when starting on a new drug therapy, as the effectiveness and tolerability are unknown for the patient. Dispensing a 2 or 3 month supply as a first fill to a patient who is naïve to therapy may result in excessive waste, as well as unnecessary expense, if the patient ultimately does not use the full amount dispensed.

Starting in 2017, plan sponsors will now also have the option to indicate in the PBP at the tier level if any drugs are available for an extended days' supply on all but the first fill. This change allows sponsors to designate drugs where they will only cover up to a one month supply the first time the drug is filled, providing an opportunity to limit drug waste when a new therapy is not working for the patient or has adverse effects. While some prescribers may choose to schedule another visit with a patient beginning a complex therapy to determine the need for adjustments or discontinuation of therapy, Part D sponsors may not require such a step or a new prescription for

the second fill to be covered for the extended days' supply. After the first one month supply, the change to extended days' supply should be seamless for the beneficiary.

Given the support received, sponsors will be permitted to implement this starting in 2017; however, the specific drugs available for an extended days' supply on all but the first fill will not be included in an HPMS supplemental file for 2017. Sponsors should make clear in beneficiary materials information about first fill quantity limits and which drugs are affected.

Establishing Mail Order Protocols for Urgent Need Fills to Prevent Gaps in Therapy

Many Part D sponsors contract with mail order pharmacies to offer beneficiaries an alternative way to fill prescriptions under the Part D benefit, often at much lower cost-sharing than is available at network retail pharmacies. While mail order pharmacies make up a relatively small percentage of total prescriptions filled under the Part D program, we are committed to ensuring consistent and reliable beneficiary access to medications, regardless of what type of pharmacy fills the prescription.

One aspect of providing consistent access includes responding to urgent medication needs. Various scenarios can result in a beneficiary running out or having only a small amount of a medication remaining, such that a standard mail order fill may arrive too late to avoid a gap in therapy. As stated in §423.120, a Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering mail order, provided the requirements assuring pharmacy access are met. In our experience, under such circumstances some Part D sponsors direct their enrollees to retail pharmacies to obtain a needed medication. Other sponsors provide rush orders (e.g., next day delivery) from mail order pharmacies to supply the medication.

CMS has received beneficiary complaints about mail order pharmacies indicating that they will rush ship an urgently needed order, but the order does not arrive when promised or at all**,** potentially resulting in gaps in therapy. To protect beneficiaries from inconsistent or unreliable practices that may jeopardize timely access to medications, CMS expects Part D sponsors to work with their mail order pharmacies to develop and implement protocols for providing access to urgently needed medications. Further, beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials. Having established protocols and beneficiary information in place can streamline how sponsors respond to such needs. We expect sponsors to have protocols in place to address how to handle urgently needed medication requests from beneficiaries by CY 2017 if not sooner and to be able to clearly communicate this to their beneficiaries. We will continue to monitor complaints for issues related to mail order or access to urgently needed medications.

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 2017 COB user fee will be collected at a monthly rate of $0.116 for the first 9 months of the coverage year (for an annual rate of $0.087 per enrollee per month) for a total user fee of $1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2017 bids.

In contract year 2017, we will use the COB user fees for activities including:

- Part D Transaction Facilitator operation and maintenance;
- The Benefit Coordination and Recover Center (BCRC) operation and maintenance;
- 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 System (MARx) management of COB data; and
- Review of Workers' Compensation settlement set-aside funds, which verify that medical services are paid for by the appropriate party

Part D Low Enrollment

CMS has the authority under 42 CFR §423.507(b)(1)(iii) to non-renew Part D plans (at the benefit package level) that do not have sufficient number of enrollees to establish that they are viable plan options. While we are particularly concerned with plans that have fewer than 500 enrollees, we urge sponsors to voluntarily withdraw or consolidate any stand-alone plan with less than 1,000 enrollees. Sponsors are strongly encouraged to view data on plan enrollment at: https://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 2016, we will notify plans with less than 1,000 enrollees of available options for 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.

Section IV – Medicare-Medicaid Plans

Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2017

This section provides an overview of the contract year (CY) 2017 Medicare requirements and timeframes for Medicare-Medicaid Plans (MMPs). We will also provide guidance shortly after the issuance of the Final CY 2017 Call Letter about which provisions in other sections apply to MMPs. Finally, we remind MMPs of the policy regarding the use of past performance information for determining plan eligibility to receive passive enrollment.

Annual submission timelines for MMPs are aligned with the standard Medicare Advantage (MA) and Part D annual schedule, as detailed in this Call Letter. As is the case for other MA and Part D plans, MMPs must submit a formulary, medication therapy management (MTM) program, and plan benefit package (PBP).

In addition to the requirements for MA-PD plans and PDPs, MMPs must also submit:

- On an annual basis, information to ensure the plan has a network adequate to provide enrollees with timely and reliable access to providers and pharmacies for Medicare drug and medical benefits based on requirements in the Medicare Parts C and D programs. In addition, states will evaluate networks for Medicaid service providers, including long-term supports and services.
- If applicable based on the approval period given to the most recent model of care (MOC) submission, a MOC that meets CMS's requirements for SNPs, as well as any applicable state requirements.
- The Additional Demonstration Drug (ADD) file to supplement the Part D formulary submission.

Table 22 below catalogues previously released guidance for MMPs or guidance that may be of particular interest to MMPs. CMS will release updated or new guidance as necessary; where more recent guidance exists or is released for topics that appear in previously released documents, MMPs should use the most recent document.

Table 22: Previously Released Guidance

Topic	Link to document
MMP Enrollment and Disenrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMPFinalEnrollGuidance.pdf
Additional State-specific Enrollment Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
State-specific Marketing Guidance	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html
Waiver of Part D LIS Cost-Sharing Amounts	https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Part_D_Cost_Sharing_Guidance.pdf
Past Performance Review Methodology Updates for CY 2017	https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/index.html

Network Adequacy Determinations

MMPs will be required to resubmit the Medicare medical provider and facility portion of their network information in September 2016 to ensure that each MMP continues to maintain a network of providers that is sufficient in number, variety, and geographic distribution to meet the needs of the enrollees in its service area. MMPs may assess the Medicare portion of their networks at any time using the plan-only upload functionality in the HPMS Network Management Module (NMM). The current reference file that provides the MMP standards is available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html as well as on the reference page within the NMM. CMS will release additional guidance on the submission process, including how MMPs will be able to submit exception requests in the summer of 2016. The Medicare pharmacy portion of the network will be checked per the requirements in the Part D reporting requirements.

Model of Care (MOC)

As discussed in January 14, 2016 HPMS memorandum, "Changes to Special Needs Plans and Medicare-Medicaid Plan Model of Care Submissions and Updates in the Health Plan

Management System for CY 2017," we strongly encourage MMPs to avail themselves of the new off-cycle update process, as MMPs' MOC submissions preceded the development of three-way contract requirements on care management and care coordination under each demonstration. Submission of changes through this process, as outlined in that memorandum and other guidance from CMS, will allow MMPs to align their current MOCs with all relevant demonstration requirements.

Formulary and Supplemental Drug Files

Each contract year, MMPs must submit and be approved to offer a demonstration-specific, integrated formulary that meets both Medicare Part D and Medicaid requirements. For CY 2017 formulary approval, MMPs must submit: (1) an updated base Part D formulary and supplemental Part D formulary files, as applicable, consistent with CY 2016 Part D formulary application guidance; and (2) an updated Additional Demonstration Drug (ADD) file containing non-Part D drugs. MMPs must submit their base formularies no later than June 6, 2016. Supplemental formulary files are due in HPMS on June 10, 2016 at 11:59 a.m. EDT.

All MMPs must submit an ADD file which can only contain non-Part D drugs. Non-Part D drugs include drugs in Medicare Part D excluded categories, over-the-counter drugs, and other products required by the state to be included on the integrated formulary. CMS will work with states to provide ADD file guidance to MMPs by May 2016. This guidance should include a list of the drugs the MMPs are required to include on the ADD file (by NDC and/or UPC). It is at the states' discretion whether to require their plan applicants to include one proxy NDC or multiple NDCs on the ADD file for each covered product.

State reviewers are solely responsible for reviewing and approving the ADD file. CMS will approve all other submitted formulary files. Reviews will begin immediately after the submission deadlines and will continue until all deficiencies have been resolved.

We clarify that mid-year ADD file change submissions – that is, changes to the ADD file after the contract year has begun – are at the discretion of each state. CMS will work with states to open HPMS gates for ad hoc and/or regular ADD file resubmissions as necessary.

CMS released a CY 2017 formulary training video for plans in on March 24, 2016.

We received several comments recommending better coordination of the ADD file and Part D formulary portions of the formulary review and approval process to avoid access issues related to prescription drugs that could be covered by either Part D or Medicaid depending on the circumstances. CMS will work to further streamline the formulary submission and review process to ensure that such access issues are mitigated.

Plan Benefit Package (PBP)

MMPs' plan benefit packages (PBPs) are reviewed annually to ensure that MMPs accurately describe the coverage details and cost-sharing for all Medicare, Medicaid, and demonstration-specific benefits. CMS will launch the HPMS PBP module on April 8, 2016, and we expect to provide further guidance at that time on MMP-specific updates to the PBP software for CY 2017. In addition, CMS will release an online training module on the CY 2017 PBP software for plans on April 8, 2016.

MMPs must submit their integrated PBPs to CMS no later than June 6, 2016 (11:59 p.m. PDT). Non-timely submission of a PBP is considered a plan notice of non-renewal. In addition, to the PBP, MMPs are required to submit the following as part of a complete bid submission:

- Service Area Verification
- Plan Crosswalk (NOTE: This is only for renewing contracts in CY 2017)
- Formulary Crosswalk

CMS will work with states to issue PBP guidance that clearly defines the state-required Medicaid benefits and supplemental demonstration benefits by the time the PBP module is launched in April 2016. The PBP review will be conducted jointly between CMS and states to ensure the data entry is consistent with minimum coverage and cost-sharing requirements under Medicaid, Medicare Parts A, B, and D, and each state's demonstration.

As part of our demonstration implementation activities, the Medicare-Medicaid Coordination Office, in partnership with the Center for Medicare, has provided additional flexibility to MMPs with respect to PBP corrections after the time of final PBP approval. This flexibility has been necessary to make accommodations, including but not limited to mid-year legislative changes to Medicaid benefits, as well as the timing of payment rate finalization.

The following policies apply to MMP changes to PBPs:

- CMS will consider MMPs' requests to make PBP revisions to add or remove plan-offered supplemental benefits between the time of the release of the National Average Monthly Bid Amount in early August and sign-off of PBPs in HPMS in late August 2016. This opportunity, if approved, will allow plans to accommodate any benefit changes in their required documents (including the Annual Notice of Change, Evidence of Coverage/Member Handbook, and Summary of Benefits) during the Annual Election Period.
- Rate-related PBP corrections to supplemental benefits are permissible during the Center for Medicare's annual correction window in September 2016 (see the calendar in this Call Letter for more information), but only for purposes of adding supplemental benefits to PBPs. MMPs that elect to correct their PBPs must work with their contract

management team on an appropriate member communication strategy (e.g., addenda or errata sheets for materials that have already been mailed to members; updates to other materials for current and prospective members). In addition, there will be no compliance penalty for a PBP correction provided an MMP meets these conditions.

- Any PBP corrections after the Center for Medicare's annual correction window in September 2016 will be considered on a case-by-case basis. PBP corrections due to plan error will be subject to compliance action, regardless of whether they are positive or negative changes.

Past Performance Information and Eligibility for Passive and Opt-in Enrollment

Our policy regarding the use of past performance information is articulated in previous guidance memoranda, including – most recently – in the February 23, 2015 HPMS memorandum, "Medicare-Medicaid Plan Annual Requirements and Timeline for CY 2016." MMPs should refer to that guidance for additional information regarding the impact of sanctions, treatment of new legal entities, and eligibility for passive enrollment after effectuation of the three-way contract.

Appendix 1 – Contract Year 2017 Guidance for Prescription Drug Plan (PDP) Renewals and Non-Renewals (Updated)

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 6, 2016). 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 2017 is summarized below and defined in Appendix 2. These are the same options that existed in CY 2016. All but one of these actions can be effectuated by PDP sponsors in the HPMS Plan Crosswalk.

Please note, Medicare Advantage Organizations should reference Chapter 4, Chapter 16a, and Chapter 16b of the Medicare Managed Care Manual for Contract Year 2017 guidance on renewals and non-renewals.

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 divide a current PBP among more than one PBP for the following contract year. A PDP sponsor consolidating two or more entire PBPs must make certain 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, absent a compelling reason in CMS's determination, such as a sponsor that is under a consolidation plan.

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 6, 2016. CMS expects the sponsor to crosswalk the affected enrollees into the most comparable plan, which includes the sponsor's basic plan if that is the only plan available. However, as stated in the CY 2015 Call Letter, CMS reminds 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. In a situation where enrollees are crosswalked to a comparable plan, 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 allow the merger of 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.

Appendix 2 – Contract Year 2017 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 2017 that is not linked to a 2016 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 2016 PBP in CY 2017. 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 2016.	HPMS Plan Crosswalk Definition: A 2017 plan that links to a 2016 plan and retains all of its plan service area from 2016. The 2017 plan must retain the same plan ID as the 2016 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 2017. 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 2016 into a single renewal PBP for CY 2017. The PDP sponsor must designate which of the renewal PBP IDs will be retained in CY 2016 after consolidation.	HPMS Plan Crosswalk Definition: Two or more 2016 plans that merge into one 2017 plan. The2017 plan ID must be the same as one of the consolidating 2016 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 2017.	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 2016 prescription drug PBP in CY 2017 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 2017.	HPMS Plan Crosswalk Definition: A 2017 800-series plan that links to a 2016 800-series plan and retains all of its plan service area from 2016, but also adds one or more new regions. The 2017 plan must retain the same plan ID as the 2016 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 2017. 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 2016 PBP.	HPMS Plan Crosswalk Definition: A 2016 plan that is no longer offered in 2017. HPMS Plan Crosswalk Designation: Terminated Plan	CMS expects the sponsor to crosswalk theaffected 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 theservice 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 crosswalk-ed must be marked as a terminated plan in the HPMScrosswalk. The remaining 2017 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 2017. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Appendix 3 – Improvement Measures (Part C & D)

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Breast Cancer Screening	Process Measure	1	Yes
C	Colorectal Cancer Screening	Process Measure	1	Yes
C	Annual Flu Vaccine	Process Measure	1	Yes
C	Improving or Maintaining Physical Health	Outcome Measure	3	No
C	Improving or Maintaining Mental Health	Outcome Measure	3	No
C	Monitoring Physical Activity	Process Measure	1	Yes
C	Adult BMI Assessment	Process Measure	1	Yes
C	Special Needs Plan (SNP) Care Management	Process Measure	1	Yes
C	Care for Older Adults – Medication Review	Process Measure	1	Yes
C	Care for Older Adults – Functional Status Assessment	Process Measure	1	Yes
C	Care for Older Adults – Pain Assessment	Process Measure	1	Yes
C	Osteoporosis Management in Women who had a Fracture	Process Measure	1	Yes
C	Diabetes Care – Eye Exam	Process Measure	1	Yes
C	Diabetes Care – Kidney Disease Monitoring	Process Measure	1	Yes

Part C or D	Measure	Measure Type	Weight	Improvement Measure
C	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measure	3	Yes
C	Controlling Blood Pressure	Intermediate Outcome Measure	3	Yes
C	Rheumatoid Arthritis Management	Process Measure	1	Yes
C	Reducing the Risk of Falling	Process Measure	1	Yes
C	Plan All-Cause Readmissions	Outcome Measure	3	Yes
C	Getting Needed Care	Patients' Experience and Complaints Measure	1.5	Yes
C	Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	Yes
C	Customer Service	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	Yes
C	Rating of Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Care Coordination	Patients' Experience and Complaints Measure	1.5	Yes
C	Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
C	Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	No
C	Health Plan Quality Improvement	Improvement Measure	5	No
C	Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5	Yes
C	Reviewing Appeals Decisions	Measures Capturing Access	1.5	Yes
C	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes

Part C or D	Measure	Measure Type	Weight	Improvement Measure
D	Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	Yes
D	Appeals Auto–Forward	Measures Capturing Access	1.5	Yes
D	Appeals Upheld	Measures Capturing Access	1.5	Yes
D	Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	No
D	Drug Plan Quality Improvement	Improvement Measure	5	No
D	Rating of Drug Plan	Patients' Experience and Complaints Measure	1.5	Yes
D	Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1.5	Yes
D	MPF Price Accuracy	Process Measure	1	No
D	High Risk Medication	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Diabetes Medications	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measure	3	Yes
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measure	3	Yes
D	MTM Program Completion Rate for CMR	Process Measure	1	Yes

Appendix 4 - 2017 Draft Call Letter Star Ratings Summary of Comments and Responses

Call Letter Section	Summary of Comments	CMS Final Course of Action
Improvement Measures (C & D)	A few comments were received from sponsors with specific suggestions for methodology changes to the Improvement Measures, including: • Calculate Star Ratings separately for Part C and Part D with and without the Improvement Measures, or allow for inclusion of the Part C or D Improvement Measures. • Evaluate performance on a log scale instead of a linear scale. • Adjust the threshold for what is considered an improvement relative to the plan's level of performance. • Weight improvement achieved relative to current performance. A small number of comments were received about specific measures in the Improvement Measures (such as CAHPS, HRM, MTM, and Call Center).	Proceed as proposed. CMS wants to incentivize improvement for all contracts while addressing the challenges faced by contracts at different levels of performance. We continue to evaluate potential enhancements to the improvement methodology.
Appeals Timeliness/Reviewing Appeals Decisions measures (Part C) and Appeals Upheld (Part D)	All comments supported the change to allow reopenings completed by May 1 to be incorporated into these two measures.	Proceed as proposed.
Contract Enrollment Data (Part C & D)	The majority of commenters agreed that CMS should keep the current enrollment methodology.	Proceed as proposed and make no changes.
Transition from ICD-9 to ICD-10 (Part C & D)	There were only a few comments acknowledging the transition with one suggesting CMS monitor the impact on Star Ratings measures.	Proceed as proposed as the ICD-10 codes have been implemented.
Appeals Upheld measure (Part D)	All comments supported no longer excluding cases for beneficiaries enrolled in hospice.	Proceed as proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMS) measure (Part D)	Most comments were submitted by sponsors, and were supportive of the additional data to be provided during plan preview periods. Some proposed specification changes, or additional MTM performance measures.	Proceed as proposed. CMS shared additional comments received with the PQA.
Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Ratings)	A small number of comments were received, but all supported the specification change to exclude patients with one or more claims for sacubitril/valsartan from the measure. Other commenters suggested additional revisions to the measure specifications, which will be shared with the PQA.	Proceed as proposed.
Removal of Measures from Star Ratings		
Improving Bladder Control (Part C)	A small number of plans, associations and advocates commented on the plans for this measure. All supported the move of the measure to the display page, but a number requested the measure not return to Star Ratings any time soon, in part from doubts about data from patient surveys, but especially to give plans adequate time to respond when the measure is returned to Star Ratings. One association argued that treatment receipt should be retained as a focus, rather than shifting it entirely to the discussion of treatment.	No change, except to state in the CY 2017 final Call Letter plan to leave measure on display page for 2018 as well as for 2017. Follow NCQA's lead as the HEDIS measure steward, paying attention to how much notice plans have.
High Risk Medication (Part D)	Support among sponsors, associations, PBMs, and other organizations was split between moving the High Risk Medication (HRM) measure to the display page for 2017 and keeping the measure in the Star Ratings. Most commenters that opposed the change requested that the measure remain in the Star Ratings for 2017 since this change was being made after the measurement period in which efforts were invested. Other commenters provided feedback including specification revisions which will be shared with the measure developer, PQA.	Keep the HRM measure in the Star Ratings for 2017 due to the measurement period concerns raised and move it to the display measures for 2018. The measure will be reconsidered for the Star Ratings again in the future once analyses and specification changes, if any, are completed by the PQA.
Data Integrity		

Call Letter Section	Summary of Comments	CMS Final Course of Action
Data Integrity	Commenters included sponsors, advocacy groups and trade organizations, and all support that CMS Star Ratings only use accurate data. Some sponsors requested the opportunity to correct erroneous data, or that CMS only reduce scores when errors were intentionally made. Others requested CMS provide detailed methodologies for data integrity checks, or establish allowed thresholds for data errors.	Proceed as proposed. The Call Letter provides examples of non-compliance that would directly bias measure-level data. We will add links for more information about these areas, for example CMS Data Validation Standards and HEDIS Technical Specifications.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Impact of Socio-economic and Disability Status on Star Ratings		
Interim Analytical Adjustments	The majority of the comments received for the draft Call Letter provided feedback on the dual/LIS Star Ratings section of the draft Call Letter. Almost all commenters supported moving forward with Categorical Adjustment Index (CAI) as an interim solution. A few commenters wanted to wait, but supported CAI if the Agency were to move forward with an interim solution. Some commenters wanted additional measures to be adjusted for an LIS/DE and/or disability effect, with a couple of commenters not supporting CAI unless additional measures were added. However, commenters did not suggest specific measures. Some commenters wanted CMS not to move forward with an interim solution; many of these commenters represented beneficiary advocacy groups and were concerned about masking true disparities of care. Other commenters who preferred to wait did not want a complex interim solution implemented prior to ASPE and measure developers completing their work. Some commenters, representing plans, requested a hold harmless provision such that the CAI values would only be applied if it resulted in a positive adjustment. A handful of commenters expressed support for CMS efforts in this area, but did not express a preference on the proposed approach. No comments were received that supported Indirect Standardization (IS). There were some questions about the duration of the interim fix and the process to update CAI values.	Proceed with the CAI as an interim analytical adjustment for the 2017 Star Ratings Program and provide additional clarifications in the CY 2017 final Call Letter to address commenters' questions. In the final Call Letter we will reiterate that the duration of the interim adjustment will be dependent on the ASPE and measure developers' work coupled with our work to simulate any recommendations. We will also provide additional information about CMS' commitment to update the CAI values (measures and differences in performance) on an annual basis.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Puerto Rico	The vast majority of the submissions expressed support for the estimated LIS indicator and for the reduction in the weights for the three Part D adherence measures. One of the commenters suggested modifications to the methodology to estimate the LIS indicator, while another submitter suggested using Census data. There was a single commenter that did not support moving forward with the reduction in the adherence weights.	Proceed with using the LIS indicator for PR in the interim analytical adjustment and reducing the weights of the three Part D adherence measures in PR. We will add additional language to the final Call Letter that we hope to continue discussions with PR stakeholders about alternative data sources and methodological enhancements for 2018 stars and beyond.
2017 CMS Display Measures		
Timely Receipt of Case Files for Appeals (Part D) & Timely Effectuation of Appeals (Part D)	All commenters supported the change to match the measurement periods of the Part D Appeals Star Ratings measures.	Proceed as proposed.
Medication Reconciliation Post Discharge (Part C)	While some of the commenters supported the measure, others recommended for the measure to remain on the display page until 2018 or 2019 for monitoring. Some had methodology or validity concerns and they requested more time to address accurate data collection, appropriateness of the population for the measure, and application to Part D.	Proceed as proposed as this measure has been collected by SNPs for many years. CMS is planning to include this measure on the 2017 display page and in the 2018 Star Ratings to expand the focus on care coordination.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Hospitalizations for Potentially Preventable Complications (Part C)	The majority of the comments requested the measure remain on the display page longer and a few others had validity or methodology concerns. Commenters recommended further testing and refinement for the measure.	Proceed as proposed. CMS is planning to include this measure on the 2017 display page and in the 2018 Star Ratings to expand the focus on care coordination. If there are issues during the first year of data collection and reporting, CMS will re-consider this decision.
Statin Therapy for Patients with Cardiovascular Disease (Part C)	The majority of the comments supported the measure and continuance of it as a display measure through 2018. Others recommended continued validation of the measure. Some provided recommendations, including excluding those taking PCSK-9 inhibitors, patients with counter indications, those unable to tolerate medication, and ESRD patients.	CMS plans to include this measure on the 2017 and 2018 display pages and consider it for inclusion in Star Ratings in future years.
Asthma Measures (Part C)	The majority of comments were against the two measures. Commenters expressed opinions that expanding the asthma measure to the age 65 and older population was inappropriate due to the difficulty of distinguishing asthma from COPD in this population; that asthma should not be identified by medication but by diagnosis; and that the asthma medication ratio measure is contrary to NIH recommendations. Support for the measures was received from pharmaceutical companies.	CMS plans to include these two measures on the 2017 and 2018 display pages and consider them for potential inclusion in Star Ratings in future years.
Statin Use in Persons with Diabetes (SUPD) (Part D)	Substantially all of the comments received from sponsors and organizations supported adding the SUPD measure to the 2017 display page, where it will remain for two years before adding to the Star Ratings. One sponsor commenter opposed. A few commenters requested that the PQA revisit its decision not to exclude beneficiaries who use PCSK-9 inhibitors from the measure calculation.	Proceed as proposed. We shared comments regarding measure specifications with the PQA.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Forecasting to 2018 and Beyond		
New Measures:		
Care Coordination Measures (Part C)	Commenters were largely supportive of this work, but cautioned CMS to consider burden on sponsors, coordinate with Medicaid, and consider contributions of non-physician providers. They also requested that CMS clarify the intent of this work as well as provide a working definition of care coordination.	Proceed as proposed to develop care coordination measures, taking into account commenter concerns. CMS will provide more information about this work as it is available.
Depression Measures (Part C)	Commenters requested that CMS delay implementation of these measures due to concerns about data and privacy issues, as well as the use of other screening tools. Several suggested that CMS first implement a depression screening measure before including a depression outcome measure.	Proceed as proposed to monitor development of these measures. CMS shared additional comments received with NCQA.
Appropriate Pain Management (Part C)	Commenters were supportive of the development of appropriate pain management measures but mentioned the need to develop screening protocols for pain. Commenters requested to be kept informed of measure development and to be provided detailed measure specifications prior to inclusion in Star Ratings.	Proceed as proposed. CMS shared comments received with NCQA.
Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D)	Most commenters supported adding new opioid overutilization measure reports through the Patient Safety Analysis Website, and adding the measures to the 2019 display page, and a few expressly supported not moving to the Star Ratings (at least until consensus guidelines). A small number of commenters opposed adding the new measures to the display page or additional reporting outside of the OMS.	Proceed as proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Antipsychotic Use in Persons with Dementia (APD) (Part D)	Most commenters supported adding new APD reports through the Patient Safety Analysis Website, and adding the measures to the 2018 display page. A few commenters did not support adding the new measure, or expressly supported not moving the measure to the Star Ratings (or at least until certain conditions are met). Some commenters recommended additional specification changes which will be shared with the PQA.	Proceed as proposed.
Changes to Existing Star Ratings and Display Measures and Potential Future Changes:		
Colorectal Cancer Screening (Part C Star Ratings	Commenters requested to be kept informed of measure development and to be provided detailed measure specifications prior to inclusion in Star Ratings.	Proceed as proposed. CMS shared comments received with NCQA.
Fall Risk Management (Part C Star Ratings)	A small number of plans, associations, and advocates commented, and almost all supported the changes proposed by CMS. There was some distrust of the measure or its source being a patient survey, some concern that Vitamin D should not be used as an example of a Fall Risk Management intervention, and a wish that audiologists could have a greater role in measures related to vestibular disorders. Some concerns were raised about whether or not this measure should be included in the subset of measures adjusted for SES/disability factors, especially that adjustments could disincentivize plans from developing programs to serve dual populations. However, most comments were supportive and only asked that plans be given sufficient notice when the measure is moved back into Star Ratings.	Proceed as proposed by following NCQA's lead as the HEDIS measure steward. CMS will monitor the potential unintended consequences of adjusting for SES/disability.
Pneumococcal Vaccination Status for Older Adults (Part C Display)	Half the organizations demonstrated concern with recall bias and using CAHPS for tracking clinical measures. Recommendations include basing the measure on claims or keeping the measure as display.	Proceed as proposed.

Call Letter Section	Summary of Comments	CMS Final Course of Action
CAHPS Measures (Part C & D)	Commenters support the CAHPS 5.0 changes, and very few commented on the sampling proposal. Several expressed general concerns about CAHPS or requests for clarification, including the length of the survey, sample size, use of proxy respondents, language translations, availability of case-mix information, and duplication with Medicaid.	Proceed as proposed and provide additional information about CAHPS in the final Call Letter. CMS will remove some CAHPS questions not used in Star Ratings in order to reduce the length of the 2017 MA CAHPS survey.
MPF Price Accuracy (Part D Star Rating)	Commenters expressed concern with the timing and frequency of point-of-sale (POS) price changes (PDE) versus the MPF price changes. This is a standard comment that does not change the CMS approach as we would not expect this limitation to keep plans from lowering their prices at the POS. Other commenters discussed MA-PD cut-points and performance.	Proceed as proposed.
Drug-Drug Interactions (DDI) (Part D Display)	One commenter expressed support for the evaluation of the DDI measure, while others provided technical suggestions.	Proceed as proposed.
Center for Medicare and Medicaid Innovation Model Tests	Commenters support excluding participating plans from cut-points or establishing separate cut-points for model participants in order to ensure a level playing field. They also requested more details about CMS' Star Ratings approach for model participants.	The model tests will not be implemented until 2017, so they will not affect ratings until 2019 Star Ratings. CMS will provide additional details about our approach for model participants' Star Ratings in a future Call Letter.

Call Letter Section	Summary of Comments	CMS Final Course of Action
Measurement and Methodological Enhancements		
Ad hoc Comments	Sanctions: In response to the draft CY 2017 Call Letter, we received multiple comments suggesting that CMS revise its policy of automatically reducing the Star Ratings of sanctioned contracts to 2.5 stars, or reducing by one star the ratings of those contracts already rated at 2.5 stars or lower. Commenters raised several concerns, including one noting that high-rated contracts can be subjected to a more severe penalty than low-rated contracts as their rating can be reduced by multiple stars to reach 2.5 stars, while low-rated contracts face a rating reduction of only one star. Commenters stated that CMS should re-evaluate the current policy given these concerns and the state of the Part C and D Star Rating program today. Assorted Comments: Comments ranged in topics from general to measure-specific. They included questions and comments related to the process, ideas for changes for other Star Rating or display measures, cut-points, and the development of outcome measures.	As announced in the March 8, 2016 HPMS memo, CMS is suspending the sanction deduction, while it re-evaluates the impact of sanctions, audits and CMPs on the Star Ratings. CMS plans to include any potential changes in the Request for Comments in Fall 2016. We are reviewing all comments as we consider future enhancements to the Star Ratings.

Appendix 5 – Adjusted Measure Selection Criteria

Variation Across MA and PDP Contracts of Within-Contract LIS/DE Differences

MA Measure	Minimum	Median	Maximum
Adult BMI Assessment	−0.133	0.009	0.231
Rheumatoid Arthritis Management	−0.098	−0.034	−0.008
Breast Cancer Screening	−0.236	−0.085	0.053
Controlling High Blood Pressure	−0.028	−0.005	0.028
Diabetes Care: Blood Sugar Controlled	−0.119	−0.064	0.006
Diabetes Care: Eye Exam Performed	−0.153	−0.045	0.125
Diabetes Care: Kidney Disease Monitoring	−0.057	−0.006	0.033
Colorectal Cancer Screening	−0.179	−0.061	0.095
Osteoporosis Management in Women Who had a Fracture	−0.077	−0.056	−0.029
No All-Cause Readmission[27]	−0.036	−0.015	−0.003
Annual Flu Vaccine	−0.070	−0.035	0.020
Monitoring Physical Activity	−0.092	−0.006	0.099
Reducing the Risk of Falling	0.108	0.131	0.155
Medication Adherence for Diabetes	−0.066	−0.006	0.081
Medication Adherence for Hypertension	−0.081	−0.023	0.102
Medication Adherence for Cholesterol	−0.095	−0.002	0.112
PDP Measure			
Medication Adherence for Diabetes	−0.106	−0.038	0.018
Medication Adherence for Hypertension	−0.139	−0.062	−0.018
Medication Adherence for Cholesterol	−0.103	−0.034	0.021

For PDPs, the research showed that the median absolute difference in performance between LIS/DE and non-LIS/DE enrollees was greater than 5% for Medication Adherence for Hypertension. It was slightly smaller for MA-PDs, but to apply consistent adjustments across MA-PDs and PDPs it is included for both delivery systems.

The measures selected for adjustment included the following six Part C measures for MA (MA-only, MA-PD) and 1876 contracts: Breast Cancer Screening, Colorectal Cancer Screening, Diabetes Care – Blood Sugar Controlled, Osteoporosis Management in Women who had a Fracture, Rheumatoid Arthritis Management, and Reducing the Risk of Falling. In addition, Medication Adherence for Hypertension (RAS antagonists) was adjusted for MA-PDs and PDPs.

[27] Readmissions was reverse coded in the analysis. Readmissions is excluded from the subset of measures for adjustment, since the measure is already adjusted for factors associated with disability status. In addition, CMS is reviewing the measure.